



What Employers Need to Know as FDA Fully Approves Pfizer Vaccine: 6-Step Plan to Impose a Vaccine Mandate

Insights

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The news this morning that the federal government fully approved the Pfizer COVID-19 vaccine could be a pivotal milestone in the fight against the coronavirus – especially when it comes to employers’ role in the battle. After all, in a survey conducted by Fisher Phillips earlier this month, 10% of employers said they were hesitant to impose a vaccine mandate until the Food and Drug Administration (FDA) removed the Emergency Use Authorization and fully approved the vaccine. Now that this concern is lifted and the risk of legal exposure diminishes by the day, employers may feel more comfortable requiring their workers to receive the vaccine as a condition of employment. What do employers need to know about today’s development, and what steps do you need to consider if you are deciding whether to impose your own workplace mandate?

“Emergency Use” Label is Dropped as Pfizer Gets the Full Okay

The Pfizer, Moderna, and Johnson & Johnson vaccines were all approved pursuant to the FDA’s Emergency Use Authorization (EUA), which permits the agency to clear drugs, vaccines, medical devices and other products for use on an expedited basis. Although the development process for the vaccines was expedited, they were still subject to trials on tens of thousands of people to determine safety and efficacy – the same stringent testing process of other vaccines.

Today, the FDA gave the Pfizer-BioNTech vaccine the highest level of clearance that a medical drug can receive from the government. “The public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product,” acting FDA Commissioner Janet Woodcock said in announcement that accompanied the approval. According to the statement, the Pfizer vaccine will now be known in by the brand name “Comirnaty.”

EUA Has Caused Confusion – But Legal Exposure Remained Low

The FDA’s 2017 guidance on EUA products notes that recipients must be informed about the right of refusal and any accompanying consequences. For example, the EUA includes paperwork instructing healthcare providers administering the vaccine to tell recipients that they can “refuse” the shot. This language has caused confusion among those who believe they should not be subject to an employer mandate. But this directive is targeted at whether an individual can be forced to take the vaccine by a

government entity, not whether an employer can condition an individual's continued employment on taking the vaccine. After all, in at-will employment settings, an employee can always pursue alternative employment if they do not want to get vaccinated as a condition of their current job.

Three legal developments over the past nine months have demonstrated that the EUA presented no barrier to workplace vaccine mandates:

- Late last year, the Equal Employment Opportunity Commission (EEOC) stated that employers can require their workers to get the current COVID-19 vaccines without violating most federal anti-discrimination laws (subject to reasonable accommodation principles, of course).
- Multiple courts have upheld mandates in the face of lawsuits filed by disgruntled workers who did not want to comply with a vaccine requirement. In the most high-profile case, 117 hospital workers in Texas sued to block the hospital's mandatory vaccination policy, relying on – among other arguments – the FDA's EUA. The plaintiffs claimed the emergency provisions under which the vaccines were authorized do not even apply to private employers. Federal Judge Lynn Hughes was not persuaded and dismissed that lawsuit. The plaintiffs have appealed this decision.
- Less than a month ago, the U.S. Department of Justice expressed the opinion that EUA status does not prevent employers, schools, and other entities from mandating COVID-19 vaccinations.

Still, despite the mounting body of evidence that legal exposure was low, some employers were waiting for removal of the EUA designation as the final step before considering a mandate. Now that the Pfizer vaccine has been fully cleared and other COVID-19 vaccine approvals are soon to follow in the coming weeks and months, the time is right for employers hesitant to mandate vaccination to brush up on the basics.

6 Steps to Consider with a Vaccine Mandate

If you decide that now is the time to impose a vaccine mandate on your workforce, here are the six steps you should consider:

1. Spend time considering how your employees, customers, and other constituents are likely to respond to the policy, including how you will handle pushback. Anticipate and prepare for certain levels and forms of anxiety and/or resistance – even if the EUA has been removed.
2. Figure out the best way to communicate your policy to employees, including how much notice to provide before implementing the requirement, how proof of vaccination will be kept, and who within the company will have access to the confidential information.
3. Consider related logistics, including compensation issues that may be implicated for the time spent traveling to and receiving the vaccine and any related reimbursement costs. Make sure you also understand when employees are entitled to be paid for their time, such as supplemental paid sick leave for time taken to receive the vaccine or to recover from vaccine side effects.

4. Develop a robust and clear reasonable accommodation policy to [address religious and disability issues](#). Take special care to communicate and administer the accommodation process in a thoughtful way, with emphasis on individualized, confidential consideration of each request.
5. Be wary about the issues raised by posing pre-screening vaccination questions that may trigger ADA requirements ([more detail found here](#)).
6. Develop a designated “vaccine team” for coordinating this entire process.

And if You’re Not Ready to Impose a Mandate...?

For those employers still not ready to require their workers to get inoculated against COVID-19, there are at least four other options to consider.

- You could launch an **information campaign**, driving to improve vaccination rates by offering targeted educational opportunities to your workers about the vaccines. Many people are flooded with disinformation about COVID-19 vaccines from social media, disreputable news sources, and word of mouth, and such a campaign might be of critical assistance.
- You could offer **workplace incentives** to any employee who can prove they are fully vaccinated. The most common incentives employers have offered include cash, gifts, or paid time off. [Thanks to clear guidance from the EEOC earlier this summer](#), you have simple directions to ensure you don’t run afoul of any discrimination laws if you decide to offer incentives.
- You can require all non-vaccinated personnel to be subjected to **regular COVID-19 testing** to ensure the highest level of workplace safety.
- You can also require those who do not prove vaccinated status to comply with **additional safety restrictions** as necessary to maintain a safe working environment. These can include renewed masking requirements, social distancing rules, restrictions on business-related travel, and other concepts relevant to your work environment.

Each of these options requires some level of consideration and should be carefully planned. [A detailed description for each option can be found here.](#)

Conclusion

We will continue to monitor developments related to the COVID-19 vaccines and related workplace questions that arise. Make sure you are subscribed to [Fisher Phillips’ Insight system](#) to get the most up-to-date information. If you have questions about how to ensure that your vaccine policies comply with workplace and other applicable laws, visit our [Vaccine Resource Center for Employers](#) or contact your Fisher Phillips attorney, the authors of this Insight, or any attorney on our [FP Vaccine Subcommittee](#).

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