

COVID-19 Vaccines: What Employers Need to Know

While COVID-19 cases continue to climb, several promising vaccines are coming to market. As people around the world get inoculated, life, business and the economy will begin to recover. Although the post-pandemic world will certainly be different, vaccines provide hope that the "new normal" will closely resemble pre-pandemic life.

Information on COVID-19 vaccines is generated from multiple sources. In this report, the experts at USI Insurance Services distill the currently available information regarding the vaccine and its impact on employers.

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The COVID-19 Vaccines

The Pfizer and Moderna COVID-19 vaccines have both received Emergency Use Authorization (EUA) in the U.S. to be administered to people ages 16 years and older and 18 years and older, respectively. Both vaccines have been shown to be more than 94% effective against COVID-19. The EUA allows the FDA to permit unapproved medical products to be used in an emergency to diagnose, treat or prevent serious or life-threatening diseases.¹

Company Name	Pfizer & BioNTech	Moderna
Туре	mRNA	mRNA
Efficacy Rate	95%	94.5%
Doses	2 doses; 21 days apart	2 doses; 28 days apart
Age	16 years and older	18 years and older
Storage	Ultra-low temp -75°C (-94°F)	Low temp -20°C (-4°F)
Emergency Authorization Use Hearing	December 10, 2020	December 17, 2020
Projected Production of Vaccine for 2020	25 million doses to vaccinate 12.5 million Americans	20 million doses to vaccinate 10 million Americans

¹ https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization



It is reported that both **AstraZeneca** and **Johnson & Johnson** might apply for EUA for their vaccines in early 2021. AstraZeneca released data that showed its standard two-dose vaccine was 62% effective. The data also showed that providing a lower dose during the first injection and then a standard-strength second dose was 90% effective. Johnson & Johnson's COVID-19 vaccine is designed as a single dose, and it may apply for EUA in late January or February 2021.²

Vaccine Distribution & Administration: Who Will Get the Vaccine First, and How?

In the U.S., the country's 24 million healthcare workers and residents of long-term care facilities are the first group of Americans receiving the vaccine, as advised by the Advisory Committee on Immunization Practices (ACIP) to the Centers for Disease Control and Prevention (CDC). On December 20, 2020, the ACIP voted that the next group to receive the COVID-19 vaccine should be adults ages 75 and older and "frontline essential workers." The committee advised that frontline essential workers include first responders, people working in the education sector, corrections workers, U.S. postal service workers, public transit workers, grocery store workers, and people who work in the food, agriculture and manufacturing sectors. Third in line to receive the vaccine is people 65 to 74 years old, people 16 to 64 years old with high-risk medical conditions, and "other essential workers" not previously accounted for in the prior group. ³

While the CDC puts forth recommendations as to who should receive the vaccine, actual distribution and administration is coordinated at the state level. The CDC published interim COVID-19 vaccination playbooks by state on its <u>website</u>; however, for the most up-to-date information, visit the website set up by each state for COVID-19 communications. This can be easily found by typing "state name" + "COVID-19 vaccine" into any search engine.

In the early phases of vaccination rollout, each state will select a network of providers that will likely include hospitals, physician offices, pharmacies, health departments, federally qualified health centers, and other clinics to administer the vaccines. States will also direct citizens meeting the criteria for each phase as to where to receive the vaccine.⁴

Vaccine Coverage & Cost

The initial round of COVID-19 vaccine doses has been paid for in advance by the U.S. government. The advance payments include the costs of the vaccine and its distribution.⁵ To date, the only component of the vaccine delivery process that has not been prepaid is the cost to administer the vaccine.

Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, **non-grandfathered group health plans and individual health plans must have covered, without cost-sharing (both in-network and out-of-network⁶), qualifying coronavirus preventive services (including immunizations) within 15 business days** following the recommendation by the ACIP and adopted by the CDC (i.e., no later than December 28, 2020). Grandfathered group health plans are encouraged to provide similar coverage. As a result, covered participants and beneficiaries enrolled in a non-grandfathered group health plan will be able to receive the vaccine and its administration free of charge.

With respect to qualifying coronavirus preventive services provided by an out-of-network provider, a group health plan must reimburse the provider for such service in an amount that is reasonable, as determined in comparison to prevailing market rates for such service, such as what Medicare reimburses. In addition, providers are barred from billing patients for the vaccine or its administration, including balance billing.

² https://www.politico.com/news/2020/12/14/more-vaccine-developers-fda-approval-445194

³ https://www.cnn.com/2020/12/20/health/acip-cdc-covid-19-vaccine-phase-1b-allocation-bn/index.html

⁴ https://www.kff.org/coronavirus-covid-19/issue-brief/states-are-getting-ready-to-distribute-covid-19-vaccines-what-do-their-plans-tell-us-so-far

⁵ https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf

⁶ Must provide out-of-network coverage without cost-sharing during the Public Health Emergency Period for COVID-19



The Medicare reimbursement for administering a COVID-19 vaccine is \$28 for a single dose. In cases where two or more doses are needed (the expectation for several of the vaccines), the initial rate of administration is \$17, and the final dose is \$28.7 However, plan sponsors should expect to pay more than the Medicare rate, given the typical insurance carrier practice of reimbursing providers at rates in excess of Medicare. Charges will further vary depending on factors such as geography and contracted rates with providers. A conservative estimate of costs is \$30 for the administration of the initial dose and \$40 for the final dose.

Several health plans and pharmacy benefits managers (PBMs) are asking employers if they want the administration of the vaccine to be covered under the medical and/or pharmacy benefits. USI pharmacy consultant Dr. Dominic Vu recommends that employers opt to have vaccine administration covered under both medical and pharmacy benefits. He says that in more rural areas, hospitals may not have the resources to store the vaccines at the proper temperatures, but national chain pharmacies like CVS and Walgreens have allocated resources to store and administer the vaccine.

The reimbursement rate for a vaccine administered at a pharmacy may be lower than the rate administered at a physician's office, and the difference is nominal. Also, it may be more convenient for plan members to obtain the vaccine at a pharmacy rather than a physician's office, as visits with a physician will incur standard office fees subject to deductibles and out-of-pocket requirements. USI's lead actuary, Nick Allen, projects that COVID-19 vaccines will cost plan sponsors no more than 1% of their total healthcare spending in 2021. Further, this cost will likely be offset by fewer COVID-19-related hospitalizations and treatments. Assuming the vaccines' efficacy, employers can also expect an uptick in elective healthcare services performed, proportional to the reduction in elective services from April 2020 to December 2020. All told, it's unlikely that the cost of vaccine administration will be detectable by employers without a close examination of their monthly healthcare claims.

Employer Involvement In COVID-19 Vaccinations: Employment Practice Liability Considerations

USI Medical Director Dr. Eric Kerstman, MPH, states, "It is important to continue to follow current CDC guidelines regarding wearing masks and social distancing even after receiving a vaccination." As vaccines become available, employers are challenged with balancing workplace safety with federal and state employment laws and regulations. There are various legal issues that employers should evaluate with counsel when considering a COVID-19 vaccination program.

On December 16, 2020, the Equal Employment Opportunity Commission (EEOC) updated its COVID-19 guidance to include information regarding how COVID-19 vaccines interact with the legal requirements of the Americans with Disabilities Act (ADA), Title VII of the Civil Rights Act of 1964, and the Genetic Information Nondiscrimination Act (GINA).⁸ In summary:

- The ADA prohibits employers from making disability-related inquiries or requiring medical exams of employees unless "job related and consistent with business necessity".
- Among other things, Title VII prohibits discrimination on based on religious belief, practice or observance.
- GINA Title II prohibits genetic information discrimination in employment.

The updated guidance and frequently asked questions can be found here: What You Should Know About COVID 19 and the ADA, the Rehabilitation Act, and Other EEO Laws

<u>ADA, Title VII — Religious Discrimination & GINA</u>: The latest guidance provides some helpful clarification for employers considering COVID-19 vaccination policies.

⁷ https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment

⁸ The ADA, Title VII and GINA apply to employers with at least 15 employees



- The administration of an FDA-approved or authorized COVID-19 vaccine by an employer (or an employer's third-party contractor) is not considered a medical exam under the ADA. However, pre-vaccination screening questions would be subject to ADA standards for disability-related inquiries (i.e., must be job-related and consistent with business necessity).
- There are two circumstances in which disability-related screening questions associated the COVID-19 vaccine may be asked without satisfying the "job-related and consistent with business necessity" requirement:

<u>Voluntary Programs</u>. When an employer has offered a vaccination to employees on a voluntary basis (i.e., employees choose whether or not to be vaccinated), the ADA requires that the employee's decision to answer pre-screening, disability-related questions also must be voluntary. If an employee chooses not to answer these questions, the employer may decline to administer the vaccine but may not retaliate against, intimidate, or threaten the employee for refusing to answer any questions.

<u>Unrelated Third Party</u>. When an employee receives an employer-required vaccination from a third party that does not have a contract with the employer, such as a pharmacy or other healthcare provider, the ADA "job-related and consistent with business necessity" restrictions on disability-related inquiries would not apply.

- Asking or requiring an employee to show proof of receipt of a COVID-19 vaccination alone is not a
 disability-related inquiry (however, follow-up questions could elicit information about a disability). Employers that
 ask employees to provide proof of receiving a COVID-19 vaccination should warn the employee not to provide
 any medical information as part of the proof in order to avoid implicating the ADA.
- Reasonable accommodations are necessary when an employee indicates they are unable to receive a COVID-19 vaccination due to a disability or sincerely held religious belief.⁹ Engagement in the interactive process with an employee in connection with a requested accommodation is an important step in employer compliance. Failure to engage in the interactive process is an area that has historically resulted in allegations that an employer violated the ADA and/or engaged in religious discrimination.
- The ADA requires employers to keep any employee medical information obtained in the course of the vaccination program confidential.
- While GINA is not implicated when requiring employees to provide proof of a COVID-19 vaccination, it may be an issue if the employer (or the employer's contractor) is asking pre-vaccination screening questions that include inquiries about genetic information (including family medical history).

<u>FDA's Emergency Authority</u>: It is currently unclear whether vaccines authorized under the FDA's emergency authority can be mandated.¹⁰ The EUA is different from approval under the FDA vaccine licensure.

The FDA has an obligation to ensure that recipients of the vaccine under an EUA are informed, to the extent practicable under the applicable circumstances, that the FDA has authorized the emergency use of the vaccine, of the known and potential benefits and risks, the extent to which such benefits and risks are unknown, **that the recipients have the option to accept or refuse the vaccine,** and of any available alternatives to the product. Typically, this information is communicated in a patient "fact sheet."¹¹

OSHA & NLRA: Employers should also be mindful of potential implications of the Occupational Safety and Health Act (OSHA) and National Labor Relations Act (NLRA).

• The whistleblower provision of OSHA may protect an employee who refuses to be vaccinated under an employer vaccine mandate if there is a reasonable belief that a medical condition may cause a reaction to the vaccine resulting

⁹ While not addressed in the latest guidance, presumably a reasonable accommodation is also necessary for employees who are unable to receive a COVID-19 vaccine due to pregnancy under the Pregnancy Discrimination Act

¹⁰ Statement from Beth Bell, a member of the federal advisory panel on immunizations that will recommend to the CDC who should get the first

doses. Johnson, Carolyn. "What you need to know about the Pfizer, Modern and AstraZeneca vaccines." Washington Post (November 17, 2020).

¹¹ Emergency Use Authorization for Vaccines Explained (visited December 17, 2020)



in serious injury or death. Section 11(c) of OSHA prohibits retaliation against employees who complain about unsafe or unhealthful conditions or exercise other rights under the Act. On the flip side, employees could allege that an employer without a vaccination program has failed to provide a safe and healthy work environment.¹²

The NLRA protects all employees' rights to engage in "concerted activity" concerning their workplace. If employees jointly protest an employer COVID-19 vaccine program, or lack of one, and an employer takes any adverse employment action against those employees as a result, it could lead to allegations of violation of Section 7 of the NLRA and employees' rights to openly discuss conditions of the workplace. The right to engage in concerted activity in discussion conditions of employment applies to all employees and not just those belonging to a Union.

<u>Next Steps</u>: Employers considering COVID-19 vaccination policies in the workplace should review the federal and any state rules with their employment counsel prior to implementation. This is a rapidly developing area, so employers should continue to monitor the changing laws and regulations, including any that may prohibit or limit employers from mandating employee vaccination.

Employers may also want to consult with experts to prepare and train HR in responding to requests for accommodations under the ADA and Title VII, as well as how to best engage an employee in the interactive process, in efforts to mitigate potential exposure to allegations of employment-related discrimination, harassment, retaliation or wrongful termination.

For employers that purchase or are considering purchasing employment practices liability (EPL) insurance, be prepared to answer specific underwriting questions regarding your planned protocols for employees as the vaccine becomes readily available. Of course, if any EEOC charges or employment-related litigation arise, report any claims to any appropriate insurance policy(ies), per the reporting obligations of those policy(ies).

COVID-19 Vaccination Personal Injury Exposure

Employers should be aware that, in certain situations, an employee's adverse medical reaction (i.e., personal injury) to an employer-mandated vaccine may trigger coverage under workers' compensation or employer's liability. Many cases in different states have held if an employer requires an employee to get a vaccination, and the employee gets sick from the vaccination, that resulting illness is considered a compensable injury. Employers considering a mandatory vaccine program should evaluate the potential implications of such vaccination claims against the established and expanding exposure to direct COVID-19 infection workers' compensation claims.

The same ideas and principals could apply to consultants and vendor/third-party service provider employees who suffer an adverse medical reaction (personal injury) to a customer-mandated vaccination. The greater challenge in this type of claim is for the claimant to show that the customer was liable for the resulting personal injury; this may be a very high bar. However, companies considering a mandatory vendor vaccine rule should also evaluate the potential implications of such vaccination claims against the increased liability employers have for employees contracting COVID-19 at work. USI will continue to update you as developments occur on the COVID-19 vaccine.

Helpful Resources

To help clients navigate these challenging times, USI has implemented a **STEER** (Steer Through Epidemic & Economic Recovery) **Task Force**. This cross-functional team is working to provide timely COVID-19 information, understand cross-industry and geographic impact and evolving responses, and to develop and deliver tailored solutions to help clients steer through this epidemic challenge and economic recovery.

For additional resources, tools, and information, please visit our COVID-19 resource page: www.usi.com/public-health-emergencies



¹² OSHA Interpretation letter (November 9, 2009). https://www.osha.gov/laws-regs/standardinterpretations/2009-11-09

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