LOCKTON

UNCOMMONLY INDEPENDENT

COVID-19 questions and answers for U.S. employers:

Coronavirus vaccine update

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Please note: *For the most up-to-date information and resources, please visit the Centers for Disease Control and Prevention and the Food and Drug Administration. The below information is designed to guide businesses to known, credible resources covering COVID-19 and does not constitute medical advice. Employers with offices outside the U.S. should review their obligations with employment counsel to ensure compliance with local and national legislation.*

For the latest updates on COVID-19 vaccines and vaccine rollout plans, please visit the Centers for Disease Control and Prevention and the Food and Drug Administration websites. Lockton also offers a vaccine checklist for employers.

What vaccines are approved and when will new vaccines be approved?

The Food and Drug Administration (FDA) issued emergency use authorization (EUA) on Dec. 11, 2020, for the Pfizer-BioNTech vaccine, on Dec. 18, 2020, for the Moderna vaccine, and on Feb. 28, 2021, for the Johnson & Johnson vaccine. An EUA permits a drugmaker to bring a product to market at an earlier stage in the FDA's review process than is typical.

Pfizer-BioNTech, Moderna and Johnson & Johnson are a part of the program formerly known as Operation Warp Speed (OWS), the U.S. government's program to fast-track COVID-19 vaccines and therapies. Of the six candidates in the program, two others are likely to seek EUA from the FDA in 2021, on top of the three vaccines with EUAs. While Moderna and Johnson & Johnson are approved for those aged 18 and older, the Pfizer-BioNTech vaccine is the only vaccine with EUA approval for ages 12-15. Additionally, more than 100 COVID-19 vaccines undergoing various stages of clinical evaluation around the world as of May 14, 2021.

The Pfizer-BioNTech and Moderna vaccines have challenging shipping and cold storage requirements which originally limited the locations where they are administered. However, the FDA allowed more flexible storage and transportation conditions for the Pfizer-BioNTech vaccine, which will alleviate some of these logistical challenges.

As EUA does not constitute unconditional FDA approval, and the vaccines will likely be considered investigational/experimental treatments of the sort typically excluded by employer group health plans. However, see the discussion that follows about the group health plan mandate to cover vaccines recommended by the Centers for Disease Control and Prevention (CDC) and the U.S. Preventive Services Task Force (USPSTF), whether experimental or not. We will be following this topic closely as more information becomes available.

Pfizer-BioNTech filed for full FDA approval on May 7, 2021, and Moderna filed on June 1, 2021. Approval means the vaccines can stay on the market in the U.S. after the emergency is over and allows companies to begin marketing the vaccines directly to consumers.

The FDA approved the first COVID-19 vaccine Aug. 23, 2021. The vaccine, formerly known as Pfizer-BioNTech, will now be marketed as Comirnaty for individuals 16 and older. The vaccine continues to be available under EUA for 12-15 year olds and for the administration of the third dose for immunocompromised individuals.

Who is eligible to receive vaccines first and how are vaccines being distributed?

All Americans 16 and older were deemed eligible for vaccinations by May 1, 2021. However, due to Pfizer-BioNTech's expanded EUA authorization, patients 12 and older are now eligible to receive the vaccine.

When vaccines first started rolling out, the CDC published an initial playbook to guide state and local public health officials in administration. The playbook prioritized healthcare personnel and residents of long-term care facilities and recommended three different phases of vaccine rollout. States and large metropolitan areas developed their own distribution plans as well.

As more vaccines become available to the public, it is important for people to take the first authorized vaccine that is offered instead of waiting for a preferred vaccine. All authorized vaccines have high efficacy rates and getting vaccinated as quickly as possible will slow the spread of the virus.

Will an annual COVID-19 booster be necessary?

CDC recommends that people with moderately to severely compromised immune systems receive an additional dose of mRNA COVID-19 vaccine at least 28 days after a second dose of Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine.

What is the difference between a booster shot and a third dose of the COVID-19 vaccine?

An **additional dose** is the term to describe giving a full third dose of the Pfizer or Moderna vaccine to an individual who has likely not developed full immunity to the first two doses. This additional dose has been referred to as a 'booster' in the media but is not the same as a booster per the CDC's definition. The CDC recommends an additional dose of Pfizer or Moderna only for moderately to severely immunocompromised individuals.

A **booster dose** is another dose of vaccine given to **a person who has likely developed protective immunity**. The Pfizer booster is the only approved booster recommended for certain groups who do not meet the immunocompromised criteria. The FDA is evaluating whether a Moderna **half dose** can serve as a booster for other groups who do not meet the immunocompromised criteria, but it is not yet approved.

Can someone who has had a reaction to another immunization receive a COVID-19 vaccine?

If the patient has had a true ALLERGIC reaction (hives, swelling, wheezing, respiratory distress) to a previous COVID-19 vaccine dose, subsequent doses are not recommended. "COVID rash" and other known post-vaccination symptoms (fatigue, headache, swollen lymph nodes) do not disqualify a patient from a subsequent dose.

Patients with allergy to PEG (a component of some vaccines) should not receive either of the currently available COVID-19 mRNA vaccines (Pfizer, Moderna), but they may receive the Johnson & Johnson vaccine. Patients with an allergy to polysorbate should not receive the J&J vaccine, but may receive one of the other two.

Ultimately, a patient's treating physician should be the one to advise on whether vaccination is safe, and which vaccination to receive based upon a review of the specific nature of the prior reaction.

Is the vaccine needed if someone has already been infected with COVID-19?

Vaccination is still recommended in individuals who have had COVID-19, as we do not know how long natural immunity lasts after infection. Early data suggests that

individuals who have had COVID-19 infection alone without vaccination are 2x more likely to get COVID-19 again versus those who have had the vaccine. Keep in mind, this is one small study, and more research is needed on this topic. Check with the CDC and/or your personal physician for guidance on timing of receiving the vaccine after infection.

What is the recommended guidance on administering flu and COVID-19 vaccines?

COVID-19 vaccines and other vaccines may be administrated without regard to timing. This includes simultaneous administration of the COVID-19 vaccine and other vaccines on the same day, as well as co-administration within 14 days. Find more information on co-administration from the CDC.

What else should employers be thinking about in the meantime?

A concern is public reluctance to receiving a COVID-19 vaccine. Some of this resistance has come from anti-vaccine campaigns as well as from concerns about safety and efficacy data being rushed through too quickly without sufficient scientific rigor. The CDC provides a complete communication tool kit for employers to use with their workforce to educate employees about the COVID-19 vaccine.

The Equal Employment Opportunity Commission (EEOC) recommends that employers help employees locate vaccination sites, assist them in scheduling vaccines when internet access is limited and help them find low-cost or no-cost transportation to the vaccination sites when transportation is not readily available outside of working hours.

Employees should also be reminded that there is no charge for the vaccine. See vaccines.gov for more details.

We recommend employers consider developing a vaccine communication strategy for their employees. Refer to our Vaccine Employer Checklist for additional details.

Are we permitted to ask employees if they are fully vaccinated?

Yes, but be sure you have a business reason for doing so and the inquiry is job related. You can ask employees whether they are vaccinated but you should not ask employees why they were *not* vaccinated as that inquiry could elicit medical information protected by the ADA.

For employees answering "no," you can ask the employee, "Do you plan to get the vaccine when it is available to you?" If the answer to that question is "yes," you can ask "When do you plan to get the vaccine? Within the next 30 days? 31-60 days? Within 90 days?" to get an idea as to when an employee may be fully vaccinated. You will need to

maintain information related to your employees' vaccination status as confidential and on a "need to know" basis.

Employers should check state and local laws as well. While there is currently no prohibition on an employer asking whether or not an employee is vaccinated, or whether they plan to get vaccinated, some states and localities require employers to determine the vaccination status of their employees. So far, only one state (Montana) prohibits discrimination on the basis of COVID-19 vaccination status. It is noteworthy that Montana's law does not prohibit an employer from asking employees their vaccination status, but limits what an employer may do with that information if it does collect it. Certainly, employers in Montana choosing to elicit this information should proceed with caution.

Can we ask employees for proof of the COVID-19 vaccination or do we have to rely on them to truthfully self-identify?

You can require employees to provide proof of the COVID-19 vaccination but should caution employees not to provide any medical information as part of the proof.

Employers may choose to use any one or more of the following to confirm vaccination status:

- COVID-19 vaccination record card (issued by the Department of Health and Human Services Centers for Disease Control & Prevention or WHO Yellow Card), which includes name of person vaccinated, type of vaccine provided and date last dose administered
- A photo of a vaccination record card as a separate document
- A photo of the employee's vaccination record card from a cell phone or other electronic device
- Documentation of COVID-19 vaccination from a healthcare provider
- Digital record that includes a QR code that when scanned by a SMART Health Card reader displays to the reader the individual's name, date of birth, vaccine dates and vaccine type.

Keep in mind that there are already resources circulating which explain how to make a counterfeit CDC card, and others that offer such cards for a fee. It is tough for employers to police this. One option to help reduce fraud is to require that employees provide an attestation of their vaccine status. First, the attestation is not a document created by a healthcare provider and is less likely to trigger medical record retention requirements.

The attestation also provides an employer with the ability to remind employees that attesting to incorrect information, or knowingly providing false information, will lead to discipline. An employer could also opt to require proof of the vaccine along with an attestation to hopefully reduce fraud.

Once again, check state and local laws to ensure compliance with any privacy laws.

Can we ask job applicants about their vaccination status and for proof of the vaccination?

Generally, yes, but review applicable state or local laws. Employers can ask job applicants about their vaccination status if there is a business reason for doing so and the inquiry is job related. If the employer has mandated the vaccination, this should be included on the job posting as a condition of employment (subject to accommodation for a valid religious objection or medical reason).

On religious declinations, how do you handle when you only receive blanket statements or Bible verses?

The accommodation process is an interactive process. The employee needs to explain how the religious belief is contrary to the vaccine mandate. If you doubt the sincerity of the asserted religious belief or have objective facts for suspecting the request for religious accommodation is not genuinely related to a religious belief, you can request additional information that may help better assess the request. Note that the EEOC recommends that employers should presume that the request for a religious accommodation is sincere in the absence of an objective basis for questioning the religious nature or sincerity of the asserted religious belief, practice or tenet.

What should an employer consider before mandating a COVID-19 vaccination?

At this stage, given that the vaccine is widely available, employers may want to ask employees if they've been vaccinated (if not already required to ask under applicable state or local law) to evaluate whether a mandatory vaccination policy is the right next step. See our checklist for more details. Employers contemplating a mandatory COVID-19 vaccination program need to consider how they will respond when employees refuse to be vaccinated for reasons that are not legally protected (e.g. disability, pregnancy or religion). It is projected that around 25% of the population is hesitant about the vaccine and will not be immunized. Is an employer ready to terminate all employees who refuse a vaccine and do not have a disability-related or religious reason for objecting? Employers may consider limiting the mandate to particular job classifications so long as there is a legitimate business reason which is consistent with CDC guidance. Similarly,

multistate employers may determine that only certain locations need a mandatory vaccine policy depending upon the prevalence of COVID-19 cases in that locale.

As addressed above, to avoid ADA issues related to the prescreening questions, employers will need a third party with no connection to the employer to handle vaccination programs. Employers should be cognizant of wage and hour implications of a mandatory vaccination program as well. Time spent by hourly, non-exempt employees traveling to/from a vaccination location and time spent being vaccinated will likely be compensable time.

In the May 2021 updated guidance, the EEOC notes that some individuals and demographic groups may face greater barriers to receiving the COVID-19 vaccine than others. As a consequence, employers should ensure that a vaccine program does not disparately impact or disproportionately exclude employees based on any protected characteristic (race, color, religion, sex, national origin or age).

Encouraging and incentivizing employees to be vaccinated may be the more practical approach, which is further discussed below. Also, having different protocols for unvaccinated employees consistent with CDC guidance and state or local requirements is lawful and may encourage unvaccinated employees to get the vaccine voluntarily if it meant they did not have to wear a face mask while at work.

Refer to our Vaccine Employer Checklist for additional details.

Can employers offer incentives to employees for getting a COVID-19 vaccination?

Yes. Employers should consider whether to offer employees incentives to be vaccinated as opposed to mandating vaccines.

Some of the same legal hurdles exist when offering incentives. That is, there may be employees with valid objections to vaccines based on a religious belief or medical reason (including pregnancy). To be equitable, an incentive program would need to take into consideration persons with valid, legal objections to being vaccinated and offer the same incentive to them even without being vaccinated. One way to avoid any legal issues with respect to an incentive would be to offer the incentive to all employees regardless of whether they get the vaccine. If an employer chooses to only provide the incentive to employees who are vaccinated, to avoid discrimination issues, they will need to offer the incentive (or an equivalent) to employees with a valid legal objection to the vaccination.

> **Lockton comment:** Educating employees about the benefits of COVID-19 vaccines and offering an incentive may encourage a large portion of an employee

population to choose to be vaccinated. The key will be to ensure the program is equitable.

Refer to our Vaccine Employer Checklist for additional details.

What limitations are there on incentives an employer may offer employees to be vaccinated?

The updated EEOC guidance provides some clarification to employers in this regard. The answer depends on whether the employee is vaccinated "in the community" or through the employer or its agent. If the latter, the incentive cannot be so "substantial" that it is deemed "coercive." The EEOC does not define substantial but indicates it would be something large enough that it could make employees feel pressured to be vaccinated which means they would answer the prescreening questions and disclose protected medical information. However, when an employer offers an incentive to employees to be vaccinated "in the community" – through a pharmacy, clinic or personal healthcare provider – there is no disability-related inquiry, so incentives have no limitations.

> **Lockton comment:** Employers thinking about incentivizing the vaccine who want to avoid risk would be best served by having employees vaccinated "in the community" so there is no issue regarding the size of the incentive. If an employer wants to administer the vaccine or do so through its agent, it seems reasonable that some form of paid leave as an incentive would pass muster with the EEOC in light of the voluntary paid leave provisions in the American Rescue Plan Act, the new paid leave mandate issued by OSHA applicable to certain healthcare workers, and other state and local laws mandating paid leave related to the COVID-19 vaccinations.

Does a vaccination policy that includes a mandate or incentive need to address a reasonable accommodation process in the policy?

The recent May 2020 EEOC guidance recommends employers include a reasonable accommodation process as a "best practice" in a vaccine policy that requires or incentivizes employees to be vaccinated. When a disability or pregnancy precludes the employee from being vaccinated, the employer may need to obtain supporting medical documentation about the employee's condition. The Job Accommodation Network and OSHA COVID-specific resources may be of assistance to employers during the accommodation process.

The EEOC also identified potential reasonable accommodations in the case of a religious objection, disability or pregnancy as:

- Wearing a mask
- Working at a social distance from coworkers or non-employees
- Working a modified or staggered shift
- Periodic COVID-19 testing
- Teleworking
- Reassignment

Do employers need to provide reasonable accommodations to fully vaccinated employees?

Yes. The updated EEOC guidance acknowledges that there may be situations in which even fully vaccinated employees may be entitled to reasonable accommodations in the workplace. Some employees, such as those who are immunocompromised, may have a continuing concern of heightened risk of severe illness from COVID-19. If a fully vaccinated employee seeks a reasonable accommodation, employers should engage in the interactive process to determine if there is a disability-related need for an accommodation and process that request as any other ADA accommodation request.

Can employers require employees to show proof that they received a COVID-19 vaccination?

Yes. The EEOC advises that employers can require employees to provide proof of COVID-19 vaccinations received "in the community" as this inquiry is not likely to elicit information about a disability. If an employer requires written proof of vaccination, employees should be cautioned to not provide any medical or genetic information as part of the proof to avoid ADA and Genetic Information Nondiscrimination Act (GINA) implications. An employer's warning to employees to not provide such information would make the receipt of any genetic information inadvertent and not a violation under GINA. If an employer receives medical information along with the proof of vaccination, the employer should keep that information in a confidential medical file. The EEOC cautions employers to not ask an employee why they did not get vaccinated as this may be a medical inquiry under the ADA.

How do employers address ERISA and COVID-19 vaccines?

The federal Coronavirus Aid, Relief, and Economic Security (CARES) Act requires non-grandfathered group health plans to provide coverage of all COVID-19 related preventive care, including immunizations, within 15 business days after the USPSTF or ACIP recommends the vaccine.

Under federal regulations, an ACIP recommendation is considered in effect after it is adopted by the director of the CDC. That adoption is deemed to occur when the recommendation appears in the CDC's weekly publication, *Morbidity and Mortality Weekly Report* (MMWR).

ACIP recommended both the Pfizer-BioNTech and Moderna vaccines shortly after they were granted EUA by the FDA, and those recommendations appeared in MMWR on Dec. 13 and Dec. 20, respectively. Accounting for Christmas and New Year's Day as non-business days, the CARES Act coverage mandate for the Pfizer-BioNTech vaccine took effect Jan. 5, 2021, and a week later, on Jan. 12, 2021, for the Moderna vaccine. The mandate applies to the Johnson & Johnson vaccine on March 19, 2021. Of course, plan sponsors may agree to cover the vaccines with no cost sharing earlier than those dates (e.g., Jan. 1, 2021).

> **Lockton comment:** The 15-business-day window to implement vaccine coverage is a dramatic acceleration of the timeline to which plans are accustomed when the USPSTF adopts a new preventive services recommendation. Under the Affordable Care Act, plans are required to implement coverage for certain newly recommended preventive services by the first day of the plan year beginning on or after one year after the recommendation is adopted.
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> Plans sponsors may not be able to identify specific vaccines in a benefits summary and will want to confirm with their medical insurance carrier, third-party claims administrator or pharmacy benefit manager that they are able to implement and administer coverage within the timeframe.

A vaccine is embraced by the mandate even if not listed for routine use on the immunization schedules of the CDC.

Like the COVID-19 testing coverage mandate, plans must cover the recommended preventive care, including a vaccine and its administration (and, unless billed separately, the office visit), without cost sharing for in-network or out-of-network providers. For out-of-network providers, plans pay either a rate negotiated with the provider, or the market rate for such vaccinations.

> **Lockton comment:** While the mandate that plans cover COVID-19 testing will ultimately expire upon the recission of the public health emergency declared by the Department of Health and Human Services (HHS expects this emergency declaration to remain in force at least through 2021), the preventive care mandate, which includes coverage of the vaccine and its administration (but not necessarily a related office visit charge), has no expiration date.