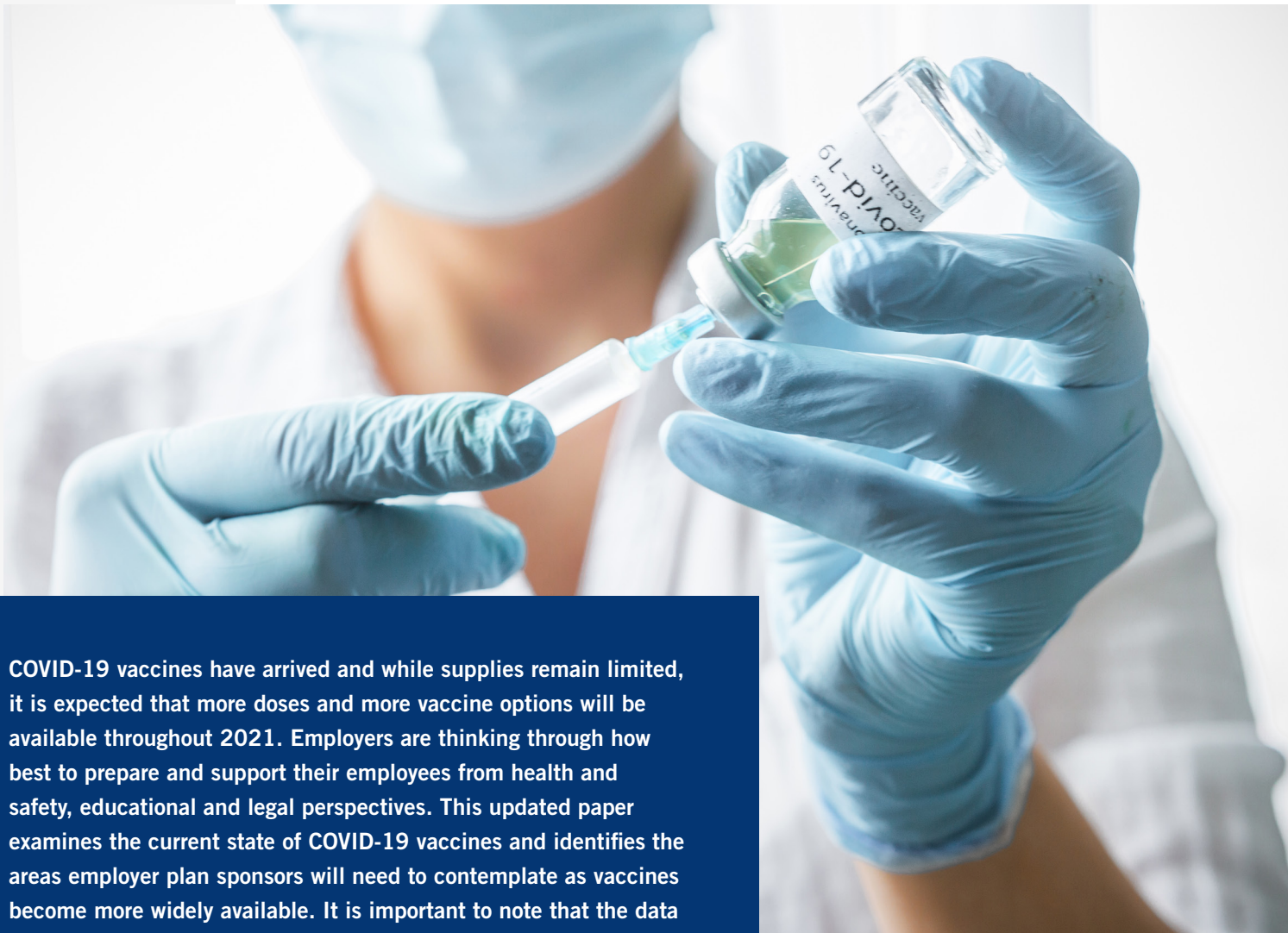




COVID-19 Vaccine & The Role of Employers

Louise Short, MD, MSc, National Clinical Leader // Updated March 2021



COVID-19 vaccines have arrived and while supplies remain limited, it is expected that more doses and more vaccine options will be available throughout 2021. Employers are thinking through how best to prepare and support their employees from health and safety, educational and legal perspectives. This updated paper examines the current state of COVID-19 vaccines and identifies the areas employer plan sponsors will need to contemplate as vaccines become more widely available. It is important to note that the data and the opinions reflected in this paper are captured at a point in time and could change rapidly in the current environment.



Vaccine Headlines

Pfizer/BioNTech and Moderna vaccines were first to market in December 2020, after being given emergency use authorization (EUA) by the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Johnson & Johnson followed and received their emergency use authorization on February 27, 2021. The vaccines in the near pipeline are Astra Zeneca and Novavax. They are both expected to file for EUA in Q1-Q2 2021.

WHAT DO WE KNOW ABOUT THE VACCINE SAFETY AND EFFECTIVENESS?

While current COVID -19 vaccines have been approved for use under the Emergency Use Authorization process, they are **showing high efficacy rates** in preventing hospitalizations and deaths from the illness. The speed in which these vaccines have been made available to the public is unprecedented.

Some consumers, however, have expressed safety concerns with receiving the vaccine. It is important to understand that these vaccines are based on years of research in vaccine safety and development. Now, with more than 52 million shots administered in the United States, the CDC has advised that COVID -19 vaccines have undergone the most intensive safety monitoring in U.S. history. This monitoring includes using both established and new safety monitoring systems to ensure that COVID-19 vaccines are safe.

Results from these monitoring efforts are reassuring. While some people don't have any side effects after receiving a COVID-19 vaccine, many people will have mild side effects such as pain or swelling at the injection site, and some may have more robust side effects including headaches, chills, or fever. Approximately 80–89% of vaccinated persons experience at least one local symptom and 55–83% experience at least one systemic symptom following vaccination.

These reactions are normal and show the vaccine is working in revving up the immune system to protect against COVID. Continued safety monitoring of mRNA COVID-19 vaccines in the U.S. has confirmed that anaphylaxis following vaccination is a rare event, with rates of 4.7 cases/million Pfizer-BioNTech vaccine doses administered and 2.5 cases/million Moderna vaccine doses administered, based on information through January 18, 2021.



What is Emergency Use Authorization?

Emergency use authorization (EUA) is a mechanism for the FDA to facilitate use of medical treatments, including vaccines, during public health emergencies. For an EUA to be issued for a vaccine, the FDA — advised by an external panel of scientific and public health experts — must determine that the known potential benefits outweigh the known and potential risks by reviewing safety and efficacy data.

Source: <https://jamanetwork.com/journals/jama/fullarticle/2776557>



HOW ARE THE VACCINES DIFFERENT OR SIMILAR?

Both Pfizer/BioNTech and Moderna vaccines are based on two doses, 21 days apart and 28 days apart, respectively. Although partial immunity is conferred after the first dose, full immunity does not develop until 1-2 weeks after the second dose.

It is important to note that **mRNA COVID-19 vaccines are not interchangeable** with each other or with other COVID-19 vaccine products. The safety and efficacy of a mixed-product series have not been evaluated. Both doses of the series should be completed with the same product*.

Johnson & Johnson's vaccine is a one-dose shot, considered to be the best option in a pandemic setting by offering improved access and compliance compared to two-shot doses. Full immunity is conferred after 4 weeks.



Facts About COVID-19 mRNA Vaccines

They cannot give someone COVID-19.

- + mRNA vaccines do not use the live virus that causes COVID-19

They do not affect or interact with our DNA in any way.

- + mRNA never enters the nucleus of the cell, which is where our DNA (genetic material) is kept
- + The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions

[Understanding mRNA COVID-19 Vaccines | CDC](https://www.cdc.gov/media/releases/2020/s110320-covid-vaccine-mrna.html)

COVID-19 VACCINES AND GLOBAL PIPELINE

Pfizer/BioNTech
December 2020
1.3B doses by end of 2021



Moderna
December 2020
Stretch to 1B in 2021



J&J
Week of 3/1/21
1B doses in 2021



Astra-Zeneca
Expected Q1-Q2 2021
2B doses annually

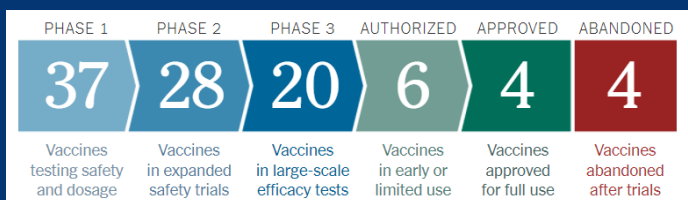


Novavax
Expected Q1-Q2 2021
Up to 2B doses annually



No. of Doses
Storage Requirements

- Ultra-Cold
- Freezer
- Refrigeration



<https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>

WHO CAN GET THE VACCINES WHEN AVAILABLE?

The Pfizer/BioNTech vaccine is approved for individuals over 16 years old, and the Moderna and Johnson & Johnson vaccines are approved for individuals over 18. Current clinical trial data did not include sufficient data collection in individuals under 16 to determine safety and efficacy. Data collection is ongoing, and there may be enough evidence for FDA review within the next four to six months for children over 12. There is insufficient data on pregnant or breastfeeding women regarding vaccine safety. These individuals, as well as those with a history of severe allergic reaction or significant adverse reaction to the first vaccination, should discuss the risks and benefits with their physician.

* <https://jamanetwork.com/journals/jama/fullarticle/2776557>



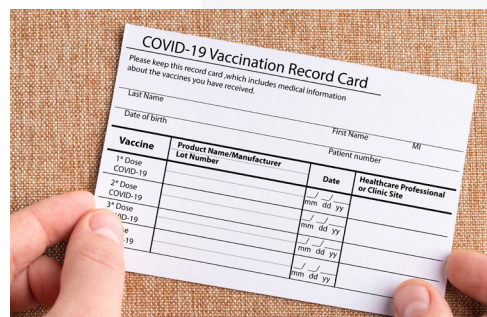
WHAT ABOUT THE VARIANTS?

Over the course of the pandemic, a number of variants of COVID-19 have arisen. A form first detected in Britain is reported to be up to 50 percent more contagious than the original COVID-19 virus, and researchers have begun to think that it may also be slightly more deadly. Researchers in South Africa identified another variant after doctors there discovered a jump in COVID-19 cases in October and alerted the World Health Organization that the variant might make the virus less susceptible to vaccines. While the variant found in Brazil has many of the mutations seen in the South African form, genetic evidence suggests that the two variants evolved independently*.

Some of the variants are raising concerns that they may draw out the pandemic or reduce vaccine efficacy or the effects of natural immunity. As new and more severe variants of the virus emerge, all manufacturers are focused on possible boosters and potentially modifying current vaccines to cover these variants. The three vaccines that have EUA in the U.S. have slightly less coverage for some of the variants, but they still have very high efficacy in preventing severe disease and death due to these variants.

Tracking & Monitoring

The CDC has produced paper vaccination tracking cards, and there are several digital apps and vaccination passports under development to assure accurate tracking. As noted above, it is important to accurately document the type of vaccine received, especially for two-dose vaccination regimens. While studies have begun to test the efficacy of mixing vaccine manufacturers for two-dose shots, it is critical to request and record the manufacturer of your first shot to assure the same vaccine is given for the second dose. Since the vaccination card contains personal information, proper protection should be taken to prevent risk of identity theft.



The CDC has also expanded new safety surveillance systems that include:

- **CDC | V-safe:** A new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines. V-safe uses text messaging and web surveys from the CDC to check-in with recipients following COVID-19 vaccination. V-safe also provides second vaccine dose reminders if needed, and telephone follow-up to anyone who reports medically significant (important) adverse events.
- **CDC | National Healthcare Safety Network (NHSN):** An acute and long-term care facility monitoring system with reporting to the Vaccine Adverse Event Reporting System (VAERS) that will allow for determination of COVID-19 vaccine adverse event reporting rates.
- **FDA | Other large insurer/payer databases:** A system of administrative and claims-based data for surveillance and research.



* <https://www.nytimes.com/2021/01/25/health/coronavirus-moderna-vaccine-variant.html>



WHAT DOES THE VACCINE MEAN FOR THE FUTURE?

At present it is unclear how long protection from these vaccines will last, and whether people who get the vaccine could still be asymptomatic carriers and spread COVID-19. Therefore, until more studies are done, it is critical that everyone maintain the current protocols and precautions of using masks, social distancing, and washing up.

Many employers will also continue with remote working where feasible to accommodate social distancing. For those who are not working remotely, testing protocols and contact tracing should be considered. As employees return to work, employers may consider vaccination tracking to guide policies and procedures.



According to the CDC's current guidelines, vaccinated persons with an exposure to someone with suspected or confirmed COVID-19 are not required to quarantine if they meet all of the following criteria*:

- + Are fully vaccinated (i.e., ≥ 2 weeks following receipt of the second dose in a 2-dose series, or ≥ 2 weeks following receipt of one dose of a single-dose vaccine)
- + Are within 3 months following receipt of the last dose in the series
- + Have remained asymptomatic since the current COVID-19 exposure

* <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

Persons who do not meet all three of the above criteria should continue to follow current [quarantine guidance](#) after exposure to someone with suspected or confirmed COVID-19. Although the risk of transmission from vaccinated persons to others is still uncertain, vaccination has been demonstrated to prevent symptomatic COVID-19; symptomatic and pre-symptomatic transmission is thought to have a greater role in transmission than purely asymptomatic transmission.

Fully vaccinated persons who do not quarantine should still watch for [symptoms of COVID-19](#) for 14 days following an exposure. If they experience symptoms, they should be clinically evaluated for COVID-19, including testing if indicated. In addition, vaccinated persons should continue to follow current guidance to protect themselves and others.





Vaccine Distribution

The federal government and the CDC are currently overseeing all vaccine supply to individual states, and each state then controls how the vaccine will be distributed and administered. As of February 23, more than 82.1M vaccine doses have been distributed nationwide, and approximately 65M of those have been administered (79% of distributed doses). Although the government initially held back doses to ensure supply for second doses, they have now released that supply and are getting assurances from manufacturers that more supply will become available.

While challenges remain in vaccine deployment within states and jurisdictions, attention to expanding and creating additional vaccine sites is beginning. The Federal Retail pharmacy program went into effect on Feb 11 to make 1M vaccine doses available directly to select retail pharmacies. Vaccine allotments from the government to pharmacies are still required to follow the appropriate phased approach. Below is general representation of essential workers within Phase 1b and Phase 1c. States are reprioritizing as vaccine supply and resources become more readily available; therefore these phases may differ by state and local jurisdictions.

FRONTLINE ESSENTIAL WORKERS

Workers who are in sectors essential to the functioning of society and are at substantially higher risk of exposure to COVID-19.

Frontline Essential Workers (~30M)

- + First responders (firefighters, police)
- + Education (teachers, support staff, daycare)
- + Food & agriculture
- + Manufacturing
- + Corrections workers
- + U.S. Postal Service workers
- + Public transit workers
- + Grocery store workers

Other Essential Workers (~57M)

- + Transportation and logistics
- + Food service
- + Shelter & housing (construction)
- + Finance
- + IT & Communication
- + Energy
- + Media
- + Legal
- + Public safety (Engineers)
- + Water & wastewater



HOW WILLING ARE PEOPLE TO TAKE A VACCINE?

According to the latest Gallup poll, 71% of Americans are now willing to or already have been vaccinated, up from [65% in late December](#).

This is the highest recorded percentage since July 2020, when the measure was first included in Gallup's probability-based online tracking survey. The current figure includes 62% who indicate they would be willing to be vaccinated if it were available to them right now at no cost, and 9% who indicate they have already received at least one of the two doses needed to be fully inoculated.

Asked for the main reason behind their reluctance, those who are unwilling to receive a COVID-19 vaccine are most likely to indicate they have **concerns about the rushed timeline (25%)**. However, the percentage giving this response has dropped by 12 points since the question was last asked in the fall. Twenty-two percent say they want to wait and confirm it is safe, 16% say they do not trust vaccines in general, and 9% want to see how effective it is. Another 28% cite other reasons, including views that the risks of the virus are overblown, a belief that they already have COVID-19 antibodies, concerns about adverse reactions to the vaccine and a general distrust of the government.*

Racial and economic equity remains at the forefront of the COVID-19 vaccine conversation. Black and Hispanic adults and those with lower incomes are less likely than their White and higher-income counterparts to say they have personally received at least one dose of the vaccine or that they know someone who has. Black and Hispanic adults are also among those most likely to say they want to "wait and see" how the vaccine is working for other people before getting vaccinated themselves.**

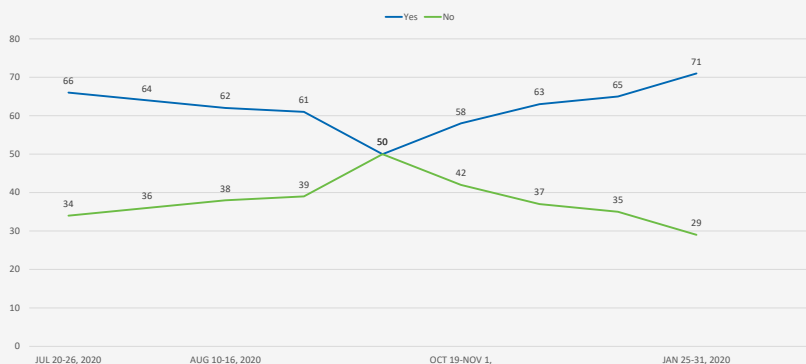
Employers will likely want and need to play a role in education around the safety and efficacy of the COVID-19 vaccine. Communication strategies and awareness campaigns should consider the variety of attitudes toward the vaccine across the demographic composition of the population. There is still a high percentage of people that say they would probably or NOT take the vaccine, or only take it after many others had received it.

* <https://news.gallup.com/poll/329552/two-thirds-americans-not-satisfied-vaccinerollout.aspx>

** https://www.kff.org/coronavirus-covid-19/dashboard/kff-covid-19-vaccinemonitor/?utm_source=web&utm_medium=trending&utm_campaign=COVID-19-vaccine-monitor

American's Willingness to Receive Coronavirus Vaccine

If one of the FDA-approved vaccines to prevent coronavirus/COVID-19 was available to you right now at no cost, would you agree to be vaccinated?



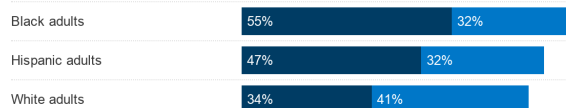
% Yes for Jan. 25-31, 2021, includes 9% who have already received at least one dose of the vaccine. Before January 2021, question wording was: If an FDA-approved vaccine to prevent coronavirus/COVID-19 was available right at no cost, would you agree to be vaccinated?

GALLUP PANEL

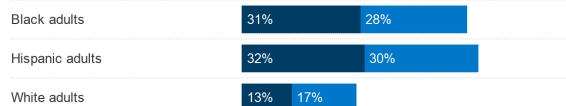
Percent who say they are either "very concerned" or "somewhat concerned" about each of the following:

Very concerned Somewhat concerned

They might experience side effects



They might get COVID-19 from the vaccine



NOTE: Among those who want to "wait and see" how the COVID-19 vaccine is working for others. See [topline for full question wording](#)
SOURCE: KFF COVID-19 Vaccine Monitor (Jan. 11-18, 2020)

KFF COVID-19 Vaccine Monitor

Messages the public finds the most convincing come from trusted sources that emphasize the vaccine's effectiveness, protection from illness, and the ability to return to normal life.



The Employer Response

Never in history have employers realized just how much public health can impact their bottom line. Coexistence with the virus requires continuing commitment to precautions, possible shutdowns, and curtailing of business as well as social and cultural activity—leading to economic suffering for millions.

Yet we will continue coexisting with the virus until we achieve herd immunity. Scientists have estimated that in order to achieve herd immunity, 70% or more of the population needs to be immune to COVID-19 through a vaccine and/or illness to make its spread from person to person unlikely. The U.S. has reported approximately 28 million confirmed cases of COVID-19, representing just under 12% of the general population.*

Because current surveillance systems do not capture all cases of COVID-19 occurring in the United States, the CDC provides testament to better reflect the larger burden of COVID-19. The CDC estimates that from February–December 2020 a total of 83.1M representing ~25% of the U.S. population has been infected with COVID-19. According to a recent McKinsey and Co. study, the highest probability of reaching herd immunity in the U.S. is at the end of 2021; however, that timing could shift to early 2022 depending on the speed and efficiency of vaccine production, distribution and administration, vaccine hesitancy, the potential development of more contagious and/or lethal variants, and other factors.

Employers can play a critical role in breaking down vaccine hesitancy through two key efforts: education and access. Education could include reinforcing the fundamental components of precaution and safe practices, as well as providing proactive, factual information about vaccine safety. Access could mean directing the workforce to settings where they can get vaccinated or providing points of distribution themselves through onsite clinics or onsite events in the future.

* <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html>



How much will the COVID-19 vaccine administration cost?

Approximately \$45 per 2 dose vaccine

Health plans and PBMs are following the approved Medicare rate for administration of the vaccine of \$28.39 for a single dose vaccine and \$16.94 for additional doses

COST AND COVERAGE

The Federal Government, through Operation Warp Speed (OWS), set a goal of no upfront costs to providers and no out-of-pocket cost for vaccine recipients. The government will fund the cost of the vaccine serum, supplies, and distribution, but self-insured employers and fully-insured health plans are required to cover the cost of administration of the vaccine. The CARES Act requires health insurance issuers and plans to cover any CDC-recommended COVID-19 preventive services, including vaccines, without member cost-sharing.

It is unclear how long the government will fund the cost of the vaccine serum. Presumably, employers will be responsible for the cost—which currently ranges from \$20–\$37 per dose—in the future.

COMPLIANCE

COVID-19 vaccines may present complex workforce compliance challenges. For example, can an employer require an employee to take the vaccine?

In general, an employer can mandate that employees receive the COVID-19 vaccine, although many employers appear to be encouraging rather than mandating. Still, employers may find themselves in situations where work status is impacted for non-vaccinated employees. The EEOC issued a publication on December 16, 2020, [What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws](#), which provides updated guidance on the responsibilities and rights of employers and employees.



There are several compliance and anti-discrimination laws that must be considered. In addition, COVID-19 concerns will span across broader Human Resources policy risks, including privacy, discrimination, and employee relations. It is critical for employers to coordinate with legal counsel to have a clear position that is communicated to employees.

Brown & Brown and Hays recently conducted a survey of large employer groups. While many employers are still actively developing their vaccination strategy and protocols, initial findings indicate a large majority of respondents noted they will not be mandating vaccination.

While some employers may not want to require their employees to get vaccinated, many may want to encourage them to get vaccinated by incentivizing their employees to voluntarily receive the COVID-19 vaccine.

There are a few compliance issues to keep in mind when thinking about instituting an incentive program. These issues arise primarily because a vaccine incentive program likely qualifies as a wellness program for purposes of Federal law.

Due to a lack of guidance on this issue, and because some individuals cannot receive the COVID-19 vaccine because of certain health conditions, it is the safest course of action is to treat an incentive program as an activity-only, health-contingent wellness program for purposes of the HIPAA wellness rules. For this type of wellness program, the employer would need to provide a reasonable alternative standard for obtaining the incentive/reward. The medical questionnaire that must be completed before the vaccine is received could be considered a disability-related inquiry, triggering the EEOC’s wellness regulations.

Given the complexities and lack of legal clarity regarding the above-highlighted issues, it is imperative that employers work with their attorneys who have specialization in employment and labor (the EEOC wellness regulations and HIPAA) to determine what course of action is best for their organization.

MANDATORY <ul style="list-style-type: none">+ 75% will not mandate the vaccine+ 23% are unsure	INCENTIVIZED <ul style="list-style-type: none">+ 15% have committed to providing incentives+ 35% will not+ 46% are unsure
ON-SITE CLINIC <ul style="list-style-type: none">+ 41% plan to have on-site clinic services available+ 36% are unsure+ 23% will not	TYPE OF INCENTIVE <ul style="list-style-type: none">+ 35% are unsure of the type+ 29% plan to provide via wellness program+ 13% plan to use PTO

Brown & Brown's team of companies surveyed 74 customers of various sizes about their plans for administering the COVID-19 vaccine to their employees. 01252021

MONITORING & REPORTING

As employers grapple with vaccination strategy and return to the workplace planning, a key factor to consider is if or how they plan to monitor vaccination status. At this time, there is no formal guidance requiring employers to track vaccination records for employees. Similar to the requirements to conduct COVID-19 screening for employees entering a worksite, this may come later as workplaces open up more broadly.

The current vaccination record system does not readily support convenient access, control and sharing of verifiable vaccination records. As with considerations for vaccine mandates or incentive policies, employers must carefully consider a number of elements:

- + Do they plan to monitor employee vaccination status?
- + What will the data be used for?
- + Where will the data come from—PBM, claims, vendor partners, public health departments, self-report?
- + What safeguards are needed to protect HIPAA/ADA disclosure?
- + What tools are available in the marketplace to support monitoring efforts?



Mayo Clinic, Epic, Cerner, Microsoft and Oracle are among a group of providers and software companies working on an initiative to make it easier for recipients to prove they have received a shot. The Vaccination Credential Initiative, spearheaded by the Commons Project foundation, a non-profit that promotes safe digital access to health records, would allow individuals to keep an encrypted copy of their vaccination record in a digital wallet, or provide a QR code for those without access to smartphones or other high tech.*

As these and other resources come to market, Hays will gather program details, pricing and scalability information. From new online vaccination passport apps to tools that screen employee intent to vaccinate status, employers should consider their unique variety of needs and partner with reputable resources to support those requirements.

COMMUNICATION

Employees are likely to expect communications from their employer about the COVID-19 vaccine. Should I trust it? Will the cost be covered through my health insurance? What about my covered family members? How will you make it more convenient for me?

Employers will want to create awareness for where, when, and how employees and their families can get the COVID-19 vaccine. It will be critical to communicate the coverage under the employer health plan for those enrolled, while also directing employees to credible resources regarding the safety and efficacy of vaccines.

Employers should consider development of FAQs and appropriate training materials for both HR business partners and benefits center representatives who will likely be fielding many of the employee questions. Building trust and vaccine confidence is an essential part of successful vaccine implementation and uptake. Transparent communication, providing clear and accessible information on vaccine benefits and safety, addressing misinformation, promoting vaccine confidence among healthcare personnel, and engaging communities to collaborate with trusted messengers are all components of reinforcing confidence in COVID-19 vaccines.

Most employers will want to tailor communications to their specific populations to supplement the guidance being provided by federal, state, and local governmental resources. The level of support around vaccine education, access, and post-vaccination protocol will vary by employer. In preparation for widespread vaccine distribution, employers should proactively be planning their internal communication strategies and coordination with key vendor partners (health plans, PBMs, on-site resources).

* <https://www.healthcarediver.com/news/mayo-epic-and-cerner-teaming-to-create-digital-covid-19-vaccine-passport/59345>



Vaccination Partnerships

Will employers be able to partner with on-site vaccine providers, like flu clinics, to provide on-site vaccines as early as mid-2021? Vendors are beginning to develop their capabilities and employers are in discussions for both on-site, near-site and off-site vaccinations programs for post phase 1a essential employees followed by their general population.



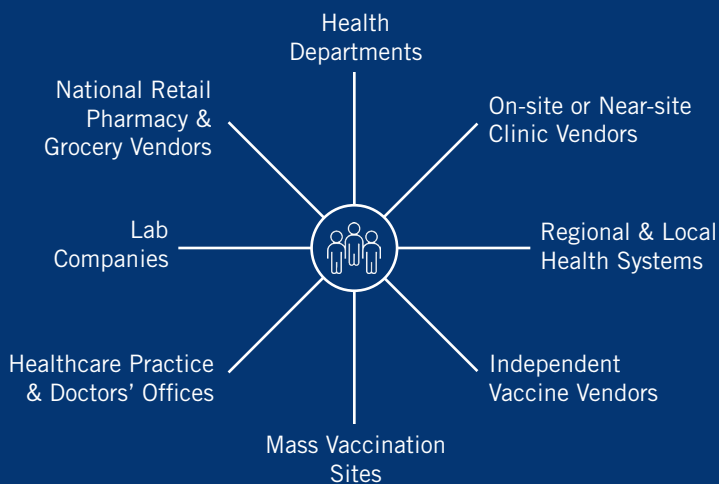
A Preliminary Considerations Checklist

The return to normalcy for employers from COVID-19 will create multi-faceted challenges across the organization, many of which are still unknown. In the interim, employers will need to proactively identify and align resources within their organization to build the infrastructure required to tackle the associated operational, financial, compliance, and Human Resource issues ahead—so they're able to ensure the best possible outcome for their workforce.

Preliminary activities for early 2021 will likely include the following:

- ☐ Consider establishing a cross-functional work stream vaccination team within your organization
- ☐ Determine if the vaccine will be required or encouraged for your workforce
- ☐ Leverage vendor and health plan partnerships
- ☐ Plan for cost and coverage of vaccine administration
- ☐ Develop communication and engagement strategy leveraging CDC and other resources
- ☐ Enforce ongoing precautions against the spread of COVID-19

CONSIDERING PARTNERSHIP OPTIONS



Please be advised that any and all information, comments, analysis, and/or recommendations set forth above relative to the possible impact of COVID-19 on potential insurance coverage or other policy implications are intended solely for informational purposes and should not be relied upon as legal or medical advice. As an insurance broker, we have no authority to make coverage decisions as that ability rests solely with the issuing carrier. Therefore, all claims should be submitted to the carrier for evaluation. The positions expressed herein are opinions only and are not to be construed as any form of guarantee or warranty. Finally, given the extremely dynamic and rapidly evolving COVID-19 situation, comments above do not take into account any applicable pending or future legislation introduced with the intent to override, alter or amend current policy language.