



# COVID-19 Vaccine Distribution Update

**Presented by Aon**

**Issue Date: April 29<sup>th</sup>, 2021**

(Note: Aon is updating this information regularly. This update replaces all prior dated and undated versions.)

# Today's Discussion

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- Status of Vaccine Development—Approvals and Safety
- Updated CDC Guidance for Vaccinated Individuals
- Update on COVID-19 Variants
- Vaccine Availability and Distribution—Employer Considerations
- Support for Employee Vaccinations—Employer Options
- Sources of Information
- Next Steps

# U.S. Status of Vaccine Development—Approvals and Safety (as of April 29<sup>th</sup>)

## Vaccines in Development/Approval Process

Manufacturer*	Status
Pfizer-BioNTech	Authorized by FDA for emergency use
Moderna	Authorized by FDA for emergency use
Janssen (J&J)	Authorized by FDA for emergency use
AstraZeneca	Applied for EUA Approval

\* Pfizer-BioNTech & Moderna are mRNA vaccines. J&J and AstraZeneca are using a non-replicating viral vector vaccine; not mRNA

## All COVID-19 Vaccines Will Be Rigorously Evaluated for Safety

- mRNA vaccines are being held to the same rigorous safety standards as all other types of vaccines in the U.S.
- While an mRNA vaccine has never been on the market anywhere in the world, mRNA vaccines have been tested in humans before, for at least four infectious diseases: rabies, influenza, cytomegalovirus, and Zika.
- Viral vector vaccines are well established and produce strong immune responses.

Source:

1. <https://www.jhsph.edu/covid-19/articles/what-is-emergency-use-authorization.html>
2. <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
3. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html>
4. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7250668/>

## FDA EUA vs. FDA Approval

### ▪ FDA EUA

- A mechanism to facilitate the availability during public health emergencies
- In an emergency, the FDA makes a product available to the public based on the best available evidence, without waiting for all the evidence that would be needed for FDA approval
- FDA must determine that the known and potential benefits outweigh the known and potential risks

### ▪ FDA Approval

- Data on the drug's effects reviewed by CDER (Center for Drug Evaluation Research)
- Extended data retrieval period

# J&J Vaccine FDA Reinstatement and CDC Guideline update

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**On April 23, 2021, the FDA lifted the pause on J&J vaccine distribution in a joint press release with the CDC, recommending that use of the vaccine continue and noting:**

- The FDA and CDC have confidence this vaccine is safe and effective in preventing COVID-19.
- The available data shows the vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 years of age and older.
- The issue that led to the pause relates to blood clotting. Specifically, blood clots in the veins in the brain (CVST), combined with thrombocytopenia (low blood platelet count); a condition called TTS (Thrombosis-Thrombocytopenia Syndrome).
  - The chance of TTS occurring is very low (see next slide for more perspective on how low)
  - The FDA and CDC will continue a vigilant monitoring process.
- Health care provider, recipient and caregiver fact sheets must now include information about the risk of this syndrome.

Sources:

1. <https://www.fda.gov/news-events/press-announcements/fda-and-cdc-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough>
2. [Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen \(Johnson & Johnson\) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021 | MMWR \(cdc.gov\)](#)
3. [CDC Recommends Use of Johnson & Johnson's Janssen COVID-19 Vaccine Resume | CDC](#)
4. [Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen \(Johnson & Johnson\) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021 | MMWR \(cdc.gov\)](#)

# Further Insight into Blood Clot Risk from J&J Vaccine

Age Group (Female)	TTS Cases	Doses Administered	Reporting Rate
18-49 Years Old	13	1,866,294	7.0 per million
50+ Years old	2	2,125,239	0.9 per million

Age Group (Male)	TTS Cases	Doses Administered	Reporting Rate
18-49 Years Old	0	1,977,330	0.0 per million
50+ Years old	0	2,010,144	0.0 per million

Statistics above are taken from the ACIP (Advisory Committee on Immunization Practices) presentation on April 23 2021. For the full ACIP meeting presentation, please see this link: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-04-23/03-COVID-Shimabukuro-508.pdf>

The chance of TTS occurring is very low (0.000188% chance, which is less than 1 per 1,000,000 people vaccinated). In contrast, the risk of dying from COVID-19 infection is 1.8%, which is significantly higher than the risk of getting TTS from the vaccine.

National Center for Immunization & Respiratory Diseases



**Thrombosis with thrombocytopenia syndrome (TTS) following Janssen COVID-19 vaccine**

Advisory Committee on Immunization Practices (ACIP)  
April 23, 2021

Tom Shimabukuro, MD, MPH, MBA  
CDC COVID-19 Vaccine Task Force  
Vaccine Safety Team

# CDC Guidance for Fully Vaccinated People – Updated April 27, 2021

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## Overview of Updated Guidance for Fully Vaccinated People

- Guiding principles for fully vaccinated people are now provided.
- Immunocompromised people, need to consult their healthcare provider about these recommendations, even if fully vaccinated.
- Fully vaccinated people no longer need to wear a mask outdoors, except in certain crowded settings and venues.
- Clarification that fully vaccinated workers no longer need to be restricted from work following an exposure as long as they are asymptomatic.
- Fully vaccinated residents of non-healthcare congregate settings no longer need to quarantine following a known exposure.
- Fully vaccinated asymptomatic people without an exposure may be exempted from routine screening testing, if feasible.

# CDC Guidance for Fully Vaccinated People – What to Keep Doing

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## What You Should Keep Doing if You're Fully Vaccinated

- You should still protect yourself and others in many situations by wearing a mask that fits snugly. Take this precaution whenever you are:
  - In indoor public settings
  - Gathering indoors with unvaccinated people (including children) from more than one other household
  - Visiting indoors with an unvaccinated person who is at increased risk of severe illness or death from COVID-19 or who lives with a person at increased risk
- You should still avoid indoor large gatherings.
- If you travel, you should still take steps to protect yourself and others. You will still be required to wear a mask on planes, buses, trains, and other forms of public transportation traveling into, within, or out of the United States, and in U.S. transportation hubs such as airports and stations. Fully vaccinated international travelers arriving in the United States are still required to get tested within 3 days of their flight (or show documentation of recovery from COVID-19 in the past 3 months) and should still get tested 3-5 days after their trip.
- You should still watch out for symptoms of COVID-19, especially if you've been around someone who is sick. If you have symptoms of COVID-19, you should get tested and stay home and away from others.
- You will still need to follow guidance at your workplace.
- People who have a condition or are taking medications that weaken the immune system, should talk to their healthcare provider to discuss their activities. They may need to keep taking all precautions to prevent COVID-19.

Source: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html>

# Choosing Safer Activities

The screenshot shows the CDC website's 'Daily Activities & Going Out' page. The 'Choosing Safer Activities' section includes the following text:

- If you are **fully vaccinated** you can start doing many things that you had stopped doing because of the pandemic.
- When choosing safer activities, consider how COVID-19 is spreading in your community, the number of people participating in the activity, and the location of the activity.
- Outdoor visits and activities are safer than indoor activities, and fully vaccinated people can participate in some indoor events safely, without much risk.
- If you haven't been vaccinated yet, [find a vaccine](#).

The 'What you need to know' section includes:

- In general, the more closely you interact with others and the longer that interaction, the higher the risk of COVID-19 spread.
- If you decide to engage in public activities, continue to protect yourself by [practicing everyday preventive actions](#).
- Keep these items on hand when venturing out: [a face mask](#), tissues, and a hand sanitizer with at least 60% alcohol, if possible.

A red arrow points from the 'Updated CDC guidance and resources for fully vaccinated individuals' text to the 'Safer Activities' button in the screenshot.

Updated CDC guidance and resources for fully vaccinated individuals

Source: [https://www.cdc.gov/coronavirus/2019-ncov/vaccines/pdfs/324153\\_choosingSaferActivities11.pdf](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/pdfs/324153_choosingSaferActivities11.pdf)

## Choosing Safer Activities

	Unvaccinated People	Your Activity	Fully Vaccinated People
		<b>Outdoor</b>	
Safest		Walk, run, or bike outdoors with members of your household	
		Attend a small, outdoor gathering with fully vaccinated family and friends	
		Attend a small, outdoor gathering with fully vaccinated and unvaccinated people	
Least Safe		Dine at an outdoor restaurant with friends from multiple households	
		Attend a crowded, outdoor event, like a live performance, parade, or sports event	
		<b>Indoor</b>	
Less Safe		Visit a barber or hair salon	
		Go to an uncrowded, indoor shopping center or museum	
		Ride public transport with limited occupancy	
Least Safe		Attend a small, indoor gathering of fully vaccinated and unvaccinated people from multiple households	
		Go to an indoor movie theater	
		Attend a full-capacity worship service	
		Sing in an indoor chorus	
Least Safe		Eat at an indoor restaurant or bar	
		Participate in an indoor, high intensity exercise class	

### Get a COVID-19 vaccine



**Prevention measures not needed**

**Take prevention measures**

Fully vaccinated people: wear a mask.  
Unvaccinated people: wear a mask, stay 6 feet apart, and wash your hands.

Safety levels assume the recommended prevention measures are followed, both by the individual and the venue (if applicable).

CDC cannot provide the specific risk level for every activity in every community. It is important to consider your own personal situation and the risk to you, your family, and your community before venturing out.



# Update on COVID-19 Variants Circulating in the U.S.

Viruses constantly change through mutation, and new variants of a virus are expected to occur over time. Sometimes new variants emerge and disappear. Other times, new variants emerge and persist. Multiple variants of the virus that causes COVID-19 have been documented in the United States and globally during this pandemic.

## What we know

- There are five Variants of Concern (VOC) in the U.S. today:
  1. B.1.1.7: First identified in December 2020. It was initially detected in the UK.
  2. B.1.351: First identified in the U.S. end of January 2021. It was initially detected in South Africa in December 2020.
  3. P.1: This variant was first detected in the US in January 2021. P.1 was initially identified in travelers from Brazil, who were tested during routine screening at an airport in Japan, in early January.
  4. B.1.427 and B.1.429: These two variants were first identified in California in February 2021 and were classified as VOCs in March 2021

## What We Don't Know

- Scientists are working to learn more about these variants, and more studies are needed to understand:
  - How widely these new variants have spread
  - How the disease caused by these new variants differs from the disease caused by other variants that are currently circulating
  - How these variants respond to existing therapies and vaccine

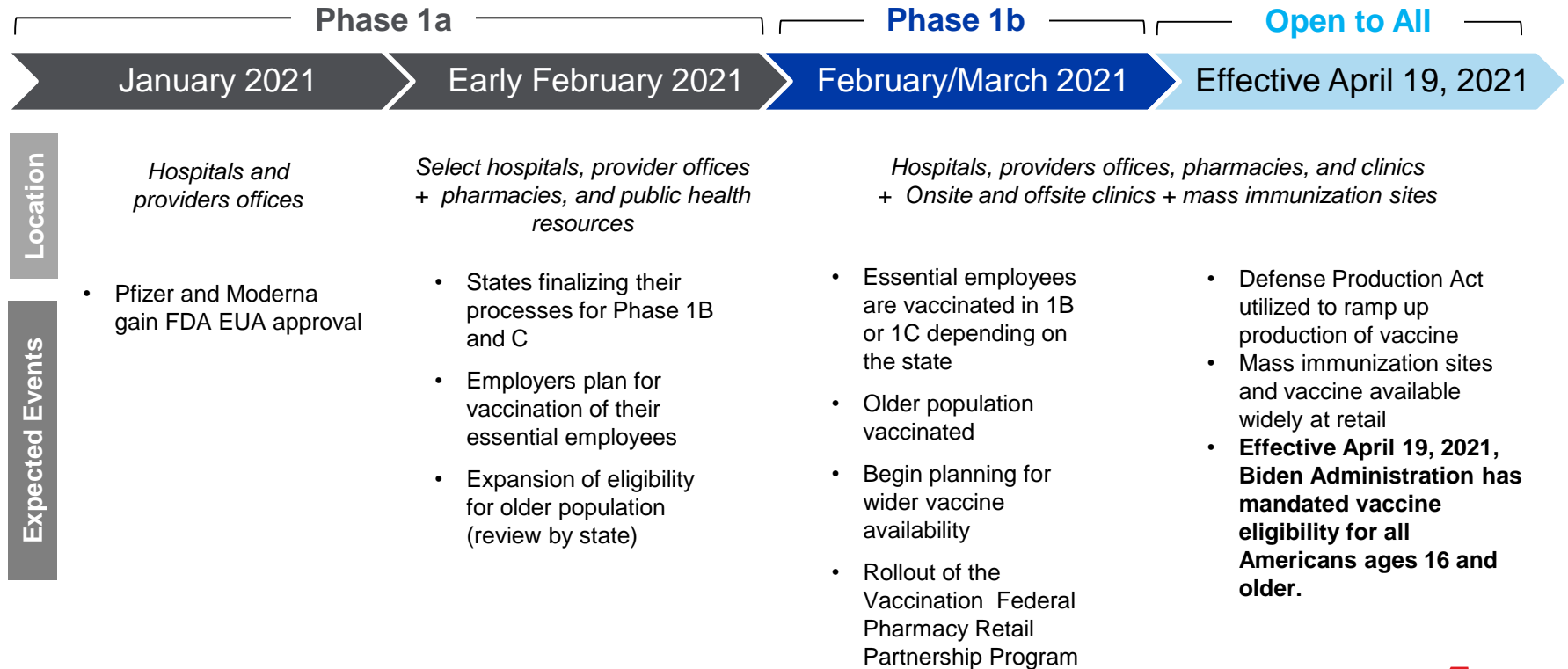
## CDC Variant Classifications

- CDC established a classification scheme for variants of SARS-CoV-2. These classifications include definitions and attributes of the variant:
  1. Variant of Interest (several circulating in U.S.)
  2. Variant of Concern (currently five circulating in U.S.)
  3. Variant of High Consequence (currently none circulating in U.S.)

### Sources:

1. <https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html>
2. <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html>

# Potential Six-Month U.S. Vaccine Distribution Timeline



# Vaccine Distribution Employer Considerations – Preparation/Execution

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## What should firms do right now to respond to current market conditions?

- Build/review approach for communicating and educating the workforce to confirm messaging aligns with open vaccination status in the U.S. effective April 19<sup>th</sup>, 2021
- Build a strategy for onsite vaccination if/where needed to augment local retail options
  - Inventory/survey employees on a state-by-state basis to determine where efforts should focus
- Understand cost implications of vaccine administration, given vaccination sites and coverage details
- Continue to monitor state requirements and changes in eligibility rules

# Addressing Vaccination Hesitancy – Employer Options & Considerations

## Educate

- What sources of information will be available?
- How will materials be updated based on emerging evidence?
- Will the education be factual only or meant to drive behavior?
- If mandate or incentive exists, communication should include availability, payment, timelines, consequences
- Expect significant difference of opinion from employees on the issue of vaccination
- Are there legal risks if available information turns out to be incorrect?
- Is this consistent with desired culture?

## Incentivize

- Will require significant education to support
- Similar to an incentive for a flu vaccine
- Tax/legal considerations of incentivizing dependents vs. employees and those enrolled in the health plan vs. not enrolled
- Guidance under ADA and GINA is outstanding for wellness programs
- Reasonable accommodation may be needed
- What constitutes proof of vaccination—HIPAA issue?
- Is this consistent with desired culture?

## Mandate

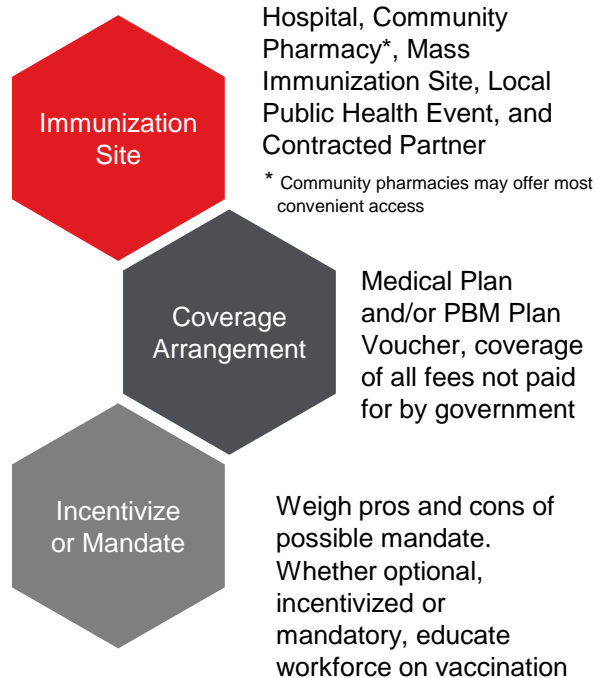
- Will require significant education to support
- Consider workplace discrimination laws
- EEOC advises the COVID vaccine is no longer a medical exam, employers must administer disability-related and religious exemptions
- What possible business liabilities exist if a negative reaction occurs?
- What constitutes proof of vaccination—HIPAA issue?
- Is this consistent with desired culture?

## No Action

- Position as a personal decision for employees
- What business risks exist if some significant percentage of employees choose to not receive a vaccination?
- If employees are required to come to work, will they expect support from the employer for vaccination?
- Is this consistent with desired culture?

Decisions should be made in concert with legal counsel and adjusted as new information becomes available

# Provider Delivery Considerations and Pricing – U.S.



## Who pays for the vaccine?

U.S. Government\*



Vaccine Doses

Employer\*\*



Administration of Vaccine



Other Costs (transport, vendor fees, etc.)

Vaccine doses purchased with U.S. taxpayer dollars will be given to the American people **at no cost**. However, vaccination providers will be able to charge an administration fee for administering the shot. Vaccine providers can get this fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration's Provider Relief Fund. (per CDC 2021<sup>4</sup>)

### \*Initial Cost of Vaccine to US Government

US Government has paid for cost of vaccine to vaccinate anyone who wishes to be vaccinated

- Pfizer/BioNTech (two doses necessary)<sup>1</sup>
- Moderna (two doses necessary)<sup>2</sup>
- Janssen (one dose)<sup>3</sup>

### \*\*Initial Cost of Vaccine Administration

In order to administer the vaccine, a provider will need to get the vaccine to the site, store it, ensure there are licensed healthcare providers available to vaccinate, and provide necessary equipment (syringes, dry ice, PPE). The costs for administering each dose has been set at \$40 by the Centers for Medicare and Medicaid. That said, it is clear that individuals will not be charged to receive vaccination..

Source:

1. <https://www.barrons.com/articles/covid-19-vaccine-makers-could-be-heroes-but-not-if-the-price-tag-is-too-high-51595623222><sup>1</sup>
2. <https://www.cbsnews.com/news/coronavirus-vaccine-moderna-charging-more-rival-treatments/><sup>2</sup>
3. <https://scrip.pharmaintelligence.informa.com/SC141970/COVID19-Vaccine-Could-Cost-As-Little-As-10-A-Dose-Says-Janssen><sup>3</sup>
4. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html><sup>4</sup>

# Vaccine Distribution Employer Considerations – Adverse Medical Reactions

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In the rare event of an adverse medical reaction to the vaccine – what recourses might be pursued?

## Injury Support and Compensation

- Vaccine distribution, policies and communications can impact workers' compensation applicability.
- Some considerations:
  - Vaccine Sponsor: Are you bringing vaccinations onsite? Are you leveraging public community sites?
  - Vaccine Campaigns: What is the communication content?
  - Required or Voluntary: Will you mandate for employees?



## Countermeasures Injury Compensation Program (CICP)

- In the unlikely event a serious injury stems from a covered countermeasure, persons can apply for compensation from lost wages, medical wages or death of a family member.
  - Covered countermeasure is broadly defined and includes prescription drugs or devices used to treat COVID-19
- Program run by Health and Human Services (HHS) and “vaccine court” orders claim payouts
- Workers must apply on their own
- CICP is only a payor of last resort and only after extensive review of the applicant's case

# Biden Administration – Executive Orders for COVID-19

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## January 21<sup>st</sup>, 2021 – Inauguration + 4 Crises (one of which is COVID-19)

1. **Mask Mandate EO:** Directs Agencies to require mask wearing and other public health practices for federal workers, in federal buildings, and on federal lands
2. **WH Structure EO:** Establishes the White House structure to combat COVID-19
3. **WHO Letter:** Reversing the Trump Administration's decision to withdraw

## January 21<sup>st</sup>, 2021

1. **Supply Chain EO:** Direct review of COVID supply chain and lays groundwork for invoking Defense Production Act
2. **National Guard and FEMA EO:** Reimburses states up to 100% for using national Guard to combat COVID-19
3. **Safe Travel EO:** Directs agencies to implement public health measures on certain public modes of transportation (airports, aircraft, trains, public maritime vessels, intercity buses, and all forms of public transportation); directs agencies to act within 14 days to require that any person who seeks to board a flight to the U.S. from foreign country is required to provide a proof of a recent negative COVID-19 test prior to departure
4. **Global Health PPD:** Directs Agencies to strengthen efforts to combat COVID-19 globally and strengthen global pandemic preparedness
5. **Testing/Workforce EO:** Creates Pandemic Test Board and directs HHS to support states' efforts to deploy public health personnel to combat COVID-19
6. **Data EO:** Strengthens pandemic related data collection and transparency
7. **Treatment EO:** Directs actions to support research into novel COVID-19 treatment, secure an adequate supply, and promote equitable distribution

## February 2021

1. **DPA:** Defense Production Act (DPA) put in place to increase vaccine production and distribution

# Opportunity for Employers to Participate in Distribution – Employer Options

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Aon leaders and subject matter experts discuss the issues surrounding COVID-19 and approaches related to mitigating its impact. All webinar recordings can be found here: [aon.com/coronavirus](https://aon.com/coronavirus), or you can use the working links below (Note: FAQ documents are as important as the webinar recordings themselves):

February 4, 2021:

[Installment One: New Dawn in COVID-19 Vaccination, Biden Administration Actions and Implications for Distribution](#)  
[New Dawn in COVID-19 Vaccination – Webinar FAQ](#)

February 23, 2021:

[Installment Two: Tactical and Logistical Planning for COVID-19 Vaccinations](#)  
[Tactical and Logistical Planning for COVID-19 Vaccinations – Webinar FAQ](#)

March 9, 2021:

[Installment Three: Managing a Partially Vaccinated Workforce](#)  
[Managing a Partially Vaccinated Workforce – Webinar FAQ](#)

March 30, 2021:

[Installment Four: Planning for Return to Travel and Convening](#)

April 20, 2021:

[Installment Five: Preparing for Future Risks and Reshaping the Workforce of the Future](#)  
[Preparing for Future Risks and Reshaping the Workforce of the Future - Webinar FAQ](#)



# Sources of Information – Topics from CDC Website (April 29<sup>th</sup>, 2021)

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1. [The CDC Website](#)
2. [State and Local Government Vaccine Distribution Plans](#)
3. Aon FAQ Documents
4. [CDC Interim Playbook for States](#)

## Vaccine Information for You and Your Family

8 Things to Know about the U.S. COVID-19 Vaccination Program >

Different COVID-19 Vaccines >

When Vaccine Supply is Limited, Who Gets Vaccinated First? >

Ensuring Safety of COVID-19 Vaccines >

What to Expect at Your COVID-19 Vaccination Visit >

Ensuring COVID-19 Vaccines Work >

Frequently Asked Questions about COVID-19 Vaccination >

Benefits of Getting a COVID-19 Vaccine >



## For Healthcare Professionals

Resources for the planning, allocation, distribution, administration, storage & handling, patient education, and more for COVID-19 vaccine.

[Vaccine Information for Healthcare Professionals](#)

Source: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>

# Next Steps for post-April 19 2021 Vaccination Environment

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- Confirm preferred employer approach to supporting employee vaccinations
  - Determine business preference regarding education, incentives and/or mandates
  - Determine if position on mandates may change as more people become fully vaccinated
  - Consult with legal counsel
  - Build/review administration and communication action plans accordingly
- Take action to support easy access to vaccine:
  - Establish connections with the state health departments—most often facilitated via existing state public relations resources
  - Confirm availability/access for each group of the population and determine if/where onsite options might be appropriate to augment existing retail options
- Contact your Aon team or send us a message if you would like to know more about how Aon might assist you in further developing or executing your workforce vaccination plan

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