COVID-19 Vaccination – Employer Considerations and FAQs

Issue Date: January 14th, 2021

(Note: This document replaces all prior dated and undated versions)

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COVID-19 Vaccination – Employer Considerations

Overview and Summary of Changes from prior version

Aon has developed this document to assist employers in shaping their organization's understanding of the COVID-19 vaccination process. This document shines a light on issues that employers should consider, and we will update this as more information becomes available.

We've organized our content around key questions employers should consider as they digest latest guidance regarding COVID-19 vaccination and determine how it applies to their workforce.

This document includes the following updates from prior version:

- Added a Table of Contents to make the document easier to navigate.
- Updated view of suggested prioritized populations for Phases 1a, 1b and 1c.
- Updated count for countries/economies participating in the COVAX Facility.
- Updated EEOC guidance as of December 16, 2020 with respect to COVID vaccination considerations for employers.

Please see the discussion which follows.

What business is my organization in?

The "What business is my organization in?" question is important because it helps an organization understand how the COVID-19 vaccination framework applies to its workforce. While each country's goal is to have enough COVID-19 vaccine for all of its people who wish to be vaccinated, early vaccine availability will be scarce in each country and a phased and prioritized approach to vaccination is important. As such, we expect that initial focus will be on people who are most critical to the response: those providing direct care and maintaining societal function, and those at highest risk for developing severe illness from COVID-19. Therefore, an employer may want to think about the following questions to understand how their workforce may fit into a country's priority focus:

- Is my organization in the healthcare industry, including the long-term care industry?
- Is my organization involved in providing first responders to state, local, territorial and/or tribal communities?
- Is my organization involved in creating a COVID-19 vaccine and/or its source components and/or administration supplies?
- Is my organization involved in delivering a COVID-19 vaccine?
- Is my organization involved in other essential services and/or critical infrastructure sectors? (Examples per CDC include Education Sector, Food & Agriculture, Utilities, Police, Firefighters, Corrections Officers, Transportation)

National governments have established frameworks to guide distribution and vaccination priorities, and those distribution and priorities may differ at the country level (as well as at the state and local level, depending on the country). Furthermore, most governments are utilizing a phased approach from a vaccine availability and timing perspective. It is likely that employers will need to evaluate the answers to the above questions in the context of where employees are located because distribution channels and networks for Phase 1 priority populations might differ from later phases where broader supplies are available.

Where is my organization's workforce located? US? Outside the US? Multinational?

The answer to this question is fundamental to understanding what parameters your organization must consider. It influences employer and workforce access, as well as cost and liabilities associated with COVID-19 vaccination.

Vaccine distribution is subject to country-level parameters

How the vaccine(s) will be distributed will be governed by each sovereign nation's COVID-19 response plan. As a result, an employer with a workforce located in US will be subject to US regulations as defined by Operation Warp Speed (OWS), Department of Health & Human Services (HHS) and state, local, territorial and tribal public health organizations, whereas an employer with a workforce located outside the US will be subject to the parameters of each of the countries in which it has employees. This creates complexity for multinational organizations that will be subject to laws and regulations in various national jurisdictions.

Understanding who owns the vaccine(s)

National governments own the initial vaccine supply and control distribution within their sovereign borders, via pre-negotiated contracts between vaccine developers/manufacturers and OWS (for US), COVAX Facility (on behalf of the184 countries participating in COVAX) and/or bilateral agreements that some individual countries may have made directly with vaccine developers/manufacturers. The vaccine developers/manufacturers do not own the initial vaccines they are producing; rather, their product is pre-committed and paid for through those contracts with OWS, COVAX Facility and/or the aforementioned bilateral agreements.

Only after the pre-contracted supplies have been exhausted might developers/manufacturers have more flexibility around vaccine allocation and financial terms and conditions, but even then, the national governments may still control within their sovereign borders until such time as they determine the needs of their population have been met.

How are vaccine costs handled?

Where costs of COVID-19 vaccines are shown, **those are costs to the national governments**. It is up to each national government as respects whether/how those costs are transferred to the nation's public and private health insurers and/or the general population (or, where a country addresses healthcare through local schemes, how they manage it through that local scheme). At least initially in the US, the US government is supplying the vaccine(s) free of charge to the US population; however, there will likely be vaccine administration costs charged by entities involved in administering vaccine, and those administrative costs may be paid for by public and private health insurance.

For US populations, a deeper dive into how costs may be handled might be helpful. We encourage employers to seek understanding from their own resources, but Kaiser Family Foundation (KFF) has published a view on this issue and it may be a helpful data point for understanding. KFF's perspective is captured below, and further discussion is available in their website at https://www.kff.org/report-section/distributing-a-covid-19-vaccine-across-the-u-s-a-look-at-key-issues-issue-brief/:

> *"In the US, the Families First Coronavirus Response Act and the CARES Act put specific requirements in place for no-cost COVID-19 vaccine access under private insurance, Medicaid, and Medicare. These build on existing protections provided under the Affordable Care Act (ACA). However, despite these measures, limitations and gaps related to a COVID-19 vaccine remain, and some individuals, particularly adults, may still face cost and access barriers. Some of the key provisions and outstanding issues include:*
>
> - ***Private Insurance**: Under federal legislation, most private insurers will be required to cover COVID-19 vaccines at no-cost. The ACA requires private health insurers to cover any vaccine recommended by ACIP at no-cost, although insurers have up to one year*

from the time of recommendation to implement coverage. The CARES Act specifically requires group health plans and health insurance issuers (those subject to ACA requirements for preventive services, but not including short-term limited duration or association health plans) to cover any ACIP-recommended COVID-19 vaccine without cost-sharing, including the cost of administration. Such coverage must begin 15 business days after an ACIP recommendation, which eliminates the usual up to one-year timeframe. However, these cost protections are not necessarily available if a patient seeks a vaccine from an out-of-network provider.

- ***Medicaid**. All children and some adults in Medicaid have coverage for vaccines at no cost, and Congress has temporarily addressed the gap for other adults to ensure coverage for a COVID-19 vaccine. The ACA requires Medicaid coverage of all ACIP-recommended vaccines at no-cost for adults in the Medicaid expansion population. However, for adults covered through traditional Medicaid pathways, immunizations are an optional Medicaid benefit and, when covered, cost-sharing may be imposed. Currently, less than half of states cover all ACIP-recommended adult immunizations. The Families First Act addressed this by authorizing a 6.2 percentage point increase in federal Medicaid matching funds to help states respond to COVID. As a condition of receiving these enhanced funds, states must cover COVID-19 vaccines without cost-sharing, during the public health emergency. When the public health emergency declaration ends, however, adults in traditional Medicaid could face cost-sharing or may not have coverage for the vaccine. For children, Medicaid covers vaccines at no-cost through the Vaccines for Children Program (VCP), a 100% federally funded entitlement program created by Congress in 1993. The VCP also provides no-cost vaccine coverage for American Indian and Alaskan Native children, uninsured children, and children who meet the program's criteria for being underinsured. In addition, the Children's Health Insurance Program (CHIP) also provides vaccine coverage for its enrollees, uninsured children who have incomes above Medicaid eligibility levels.*

- ***Medicare**. Vaccines are covered through Medicare, but some beneficiaries may face cost-sharing or delayed access for a COVID-19 vaccine, depending on the process used by FDA to make a vaccine available for use. Medicare covers vaccines under Parts B and D, with most vaccines covered under Part D. Part D plans must cover all FDA-approved vaccines, although they may impose cost-sharing. The CARES Act requires Medicare Part B to cover a COVID-19 vaccine and its administration without cost-sharing upon licensure by the FDA; this applies to beneficiaries in both traditional Medicare and Medicare Advantage plans. It does not, however, require such coverage upon issuance of an [FDA Emergency Use Authorization (EUA)], which could limit access to vaccines for the more than 60 million people covered by Medicare if a vaccine first becomes available via an [EUA].*

- ***Uninsured and underinsured adults:** There is no federal entitlement vaccination program for uninsured and underinsured adults. Instead, existing federal programs that support vaccination for the uninsured and underinsured are discretionary and rely on annual Congressional appropriations for funding. These include Section 317 of the Public Health Service Act, which authorizes the federal purchase of vaccines for uninsured or underinsured adults (as well as children and adolescents), and can be used during an outbreak, and funding for FQHCs, which provide vaccinations regardless of ability to pay. During [the H1N1 pandemic], the federal government purchased the vaccine and funded public health authorities to ensure that uninsured and underinsured adults received it free of charge, as long as they were vaccinated at a public health clinic or other designated site. Similarly, it is expected that the federal government's purchase of COVID-19 vaccines will be used to support free vaccination of adults who are uninsured and underinsured. Funds to providers to cover vaccine administration costs will be available through a "COVID-19 claims reimbursement program", part of a new Provider Relief Fund created and funded through the CARES Act and the Paycheck Protection Program and*

Health Care Enhancement Act. Despite these measures, it is not yet known if the existing advance purchase of COVID-19 vaccines or the claims reimbursement program will be sufficient to support vaccination for all those who are uninsured and underinsured, and whether additional funding or other remedies might be needed."

How does the vaccine distribution process work in the geography(ies) where my workforce is located?

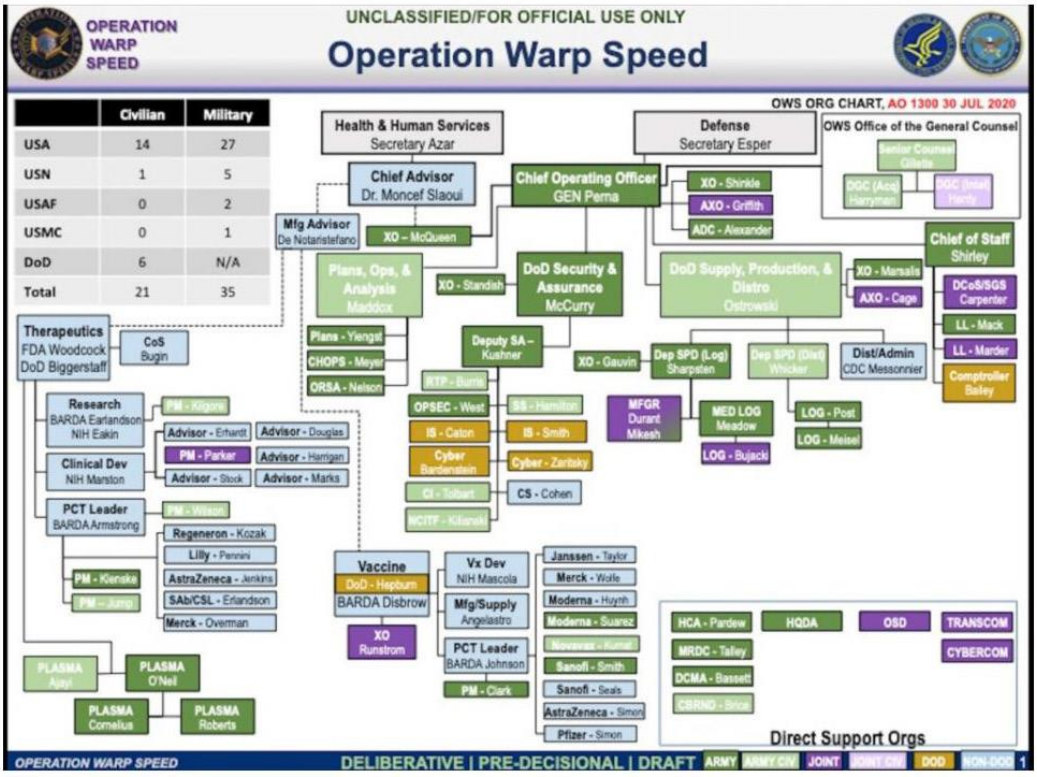
For this discussion, we'll divide the conversation into US and countries outside the US.

Geography: US

Overall, response efforts to the COVID-19 pandemic are locally executed, state managed, and federally supported.

Plans for U.S. Distribution of COVID-19 Vaccines

The federal government has released several documents addressing how vaccine distribution will proceed. On August 4, the Centers for Disease Control and Prevention (CDC) provided state and local health departments with interim vaccine planning assumptions and action steps to inform development of COVID-19 pandemic vaccination plans. Actual planning documents were provided to health authorities on August 27; at this time, CDC also sent a letter to governors asking them to ensure distribution sites in their states could be operational by November 1. OWS provided Congress with a federal vaccine distribution strategy, and on November 5, 2020, CDC released their COVID-19 Vaccination Program Operational Guidance (which includes an updated interim playbook for jurisdiction operations with an issue date of October 29, 2020) at https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html. In addition, Operation Warp Speed (OWS) has provided a view of their organization chart to show how they are addressing various areas of focus:https://www.statnews.com/2020/09/28/operation-warp-speed-vast-military-involvement/. We've displayed that chart below:



Based on these documents, current U.S. distribution plans are as follows:

- After FDA authorization or approval, the federal government and 64 state, local, and territorial jurisdictional immunization programs that CDC funds and works with will begin to oversee delivery of available vaccine doses to approved administration sites across the country. At first, there will be few vaccine doses available, so the federal government will determine the number of doses to be allocated to each jurisdiction. This allocation will depend on which vaccine(s) are approved, the number of doses available for those vaccines, and the population of each state (at least initially).

- Distribution in the US is expected to unfold in three phases.

  The CDC sets the U.S. adult and childhood immunization schedules based on recommendations from the Advisory Committee on Immunization Practices (ACIP), a group of medical and public health experts that develops recommendations on how to use vaccines, and as such, ACIP is involved in the discussion of COVID-19 vaccine for the US. As of December 22, 2020, the CDC has issued ACIP guidance as respects COVID-19 vaccination that follows three vaccine distribution phases:

  - Phase 1 – In the early days, vaccine supply will be ramping up and supplies will be scarce. Priority: Tightly focused vaccine administration. Vaccine administration to occur in closed settings best suited for reaching critical Phase 1a populations:
    - Phase 1a population includes:
      - Healthcare personnel due to their direct exposure to the virus and their critical role in keeping the nation's hospitals and clinics functioning.
      - Residents and employees of long-term-care facilities who account for nearly 40 percent of deaths from COVID-19.
        Note: OWS has contracted with CVS and Walgreens to administer the vaccinations in the long-term care facilities.
    - Phase 1b and 1c: ACIP has expressed support for these groups to get the shots next:
      - Phase 1b: People 75 years or older, and non-healthcare front line essential workers. Examples of non-healthcare front line essential workers include employees in these industry sectors, per CDC: Education Sector, Food & Agriculture, Utilities, Police, Firefighter, Corrections Officers, Transportation.
      - Phase 1c: People between 65-74 years old, people aged 16-64 with high-risk medical conditions, and essential workers not included in Phase 1b.

  Note: The groups involved in Phase 1 may overlap. Many healthcare and essential workers also have underlying conditions, and some are over 65.

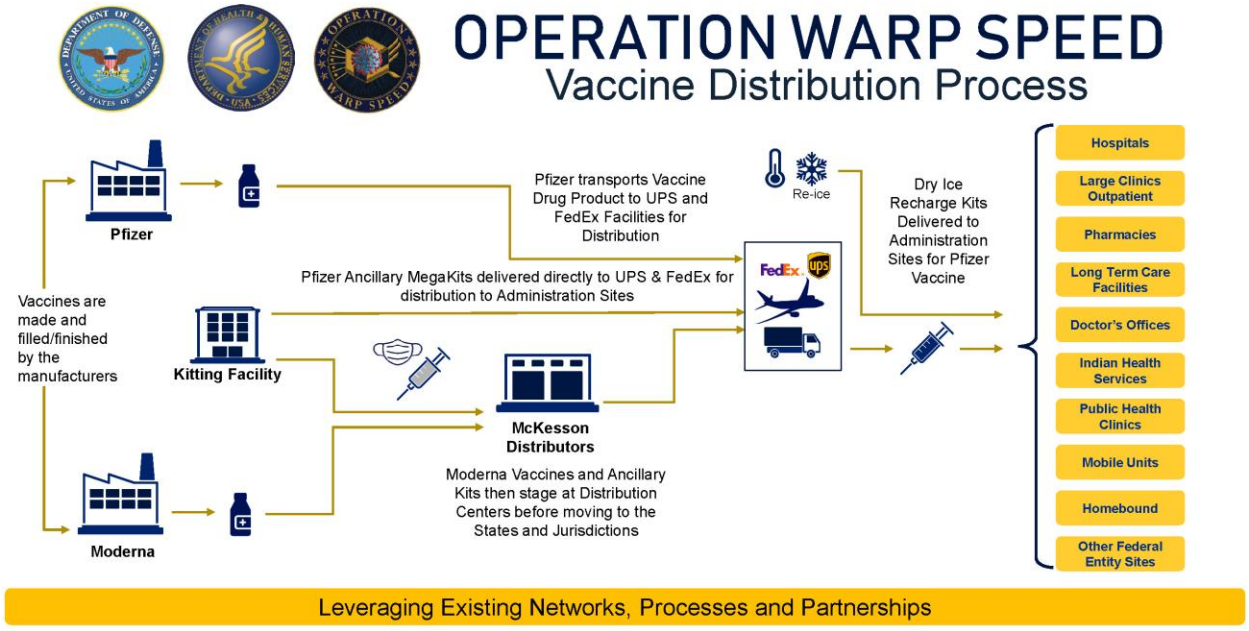
  Note also that, while the above discussion captures ACIP's suggested guidance, such guidance is being customized by state, local, territorial and/or tribal communities to reflect the unique circumstances of their populations, so may vary by jurisdiction.

  - Phase 2 – Larger number of doses available.
    Priority:

    - Remainder of Phase 1 populations
    - Vaccine administration will rely on a broader provider network and settings.
      Note: This is where pharmacies and public health venues come into play as vaccine administrators – organizations who have contracted with Federal Pharmacy Partnership for COVID-19 Vaccinations and have completed the required steps to comply with requirements..

  - Phase 3 – Large number of doses available. Continued vaccination; shift to routine strategy
    Priority:
    - Remainder of Phase 1 and Phase 2 populations
      Open access to vaccination, and administration through additional private partners

See chart below which illustrates OWS' view of the distribution process. This distribution process may become more widely sourced for Phases 2 and 3, but it provides perspective on how things look for Phase 1. https://www.hhs.gov/sites/default/files/ows-vaccine-distribution-process.pdf



With respect to additional steps, please see these perspectives from KFF (taken from https://www.kff.org/report-section/distributing-a-covid-19-vaccine-across-the-u-s-a-look-at-key-issues-issue-brief/):

- Per KFF, "*Pre-approved administration sites will make requests for vaccine doses to their jurisdiction's immunization program, which will review and approve these requests according to its allocation of vaccines from the federal government. Jurisdictions' immunization programs will submit orders to the federal government (initially to OWS, potentially later to CDC as well). Once reviewed by federal officials, vaccine doses will be delivered by a central distributor to administration sites within 48 hours of approval.* ***This stands in contrast to the distribution system used for seasonal influenza where, outside of the CDC's Vaccines for Children Program (VCP) and the Section 517 Immunization Program (described below), vaccine production and distribution are primarily handled by the private sector.*** *For COVID-19, the federal government has selected McKesson Corporation as its central distributor. McKesson currently serves as the central distributor for the VCP and was the central distributor during H1N1 pandemic influenza in 2009-2010."*

- *In addition to vaccines being delivered by the central distributor via orders received from jurisdictions' immunization programs, the federal government may also ship doses to designated secondary vaccine depots and receive orders from and ship doses directly to some private partners with agreements in place such as large retailers and pharmacies, especially as more doses become available.*

- *Indications are that the administration of the vaccine to individuals will likely take place in a wide variety of locations, including:*
    - *public and private hospitals and clinics (e.g., federally qualified health centers, rural health centers),*
    - *medical practices,*
    - *pharmacies, and*
    - *potentially, government-run mass vaccination locations.*

Jurisdictions' immunization programs and the federal government will work together to identify and approve distribution sites and expect the need to expand the network of partner sites to reach all target populations.

- *While the U.S. military has been a key part of the OWS effort by supplying logistical, program management, and contracting expertise, current plans do not include a major role for the military in distributing COVID-19 vaccines to the general public."*

Understanding the Numbers – Using US as example, shown below is why prioritizing is important when vaccine supply is limited (Figures per ACIP at https://www.cdc.gov/vaccines/acip/index.html):

Initial commitment for US in December: 40 Million doses to cover 20 Million people

Counts:

21 Million – US Healthcare employees

2 Million – US long-term care (LTC) residents

23 Million – Phase 1a priority (given initial supply of 20 Million, *we are 3 Million short for Phase 1a*)

Supply, logistics, and monitoring (these are additional perspectives from KFF taken from https://www.kff.org/report-section/distributing-a-covid-19-vaccine-across-the-u-s-a-look-at-key-issues-issue-brief/)

"Government-led vaccine distribution in the timeframe and at the scale being contemplated for COVID-19 has never before been done in the U.S., with hundreds of millions of doses needing to be distributed, over as short period of time as possible, in order to vaccinate most of the U.S. population. In addition to the sheer number of doses likely to be needed, there are a host of logistical issues and supply challenges that come with the effort to distribute COVID-19 vaccines, including:

- *The actual set of sites where vaccines will be administered, especially for the earliest phases of distribution, remains unclear. Federal guidance and operational plans indicate that it will be a mix of providers (such as hospitals and medical practices), pharmacies, state and local public health departments, and potentially government-run mass vaccination sites. Thousands of specific partners and site locations will have to be identified (and in some cases created), vetted, and approved before vaccine doses can be distributed to them. The accessibility of these sites will have implications for equitable access to the vaccine, given that lower income individuals and people of color are more likely to face transportation/location-based barriers to health care.*

- *Existing state and local governmental distribution networks are primarily focused on delivering childhood, but not adult, vaccines. Especially early on, adults will likely be the focus for COVID-19 vaccine distribution, and mass distribution of vaccines to adults has, in the past, proven more challenging than delivering to children. This is because there are fewer pre-existing relationships and networks through state and local governments for adult vaccinations.*

- *There will be a need to account for flexibility in planning and implementation of distribution. As the CDC and HHS distribution plans already recognize, there will be few doses available early on in the distribution process, with the supply of vaccine extremely limited compared to the demand. This will mean the first doses will be rationed, and that roll out will occur with unpredictable timing, as vaccine doses become available as production expands. Therefore, it will be important to set realistic expectations on initial supply.*

- *Several of the likely COVID-19 vaccine candidates need to be preserved at extremely cold temperatures, which will require specialized equipment not currently available in many distribution sites. Urban areas, where specialized equipment is more likely to be present, will likely be able to manage cold chain supply processes more easily than rural areas where the equipment may not be available, which could introduce inequities in distribution. The federal government has stated it would*

likely not require jurisdictions to procure additional equipment but could implement a distribution approach that involved distributed networks of federally managed cold chain sites and use of mass vaccination to reach target populations.

- *Several leading vaccine candidates will require two doses for immunization, with the second dose given several weeks after the first, which raises additional challenges. Vaccines with two-dose regimens will require careful tracking of doses and follow up with each individual receiving the vaccine to ensure they receive the same vaccine, with the second dose given at the proper time. The CDC and local jurisdictions are in the process of implementing a new vaccine tracking system to monitor COVID-19 vaccine administration and help with multiple dose tracking, but it is unclear if, or how, the new system will integrate with existing immunization information systems (IIS). There is already great variation in IIS across jurisdictions, and many have gaps and face other challenges including low provider participation rates and lack of interoperability of immunization records with patients' electronic health records and across jurisdictional borders.*

- *Vaccines may be released on an accelerated schedule, and some may be administered under an EUA without having gone through a full safety review initially, so the government is planning on implementing enhanced safety monitoring to track vaccine adverse events. Close tracking of safety and adverse events is yet another layer of planning and administration falling primarily on state and local health authorities. Tracking adverse events closely will be important not only to determine the safety of the vaccines, but also to establish evidence of harm in individuals for potential compensation purposes. Under the liability protections outlined in the Public Readiness and Emergency Preparedness (PREP) Act manufacturers cannot be held liable for damages caused by their vaccines (except where there has been willful misconduct). However, individuals who die or suffer serious injuries directly caused by the administration of an approved vaccine under conditions of a public health emergency could receive compensation from the federal government through the Countermeasures Injury Compensation Fund (CICF), although there are some limitations to the CICF.*

- *Given that demand will be high and supply low during the initial phase of distribution, vaccine doses will be seen as highly valuable and therefore vulnerable to theft, fraud or corruption. This means physical security and close tracking of the shipments of doses will be required to ensure that vaccine doses get to delivered and administered properly, a level of planning and oversight beyond what is normally needed for vaccine distribution."*

Vaccination Administration

Phase 1a - In the US, Department of Health & Human Services (HHS) has signed agreements with CVS and Walgreens to deliver to nursing homes and administer shots at nursing homes for residents and employees.

Per CDC Playbook as of October 29 2020, for **AFTER** Phase 1a is completed, HHS has signed agreements with these pharmacies and grocery stores:

• Walgreens • CVS Health Corporation • Walmart Stores, Inc (including Sam's) • Rite Aid Corp • The Kroger Co (i.e., Kroger, Harris Teeter, Fred Meyer, Frys, Ralphs, King Soopers, Smiths, City Market, Dillons, Marianos, Pick-n-Save, Copps, Metro Market) • Publix • Costco 75 | Page Version 2.0 • Albertsons Companies (i.e., Osco, Jewel-Osco, Albertsons, Albertsons Market, Safeway, Tom Thumb, Star Market, Shaws, Haggen, Acme, Randalls, Carrs, Market Street, United, Vons, Pavilions, Amigos, Lucky's, Pak n Save, Sav-On) • Hy-Vee • Meijer • H-E-B • Retail Business Services (i.e., Food Lion, Giant Food, The Giant Company, Hannaford Bros Co, Stop & Shop).

Per CDC playbook, *"together, these pharmacy partners will extend the COVID-19 vaccination provider network to over 35,000 store locations. Store lists for each of these partners will be shared with jurisdictions. Additional partners are also expected to sign on, further expanding the program. Details on additional partners will be shared with jurisdictions as soon as they are available.*

Based on their (1) size and reach, (2) capability to store vaccines and ensure cold chain management, (3) ability to meet data reporting requirements to jurisdictions and CDC, and (4) estimated daily number of doses each facility is able to administer, these partners stand ready to assist jurisdictions in COVID-19 vaccination efforts."

Vaccination Partners (taken from https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf)

Per CDC Playbook, "*jurisdictions are encouraged to reach out to potential COVID-19 vaccination providers and target the appropriate settings so that COVID-19 vaccination services are accessible to the initial populations of focus when the first COVID-19 vaccine doses arrive. Providers and settings that maximize the number of people who can be vaccinated should be prioritized for enrollment; however, jurisdictions should ensure social distancing and other infection control procedures can be maintained in selected settings (see CDC guidance on vaccination during a pandemic).*

- *All providers/settings, especially those enrolled for Phase 1, must be able to meet the reporting requirements discussed in Section 9: COVID-19 Vaccine Administration Documentation and Reporting and Section 11: COVID-19 Requirements for Immunization Information Systems or Other External Systems.*

- *Jurisdictions should consider partnering with the private sector and with local hospitals or health systems to provide COVID-19 vaccination in the closest proximity possible to the initial populations of focus. For example, partnering with critical access hospitals will be key to vaccinating Phase 1 populations in rural areas. Suggested early COVID-19 vaccination providers/settings include: • Large hospitals and health systems • Commercial partners* (e.g., pharmacies) • Mobile vaccination providers • Occupational health settings for large employers • Critical access hospitals, RHCs, community health centers, or other central locations that can provide vaccination services for a broad area *CDC has agreements with CVS and Walgreens to assist with on-site vaccination in LTCFs. These partners have existing distribution (including cold chain), administration, and reporting infrastructure and relationships with some LTCFs to provide medication and, in some cases, vaccination services (e.g., seasonal influenza) for staff and residents; this may reduce burden on jurisdictional health departments. CDC will ensure jurisdictions have visibility on this work with retail pharmacy partners.*

- *Jurisdictions should recruit additional COVID-19 vaccination providers to expand equitable access to COVID-19 vaccination when vaccine supply increases. Enrollment activities should be tracked so vaccination providers are not approached multiple times. Establishing and building upon existing relationships with community partners and collaborating with medical societies, state licensing boards, the state Medicaid agency, state rural health office, IHS/tribal health entities, and health insurance issuers and plans in the area, may assist jurisdictions in identifying COVID-19 vaccination providers and the population groups they serve.*

- *Jurisdictions should consider engaging both traditional and nontraditional vaccination providers and settings, including: In-patient healthcare facilities and Large hospitals could potentially operate as open PODs. • LTCFs (e.g., nursing homes/skilled nursing facilities, assisted living facilities) • Doctors' offices and other outpatient facilities (particularly those treating patients at higher risk of severe COVID-19 illness) • Pharmacies • Occupational health settings • Organizations serving people at higher risk for severe illness from COVID-19 (e.g., dialysis centers, social service organizations) • In-home care provider organizations • Congregate settings (e.g., correctional facilities) • Colleges and universities • Homeless shelters • Locations where people 65 years of age and older gather (e.g., senior centers, food pantries, retirement/independent living communities) • FQHCs and RHCs.*

- *Jurisdictions and tribal nations should determine the need for additional vaccination services such as satellite, temporary, or off-site clinics to meet demand/need not met by other enrolled COVID-19 vaccination providers. These clinics may operate as either closed or open PODs*."

Geography: Outside the US

Outside the US, the COVAX Facility applies for 190 economies, and there may also be bilateral agreements that exist directly between some countries and vaccine developers/manufacturers.

With respect to the COVAX Facility, it is co-led by WHO (World Health Organization), Gavi and CEPI (Coalition for Epidemic Preparedness Innovations), and currently has 184 countries participating. It is the vaccines pillar of the ACT Accelerator (ACT stands for "Access to COVID-19 Tools" which was launched by WHO, European Commission and France). COVAX Facility is a global risk-sharing mechanism for pooled procurement and equitable distribution of COVID-19 vaccines. It operates under the mission that no one is safe until everyone is safe. The information we're sharing in the discussion below has been sourced from https://www.gavi.org/covax-facility as respects how COVAX works and how it allocates.

Utilizing legally-binding agreements, COVAX is an "insurance policy" with the largest portfolio of candidates and leverages its pooled buying power to support research, development and manufacturing and negotiate pricing with vaccine developers/manufacturers on behalf of participating countries so that any participating country can gain access to vaccines, regardless of its wealth.

How does COVAX work?

COVAX has 2 phases:

Phase 1 – Provide each participating country access to initial vaccine supplies for 3% of population and continue until 20% of each country's population has been covered. Each country can prioritize who/how vaccines are distributed within their country, and WHO has made recommendations as respects priorities which countries can consider in this process.

Phase 2 – Additional doses doled out to countries where transmission is high.

According to Gavi, the COVID-19 pandemic is costing global economy **$375 Billion every month**. Of the 135+ vaccines in the COVAX pipeline, 9 candidates are already in development and a further 9 are under evaluation, per Gavi. By joining COVAX, both self-financing countries and funded countries will gain access. Self-financing countries and economies participating in COVAX can request vaccine doses sufficient to vaccinate 10%-50% of their populations, and the amount they pay into COVAX correlates to number of doses requested. For these countries, COVAX is an insurance policy that increases their chances of securing vaccines, even if their own bilateral deals fail.

Self-financing countries will be guaranteed sufficient doses to protect a certain proportion of their population, depending on how much they buy into it. They have 2 ways of structuring their commitment:

- Committed Purchase Arrangement – Country engages in a committed guarantee to procure an agreed volume of doses. In exchange, they will be required to provide a lower upfront payment of $1.60/dose, or 15% of the total cost per dose. Countries will have the ability to opt out should the price of vaccine be 2x (or more) than was expected.

- Optional Purchase Arrangement – Country can choose to opt out of receiving any vaccine without jeopardizing ability to receive their full share of doses of other candidates, subject to supply becoming available. This approach may be more attractive to participants that already have bilateral agreements with manufacturers.

With respect to funded countries, subject to funding availability, they will receive enough doses to vaccinate up to 20% of their population in the longer-term. Funded countries receive their financing through COVAX Advanced Market Commitment (AMC) which is an entirely separate funding mechanism (it is funded by official development assistance, or ODA, as well as contributions from private sector and philanthropy), and will support access to COVID-19 vaccines for these lower income economies. There are 92 middle- and lower-income countries that will get equal access to COVID-19 vaccines and at the same time the Self-Funded countries.

How will vaccine doses be allocated for COVAX?

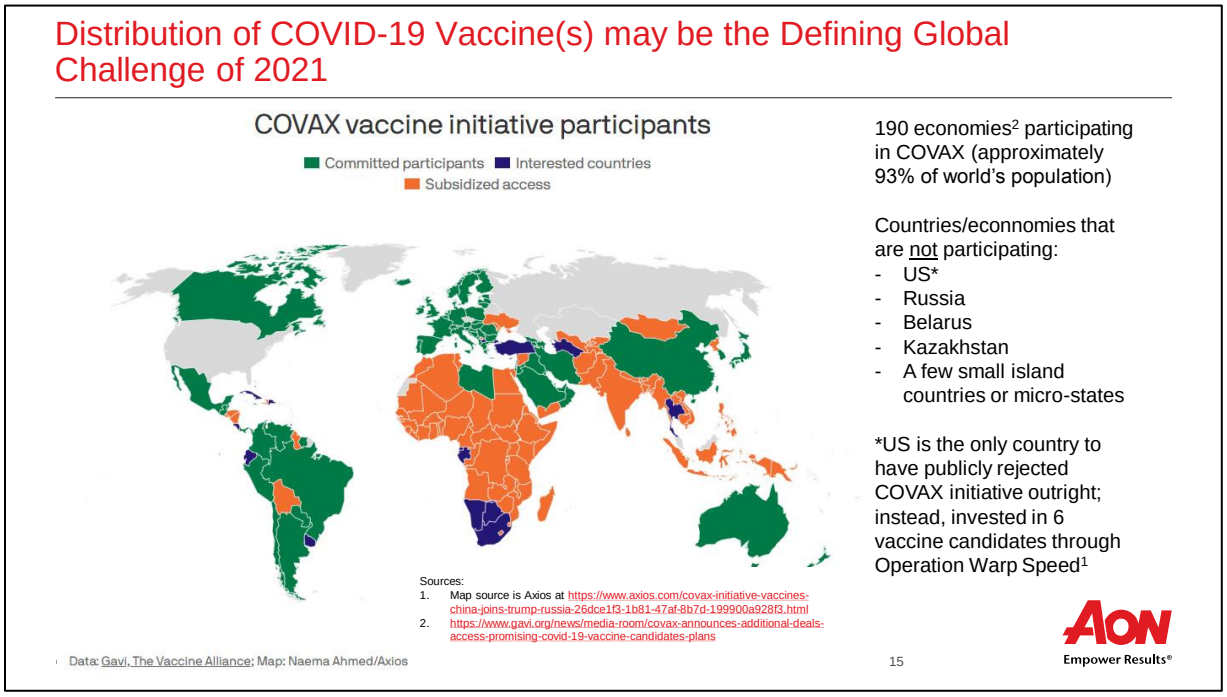
Available doses allocated to all participating countries at same rate, proportional to population size.

Small buffer of 5% of total available doses reserved for acute outbreaks and to support humanitarian organizations.

No country will receive enough doses to vaccinate more than 20% of its population until all in the "financing group" have been offered 20%. Only exception is those countries who opted to receive fewer than 20%.

What countries are participating in COVAX Facility?

The following slide from Aon's COVID-19 Vaccine Landscape slide deck describes information as outlined by Axios in their discussion of COVAX Facility at https://www.axios.com/covax-initiative-vaccines-china-joins-trump-russia-26dce1f3-1b81-47af-8b7d-199900a928f3.html.



Where to learn more about what to expect in countries participating in COVAX Facility?

For description of COVAX Facility: https://www.who.int/initiatives/act-accelerator/covax.

For description of WHO's approach to country readiness and delivery workstream: https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery/act-accelerator-country-readiness-and-delivery-for-covid-19-vaccines

For description of WHO's guidance for readiness and delivery, including the tools WHO is providing to Ministries of Health for countries participating in COVAX Facility: https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery

For description of WHO's guidance on developing a national deployment and vaccination plan for COVID-19: https://www.who.int/publications-detail-redirect/WHO-2019-nCoV-Vaccine_deployment-2020.1

How are scarce vaccine resources prioritized?

For this discussion, we're again dividing comments into US and Outside the US.

Geography: US

In the US, the Advisory Committee on Immunization Practices (ACIP) coordinates between CDC and WHO and makes recommendations about vaccine prioritization, based on the application of a decision-making framework. ACIP set the following goals to help determine which groups should receive COVID-19 vaccines first, if supply is limited::

- Decrease death and serious disease as much as possible
- Preserve functioning of society
- Reduce the extra burden the disease is having on people already facing disparities
- Increase the chance for everyone to enjoy health and well-being

Ethical principles

ACIP identified four ethical principles to guide their decision-making process if supply is limited:

- **Maximize benefits and minimize harms** — Respect and care for people using the best available data to promote public health and minimize death and severe illness.
- **Mitigate health inequities** — Reduce health disparities in the burden of COVID-19 disease and death, and make sure everyone has the opportunity to be as healthy as possible.
- **Promote justice** — Treat affected groups, populations, and communities fairly. Remove unfair, unjust, and avoidable barriers to COVID-19 vaccination.
- **Promote transparency** — Make a decision that is clear, understandable, and open for review. Allow and seek public participation in the creation and review of the decision processes.

Learn more at ACIP's Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine.

Groups considered for early vaccination if supply is limited

Before making an official recommendation, ACIP considered four groups to possibly recommend for early COVID-19 vaccination if supply is limited:

- Healthcare personnel
- Workers in essential and critical industries
- People at high risk for severe COVID-19 illness due to underlying medical conditions
- People 65 years and older

For further discussion, please see this information which ACIP includes in their website:

- **Healthcare personnel (both paid and unpaid)** continue to be on the front line of a country's fight against this deadly pandemic. By providing critical care to those infected with the virus that causes COVID-19, many healthcare personnel have a high risk of being exposed to and getting sick with COVID-19. Healthcare personnel who get COVID-19 can also spread the virus to their patients seeking care for medical conditions that, in turn, increase their patients' risk for severe COVID-19 illness. Early vaccine access is critical to ensuring the health and safety of this essential workforce (which in the US is comprised of approximately 21 million people), protecting

not only them but also their patients, communities, and the broader health of the country. Learn who is included under the broad term "healthcare personnel."

- **Workers in essential industries** are considered part of a country's critical infrastructure. Current data show that many of these workers are at increased risk for getting COVID-19. Early vaccine access is critical not only to protect them but also to maintain the essential services they provide to communities.

- **People with certain** underlying medical conditions are at increased risk for severe COVID-19 illness, regardless of their age. Severe illness means that the person with COVID-19 may require hospitalization, intensive care, or a ventilator to help them breathe, or that they may even die. Early vaccine access is critical to ensuring the health and safety of this population that is disproportionately affected by COVID-19.

- **Among adults, the risk for severe illness and death from COVID-19 increases with age, with older adults at highest risk.** Early vaccine access is critical to help protect this population that is disproportionately affected by COVID-19.

Other frameworks

Input from the public and the following professional groups is informing ACIP's discussions on who should receive COVID-19 vaccines if supply is limited:

- **Johns Hopkins Bloomberg School of Public Health:** Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United Statesexternal icon

- **The National Academies of Sciences, Engineering, and Medicine:** Framework for Equitable Allocation of COVID-19 Vaccineexternal icon

- **World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE):** WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccinationpdf iconexternal icon

- **WHO SAGE: WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supplypdf iconexternal icon**

State/Local Playbooks
State/Local Playbooks provide further customization of CDC/ACIP guidance where state/local leaders and public health agencies can take their respective allotments and address prioritization needs that align with local situation and circumstances. This link https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html takes you to CDC's site for access to their COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations (last updated October 29 2020), and on that same page, there are links to the Executive Summaries of individual State Playbooks.

Geography: Outside the US

Outside the US, WHO's suggested guidelines are taken into account. Please see these links:

- **World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE):** WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccinationpdf iconexternal icon

- **WHO SAGE: WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supplypdf iconexternal icon**

There are also country-level guidelines and frameworks that are considered. It is important for an employer to understand how prioritization is being defined in each country where an employer has employees.

How can my organization support access to vaccination for my workforce?

Employers can do a great deal to support access to vaccination by doing the following:

- Understand and inform employees about vaccination access in their geography.
- Understand the allocation frameworks for the country(ies) where you have workers located, and how your organization's business may fit into the priority populations that have been identified.
- Understand how vaccines will be distributed in the country(ies)and jurisdiction(s) where your employees are located, and how those countries/jurisdictions are handling logistics.
- Communication and Trust – Except when individuals may be subject to a vaccine mandate, receiving a COVID-19 vaccine will be voluntary. Therefore, achieving high vaccination rates and sufficient population-level protection from the virus will depend on the public's willingness to be vaccinated: people will have to trust the vaccine, the authorities overseeing distribution, and the provider administering the vaccine. All vaccines face issues of public confidence to one extent or another, yet there are indications that distrust of COVID-19 vaccines (despite the fact that no vaccine has been approved yet) may be even greater than for other vaccines. This presents a significant challenge for authorities at the federal, state, and local levels, and will require robust communication and trust-building efforts to address. Your organization can potentially contribute to improved levels of trust by educating your employees and family members, communicating known facts about vaccine development, distribution and immunization priorities as well as known benefits and risks of vaccination.
- The most common reasons given by adults for not receiving seasonal influenza vaccines are concerns about the safety and efficacy of the vaccine and a belief the vaccine itself can make a person ill.
- Polling on COVID-19 vaccines has indicated an increasing level of mistrust about the vaccines and decreasing willingness among Americans to receive one. In May, 72 percent of U.S. adults said they would definitely or probably get a vaccine to prevent COVID-19 if it were available but in September only 51 percent said the same (a 21 percent decline in four months). Partially driving this growing distrust among Americans is an increasing concern with politicization of the vaccine approval process: a majority of the public (62 percent) is worried political pressure will lead the FDA to rush to approve a coronavirus vaccine without making sure that it is safe and effective. Black adults in particular have expressed some of the highest levels of mistrust of COVID-19 vaccines even as this group has been disproportionately affected by the pandemic.
- Reducing mistrust about COVID-19 vaccines would involve a multi-pronged communication approach, including efforts to counter the growing public perception that politics is driving the vaccine approval process for COVID-19 to ensure employees have confidence that when a vaccine is approved that they believe it is indeed safe and effective. A recent letter from the HHS National Vaccine Advisory Committee to the Assistant Secretary for Health included recommendations for building public confidence, including through a unified, proactive, and highly visible, communication structure and community and stakeholder engagement. Transparency and avoiding conflicts of interest helps in reducing mistrust. In addition, having clear, consistent, and culturally-relevant messages about COVID-19 vaccines and their benefits to individuals, communities, and the country will be important, as will building partnerships in advance with individuals and groups that can serve as trusted sources for delivering such messages for different communities. Given that safety of vaccines has been the number one concern both in past vaccination campaigns and regarding COVID-19 vaccines, a particular emphasis on assuring safety will be important.

Should my organization consider a COVID-19 vaccine mandate for our workforce?

Employers are starting to ask about the impact of a COVID-19 vaccine on reopening their workplaces and permitting employees to return to work in 2021. We're sharing the following perspectives, and will continue to update as more information becomes available.

Geography: US

For employers with US populations, issues to consider include, but are not limited to:

- Implementing a Mandatory COVID-19 Employee Vaccination Program
- Updated Guidance from EEOC as of December 16th, 2020 as respect COVID vaccination
- Access to the COVID-19 Vaccine
- Communicating the Mandatory COVID-19 Vaccination Program to Employees
- Obtaining Evidence of a COVID-19 Vaccination
- Dealing with Reluctant Employees
- Risks of Employee Lawsuits

Implications of an Employer Mandate that Employees Receive the COVID-19 Vaccine

Employers, working with their human resources departments and legal counsel, must balance several competing interests in considering the advantages and disadvantages of a mandatory employee vaccination policy. Some of these considerations are set forth below.

Implementing a Mandatory COVID-19 Employee Vaccination Program

Most employers have implemented workplace policies that require employees to stay home from work if they are ill in order to avoid infecting other employees. Fewer employers, however, have implemented workplace programs that mandate employee vaccinations against certain diseases or otherwise mandate a specific course of medical treatment for employees. The COVID-19 pandemic, therefore, creates a case of first impression for many employers. These employers must consider federal and state laws on workplace discrimination and workplace safety in implementing and administering such a program.

Updated Guidance from EEOC as of December 16, 2020

On December 16, 2020, the Equal Employment Opportunity Commission (EEOC) issued updated guidance for employers on COVID-19 vaccinations and the applicability of various equal employment opportunity laws, including the Americans with Disabilities Act (ADA), the Genetic Information Nondiscrimination Act (GINA), and Title VII of the Civil Rights Act of 1964.

Some of the EEOC's guidance, which is discussed in more detail on its website, is as follows:

- Although the administration of a vaccination is not a medical examination, pre-screening vaccination questions may implicate the ADA's provision on disability-related inquiries.
- If an employer requires an employee to receive the vaccination from the employer (or a third party with whom the employer contracts to administer a vaccine) and asks a screening question to ensure that there is no medical reason that would prevent the person from receiving the vaccination, those questions are subject to the ADA standards for disability-related inquires.

- Merely asking or requiring an employee to show proof of receipt of a COVID-19 vaccination is not a disability-related inquiry. Subsequent follow-up questions, however, may qualify as disability-related inquiries.
- If an employee indicates that the employee is unable to receive an employer-mandated COVID-19 vaccination because of a disability, the employer must show that an unvaccinated employee would pose a direct threat due to a "significant risk of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation".
- Once an employer is on notice that an employee's sincerely-held religious belief, practice, or observance prevents the employee from receiving the vaccination, the employer must provide a reasonable accommodation for the religious belief, practice, or observance unless it would pose an undue hardship under Title VII of the Civil Rights Act.
- If an employee cannot get vaccinated for COVID-19 because of a disability or sincerely-held religious belief, practice or observance, and there is no reasonable accommodation possible, then it would be lawful for the employer to exclude the employee from the workplace. This does not mean the employer may automatically terminate the worker.
- Title II of GINA is not implicated when an employer administers a COVID-19 vaccine to employees or requires employees to provide proof that they have received a COVID-19 vaccination.
- Asking an employee the pre-vaccination screening questions before administering a COVID-19 vaccine may implicate Title II of GINA.

The EEOC guidance can be found on the EEOC's website, Section K, available here.

Access to the COVID-19 Vaccine

Employers that are considering implementation of a mandatory COVID-19 vaccination program should take into account the availability and distribution of an adequate supply of an effective COVID-19 vaccine.

Communicating the Mandatory COVID-19 Vaccination Program to Employees

Employers that are considering implementation of a mandatory COVID-19 vaccination program should develop a communication program that clearly informs employees of the terms of the program. This should include information on vaccine supply, availability, and payment for the vaccine, along with any applicable timelines for receiving the vaccines and the consequence for non-compliance. The communication program should consider several avenues of communication, including emails, webinars, and access to further information. Employers should review the available information on the COVID-19 vaccine and identify reliable sources of information for employees to consult.

Obtaining Evidence of a COVID-19 Vaccination

A properly administered program will have to rely on evidence of a vaccination. This evidence can be provided directly by the employee to avoid implicating HIPAA, which applies only to health plans, health care clearinghouses, and health care providers. Obtaining such evidence from the health care plan or the employee's health care provider would raise issues under federal and state privacy laws. HIPAA prohibits a plan sponsor's access to PHI in the absence of an employee authorization except for purpose of treatment, payment, and health care operations. HHS has not opined on the applicability of these exceptions to a mandatory COVID-19 vaccination program. (The public safety exception under HIPAA is available only for disclosures to public health authorities.) While an employee authorization to a health care provider to release medical records to the employer would satisfy HIPAA, it is not clear whether such an authorization made under a mandatory vaccination program would be considered "voluntary" under HIPAA.

Dealing with Reluctant Employees

Employees may refuse to receive a vaccination for any number of reasons that are not protected exemptions under federal or state law, from privacy concerns to fear of a vaccine's side effects. Employers will have to sort out the consequences for such refusals, which depending on the circumstances, could include reassignment of duties and working from home, to more extreme measures such as termination of employment. Whether such consequences are necessary, advisable, or legal should be determined by the employer in concert with human resources and legal counsel.

Risk of Employee Lawsuits

Employers remain at risk for possible lawsuits over COVID-19. These include lawsuits stemming from:

- Alleged worksite transmission of the virus to an employee, customer, or client;
- Alleged worksite transmission of the virus due to failure to design a safe workplace;
- Adverse reaction to a vaccine administered pursuant to a mandator vaccination program; and
- The legality of a particular vaccination program.

While lawsuits for workplace injuries should be litigated under workers compensation laws, plaintiffs may attempt to circumvent such laws, arguing that workers compensation laws do not apply to COVID-19. Additionally, lawsuits by customers or clients would not be subject to workers compensation laws. Therefore, employers remain vulnerable to lawsuits alleging negligence.

Note: Insurance programs for Employment Practices Liability (EPL) and other risks are designed to address exposures that may arise. We will be providing perspectives on those later in this document.

What Employers Should Do Now

Employers that are considering implementing a mandatory employee COVID-19 vaccination program should take the following steps:

- Monitor guidance from the applicable government agencies, including the CDC, the USPSTF and HHS, regarding the effectiveness, safety, supply, availability, and distribution of a COVID-19 vaccine.
- Coordinate with the employer's TPA, insurer, and all applicable vendors regarding the supply, availability and distribution of a COVID-19 vaccine.
- Working in concert with legal counsel and the human resources department, consider the legal, administrative, and communication aspects of a mandatory employee COVID-19 vaccination program, including administration of any disability-related or religious exemption-related opt-out requests and the consequences for employee refusals to participate in the program.

We will continue to update this suggested guidance as various entities in the US (legislatures, government agencies, and courts) provide additional guidance for US employers in this area.

Discussion of Vaccine mandates outside the US

Note the discussion of mandates in this document has focused on the US. However, the discussion may vary outside the US. With respect to countries outside the US, some countries may mandate vaccination; others may not. In some instances, the employer may need to align with country mandate status, and in other instances, employers may have choice about how they can address. Again, for multinationals, there will be a need to monitor country-level positions for the countries where you have workers. We will continue to monitor this and provide updates as more information becomes available.

Other insurance coverages that may be involved

In addition to the Human Resources side of the discussion, there are global and country-level considerations that come into play as respects Liability (General Liability, Professional Liability), Workers' Compensation/Employer's Liability and other Employee Injury/Illness schemes, Directors & Officers' (D&O) Liability, Employment Practices Liability (EPL), Employee Benefits Liability, Fiduciary Liability and other insurances that may be impacted by a decision to mandate or not. We are developing a view on this and will incorporate those perspectives in the next update of this document.

What uncertainties should we consider as the vaccination process unfolds?

There are several unknowns for all COVID vaccines which endure, regardless of emergency use authorization status from the FDA (Food & Drug Administration). While the vaccine will materially impact the spread of SARS-CoV-2, the coronavirus which produces COVID-19 disease, the unknowns require ongoing surveillance by employers as Return-to-Workplace strategies are built which may include vaccine campaigns or support for mass immunization programs.

Efficacy:

Limited data from peer-reviewed published journals is currently available that addresses efficacy. Initial studies indicate the efficacy for several of the vaccines may range between 60 to 95%. For the US and other countries, these results exceed the efficacy threshold required by the FDA (50% for usage in the US) for COVID-19 Vaccine approval or EUA (Emergency Use Authorization). It is important to note that, to date, vaccine trials have included relatively small numbers of participants for relatively short follow-up periods.

Safety:

Initial limited studies generally indicate the vaccines to be safe for mass immunization programs for large swaths of the populace. However, we expect new profiles of adverse events to be documented and investigated as we scale to millions of people being vaccinated. Household members' vaccination impact to other household members is not well documented to date. Limited data exists regarding long-term safety of vaccine. This is an ongoing area of investigation.

Immunity:

In initial study results for one vaccine candidate, immunity appears to begin within 10 days of first dose administration; this information may evolve as more study results become available on the various vaccine candidates being evaluated. Sterilizing immunity is anticipated by most virologists, but not yet demonstrated in large controlled trials to date by vaccine manufacturers or other independently conducted trials. This means while COVID-19 symptom severity is mitigated by the vaccine, the possibility that an immunized person may have the ability to carry and transmit the virus is still possible and to be expected, considering the viral load within the population. Social distancing and cloth face coverings are still strongly recommended (and mandatory in many geographies) for the foreseeable future. Regardless of vaccine status, social engineering controls must remain in place. Long-term immunity from vaccine or infection has not yet been established. This is an ongoing area of investigation.

Timing of Vaccine Availability:

Although nations will be discussing vaccine availability timetables once they have approved the use of vaccine(s) in their respective jurisdiction, it is possible that timing expectations might still flex with logistics needs, availability of source materials that meet quality parameters of the manufacturing process, and other factors that can impact supply chain timetables for an undertaking of this size.

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Source Notes: We've cited extensively from the following sources to collect information for this document. We encourage you to look to their websites for more details.

- CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- ACIP at https://www.cdc.gov/vaccines/acip/index.html
- OWS at https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html
- HHS at https://www.hhs.gov/coronavirus/index.html
- WHO at https://www.who.int/emergencies/diseases/novel-coronavirus-2019
- ACT Accelerator at https://www.who.int/initiatives/act-accelerator
- Gavi at https://www.gavi.org/covax-facility
- COVAX Facility at https://www.gavi.org/vaccineswork/covax-explained
- CEPI at https://cepi.net/
- Kaiser Family Foundation (KFF) at https://www.kff.org/coronavirus-covid-19/
- LT Juan Carlos Lopez, SC, USNR (Ret)

Contributors:

The following individuals contributed to this content:

For Global:

Nancy Green, CPCU, ARM
Executive Vice President | Co-Leader of Aon's Global COVID-19 Task Force

Gisele Norris, DrPH
Managing Director | Co-Leader for Aon's Global COVID-19 Task Force
.
Craig Kiebler, DVM, MPH, MS, DACVPM
Managing Director, Analytics, Aon Reinsurance | Member of Aon's Global COVID-19 Task Force

For US:

Nancy Buckman, RN, MSN, MBA
Vice President, Health Transformation | Member of Aon's Global COVID-19 Task Force

Neal Mills, MD, MBA
Chief Medical Officer, US Health Solutions | Member of Aon's Global COVID-19 Task Force

For information on COVID-19 vaccine mandate questions:

J.D. Piro.
Senior Vice President, National Practice Leader, Health & Benefits Legal Consulting Group

Rachel Arnedt
Vice President, Health & Benefits Legal Consulting Group

For EMEA:

Avneet Kaur, BHMS, PGDCAM, MBA
EMEA Wellbeing Solutions Leader

For Asia:

Amitabh Deka, MBBS, PGDBM, MPH
Head of Wellbeing Solutions, South Asia and Aon Care

Contact Us

We are offering consulting services related to this content. For more information, please contact us at coronavirus.feedback@aon.com.

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