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The **COVID-19 Vaccines:**Keeping Your Employees Safe

As COVID-19 numbers — infection rates, hospitalizations and deaths — remain at unsettling levels, recent news regarding vaccine progress, including the Food and Drug Administration (FDA) advisory panel's endorsement of Pfizer's COVID-19 vaccine on December 10, is providing a much needed dose of hope. Following the endorsement, the FDA granted an emergency use authorization for the Pfizer vaccine and priority groups are on track to start receiving their first doses this week.

The Centers for Disease Control and Prevention (CDC) continues to encourage people to wear masks, distance, get flu shots and take other steps, but they are also sharing guidance relative to vaccine planning. Employers have an opportunity to take an active role in the distribution process. And the time to begin planning to seize this opportunity is now.

What Employers Need to Know

The CDC has outlined clear objectives for what will be the largest and most complex public health initiative in our nation's history. These objectives include:

- · Prioritizing vaccine safety and effectiveness
- Decreasing instances of death and serious disease
- Reducing the burden the disease is having on society (economic, educational, etc.)
- Maximizing equity

The CDC doesn't develop vaccines but it is making COVID-19 vaccination recommendations. These recommendations are based on input from the Advisory Committee on Immunization Practices (ACIP), a federal advisory committee comprised of medical and public health experts who develop recommendations on the use of vaccines in the US civilian population.



Through this process, the ACIP has recommended four groups for COVID-19 vaccination in the early phases:

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

States will ultimately decide who gets the vaccine when. It is important that employers refer to information from their state's public health department for specific details.

Vaccines in Play

There are currently two vaccines in the spotlight.

The first, from Pfizer, was endorsed by the FDA advisory panel on December 10 and received an emergency use authorization from the FDA on December 11. It showed 94% efficacy in trials and the first vaccinations occurred in the United Kingdom on December 7. With the FDA emergency use authorization, the first immunizations are on track to take place the week of December 14.

The other is Moderna's vaccine, which showed 94.5% efficacy in trials. Moderna applied for emergency FDA approval and the first shots could happen as early as December 21.

Reports indicate that there will be 25 million doses of the Pfizer vaccine and 15 million doses of the Moderna vaccine available this month. Both vaccines require two doses three to four weeks apart.

Timeline on Pfizer Vaccine

November 18	Pfizer announces its vaccine is 94% effective
November 23	Pfizer submits trial data to FDA for emergency approval
December 3	UK approves Pfizer vaccine
December 7	First doses are given in England
December 8	FDA issues preliminary analysis saying vaccine is safe and effective, but doesn't approve it
December 9	Canada approves the vaccine; deadliest day for US with 3,045 deaths
December 10	FDA advisory panel endorses Pfizer, clearing the path for the FDA to grant an emergency use authorization
December 11	FDA grants emergency use authorization for Pfizer vaccine
Week of December 14	Priority groups expected to start receiving Pfizer vaccine

Source: Dailymail.co.uk (December 10, 2020)

Necessity Accelerating Innovation

Both vaccines use messenger RNA (mRNA). Instead of injecting a weakened germ, mRNA vaccines teach cells how to make a protein that triggers an immune response. This response produces antibodies that protect against infection. With the expected FDA approvals, the Pfizer and Moderna offerings will be the first authorized vaccines to use mRNA. The success of the COVID-19 vaccines will pave the way for other mRNA vaccines, which can be produced faster and at a lower cost relative to traditional vaccines.

Distributing the Vaccines

In terms of distribution, vaccines are typically administered in physicians' offices, so they are primarily covered by medical benefits. However, with high demand, additional channels will be required (which may alter how vaccinations are covered), including private pharmacies/pharmacists, community providers, occupational health clinics and employers. The Department of Health and Human Services has outlined its strategy for distributing COVID-19 vaccines. The strategy includes:

- Engagement with state, local and tribal health departments, territories, Tribes, and federal entities to allocate and distribute vaccines
- Direct distribution of the vaccine to commercial partners (CVS and Walgreens) as soon as FDA approval is granted
- Safe vaccine administration through additional partnerships to support proper storage and handling
- An IT vaccine tracking system for overall vaccine management

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Federal officials expect a sufficient supply to immunize about 100 million people in the US by the end of February. Additional supplies – from Pfizer and Moderna, and potentially other players who have vaccines at various stages of development – will be available in the spring and summer for those who are not in the priority groups.

Priority #1: Vaccine Safety

Despite widespread optimism, there are lingering public concerns regarding vaccine safety. The FDA has taken several steps to assure the public of its commitment to scientific rigor, integrity and transparency in their review of vaccine candidates.

- In June, the FDA issued clear guidance to drug manufacturers regarding its expectations for a clinical trial structure and related scientific data, which is required for the FDA evaluation processes.
- A Data and Safety Monitoring Board, comprised of fully independent research experts, reviewed
 emerging data from trials as they progressed and had the authority to pause or halt trials in the
 event of serious adverse events.
- Before the FDA began its review of the vaccines, the agency convened its Vaccines and Related Biological Products Advisory Committee to review aggregated trial data.

Promoting vaccine safety will be critical to the success of the vaccination effort. A variety of methods – including former Presidents Barack Obama, George W. Bush and Bill Clinton volunteering to be vaccinated on live television and ongoing public statements from leading experts – will be helpful in allaying concerns and encouraging vaccinations.

Employer Actions

For employers, this is the time to plan. Actions to consider include:

- Establishing a structure for developing a vaccination strategy (a committee or a task force)
- Surveying employees to get a sense of their perspectives (safety concerns, likelihood of getting vaccinated)
- Considering the logistics of getting your employees vaccinated (assume full participation)
- Connecting with your insurance carrier to get a clear understanding of their plans, resources and ideas related to the vaccines
- Staying current with communications from your local health department
- Reaching out to wellness providers and vaccination providers to understand their approach and how it aligns with your organization's strategy

Communication is also critical. Keep your employees up to date with activities, plans and expectations. Amplify messages regarding vaccine safety now so concerns aren't an issue when the vaccine becomes available. Express your support of the vaccines as an important step in overcoming COVID-19, while reiterating the need to focus on safety to reduce infections and hospitalizations. Finally, if your employees are working remotely, continue to support them with work-from-home and well-being resources. If they're in the office, remain diligent in executing workplace protocols (distancing, masks, cleaning).

Requiring the Vaccine

Mandating that employees get the vaccine is an issue that comes with legal, ethical and cultural implications. There is precedent where organizations require vaccinations for entry (schools being a common example), but with most people not likely to have access to the vaccines until mid-2021, discussions of how a mandate could work will continue.

The ultimate outcomes will be state specific as a federal mandate is unlikely. And much will depend on the voluntary response and progress toward herd immunity. If the number of volunteers falls short and infection rates remain above certain levels, states may take legislative action to implement requirements.

Get the Flu Vaccine ASAP

Because the flu has symptoms similar to COVID-19, it is critical to encourage employees to get the flu vaccinations this season. While the flu vaccine does not protect against COVID-19, having received the flu vaccine may help healthcare professionals rule out the flu when evaluating patient symptoms.

Looking Ahead

This is an exciting and anxious time. We are seeing tremendous progress, but obstacles will emerge. How employers plan, engage with employees and participate in the process will have an impact on the success of the vaccination effort.

Related Resources:

The Centers for Disease Control and Prevention

The US Department of Health and Human Services

Stat: "FDA advisory panel endorses Pfizer/BioNTech Covid-19 vaccine" (December 10, 2020)

The Wall Street Journal: "As Covid-19 Vaccines Roll Out, States to Determine Who Gets Shots First" (December 9, 2020)

The Wall Street Journal: "U.S. Expects to Immunize 100 Million High-Risk People by End of February, Officials Say" (December 2, 2020)

Forbes: "How Employers Should Prepare For The Covid-19 Vaccine" (November 19, 2020)



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