



**STATE OF
OHIO**
BOARD OF PHARMACY

Special Notice from the Ohio Department of Health COVID-19 Vaccine Providers

Dear Health/Medical/Public Health Partners,

I am writing to you to clarify that **ultra-cold storage is NOT required to enroll as a COVID-19 vaccination provider**. We continue to receive feedback that indicates some confusion about this issue.

If this misunderstanding has prevented you from enrolling as a COVID-19 vaccination provider, please enroll now. Go to the State of Ohio's "OH|ID" webpage at <https://ohid.ohio.gov> and follow the steps outlined in the enrollment job aid and checklist at www.pharmacy.ohio.gov/ODHvaccine.

With potential federal approval of one or more COVID-19 vaccines in the coming weeks, it is critical that we develop a strong network of vaccine providers across the state.

While the Pfizer/BioNTech COVID-19 vaccine requires ultra-cold storage, it will be shipped to enrolled vaccination providers without this capability in a storage container with dry ice if/after the vaccine receives federal approval. Vaccination providers must then replenish the storage container with fresh dry ice according to manufacturer guidelines that will be provided. The Ohio Department of Health (ODH) has prepared the attached fact sheet ("COVID-19 Ultra-Cold Vaccine Planning Considerations") which includes considerations for handling the shipping container, dry ice packaging and the ultra-cold vaccine itself.

Assuming that the U.S. Food & Drug Administration (FDA) approves the Pfizer/BioNTech application for emergency use authorization for their COVID-19 vaccine, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) must issue recommendations on how to use the vaccine, including who it should be offered to and in what order, before the vaccine can begin to be administered. **Both FDA approval and CDC ACIP recommendations are likely to occur in December.** We must be prepared to then begin administering the vaccine immediately to individuals who are identified in the first vaccination phase and choose to receive it. The vaccine supply is expected to be limited initially, and Ohio will first vaccinate individuals who are most at risk, including high-risk healthcare workers, those who work in long-term care facilities/nursing homes, and first responders.

Pfizer and BioNTech announced on Nov. 18 that data from their Phase 3 study of nearly 44,000 people has demonstrated that their vaccine was 95% effective in helping to prevent COVID-19. The companies submitted an emergency use authorization application with the FDA on Nov. 20, and the FDA has announced that its Vaccines and Related Biological Products Advisory Committee

will meet on December 10 to discuss the request. More details are available at https://www.pfizer.com/news/hot-topics/our_covid_19_vaccine_study_what_s_next.

Moderna announced on Nov. 16 that data from its Phase 3 study of more than 30,000 participants in the U.S. has demonstrated that its vaccine, which does not require ultra-cold storage, was 94.5% effective in helping prevent COVID-19. Moderna plans to submit an emergency use authorization application with the FDA in the coming weeks. More details are available at <https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy>.

AstraZeneca announced on Nov. 23 that data from its Phase 2 & 3 studies of more than 23,000 participants in the United Kingdom and Brazil has demonstrated that one particular dosing regimen of its vaccine was 90% effective in helping prevent COVID-19. The company says that the vaccine can be stored, transported and handled at normal refrigerated conditions for at least six months. More details are available at <https://www.astrazeneca.com/media-centre/press-releases/2020/azd1222h1r.html>.

On a related note, the U.S. Centers for Disease Control & Prevention recently posted on its website "10 Things Healthcare Professionals Need to Know about U.S. COVID-19 Vaccination Plans" (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/vaccination.html>) that I want to share with you.

Working together as COVID-19 vaccines become available, we can protect Ohioans and end this pandemic. Please accept my appreciation for your steadfast work and dedication through these challenges.

Sincerely,

Stephanie McCloud
Director
Ohio Department of Health
