Subject line: Johnson & Johnson (Janssen) COVID-19 vaccine emergency authorization and resources

To Enrolled Vaccine Provider Partners,

A third COVID-19 vaccine, the first single-dose COVID-19 vaccine, will become available for vaccine providers across the nation, including Ohio, this week. Following the vaccine's authorization for emergency use over the weekend, more than 96,000 doses of the new Johnson & Johnson (Janssen) vaccine will be delivered to around 200 new independent pharmacy providers as well as chain pharmacies, hospitals, and health departments through Ohio's Vaccine Program. An additional 30,000 doses of the vaccine will be available through the Federal Retail Pharmacy Program.

The U.S. Food & Drug Administration (FDA) on Saturday, Feb. 27, granted an emergency use authorization (EUA) for the single-dose Johnson & Johnson/Janssen Biotech COVID-19 vaccine. This move follows a vote by the FDA Vaccine and Related Biological Products Advisory Committee on Friday to recommend the vaccine's use during this ongoing public health emergency.

The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) met Sunday, Feb. 28, and recommended the vaccine's use. The panel continued conversations on Monday, March 1. The panel did not make any recommendations about specific groups who should receive the vaccine, and is urging members of the public to take the first vaccine available to them. Recommendations made by the ACIP are reviewed by the CDC director and, if adopted, will be published in the Morbidity and Mortality Weekly Report (MMWR).

"I know that many Americans look forward to rolling up their sleeves with confidence as soon as a COVID-19 vaccine is available to them. Having different types of vaccines available for use, especially ones with different dosing recommendations and storage and handling requirements, can offer more options and flexibility for the public, jurisdictions and vaccine providers. Getting vaccinated with the first vaccine available to you will help protect all of us from COVID-19," CDC Director Rochelle P. Walensky said in a CDC news release.

This EUA allows for another critical tool to prevent serious illness, hospitalization and death from COVID-19 disease.

This single-dose, viral vector vaccine is safe and has been proven effective at preventing serious illness, hospitalization, and death from COVID-19 disease, according to a <u>U.S. Food & Drug Administration analysis</u>.

Having different types of vaccines available for use, especially ones with different storage and handling requirements and dosing recommendations, can offer more options and flexibility for distribution, according to the CDC. The Janssen vaccine can be stored in a standard refrigerator

for up to three months.

The Ohio Department of Health (ODH) would like to share with vaccine providers what they should expect with the rollout of the Janssen vaccine:

- There will be limited supply of the Janssen vaccine in the short term. Weekly quantities may vary based on availability and allocation decisions for the first few weeks.
- Vaccine providers who will be receiving the initial shipments of the Janssen vaccine this week have been notified separately.
- The vaccine is authorized for ages 18 and older.
- The vaccine is transported and stored at refrigerated temperatures (2 to 8 degrees Celsius).
- No diluent or mixing is required.
- There are five doses per vial.
- Minimum shipments are 100 doses (20 vials).
- Each order comes with an ancillary kit.

MORE INFORMATION:

Attached you will also find the following resources: The <u>FDA's EUA fact sheets</u> for <u>healthcare</u> <u>providers</u> and <u>vaccine recipients</u>, as well as a fact <u>Janssen Vaccine Provider Fact Sheet</u> that offers guidance on storage, handling, and administration of the vaccine.

ODH has created a fact sheet for the public available at coronavirus.ohio.gov that explains how the different COVID-19 vaccines work that could provide talking points and public messaging ideas for providers.

We will continue to share additional resources for vaccine providers as they become available.

If you have any questions or issues, please call the ODH Provider Call Center between 8 a.m. – 7 p.m. Monday through Friday, and 8 a.m. – 5 p.m. Saturday and Sunday, at 1-844-90DHVAX (1-844-963-4829) or email COVIDVACCINE@odh.ohio.gov.

The information in this email is included in the attached PDF file in case the links contained in this email do not work for you.

Sincerely,

Ohio Department of Health COVID-19 Vaccination Provider Relations Team