

Mike DeWine, Governor Jon Husted, Lt.Governor Stephanie McCloud, Director

April 13, 2021

To Enrolled Provider Partners,

Today, April 13, 2021, Governor Mike DeWine, Ohio Department of Health Director Stephanie McCloud, and Ohio Department of Health Chief Medical Officer Bruce Vanderhoff, M.D., are advising all Ohio COVID-19 vaccine providers to temporarily pause using the Johnson & Johnson (Janssen) vaccine.

This is in response to a statement by the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) recommending a pause in the use of the Johnson & Johnson vaccine following rare blood-clotting events in six people in the U.S. after receiving the vaccine. The federal government is expected to pause administration of the vaccine at all federally run vaccination sites.

"We are recommending a pause in the use of this vaccine out of an abundance of caution," Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, and Dr. Anne Schuchat, principal deputy director of the CDC, said in a joint statement. "Right now, these adverse events appear to be extremely rare."

The CDC will convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday, April 14, to further review these cases. The FDA will continue to investigate the cases.

If you have received, or will be receiving, Johnson & Johnson vaccine this week, please store the vaccine per manufacturer's recommendation.

Information we recommend vaccine providers share with staff, patients, and vaccine recipients:

- Appointments Scheduled: If patients are currently scheduled for an appointment to have Johnson & Johnson administered, and you have adequate supply from another manufacturer, you should attempt to maintain that appointment and administer either the Pfizer or Moderna vaccines. If that is not possible, we recommend you contact patients and attempt to reschedule or cancel appointments during this pause.
- **Signs and symptoms:** People who have received the Johnson & Johnson vaccine who develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination should contact their doctor, according to the FDA and CDC statement.
- No impact on the Moderna or Pfizer vaccines: The Moderna and Pfizer vaccines use a different vaccine
 technology than the Johnson & Johnson vaccine. There have been no safety concerns with these COVID-19
 messenger RNA (mRNA) vaccines.
- The Johnson & Johnson vaccine is an adenovirus vaccine. The vaccine uses a modified version of a virus to deliver instructions to cells to make copies of the surface spike protein on SARS-CoV-2. An inactive virus, such as

one that causes the common cold, is used as a vector (or transportation device) to deliver instructions for making the spike protein.

- Scientists began using this technology in the 1970s.
- Besides being used in vaccines, such as flu and RSV, this technology has been studied for gene therapy, to treat cancer, and for molecular biology research. Vaccines using this technology were used during the Ebola outbreak.
- Vaccine adverse events are reported through the <u>Vaccine Adverse Event Reporting System</u> (VAERS). VAERS, managed by the CDC and FDA, is part of the larger vaccine safety system in the United States that helps make sure vaccines are safe. A report to VAERS does not mean that a vaccine caused an adverse event. But VAERS can give CDC and FDA important information. FDA and CDC will investigate further and take action as needed.

Officials at the Ohio Department of Health are following this situation closely and will continue to share updates.

Sincerely,

Ohio Department of Health COVID-19 Vaccination Provider Relations Team