Date: November 19, 2021

Subject: Updates to CDC's Interim Clinical Considerations and Issuance of Emergency Use Instructions (EUI)

Hello Immunization Partners,

On November 17, 2021, the Centers for Disease Control and Prevention (CDC) issued Emergency Use Instructions (EUI) and updated its clinical considerations to allow the COVID-19 vaccine by Pfizer-BioNTech to be given as an additional primary dose or booster dose to certain people who completed a vaccine primary series with certain COVID-19 vaccines **that are not authorized or approved by the U.S. Food and Drug Administration.** This ensures that eligible people who were vaccinated outside of the U.S. with these vaccines, or who received certain non-FDA authorized or approved COVID-19 vaccines through participation in some clinical trials, can get an additional primary dose or booster dose of Pfizer-BioNTech COVID-19 vaccine.

The new guidance mirrors CDC's recommendations about who is eligible to receive boosters and additional primary doses, allowing an additional primary dose of the COVID-19 vaccine by Pfizer-BioNTech in certain immunocompromised persons aged 12 years and older, and/or a single booster dose of Pfizer-BioNTech COVID-19 vaccine in certain adults 18 years and older **who completed their primary vaccination with a non-FDA authorized or approved COVID-19 vaccine.**

It's important to note that this update only applies to a very small number of people. However, with cases of COVID-19 still high across the U.S. and globally, this update helps to ensure these individuals are better protected from the serious consequences of COVID-19.

What are Emergency Use Instructions (EUI)?
An EUI provides information about the emergency use of FDA-approved medical products (in this case the Pfizer-BioNTech COVID-19 vaccine) that may not be included in or differ in some way from the information provided in the FDA-approved labeling (package insert).

Are there EUI Fact Sheets?
Yes. Much like the EUA fact sheets, there is an EUI fact sheet for healthcare providers and an EUI fact sheet for recipients and caregivers. When administering vaccine under an EUI, the EUI fact sheet for recipients and caregivers must be provided to each recipient/caregiver. It's important that you obtain the EUI fact sheet from the link listed above. This version includes the information statement about MCIR (as indicated in Michigan VISs). Per state law, patients/caregivers must be informed about MCIR. In addition to providing the EUI fact sheet, you must also continue providing the EUA fact sheet.

Why does the EUI only apply to Pfizer?
EUI's can only be issued for products that are FDA approved and the Pfizer-BioNTech COVID-19 vaccine is currently the only licensed and approved COVID-19 vaccine.

For detailed information regarding this recent update, please visit CDC's Interim Clinical Considerations and refer to the following two updated sections:

- Updated guidance in the section on People who received COVID-19 vaccine outside the United States
- Updated guidance in the section on People who received COVID-19 vaccine as part of a clinical trial

If you have questions, please contact checcimms@michigan.gov

Thank you for all your hard work to protect Michiganders from vaccine-preventable diseases!