

IMPORTANT COVID-19 Vaccine Updates and Time Sensitive Webinar Information

This message was sent to AIM, FAB, Health Systems, INE, IAP, LHD Health Officers, LHD Medical Directors, MACI, MACI 2, PH Imms Leads, and Imms All Staff. I apologize for any duplications

Hello Immunization Partners

We have some important education updates for you regarding the COVID-19 Vaccination Program and the recent Emergency Use Authorized (EUA) Pfizer Vaccine. In this email you will find:

- A short recap of the ACIP meeting
- Information regarding the EUA which will include the EUA fact sheets
- MDHHS Prioritization Guidance
- CDC's Communication Toolkit
- An update on CDC's education materials
- MDHHS FAQ
- Update on Ancillary Kits
- COCA call information
- Upcoming IMPORTANT Webinars
- Medical Management Guidance for Managing a Vaccine Reaction

ACIP Meeting Recap:

In emergency meetings on Friday, December 11 and Saturday, December 13, 2020, the CDC's Advisory Committee on Immunization Practices (ACIP) met, discussed, and voted on recommendations for the Pfizer-BioNTech COVID-19 vaccine. The ACIP members received an update on safety and efficacy data and they voted for use for people 16 years of age and older in the U.S. This recommendation comes one day after the Food and Drug Administration (FDA) authorized the EUA for the Pfizer COVID-19 vaccine.

The vote from the CDC's Advisory Committee on Immunization Practices (ACIP) passed with 11 votes in favor and 3 recusals. A separate vote to amend the adult and childhood immunization schedule passed unanimously by the full voting group. The CDC is expected to release detailed communications to state and local health leaders in the coming days that will provide further guidance on the clinical use of the vaccine.

ACIP

- Meeting Information may be found at: <https://www.cdc.gov/vaccines/acip/meetings/index.html>

CDC released Interim Recommendations for the Use of Pfizer BioNTech COVID-19 Vaccine on Sunday, December 13, 2020.

- ACIP issued interim recommendations, linked below, for the use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥ 16 years for the prevention of COVID-19.
- To guide deliberations regarding the vaccine, ACIP employed the Evidence to Recommendation (EtR) Framework, using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.
- Vaccination with the Pfizer-BioNTech COVID-19 vaccine consists of 2 doses (30 μg , 0.3 mL each) administered intramuscularly, 3 weeks apart.

- Providers should counsel Pfizer-BioNTech COVID-19 vaccine recipients about expected systemic and local reactogenicity.
- Adverse events that occur in a recipient after receipt of COVID-19 vaccine should be reported to the Vaccine Adverse Events Reporting System (VAERS).
 - FDA requires that vaccination providers report vaccination administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of COVID-19 vaccine under EUA.
 - Reporting is encouraged for any clinically significant adverse event, whether or not it is clear that a vaccine caused the adverse event.
 - Information on how to submit a report to VAERS is available at: <https://vaers.hhs.gov/index.html> or 1-800-822-7967.
- In addition, CDC has developed a new, voluntary smartphone-based tool, v-safe, that uses text messaging and web surveys to provide near real-time health check-ins after patients receive COVID-19 vaccination. Information on v-safe is available at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>.
- The ACIP recommendation for the use of the Pfizer-BioNTech COVID-19 vaccine under EUA is interim and will be updated as additional information becomes available.

MMWR

- The MMWR can be found here: [The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020.](#)
- All COVID-19 ACIP Vaccine Recommendations can be found here: <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>

EUA Fact Sheets

On December 11, 2020, the U.S. FDA authorized the Pfizer-BioNTech COVID-19 vaccine for emergency use to permit active immunization to prevent COVID-19 in individuals 16 years of age and older. Below you will find the EUA fact sheet that should be given to everyone that receives the vaccine. We have also provided a link to the EUA fact sheet for health care providers that details vaccine use.

- [EUA Fact Sheet for Recipients](#)
- [EUA Fact Sheet for Healthcare Providers](#)
- Questions on EUAs? Review this [FAQ on EUAs](#)

Michigan Department of Health and Human Services (MDHHS) Prioritization Guidance

Below you will find the link to the interim COVID-19 vaccination prioritization guidance from MDHHS. This guidance outlines the strategy for vaccine prioritization for the State of Michigan and will be used by MDHHS, as well as public health and health care, as they allocate and administer vaccines. This guidance may change as information evolves and more vaccine types become available. MDHHS is following the Centers for Disease Control and Prevention (CDC) [recommendations](#).

- [MDHHS Interim COVID-19 Vaccination Prioritization Guidance](#)

CDC Communication Toolkit

CDC has developed a communication toolkit for medical centers, clinics, and clinicians. This toolkit can be used or adapted to meet your needs. It includes ready-made materials to build confidence about

COVID-19 vaccination among your healthcare teams and other staff. For detailed information within the toolkit see the link below.

- [CDC Communication Toolkit for Medical Centers, Clinics, and Clinicians](#)
 - A guide for building vaccine confidence within health systems, medical offices, and clinics
 - Turn-key slide decks for healthcare personnel with information about COVID-19 vaccines, tips for building vaccine confidence, and tips for having effective vaccine conversations with patients
 - Posters, fact sheets, FAQs, and social media
 - Printable buttons/stickers for staff to wear once they have gotten their vaccine
 - A video describing how ACIP makes recommendations and advises CDC on the use of vaccines

CDC's NEW Web Page for COVID-19 Vaccination Education:

CDC created a new web page here <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html> which contains COVID-19 vaccination education materials. This page links to several CDC pages such as the storage and handling toolkit, vaccine administration, ACIP recommendations and more. It also has a link specific to Pfizer COVID-19 vaccine information where you can find the following:

- BUD Guidance and Labels
- Storage and Handling Labels
- Vaccine Expiration Date Tracking Tool
- Ultra-Cold Temperature Logs (both Celsius and Fahrenheit)
- Storage and Handling Summary
- Dry Ice Safety

Pfizer-BioNTech COVID-19 Important Information for Health Care Professionals:

Pfizer recently released a website for providers that includes very detailed information on vaccine storage and handling, including videos. In addition, the site, which you can find here <https://www.cvdvaccine-us.com/>, contains information on the following:

- Safety Information
- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)
- Fact Sheet for Recipients and Caregivers
- Full EUA Prescribing Information
- Product Storage & Dry Ice
- Adverse Event Reporting

MDHHS FAQs:

MDHHS has developed a public FAQ on COVID-19 Vaccine.

- Public FAQ can be found at: https://www.michigan.gov/documents/coronavirus/COVID-19_Vaccine_Public_FAQ_FINAL_710077_7.pdf

Vaccine Packaging Images Attached: Attached you will find images of what the COVID-19 Vaccine packaging for Pfizer and Moderna will look like.

Update on the Ancillary Kits

The ancillary supply kits for the Pfizer COVID-19 vaccine are beginning to arrive at sites that will be administering the vaccine. McKesson is getting questions regarding the contents of the kits. **Attached** is the product information guide that CDC distributed to public health partners and an update from McKesson. Also, **attached** is the McKesson update on the Mega Kit contents for Pfizer Vaccine. All questions related to the ancillary supply kits should be directed to McKesson customer service. Here is that contact information:

- McKesson Customer Service
Phone #: 833-272-6634
Email: SNSSupport@McKesson.com

Pfizer Daily Webinars on Pfizer/BioNTech COVID-19 Vaccine

Pfizer will be hosting a Manufacturer COVID-19 Vaccine Training & Education Series. Webinars for Pfizer COVID 19 providers.

- Pfizer will be holding daily webinars this week at 10:00am and 5:00pm EST.
- Providers receiving Pfizer vaccine should receive communication from Pfizer with details.
- These webinars are a series of training sessions to review information and answer questions about their COVID-19 vaccine.
- Please click on the link below to join the sessions at the designated times.

| Date & Time | Password |
|--|-----------------|
| Attendee December 14, 2020 10:00 AM ET | jQxkNAZ5h97 |
| Attendee December 14, 2020 5:00 PM ET | yyJM8HMbV23 |
| Attendee December 15, 2020 10:00 AM ET | yyXXMHkY623 |
| Attendee December 15, 2020 5:00 PM ET | cXQqYzTM352 |
| Attendee December 16, 2020 10:00 AM ET | yDxuqt6Pg52 |
| Attendee December 16, 2020 5:00 PM ET | auKMUdmJ687 |
| Attendee December 17, 2020 10:00 AM ET | TMr7GvMc2P2 |
| Attendee December 17, 2020 5:00 PM ET | PPxyyuGP249 |
| Attendee December 18, 2020 10:00 AM ET | GawpMXB2X95 |
| Attendee December 18, 2020 5:00 PM ET | w3kBrP9ReU3 |

COCA Calls/Webinars

The CDC provides [Clinician Outreach and Communication Activity \(COCA\)](#) calls. COCA provides timely, accurate, and credible information to clinicians related to emergency preparedness and response and emerging public health threats. To receive updates from COCA and hear about upcoming education opportunities, sign up for emails. COCA offers several relevant and frequent webinars for clinicians. To sign up for COCA Calls/Webinars and receive future notices, visit

<https://emergency.cdc.gov/coca/calls/index.asp>. COCA has an upcoming webinar on Monday, December 14th, see information below for more detail on upcoming webinars.

- Upcoming webinar Monday, December 14th 1:00-2:00pm EST
 - **Title:** [What Every Clinician Should Know about COVID-19 Vaccine Safety](#)

MDHHS COVID-19 Vaccine Webinars:

MDHHS will be hosting 3 webinars. A flyer was recently sent out. There is no registration needed. Please see link below for further details.

- [MDHHS COVID-19 Vaccine Webinars](#)
 - Monday, December 14th: An Update on the Pfizer COVID-19 Vaccine
 - Monday, December 21st: An Update on the Moderna COVID-19 Vaccine
 - Tuesday, December 22nd: Talking Points for Common COVID-19 Vaccine Concerns

Medical Management Guidance for managing a Vaccine Reaction:

Administering any medication, including vaccines, has the potential to cause an adverse reaction. When adverse reactions do occur, they can vary from minor (e.g., soreness, itching) to rare and serious (e.g., anaphylaxis). Be prepared. Vaccine providers should know how to recognize allergic reactions, including anaphylaxis. Have a plan in place and supplies available to provide appropriate medical care should such an event occur.

- [Medical Management of Vaccine Reactions in Adults in a Community Setting](#) (full link: <https://www.immunize.org/catg.d/p3082.pdf>)
- [Medical Management of Vaccine Reactions in Children and Teens in a Community Setting](#) (full link: <https://www.immunize.org/catg.d/p3082a.pdf>)

**We are awaiting CDC clinical guidance and hope to have further clarification from CDC on the use of COVID-19 vaccines.

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

-The Immunization Nurse Education Team,

Andrea, Heidi, Maria, and Terri