# COVID-19 VACCINE INFORMATION FOR PROVIDERS

Staff must be trained to appropriately manage and administer this federally funded vaccine. Please review this information in detail. For additional vaccine-specific information, please also review the attached document summarizing Vaccines A and B. These materials reflect information known thus far as of 12/2/20 and is subject to change. Additional information can also be found at the CDC COVID-19 Vaccination Program Interim Playbook. Materials will also be available at our NEW MDHHS website for COVID-19 Provider Guidance & Educational Resources. This new website can also be accessed from www.michigan.gov/COVIDvaccine, then select "Provider Guidance & Education."

At minimum, provider staff must understand the following (all staff should understand this information, while the site's Vaccine Primary and Backup Coordinators should be experts on this information):

## KEY STAFF

- Ensure designation of a **Vaccine Primary and Vaccine Backup Coordinator**. These staff are to be experts in storing, handling, managing and documenting COVID-19 vaccine. These staff must be registered Michigan Care Improvement Registry (MCIR) users and associated to the COVID-19 provider site performing vaccination(www.mcir.org/registration).

## VACCINE RECOMMENDATIONS & BILLING

- Pre-position providers will be the very first sites to receive vaccine – they will be shipped vaccine to be in position for vaccination once an Emergency Use Authorization (EUA) is approved and while awaiting final recommendations from the Advisory Committee on Immunization Practices (ACIP).
    - Once ACIP recommendations are released for this COVID-19 vaccine, you may vaccinate in accordance with the recommendations. MDHHS will link to these recommendations when available.
- After ACIP recommendations are in place and pre-position sites have vaccine, additional doses will be shipped to priority sites for 1A populations, based on allocation. See "Ordering & Receiving Vaccine and Ancillary Supplies"
- **Coverage & Center for Medicare Services and Medicaid (CMS) Toolkits**
    - CMS has shared the following information regarding vaccine coverage and have toolkits available to support provider education (https://www.cms.gov/covidvax-provider)
    - Providers will be prohibited from charging consumers for administration of the vaccine. To ensure broad and consistent coverage, the toolkits have specific information for several programs, including:
        - **Medicare:** Beneficiaries with Medicare pay nothing for COVID-19 vaccines and their copayment/coinsurance and deductible are waived.
        - **Medicare Advantage (MA):** For calendar years 2020 and 2021, Medicare will pay directly for the COVID-19 vaccine and its administration for beneficiaries enrolled in MA plans. MA plans would not be responsible for reimbursing providers to administer the vaccine during this time. Medicare Advantage beneficiaries also pay nothing for COVID-19 vaccines and their copayment/coinsurance and deductible are waived.
        - **Medicaid:** State Medicaid agencies must provide vaccine administration with no cost sharing for most beneficiaries during the public health emergency.
        - **Private Plans**: CMS, along with the Departments of Labor and the Treasury, is requiring that most private health plans and issuers cover a recommended COVID-19 vaccine and its administration, both in-network and out-of-network, with no cost sharing. The rule also provides that out-of-network rates cannot be unreasonably low, and references CMS's reimbursement rates as a potential guideline for insurance companies.
        - **Uninsured:** For individuals who are uninsured, providers will be able to be reimbursed for administering the COVID-19 vaccine to individuals without insurance through the Provider Relief Fund, administered by the Health Resources and Services Administration (HRSA). See below.

- **The above information is obtained from the following coverage announcement:** https://www.cms.gov/files/document/2020-10-28-mlnc-se.pdf

- **Billing and Payment**
  - The toolkits above also address issues related to billing and payment.
  - COVID-19 providers agree to administer vaccine regardless of an individual's ability to pay and regardless of their coverage status, and may not seek any reimbursement, including through balance billing, from a vaccine recipient. Providers who have questions about billing or reimbursement of vaccine administration for patients covered by private insurance or Medicaid should contact the respective health plan or state Medicaid agency.
  - **Provider Relief Fund:** People without health insurance or whose insurance does not provide coverage of the vaccine can also get COVID-19 vaccine at no cost. Providers administering the vaccine to people without health insurance or whose insurance does not provide coverage of the vaccine can request reimbursement for the administration of the COVID-19 vaccine through the Provider Relief Fund (full link: https://www.hrsa.gov/CovidUninsuredClaim).
  - CMS information on billing, including toolkits for providers, are available at https://www.cms.gov/covidvax-provider
- Vaccine Codes (CVX, NDC, CPT, etc.)
  - CDC has issued "Preview Posting of COVID-19 Vaccine Codes and Crosswalk" (Full URL: https://www.cdc.gov/vaccines/programs/iis/code-sets.html?ACSTrackingID=USCDC_11_30-DM42043&ACSTrackingLabel=New%20Preview%20of%20COVID-19%20vaccine%20codes%2011%2F4%2F2020&deliveryName=USCDC_11_30-DM42043)
  - Codes will become effective only upon EUA issuance by the Food and Drug Administration (FDA)

## PATIENT EDUCATION & ADVERSE EVENT REPORTING

**EUA Fact Sheets**

- As indicated in the Provider Agreement, providers *must provide an Emergency Use Authorization (EUA) fact sheet* or vaccine information statement (VIS), as applicable, to each vaccine recipient/parent/legal guardian prior to vaccination
- **Emergency Use Authorization (EUA):** The EUA authority allows the U.S. Food and Drug Administration (FDA) to authorize either (a) the use of an unapproved medical product (e.g., drug, vaccine, or diagnostic device) or (b) the unapproved use of an approved medical product during an emergency based on certain criteria. The EUA will outline how the COVID-19 vaccine should be used and any conditions that must be met as requirements of authorized use. FDA will coordinate with CDC to confirm these "conditions of authorization." Additional information on EUAs, including guidance and frequently asked questions, is located on the FDA website.
  - **EUA Fact Sheet:** Product-specific EUA fact sheets will be made available for vaccine recipients as well as separate fact sheets for provider education. Both will be made available on the FDA and CDC websites and once available, MDHHS will link to these. Provide the recipient fact sheet to each client/patient prior to administering vaccine.
- Vaccine information statement (VIS): VISs are required by law for certain licensed vaccines and only if a vaccine is added to the Vaccine Injury Table. Optional VISs may be produced, but only after a vaccine has been licensed. Plans for developing a VIS for COVID-19 vaccine are not known at this time.

**Vaccination Record Cards & Second-Dose Reminders**

- As indicated in the Provider Agreement, providers *must provide a COVID-19 vaccination record card to each vaccine recipient/parent/legal guardian*.
- These cards will be provided as part of vaccine ancillary kits. Vaccination providers must complete these cards with accurate vaccine information (i.e., manufacturer, lot number, date of first dose, and second dose due date), and give

them to each patient who receives vaccine to ensure a basic vaccination record is provided. Vaccination providers should encourage vaccine recipients to keep the card in case the MCIR or other system is not available when they return for their second dose. *The card provides room for a written reminder for a second-dose appointment.*

- If vaccine recipients have a smartphone, they may consider documenting their vaccine administration with a photo of their vaccination record and entering the date the next vaccine dose is due on their electronic calendar.
- Redundant methods and systems should be used to remind vaccine recipients about their need for second doses. MDHHS information on using the IIS for second-dose text message reminders is being developed - Information will be shared when available.

**EDUCATION RESOURCE:** CDC Communications Website: Looking for information on ensuring safety of COVID-19 vaccine, how CDC is making recommendations, FAQs and more? Visit CDC's new website featuring information on COVID-19 vaccine: https://www.cdc.gov/vaccines/covid-19/index.html

- For general information on talking about vaccines, vaccine safety and more, visit CDC's website on vaccine conversations: https://www.cdc.gov/vaccines/covid-19/hcp/index.html

**Vaccine Adverse Event Reporting System (VAERS):**

- VAERS is a national reporting system to detect possible safety problems with vaccines. Anyone can submit a report to VAERS. VAERS is not designed to detect whether a vaccine caused an adverse event (AE), but it can identify "signals" that might indicate possible safety problems requiring additional investigation.
- Per the CDC COVID-19 Vaccination Program Provider Agreement, COVID-19 vaccination providers are required to report the following to VAERS:
    - Vaccine administration errors (whether associated with an AE or not)
    - Serious AEs (even if they are not sure if the vaccination caused the event)
    - Multisystem inflammatory syndrome (MIS) in children or adults, and
    - Cases of COVID-19 that result in hospitalization or death
    - They are also required to report to VAERS any additional AEs and/or adhere to any revised safety reporting requirements per FDA's conditions of authorized vaccine use posted on FDA's website throughout the duration of the EUA, as applicable. Vaccination providers should also report any additional clinically significant adverse events following COVID-19 vaccination to VAERS, even if they are not sure if the vaccination caused the event. More information on submitting a VAERS report electronically can be found at https://vaers.hhs.gov/reportevent.html.

**v-safe**

- CDC will implement v-safe, a new smartphone-based tool that uses text messaging and web surveys to check in with early vaccine recipients (HCP, essential workers) to monitor for adverse events after a COVID-19 vaccination. V-safe will also provide second-dose reminders (if needed) and live telephone follow up by CDC if vaccinated individuals report a medically significant event during a v-safe check-in.
- V-safe asks questions to monitor the safety of COVID-19 vaccines. The information will be used to analyze common side effects (soreness in the arm, muscle aches, etc.) and detect unexpected, serious health problems if they occur.
- CDC will create a v-safe information sheet that contains background on the program and instructions for enrolling. Healthcare professionals and healthcare facilities that are giving COVID-19 vaccines are asked to provide printed hard copies of the v-safe information sheet to each vaccinated individual and counsel them on enrolling in v-safe. The v-safe information sheet and counseling script are in development and will be made available when completed. It is critically important for vaccine safety monitoring and assessment that healthcare professionals give each patient a v-safe information sheet at the time of vaccination and encourage patients to enroll.

## STORAGE & HANDLING (S&H)

As indicated in the Provider Agreement, COVID-19 Providers must store and handle vaccine in accordance with manufacturer package inserts and *CDC's Storage & Handling Toolkit. See page 49 for a new addendum specific to COVID-19 vaccine*. CDC is also developing COVID-19 vaccination materials, COVID-19 vaccine-product specific materials, and will provide general vaccination training materials. These will be available on our NEW COVID-19 Provider Guidance website: https://www.michigan.gov/mdhhs/0,5885,7-339-73971_4911_4914-545768--,00.html. Key points are addressed below:

**Vaccine A/Pfizer Vaccine-Specific S&H Key Points**

- The shipment packaging is as follows:
  - Vaccine A/Pfizer vaccine arrives in a dry-ice thermal shipper with a minimum of 975 doses per shipper
  - Upon receipt, ensure precautions for handling dry ice (insulated gloves, ventilated area, etc.). Verify appropriate contents and condition of the shipment. Quantities should also match inventory upload in your MCIR Pandemic Inventory (See Inventory Management, Redistribution & Waste/Loss). Immediately store appropriately.
  - Doses are arranged in a "tray" with 975 doses per tray: **195 multi-dose vials (5 doses per vial)**.
  - If the vaccine is unpacked into another storage unit, such as an ultra-cold freezer, *keep the vials within their trays* (dimension: 9" X 9" X 1.6")
  - When opening the package, you will notice an included temperature device. This also tracks receipt of the vaccine. Press "stop" on this device when opening the package to confirm receipt. The next steps on using this device depends upon your utilization of the shipper for storage or not:
    - This device may be used to monitor temperatures if the thermal shipper is used for storage (see below "Storage" section). To do so, follow instructions provided from Pfizer for reactivation of the device.
    - If NOT using the shipper for storage, the temperature monitoring device accompanying the vaccine can no longer be used; a digital data logger (DDL) must be used to monitor the storage unit utilized (ultra-cold freezer or refrigerator). See more below in Storage and Handling
  - The thermal shipper itself and embedded temperature device must be returned to Pfizer within 20 days (instructions included in shipper)
  - *CDC does not recommend transporting ultra-cold vaccine*. However, there are options if absolutely necessary - For detailed guidance, see "Transport" on page 7.
- **Presentation:** multi-dose vials (5 doses per vial); see more in Vaccine Administration
- **Storage:** Vaccine A/Pfizer vaccine is shipped at ultra-cold temperatures of -60°C to -80°C (-76°F to -112°F). It must therefore follow strict storage requirements as follows:
  - **ULTRA-COLD FREEZER**: If stored in an ultra-cold freezer between -60°C to -80°C (-76°F to -112°F), viability can be maintained up to 6 months from date of manufacture.
    - However, pre-position providers are expected to promptly utilize vaccine doses provided.
  - **SHIPPER AS INTERMEDIARY STORAGE**: the thermal shipper itself can store vaccine for up to 15 days if dry ice is replenished appropriately. To utilize this method, dry ice must be replenished within 24 hours of receipt, then every 5 days, up to two times. The shipper should only be opened twice per day. After storage for 15 days in the shipper, vaccine can be placed in a refrigerator for 5 days of additional storage at 2°C to 8°C (36°F to 46°F).
    - *It is key to ensure plans in place to utilize all doses within the storage timeframe.*
    - *Beyond Use Date (BUD) labels should be available from CDC to assist in identifying timeframes by which you must use the vaccine (i.e. if refrigerated, must use within 5 days)*
    - Amount of dry ice for replenishment of shipper: 23 kg (51 lbs.)
      - Dry ice must be in **pellet** form

- Dry ice provided for FIRST replenishment: CDC will ship dry ice to sites receiving Pfizer vaccine and do not have ultra-cold freezers. This is to be used for the first replenishment within 24 hours only. This will also include gloves, scoop, eye protection, and an instruction sheet.
- Dry ice procurement for ADDITIONAL replenishment: MDHHS is in the process of determining options for support in procuring and distributing dry ice. Additional details are to come.
- A temperature device included with the shipper may be re-activated to monitor temperatures.

o **REFRIGERATOR**: If the vaccine is stored at refrigerated temperatures of 2°C to 8°C (36°F to 46°F), it can be stored at these temperatures for up to **5 days**. *It is key to ensure plans in place to utilize all doses within the storage timeframe.*

- Vaccine A/Pfizer vaccine can be put in a refrigerator for up to 5 days even after 15 days of appropriate storage in the thermal shipper.

o **ROOM TEMPERATURE:** No more than 2 hours at room temperature. *It is key to ensure plans in place to utilize all doses within the storage timeframe.*

o Vaccine temperatures **must be monitored at all times** regardless of storage type – see below "Daily Temperature Monitoring & Temperature Excursions"

**Chart 1**: Vaccine A storage and handling guide

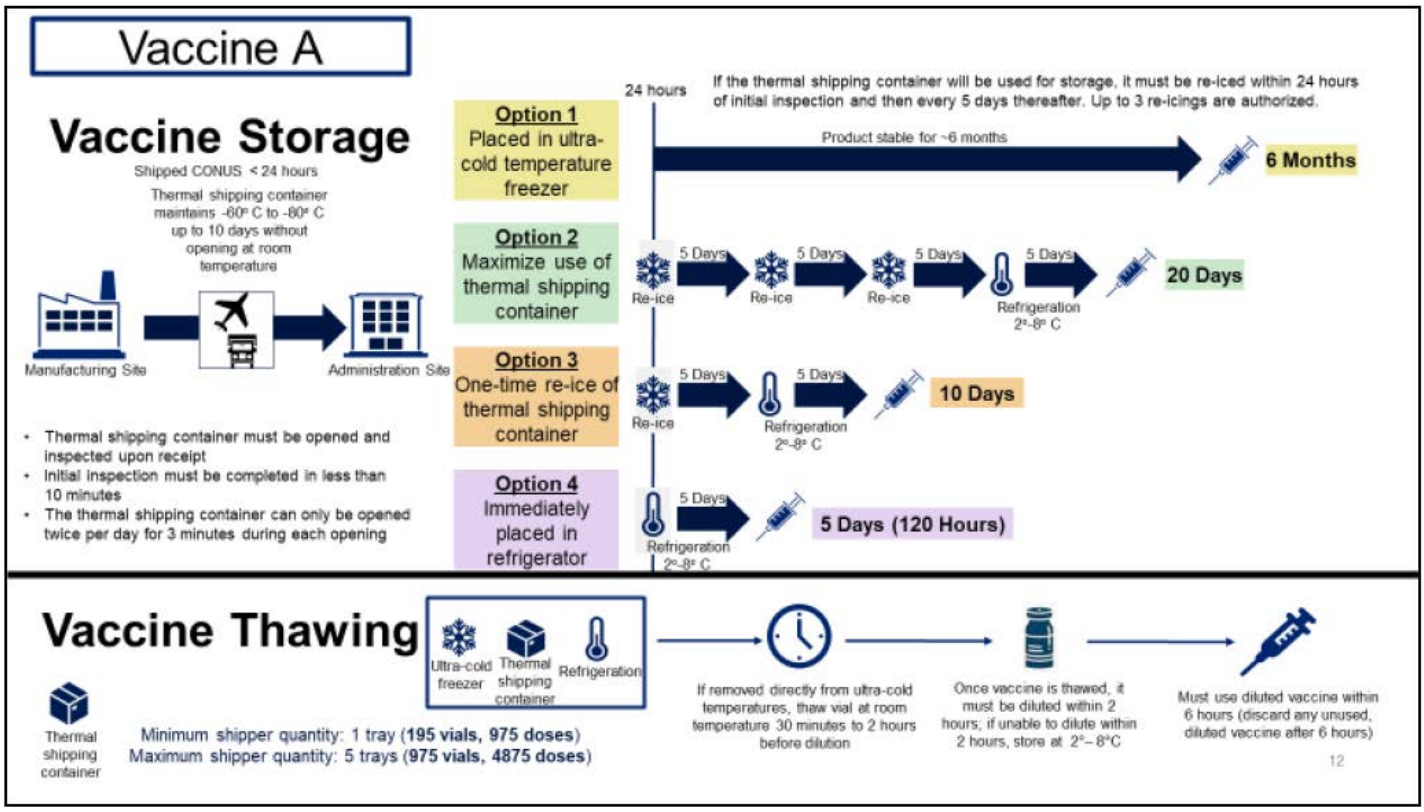



Image Source: CDC COVID-19 Vaccination Playbook Supplement #1

**Vaccine B/Moderna Vaccine-Specific S&H Key Points**

- The shipment packaging is as follows:
  - Vaccine B/Moderna vaccine arrives in a frozen shipper with a minimum of 100 doses per shipper
  - Upon receipt, verify appropriate contents and condition of the shipment. Quantities should also match inventory upload in your MCIR Pandemic Inventory (See Inventory Management, Redistribution & Waste/Loss). Immediately store appropriately.
- **Presentation**: multi-dose vials (10 doses per vial); see more in Vaccine Administration

- **Storage**: Vaccine B/Moderna vaccine is shipped at frozen temperatures of -25°C to -15°C (-13°F to +5°F). It must be stored as follows:
    - **FREEZER:** Store at -25°C to -15°C (-13°F to +5°F) for up to 6 months; *NOTE: This is a narrower range than varicella-containing vaccine storage ranges.*
    - **REFRIGERATOR:** Store at 2°C to 8°C (36°F to 46°F) for up to 30 days if the vial has not been entered (once entered, must use within 6 hours; see more in Vaccine Administration)
        - Note: Current CDC Playbook indicates "up to 7 days", however recent information from Moderna indicates seeking approval for refrigerated storage up to 30 days based on their latest viability data
    - **ROOM TEMPERATURE:** The total time between removal from refrigeration and administration should be no more than 12 hours.

**Ancillary Kits**

- Ancillary supply kits will be shipped separately. These will arrive before or on the same day as the vaccine. For each 100 doses, the following will be provided:
    - Needles, 105
        - 22–25-gauge, 1-1.5" (adult)
    - Syringes, 105 per kit (ranging from 1–3 mL)
    - Alcohol prep pads
    - 4 surgical masks and 2 face shields for vaccinators per kit
    - COVID-19 vaccination record cards for vaccine recipients
    - Vaccine needle guide detailing the appropriate length/gauge for injections based on route, age (for children), gender, and weight (for adults)
    - *Diluent will also be provided for Vaccine A (see additional details below in Vaccine Administration)*
    - Dimensions: The dimensions of the kit that accompanies Vaccine A are 24 in x 20 in x 24 in. This provides supplies needed to administer 975 doses of vaccine. The dimensions of the kit that accompanies Vaccine B are 14 in x 13 in x 9 in. This provides supplies needed to administer 100 doses of vaccine.

Ancillary supply kits will **not include** sharps containers, gloves, and bandages. Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs.

**Daily Temperature Monitoring and Temperature Excursions**

- Temperatures must be monitored at all times to ensure viability. Utilize a digital data logger (DDL) for continuous monitoring (24/7) and recording of storage temperatures (NOT min/max-only devices). *If an ultra-cold freezer is in use, be sure your data logger is capable of registering such temperatures*.
    - For additional support on DDLs, see MDHHS Data Logger Tip Sheet.
    - If using the thermal shipper for intermediary storage with dry ice for Vaccine A, the shipper will arrive with a temperature monitoring device. This device can be re-activated for continuous monitoring ability (up to 15 days if re-iced appropriately). Refer to instructions included with the shipment.
- Document temperatures at least twice daily (AM and PM) on temperature logs as follows:
    1. **AM, before vaccination:** Current temperature and minimum/maximum temperature*
    2. **PM**: Current temperature assessed and documented 30-60 minutes before leaving

    *Minimum/maximum: Min/max provides the highest and lowest temperature reached since min/max was last checked or since device was cleared. This is an important assessment as it allows you to identify an out-of-range temperature, even if "current" temperatures recovered. Some devices require that min/max is physically CLEARED after each assessment of min/max (ex: VFC5000). Others may clear automatically. Please ensure you understand these intricacies of your device features.
        - Document all temps exactly as displayed; For decimals, includes the tenth's place (i.e., 40.1°F) and do not round to the nearest whole number.

- *Temperature logs for ultra-cold temperature documentation are anticipated from CDC.*
- Temperature documentation must include temperatures, name or initials of person documenting temperatures, the exact time of temperatures taken, and any notes about excursions if noted.
- **Temperature Excursions:** Out-of-range temperatures (current, min, or max) are considered excursions. These must be documented on the temperature logs *and require immediate action*.
    - Stop vaccination while investigating any excursions. Vaccines exposed to out-of-range temperatures must be labeled "do not use" and stored at the required temperature until further information on usability can be gathered. Do NOT use vaccine exposed to excursions until manufacturer stability information has been obtained and Local Health Department (LHD) guidance provided.
    - Contact manufacturers for all products exposed to the excursion to obtain stability determinations on the vaccine. They will provide documentation as to whether use of the vaccine is supported or not.
    - *Notify the Local Health Department* of all excursions and provide all documentation to the LHD.
    - For step-by-step guidance on excursions, see MDHHS Guidance on Responding to Temperature Excursions
        - Guidance will be updated with COVID-19 manufacturer viability contact information once it becomes available.
    - Maintain all documentation related to excursions – data logger downloads, temp logs, manufacturer stability reports, etc.
- **TRAINING RESOURCE:** CDC You Call the Shots Storage & Handling module - https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp

**Transport**

- CDC **does not recommend transporting ultra-cold vaccine (Vaccine A/Pfizer vaccine)**. If necessary, this vaccine may be transported in its original shipping container with dry ice or in a portable ultra-cold freezer that can maintain -80° C. Alternatively, it may be transported at refrigerated temperatures using appropriate qualified transport containers that maintain at 2°C to 8°C (36° F to 46° F). However, *at refrigerated temperatures, Vaccine A/Pfizer vaccine is only viable for up to 5 days/120 hours*. Transport time counts against the 120-hour limit.
- Transport of Vaccine B/Moderna vaccine must comply with appropriate qualified transport containers that maintain the frozen temperature range of -25°C to -15°C (-13°F to +5°F) or refrigerated temperature range of 2°C to 8°C (36°F to 46°F). As a reminder, refrigerated storage of Vaccine B is limited to 30 days.
- Additionally, vaccine can only be transported to another site if a Redistribution Agreement has been signed by the organization that will perform redistribution to other sites. The recipient sites must have been included in the COVID-19 Provider Agreement/Enrollment (Section B of agreement) and enrolled for COVID-19 vaccine in Michigan. Redistribution must also be reflected in MCIR Pandemic Inventory – See Inventory Management, Redistribution, & Waste/Loss.
- *The cold chain must be maintained during transport*. This requires appropriate pack-out methods with qualified containers, as well as temperatures taken at least hourly using a digital data logger at the start and end of transport. All cold chain management must comply with the CDC Storage & Handling Toolkit.
- When transporting vaccine, utilize a digital data logger to monitor and record temperatures. MDHHS has a Vaccine Transport Temperature Log for documentation if needed.

**TRAINING RESOURCES:** CDC's Storage & Handling Toolkit: See the addendum on page 49 with COVID-19 vaccine information. CDC is also developing COVID-19 vaccination materials, COVID-19 vaccine-product specific materials, and will provide general vaccination training materials https://www.cdc.gov/coronavirus/2019-ncov/hcp/vaccination.html.

## VACCINE ADMINISTRATION

**Vaccine A/Pfizer Vaccine Preparation and Administration**

- **Presentation**: a 2mL preservative-free multi-dose vial with 0.45mL frozen vaccine product (5 doses per vial).

- Thaw vial prior to use: Up to 30 min at room temperature or 3 hours at refrigerated temperature 2°C to 8°C (36°F to 46°F)
- This vaccine requires reconstitution with a 0.9% saline diluent:
    - Dilute the vaccine multi-dose vial with 1.8 mL of diluent (provided in the ancillary kits). When reconstituting, do not shake – Instead, invert gently 10 times. After reconstitution, the vial contains enough for 5 doses of vaccine.
    - ONCE reconstituted, must use within 6 hours
    - Mark the vial with the time to ensure utilization of all 5 doses within 6 hours once reconstituted
- Cleanse the vial stopper with antiseptic before every withdrawal from the vial. This is a key step as the Pfizer vaccine is preservative-free.
- Dose, Schedule, and Route of Vaccine A:
    - ***Dose:*** *Each dose is* ***0.3mL*** *(NOTE THIS DOSAGE. This is different from most standard vaccine doses).*
    - **Schedule**: *2 doses, 21 days apart.*
    - **Route**: Administer as an intramuscular (IM) injection
        - Gloves are not required for IM injections. However, if gloves are worn during vaccine administration, they should be changed between patients in addition to performing hand hygiene (https://www.cdc.gov/vaccines/pandemic-guidance/index.html)
        - NEW handouts on administering IM injections:
            - IM Injection: Children 7 Through 18 Years of Age
            - IM Injection: Adults 19 Years of Age and Older
        - NEW handout – Vaccine Administration: Needle Length and Gauge
    - The **same product must be used for the first and second dose**.

**Vaccine B/Moderna Vaccine Preparation and Administration**

- **Presentation:** a preservative-free multi-dose vial (10 doses per vial).
- Thaw before use:
    - Thaw in refrigerated conditions between 2°C to 8°C (36°F to 46°F) for 2 hours. Let vial stand at room temperature for 15 minutes before administering.
    - Alternatively, thaw at room temperature between 20°C to 25°C (68°F to 77°F) for 1 hour.
    - After thawing, do not return vial to the freezer
- Once thawed, swirl vaccine gently prior to withdrawing a dose. Do NOT shake.
- No dilution required
- Dose, Schedule, and Route of Vaccine B
    - **Dose**: Each dose is 0.5mL
    - **Schedule**: *2 doses, 28 days apart.*
    - **Route**: Administer as an intramuscular (IM) injection
        - Gloves are not required for IM injections. However, if gloves are worn during vaccine administration, they should be changed between patients in addition to performing hand hygiene (https://www.cdc.gov/vaccines/pandemic-guidance/index.html)
        - NEW handouts on administering IM injections:
            - IM Injection: Children 7 Through 18 Years of Age
            - IM Injection: Adults 19 Years of Age and Older
        - NEW handout – Vaccine Administration: Needle Length and Gauge
    - The **same product must be used for the first and second dose**.
- **TRAINING RESOURCES:** CDC Vaccine Administration Resource Library: https://www.cdc.gov/vaccines/hcp/admin/resource-library.html (Videos on reconstitution, intramuscular injections, an E-Learn Training course on Administration, You Call the Shots Vaccine Administration, and more!)

**Expiration Dates**

- *The vaccine vials and cartons may not contain a printed expiration date*. Expiration dates may be updated based on vaccine stability studies occurring simultaneously with COVID-19 vaccine distribution and administration. Additional information will be provided about how to access expiry information for individual vaccines.
- CDC has worked with FDA and manufacturers to include a two-dimensional (2D) barcode on the vaccine vial (if possible) and carton (required) labels that includes a National Drug Code (NDC), lot number, and a placeholder expiration date of 12/31/2069 to be read by a scanner. The placeholder 12/31/2069 expiration date is not visible on the vaccine packaging nor found anywhere else; it is only to facilitate information system compatibility.
- CDC is developing BUD tracker labels to assist clinicians with tracking expiration dates at the point of vaccine administration. The label templates will be available on the CDC website.

## DOSE DOCUMENTATION

- Vaccine administration *must be documented in the Michigan Care Improvement Registry (MCIR) within **24 hours** of vaccination.*
    - For "type" of administration, select "Outbreak"
    - For "eligibility", select "Federal"
- Reminder: *Vaccine A (Pfizer) dosage is 0.3mL*
- Required data elements to report:

| **Required Data Element (CDC Playbook, Appendix D)** |
|---|
| Administered at location: facility name/ID |
| Administered at location: type |
| Administration address (including county) |
| Administration date |
| CVX (Product) |
| Dose number |
| Recipient race, if available |
| Recipient ethnicity, if available |
| IIS recipient ID* |
| IIS vaccination event ID |
| Lot number: unit of use and/or unit of sale |
| MVX (manufacturer) |
| Recipient address* |
| Recipient date of birth* |
| Recipient name* |
| Recipient sex |
| Sending organization |
| Vaccine administering provider suffix, if available |
| Vaccine administering site (on the body), if available |
| Vaccine expiration date |
| Vaccine route of administration, if available |

*Identifiable information

## PRIORITY GROUPS

ACIP, the National Institutes of Health, and the National Academies of Sciences, Engineering, and Medicine (NASEM) are working to determine populations of focus for COVID-19 vaccination and equity in access. The phases are outlined below, according to the CDC Playbook and most recent ACIP meeting (11/23/2020). *Note that these are interim and will be finalized by ACIP once an EUA is authorized.*

**PHASE 1:** Potentially limited supply of COVID-19 vaccine doses available - Concentrate efforts on reaching the initial populations of focus for COVID-19 vaccination. The interim subsets for phase 1 are as follows:

- **Phase 1-A**:
  - **Healthcare personnel:** Paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials
    - There may be insufficient COVID-19 vaccine supply initially to vaccinate all those who fall into the Phase 1-A subset, so jurisdictions should plan for additional subsets within that group (see CISA guidance for categories of healthcare personnel).
  - **Long-Term Care Facility Residents:** Residents of skilled nursing facilities and/or assisted living facilities, homes for the aged, adult foster care, etc.
- **Phase 1-B**:
  - **Essential Workers**: People who play a key role in keeping essential functions of society running and cannot socially distance in the workplace (e.g., Education Sector, Food & Agriculture, Utilities, Police, Firefighters, Corrections Officers, Transportation)
    - Phase 1-B and Phase 2 planning may also benefit from identifying subsets of population groups if there is high demand for vaccine. The Department of Labor's Occupational Safety and Health Administration has information on classifying workers at risk (low to very high based on position) for exposure to SARS-CoV-2. This information could prove helpful in determining subsets of critical populations.
- **Phase 1-C:**
  - **High-Risk Adults**: Adults with high-risk medical conditions who possess risk factors for severe COVID-19 illness
  - **Adults 65 years of age or older**

**PHASE 2:** Large number of vaccine doses available: Focus on ensuring access to vaccine for all critical populations who were not vaccinated in Phase 1, as well as for the general population; expand provider network.

**PHASE 3:** Sufficient supply of vaccine doses for entire population (surplus of doses): Focus on ensuring equitable vaccination access across the entire population. Monitor vaccine uptake and coverage; reassess strategy to increase uptake in populations or communities with low coverage.

## ORDERING & RECEIVING VACCINE and ANCILLARY SUPPLIES

**Ordering/Allocation of Vaccine**

- **ALLOCATION:** When quantities of vaccine provided to our state are limited, MDHHS will place orders for provider sites to ensure prioritized, equitable, and efficient distribution. Michigan has developed methods for allocation that will be based on CDC expectations: populations served by vaccination providers, geographic location for distribution throughout the jurisdiction, provider site storage and handling capacity, and will utilize ACIP recommendations as they become available, to inform distribution. Surveys have also been underway to obtain site-level capacity, storage capacity, etc. to support ordering approach.
  - Additional information on allocation and distribution is available in our Michigan COVID-19 Vaccine Plan (www.michigan.gov/covidvaccine).
  - Communication among partners in the community is key to ensure priority populations are reached for vaccination efforts. This becomes especially important for sites that cannot receive shipments directly or cannot receive minimum orders of 975 doses (when only Vaccine A is available) but have priority groups for vaccination. Partnerships with LHDs, Health Systems, and other sites with vaccination capacity for priority groups should be harnessed for such efforts.

- **OPEN ORDERING:** When doses become widely available, providers will have the ability to place orders in MCIR via users associated to the MCIR site and added as "E-order Contacts". Additional information will become available prior to this functionality becoming operational.
- When orders are placed, "E-order Contacts" associated to the MCIR site and marked "receive email notifications" will receive emails about order placement and when the shipment is en route.

## INVENTORY MANAGEMENT, REDISTRIBUTION, & WASTE/LOSS

### View Inventory in MCIR and Required Inventory Reporting to CDC

- Vaccine shipments will automatically upload to each provider's "Outbreak" Inventory in MCIR.
    - Upon receipt of shipment, verify that contents of vaccine shipment match all information uploaded in MCIR inventory (quantities, lots, etc.)
    - Ancillary supplies will not be uploaded in MCIR inventory
    - Store vaccine appropriately immediately upon receipt (see Storage & Handling).
- Inventory will deduct doses as administered only if doses are correctly documented. This is key to ensure on-hand inventory stays up-to-date and accurate in MCIR.
- **VaccineFinder:** *On-hand inventory must be reported to CDC's Vaccine Finder each day:* www.vaccinefinder.org
    - Providers enrolled in the COVID-19 vaccine program will receive an email from the "COVID Locating Health Provider Portal" with instructions for completing the enrollment process. This email will be sent to the provider organization's email address submitted in the provider enrollment form.
    - VaccineFinder overview: CDC VaccineFinder Provider Info Sheet
    - VaccineFinder instructions and upload method: CDC VaccineFinder Data Import Document
    - VaccineFinder Provider Support website
        - Includes the tip sheets above PLUS video trainings for inventory reporting

### Redistribution

- A signed CDC Vaccine Redistribution Agreement is required for a facility to conduct redistribution (as well as a fully completed CDC COVID-19 Vaccination Provider Agreement/Profile for each recipient location). Appropriate cold-chain management must be ensured during transport, including temperature monitoring.
- Inventory guidance to become available for sites redistributing COVID-19 vaccine and sites receiving redistributed COVID-19 vaccine. Pre-position sites are not intended to redistribute vaccine.
- Both the redistributing site and the recipient site must ensure their Pandemic inventory in MCIR reflects movement of vaccine prior to administration of doses (removal of X doses from redistributing site, addition of X doses to recipient site). Prior to redistribution transactions, the recipient site must manually activate their Pandemic inventory in MCIR. Further guidance will be provided for education on this process.

### Waste/Loss

- As indicated in the Provider Agreement, providers must report COVID-19 vaccines and diluents that were unused, spoiled, expired, or wasted as required by MDHHS. This is performed via MCIR transactions in the Pandemic Inventory. Educational materials to support this will be developed and disseminated.
- Additional details are pending from CDC and manufacturers regarding return of vaccine/diluents. Providers must comply with federal instruction regarding disposal of unused COVID-19 vaccine and diluent.

### MCIR Educational Support

- Information for general MCIR support, inventory education, running reports, and more will be made available to COVID-19 providers. MDHHS will link to these resources. Such materials may include:
    - How to search for a person in the MCIR
    - How to add a person to the MCIR
    - How to add a COVID immunization to the MCIR upon administration
    - How to manage inventory in MCIR and run relevant reports

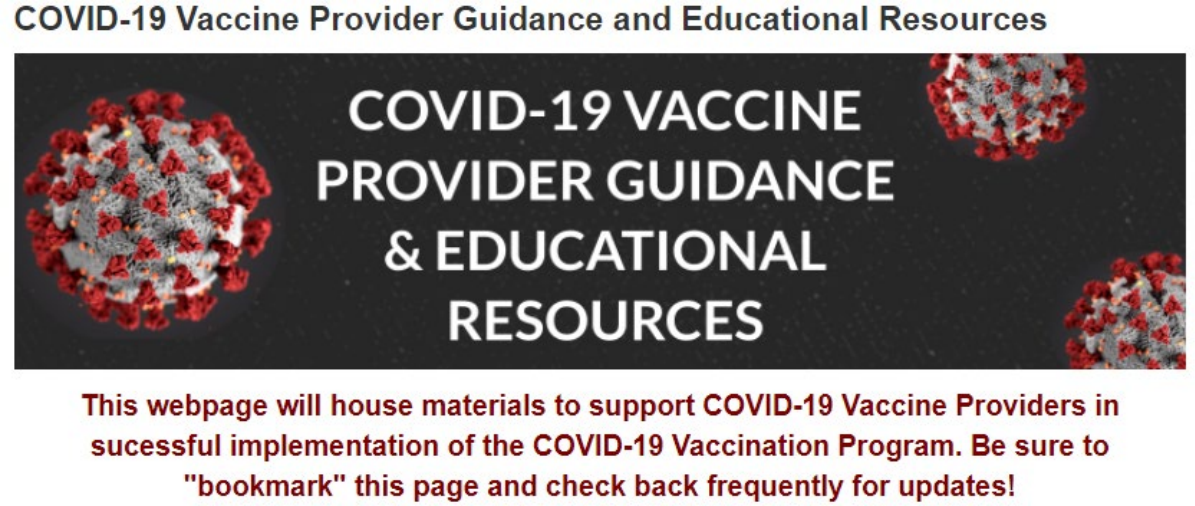
- How to generate and review HL7 transfer report, if applicable

## MISCELLANNEOUS

- Providers must maintain documents for at least three years including: vaccine administration records and all records related to COVID-19 vaccine management.
- When widely available, providers may publicize vaccine availability to VaccineFinder (www.vaccinefinder.org).
- When planning for vaccination, ensure plans consider social distancing and PPE preparation. Some resources to utilize: CDC Providing Vaccinations During a Pandemic (https://www.cdc.gov/vaccines/pandemic-guidance/index.html) and Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations (https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html)

## *NEW WEBSITE FOR PROVIDER SUPPORT*

- MDHHS COVID-19 Vaccine Provider Guidance & Educational Resources
  - Bookmark this website and visit frequently for updates!
  - May also be accessed via www.michigan.gov/COVIDvaccine, then select "Provider Guidance and Education"




**References**: CDC COVID-19 Vaccination Interim Playbook, V2 - www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf
CDC COVID-19 Vaccination Playbook Supplement #1 - https://www.michigan.gov/documents/mdhhs/Playbook_Supplement_1_11.20.20_708520_7.pdf