

Date: 11/5/2021

Subject: Correction to IMPORTANT COVID-19 Vaccine Updates

Good Afternoon Immunization Partners,

CORRECTION: A correction was made to a bullet point regarding expiration guidance - Please see the yellow highlighted correction below.

Please review the updates below regarding orders and shipments of COVID-19 vaccine, including reminders for the new pediatric Pfizer product for ages 5 through 11 years.

GENERAL PRODUCT UPDATES

- The [Product Information Guide for COVID-19 Vaccines and Associated Products](#) is **now updated** to reflect the new pediatric Pfizer vaccine for ages 5 through 11 years, including ancillary supply components.
- CDC's [redistribution tool for ancillary supplies](#) (Ancillary Redistribution Gadget for Healthcare Workers, or A.R.G.H.) is **now updated** to include all new products as well.
 - Utilize this excel tool to help assure all the syringes, needles, supplies, and diluent needed for vaccine administration move with vaccine during redistribution.
- It is crucial you update your VaccineFinder public display to ensure families can easily locate vaccine.
 - How to Update VaccineFinder Public Display (Vaccines.gov): [Public Display in VaccineFinder COVID Locating Portal: For Providers | CDC](#)
 - Please widely promote the use of www.vaccines.gov so the public can locate vaccine.

PFIZER PRODUCTS

PEDIATRIC PFIZER FOR AGES 5 THROUGH 11 YEARS (ORANGE CAP)

This product has begun arriving at offices across the state. Below are some important highlights unique to this product. We urge providers to review all product details in the [EUA for Healthcare providers](#);

- **Ordering:** This pediatric Pfizer 5-11 vaccine **will become available for ordering on Tuesday November 9th**. The minimum order quantity will be 100 doses.
 - Pre-orders are complete and no additional doses can be ordered. Currently, this product is still visible in the E-Order system so we apologize for any confusion. **LHDs, please reject orders for this product if they appear in the order queue**; MDHHS will also reject orders if they appear in the order queue.
- **Receipt & Storage Requirements**
 - Pfizer pediatric vaccine for ages 5 through 11 years will be shipped on dry ice in smaller disposable shippers. Unlike the adult shippers, these smaller shippers cannot be used for temporary storage and can therefore be disposed of.
 - Upon receipt, the contents **MUST** be removed **and placed in an ultra-cold freezer between -90°C to -60°C (-130°F to -76°F) or in a refrigerator between 2°C to 8°C (36°F to 46°F) immediately.**
 - **Do NOT store this vaccine in a standard freezer at -25°C to -15°C (-13°F to 5°F). This is also explicitly stated in the EUA.**
 - **Temperature Monitor/Logger:** Each Pfizer 5-11 shipper includes a Controlant temperature monitoring device (digital data logger or DDL). This

device cannot be used to continue temperature monitoring after delivery. Turn off the temperature monitor upon receipt and return it in the box labeled “FOR LOGGER RETURN”.

- **Important Note Regarding Expiration: The date on the vial is not the expiration date.** It is the date of manufacture.
 - You may also notice a QR code on the vial – however, this QR code provides a link to the EUA, not expiration information.
 - There is not a Pfizer expiration date look up tool.
 - **To determine the expiration date:**
 - If stored in an ultra-cold freezer: Add 6 months to the manufacture date printed on the vial.
 - **Count the date of manufacture as first month:** For example, if the manufacture date on the vial is 8/2021, it will expire 1/31/22 if stored in an ultra-cold freezer.
 - **If stored in a refrigerator: Must be used within 10 weeks from the date it was transferred from ultra-cold storage to the refrigerator (not 10 weeks from the date of manufacture); The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. Regardless of storage condition, vaccines should not be used after 6 months from the date of manufacture printed on the vial and cartons.**
 - The 6-month expiration date is uploaded to your MCIR Outbreak Inventory.
 - The COVID-19 Vaccine Lot Number report, available via CDC’s Vaccine Code Set Management Service, can help identify expiration dates. The report is updated daily with COVID-19 vaccine lot numbers and expiration dates provided to CDC by vaccine manufacturers.
 - If you have not yet registered for the report, visit [CDC's Vaccine Lot Number and Expiration Date webpage](#) and complete the registration form to request access.
- **Important Diluent Reminder:** Orders of Pfizer pediatric vaccine include ancillary kits that contain 10mL diluent vials. **While these vials appear to contain sufficient diluent for multiple vials, they must only be used once.**
 - Diluent vials are a one-time-use item and should be discarded with the remaining content after each use.
 - For each vial of vaccine, extract 1.3mL of diluent from a single-use vial to reconstitute 1.3mL of vaccine
 - Do not be tempted to puncture diluent vials more than once.
- **Note Regarding Post-dilution Timeframe:** Vials should be discarded 12 hours after dilution, as stated in the EUA. *Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the [EUA Fact Sheet](#) supersedes the number of hours printed on vial labels and cartons.*
- **Doses Extracted from the new Pediatric Pfizer Vaccine for Ages 5 Through 11 Years:** Providers have asked about extraction of an “extra” dose (11th dose) from the vial after dilution. We have sought out additional guidance which is to comply with the Emergency Use Authorization stating there are **10 doses per vial** after dilution.
- **Pfizer Webinars for Provider Support:** Pfizer is hosting Medical Updates & Immunization Site Training for All Providers with a **focus on Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccine for Children 5 through 11 Years of Age.** In addition to Medical Updates, sessions will **focus on the Storage, Handling, & Administration** for currently available vaccine presentations. See the sessions below:

Date & Time	Password
Attendee link – November 5 – 12 PM ET	rJSpNPts332
Attendee link – November 8 – 5 PM ET	BtJSxJqw942
Attendee link – November 9 – 5 PM ET	aRDjkm MD349
Attendee link – November 10 – 12 PM ET	QPfX8RM7y8M7
Attendee link – November 11 – 12 PM ET	Tntjh4UMr55
Attendee link – November 12 – 12 PM ET	m fP2vm 8HhD5
Attendee link – November 15 – 5 PM ET	SUeJ7te Yc45
Attendee link – November 16 – 5 PM ET	ZMjtfDdn438
Attendee link – November 17 – 12 PM ET	YYkSGJGT848
Attendee link – November 18 – 12 PM ET	8ZGbRrha2f8
Attendee link – November 19 – 12 PM ET	Pzp X4ZPn T63
Attendee link – November 22 – 5 PM ET	YKwPs6P85cH
Attendee link – November 23 – 5 PM ET	S4wspGuhN33
Attendee link – November 24 – 12 PM ET	iWpzipvHh667

ADULT/ADOLESCENT PFIZER FOR AGES 12 YEARS AND OLDER (PURPLE CAP)

- The ordering pause has been lifted and this product is available for ordering. However, with thousands of doses in the field, we want to stress the importance of rotating stock to ensure soon-to-expire vaccine is used first as well as obtaining vaccine via redistribution from the local health department when possible, to minimize waste.
- There is limited availability of the Pfizer 450-packs (In addition to 1170-packs). Prior to ordering Pfizer 450-packs, please take note:
 - These doses are labeled for January expiration.
 - All of these orders come shipped with only pediatric ancillary kits, which include only 1” needles.
 - Sites should proactively acquire a stock of the 1.5” needles to vaccinate residents/patients/staff who require the longer needle length.
 - Refer to the Vaccine Administration: Needle Gauge and Length chart included with ancillary kits for information about when the 1.5” needle length should be used.

MODERNA

- Moderna 14-dose vials (Moderna-14) remains available for ordering.
- Moderna 10-dose vials (Moderna-10) is NO LONGER available. CDC has indicated more inventory of Moderna 10 is expected in the near future and we will inform you when this becomes available.
 - Currently, this product is still visible in the E-Order system but we are working to have it turned off. **LHDs, please reject orders for this product if they appear in the order queue;** MDHHS will also reject orders if they appear in the order queue.
- **Moderna Expiration Extension:** Moderna continues to update data regarding extension of expired doses. A total of 78 lots have been approved for extension, but challenges within IT systems have slowed the progress considerably. We urge you to continue to monitor Moderna’s

look up tool: <https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup#vialLookupTool>

- **REMEMBER:** The Moderna vials **must be maintained in the frozen state** for the extension to be applicable (extension does not apply to thawed vials)
- No additional lists have been provided regarding extensions beyond what has been shared already.
- **Moderna Inventory and Wastage Reminders:** See [Moderna COVID-19 Vaccine Booster Dose Key Points](#)
 - Moderna wastage tables are also [available here](#)
- **Syringe Availability for Moderna Booster Administration:** The dosage for the Moderna booster dose (0.25 mL) is different than the dosage for the primary series (0.5 mL). Currently, the ancillary kits for Moderna 14 contain a combination of 1mL and 3mL syringes. **While the 3mL syringes are adequate for extracting a primary series dose (0.5 mL), they do not support extraction of the booster dose (0.25 mL).** The 1 mL syringes allow for better visualization and extraction of the smaller 0.25 mL booster dose.
 - Understandably, this has raised some challenges in accessing 1 mL syringes in the marketplace. To assure providers have an adequate supply of 1 mL syringes to support extraction of booster doses (0.25 mL) from a Moderna 14 vial, **CDC will begin shipping an additional Moderna 10 ancillary kit with all orders placed on or after October 30. As you recall, Moderna 10 ancillary kits contain only 1 mL syringes. When possible, please use 3 mL syringes for extraction of primary series doses to ensure you have an adequate supply of 1 mL syringes to support extraction of booster doses from a Moderna vial.** Do not puncture the vial stopper more than 20 times.

JANSSEN (JOHNSON & JOHNSON/ “J&J”)

- J&J remains available for ordering.

MISCELLANEOUS

Use of Vial Adaptors or Spikes

Use of vial adaptors or spikes are not recommended by either the CDC or U.S. Pharmacopeia as a means of extracting doses from a vial of COVID-19 vaccine. The risk of contaminating the vaccine is too great. Unlike many vaccines, COVID-19 vaccines do not contain a preservative, which increases the risk for potential contamination. Info can be found in the USP COVID-19 Vaccine Toolkit at www.usp.org/covid-19/vaccine-handling-toolkit (page 4): “Refrain from using transfer devices (e.g., mini spikes, dispensing pins, adaptors, etc.) or using one needle to prepare multiple syringes due to potential loss of vaccine in dead space or damage to the stopper and loss of integrity of the vial.”

Q: Is it acceptable to leave a needle inserted in the septum of a vial for multiple vaccine draws?

A: No. A needle should not be left inserted into a vial septum for multiple uses. This provides a direct route for microorganisms to enter the vial and contaminate the fluid.

[Medication Preparation Questions | Injection Safety | CDC](#)

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

Thank you,
MDHHS Division of Immunization