

From: noreply-dphimmunizations@ct.gov <noreply@everbridge.net>
Sent: Monday, May 24, 2021 2:57 PM
Subject: COVID Vaccine Provider Bulletin Week of May 24, 2021

EXTERNAL EMAIL: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.



DEPARTMENT OF PUBLIC HEALTH

Dear Connecticut COVID-19 Vaccine Providers,

Thank you again for your continued efforts in the COVID Vaccine roll-out. This email contains important information for COVID-19 vaccine providers – please read this message in its entirety.

Myocarditis and Post-Vaccination Safety Monitoring—Reminder to Report to VAERS

- In recent weeks, there have been reports of myocarditis occurring after COVID-19 vaccination, including in Europe, where the [EMA recently requested data from Pfizer and Moderna on reports of myocarditis and pericarditis after vaccination](#). CDC is aware of these reports, which are rare given the number of vaccine doses administered, and continues to monitor available data.
- As part of COVID-19 vaccine safety efforts, CDC has been monitoring myocarditis and pericarditis in multiple safety systems, including the [Vaccine Adverse Event Reporting System \(VAERS\)](#) and the [Vaccine Safety Datalink \(VSD\)](#).
- **To date, there has not been a safety signal identified in either VAERS or VSD.** CDC will continue to evaluate reports of myocarditis/pericarditis occurring after COVID-19 vaccination and will share more information as it becomes available. Healthcare providers should consider myocarditis in an evaluation of chest pain after vaccination and [report all cases to VAERS](#).

Pfizer will soon be available in a 450-dose shipment

- The new 450 dose pack configuration should be available for order beginning the first week of June. The new 450-dose pack includes 3 trays of 25 vials each.
- Vials will be shipped in the same container as the 1,170-dose orders and will include the same Controlant temperature monitor.
- The newly extended refrigerator storage temperatures (see below) should decrease the need for dry ice. Therefore, Pfizer asks that the shippers and Controlant monitors be returned within 10 days. There will be no dry ice replenishment for the 450-dose pack.
- New ancillary kits have been created to support the 450-dose minimum order size, including a potential pediatric ancillary kit containing only 1” needles.
- All other supplies in the ancillary kit remain the same.

Changes in storage temperatures for Pfizer

The FDA has amended the Pfizer EUA to allow undiluted, thawed Pfizer COVID-19 vaccine vials be stored in the refrigerator at 2°C to 8°C (35°F to 46°F) for up to 1 month. This is an update to previous guidance which stated that thawed, undiluted vaccine vials could be stored in the refrigerator for up to 5 days.

Current [Pfizer COVID vaccine storage and handling](#):

- **All Pfizer configurations are shipped ultra-cold.**
- Ultra-Cold (-70°C): Undiluted vials may be stored in ultra-cold freezer until expiration date or temporary in the shipper with regular dry ice replenishment per guidance (unchanged).
- Frozen (-20°C): Undiluted vials may be stored in freezer for up to 2 weeks (unchanged).
- **Refrigerated (2°-8°C): Undiluted, thawed vials may be stored in refrigerator for up to 1 month (NEW).**
- **Total storage time for Pfizer in freezer and refrigerator should not exceed 45 days.**
- Thawed vaccine cannot be refrozen.

[FDA In Brief: FDA Authorizes Longer Time for Refrigerator Storage of Thawed Pfizer-BioNTech COVID-19 Vaccine Prior to Dilution. Making Vaccine More Widely Available | FDA](#)

Please update your COVID Vaccine location listings

As providers consolidate schedules and locations, please check and update your listings on covidvaccinefinder.ct.gov. If any corrections are needed, please email Caroline.Hou@ct.gov.

Please ensure the following are correct:

- Vaccine type(s) offered;
- Operating hours noted in the details area;
- Walk-up appointment availability; locations with walk up appointments are now indicated on the finder
- If you have plans to close a clinic location, please let us know.

Warning from the FDA: Stop Using Certain Syringes and Needles with Needle Safety Devices Manufactured by HAIYOU

The FDA is recommending that health care providers stop using certain syringes and needles with needle safety devices manufactured by Guangdong Haiyou Medical Apparatus Co., LTD. (HAIYOU) at this time while FDA continues an evaluation of quality issues. Issues include certain HAIYOU needles detaching from the syringe after injection and other needle safety device failures. These device failures have been reported for the following HAIYOU syringe and needle configurations (combinations of syringes and needles with needle safety devices):

- 1mL syringe with 25G x 1-inch needle
- 1mL syringe with 23G x 1-inch needle

The FDA is working with federal partners to identify where these configurations have been distributed and inform those sites of the quality issues. The Letter can be found below and [here](#).

Some of these needles were distributed up to a few months ago in COVID-19 ancillary kits, but have not been distributed for the past few months. Providers may still have some of them in inventory. Should you find them in any or your ancillary kits, call the McKesson service number on the ancillary kit box for replacements.

Unneeded ancillary kit supplies

Some providers have been contacting the state about unneeded ancillary supplies left over from kits. If you have supplies in the ancillary kits that you will be unable to use, please feel free to donate them to the healthcare agency or charity of your choice. You do not need to send partial kits back to the state. This probably goes without saying, but please do not donate the HAI0U syringe and needle configurations listed above that are being investigated for quality issues by the FDA.

Memorial Holiday Ordering

There will be no vaccine deliveries over the Memorial Day weekend, including Monday May 31st. Pfizer vaccine deliveries will resume on Tuesday June 1st, while other vaccines and ancillary kits deliveries will resume on Tuesday. Please contact patricia.firmender@ct.gov by end of day May 24th if you will need an additional supply of vaccines prior to the holiday weekend.

Summary of Adolescent Vaccine Tools

Tools for the public:

- **New web page:** [COVID-19 Vaccines for Children and Teens](#) provides information about the benefits of COVID-19 vaccines for adolescents aged 12 and older, how to find a vaccination provider for adolescents, and what to expect during and after vaccination.
- **New fact sheet:** [COVID-19 Vaccines for Preteens and Teens](#) is a printable fact sheet for parents that explains the benefits of a COVID-19 vaccine for their children, safety information, and what to expect during and after vaccination.
- **New frequently asked questions:** Two [new FAQs](#) address questions about the safety and benefits of COVID-19 vaccination for adolescents aged 12 and older.

- **New myth-buster about menstrual cycles:** Your menstrual cycle *cannot* be affected by being near someone who received a COVID-19 vaccine. This [question and answer](#) explains why.
- **Myth-buster about infertility:** It is safe for people who would like to have a baby one day to get a COVID-19 vaccine. This [question and answer](#) explains why.
- **Key things to know:** The web pages [Key Things to Know about COVID-19 Vaccines](#) and [About COVID-19 Vaccines](#) have been updated to include the recommendation that adolescents aged 12 and older get vaccinated.

Information for Healthcare and Vaccine Providers:

- **New pediatric toolkit:** The [Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit](#) provides materials to help healthcare providers give parents clear and accurate information about COVID-19 vaccines. The toolkit includes answers to common questions, an explanation of how mRNA vaccines work, and printable materials to give to parents.
- **New FAQs about consent for minors:** [FAQs](#) have been posted on the Pfizer-BioNTech product page for providers with information about consent, prescreening questions, and other issues related to the vaccination of minors.
- **New sample patient letter:** Healthcare providers can customize and send this [\[How%20to%20talk%20to%20your%20patients%20about%20COVID-19%20vaccination%20|%20CDC\]sample letter](#) to encourage their patients to get a COVID-19 vaccine. It includes the new recommendation that everyone aged 12 and up get a COVID-19 vaccination.

Information for Community Groups

- **Toolkit for community-based organizations:** The [Community-Based Organizations COVID-19 Vaccine Toolkit](#) has been updated to include information and resources on COVID-19 vaccination for adolescents aged 12 and older.

REMINDERS

Census tract-level coverage information

For several weeks, Local Health Departments have had access to census tract-level information about vaccine coverage. This data is now posted publicly, and we encourage local health departments, vaccine providers, and community organizations to reference this data to inform their targeting and outreach strategies. [You can view this data here.](#)

Avoiding missed opportunities to vaccinate and minimizing wastage

- Several CoVP providers have contacted us with concerns over potentially wasting COVID-19 vaccines should they puncture a vial and not be able to use each dose within the needed timeframe.
- As access to COVID-19 vaccine increases, it is important for providers to not miss any opportunity to vaccinate every eligible person who presents at vaccine clinics.
- We recognize that as we continue to create more opportunities to vaccinate more people, it may increase the likelihood of leaving unused doses in a vial.
- Providers should follow the CDC's [clinical best practice for vaccination as well as best practices when managing inventory](#) to maximize vaccination and minimize dose wastage.
- **While we want to continue to follow best practices to use every dose possible, we do not want that to be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated.**
- Please continue to use creative strategies to avoid wastage, such as:
 - Shared provider waitlists, phoning or texting those with appointments in coming days to present early, inviting recipients to contact their friends to be vaccinated;
 - Actively inviting in individuals who are in the vicinity (e.g., some providers have made PA announcements for grocery store-located pharmacies);
 - Consider establishing and promoting standing vaccination days or half-days to increase likelihood of larger numbers of people presenting for vaccination on the same day;
 - Vaccinate family members or friends who accompany patients to medical visits even if they are not established patients at the vaccinating practice;
 - Continue outreach to employers or other community partners that have a large membership or network to arrange vaccination events.
- Once punctured, multidose vials must be used within 12 hours for Moderna, 6 hours for Pfizer, and 2 hours for J&J/Janssen.
- Continue to report vaccine wastage to the DPH [Helpdesk](#).

UPDATED CDC Webpages and Clinician Resources

- General information about COVID-19 vaccine products for clinicians and healthcare professionals can be found on the [COVID-19 Vaccination webpage](#).
- Clinical information including FAQs, Contraindications and Precautions as well as Administrative resources can be found for each vaccine on their own product webpage
 - [Pfizer-BioNTech COVID-19 vaccine](#)
 - [Moderna COVID-19 vaccine](#)
 - [Janssen/J&J COVID-19 vaccine](#)
- Recent updates to the Centers for Disease Control and Prevention's Communication and Education Product Inventory

- [FAQs for Private and Public Healthcare Providers About Implementing the CDC COVID-19 Vaccination Program in Provider Practices | CDC](#)
- [Risk Benefit Analysis \(cdc.gov\)](#)

As always, please continue to encourage patients to register for V-safe; report adverse events to VAERS.

School Clinics

School leaders and local health directors are encouraged to continue coordinating with COVID Vaccine Providers to arrange Pfizer vaccine clinics for eligible students – currently 12+. The Department recommends that school leaders also plan for ways to provide access to Pfizer vaccine clinics to all eligible students. Approaches include:

- Host an on-site clinic in a school building
- Refer students and families to off-site vaccine clinics
- Reach out to the Department to discuss other school-specific strategies

Regardless of specific approach, we have learned in recent weeks that school-supported clinics are a highly effective way to serve our younger populations. If you would like help matching your school(s) with a CoVP provider and arranging student vaccine clinics — or if you have questions regarding how to effectively communicate with students and families to ensure maximum coverage — please reach out to Cameron Cross at: Cameron.Cross@ct.gov.

Hospital Discharge Vaccination

All acute care hospitals should be offering COVID-19 vaccines to all individuals upon discharge to skilled nursing and assisted living facilities by May 17th. Hospitals should offer the J&J vaccine, but may offer an mRNA vaccine if an individual refuses the J&J vaccine. We will work with long term care pharmacy partners and other providers to ensure the individual receives their second dose of mRNA vaccine.

Hospitals are encouraged to offer vaccines in their emergency departments as well. Hospitals may offer the J&J vaccine or an mRNA vaccine. Hospitals should not be discouraged from offering mRNA vaccines due to concern for loss of follow up. Hospitals should do their best to recall patients for second doses, but it is understood that some may be lost to follow-up.

Monitoring COVID Vaccine Expiration Dates

Providers should make sure to continue to monitor expiration dates for COVID-19 vaccines. Specifically, providers are encouraged to check the expiration dates for J&J vaccines and ensure they are administering vaccine on a “first in first out” out basis to avoid expiration, as many lots of the J&J vaccine have expiration dates that are sooner than those on the mRNA vaccines.

Please report vaccines due to expire within 30 days to the COVID-19 vaccine [ordering portal](#) so we can facilitate potential transfer of the vaccine to another CoVP Provider to avoid wastage. Please report this information to the ordering portal even if you are not placing an order on that particular week.

Information on how to determine the expiration data is available for each vaccine below.

Janssen: The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date: Scan the QR code on the outer carton, or call 1-800-565-4008, or visit www.vaxcheck.jnj.

Pfizer: Use CDC’s beyond-use date labels for this vaccine to track storage time at refrigerated and frozen temperatures.

Moderna: Scan the QR code on the vial or carton, enter the lot number, and the expiration date will be displayed, or visit [http:// www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua).

Moderna vaccine: new 15 dose vials and storage and handling updates

The Moderna vaccine is now primarily being supplied in 15 dose vials. **The vial is the same size as the 10 dose vial was, but is filled to the higher volume.**

- A new NDC has been issued for the larger volume Moderna vial, which has been given a range of 13-15 doses in the EUA.
- The larger volume vial may contain 15 doses of vaccine. However, it will not always be possible to extract the 15th dose. This is based on the overfill in the vial and the type of syringes used to administer the vaccine. Therefore, vaccination providers should expect to withdraw 13-15 doses from each vial. Each dose must contain 0.5mL of vaccine.
- When the amount of vaccine remaining in the vial is not a complete 0.5mL dose, discard the vial and the residual vaccine regardless of the number of doses withdrawn. Do NOT save vials to combine residual vaccine from more than one vial to get a complete dose. An unextracted 15th dose does NOT count as waste. Inability to draw 14 or fewer doses from a 15 dose vial should be reported as wastage (please report through submitting a ticket to [Helpdesk](#)).

- Vaccination sites should continue to reliably extract 10 doses from the current volume vial and plan to extract 14 doses from the new larger volume vial using the ancillary kit supplies provided. Ancillary kits will be reconfigured to extract 14 doses per vial, plus a 5% surplus to account for damage, wastage, or additional doses.
- Moderna has also updated the volume of their 10 dose vials to now reflect a maximum of 11 doses. You should be able to reliably pull 10 doses, but documentation will reflect that there is a maximum of 11. The vaccine ordering portal has been updated to reflect these changes.

Moderna updates to storage and handling

- Frozen Vaccine Moderna vials can now be stored frozen between -50° to -15°C (-58° to 5°F). This is an increased range from the original temperatures. This new, wider temperature range is consistent with temperature requirements for other recommended vaccines stored in the freezer.
- Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours. This is an increase from 12 hours.
- Punctured vials may be held between 2° to 25°C (36° to 77°F) for up to 12 hours. Vials should be discarded 12 hours after the first puncture. This is an increase from 6 hours.

Ordering Portal Update

- **The ordering portal has been updated to remove the minimum tray size constraints from the dose requested section. Providers may now order in quantities less than the minimum tray size and we will work to partner providers to accommodate these requests.**

Upcoming Clinic Trainings and Office Hours

- **Weekly CoVP Update**

Provides CoVP Vaccinating Providers updates on the CoVP Program and Q&A with DPH staff. **Wednesdays** 9:00am-10:00am; Join: [CoVP Office Hours](#)

- **CoVP CT WiZ Enrollment Office Hours**

Provides information about the CoVP enrollment process in CT WiZ and Q&A with DPH staff. **Mondays & Thursdays** 12:00pm-12:30pm; Join: [CoVP CT WiZ Enrollment Office Hours](#)

- **Vaccine Storage and Handling Assessment**

For clinics who completed CoVP enrollment and received an invite to attend. **Tuesdays & Thursdays** 10:00am-11:00am and 1:00pm-2:00pm; **By invitation Only**

- **VAMS Live Helpdesk Office Hours**

Clinics can ask questions about VAMS functionality to DPH staff. **Tuesdays** 9:00am 10:00am & **Thursdays** – 1:00pm – 2:00pm; Join: [VAMS Live Helpdesk Office Hours](#)

Visit: [VAMS Training \(ct.gov\)](#) and [CT WiZ Training](#) for VAMS enhancement release notes and training materials on VAMS and CT WiZ.