From: noreply-dphimmunizations@ct.gov <noreply@everbridge.net>

Sent: Monday, October 25, 2021 12:45 PM

Subject: COVID-19 Vaccine Program (CoVP) Provider Bulletin, Week of October 25



Dear Connecticut COVID-19 Vaccine Providers,

This communication is being sent to all key contacts at provider organizations administering COVID-19 vaccine— please read this message in its entirety. Please feel free to share it with others in your organization who may benefit from the update. Note that all of our communications are archived on our web site.

Dear COVID Vaccine Providers,

This is a busy time, and we appreciate everyone's continued work to roll-out COVID-19 vaccines. Please read this bulletin carefully – we look forward to your active participation in our booster roll-out as well as next week's expected roll-out of the Pfizer vaccine for children 5–11. Every vaccine provider has a role to play in each campaign!

Booster Doses

There are now booster recommendations for all three COVID vaccines. All providers should actively reach out to patients to whom they gave first doses and encourage them to receive booster doses if eligible. All individuals 65 and older should receive a booster; Everyone who received J&J should receive a booster; and many individuals 18-64 who received an mRNA vaccine are likewise eligible for a booster. Please read below for details.

For individuals who received an mRNA vaccine (Pfizer-BioNTech or Moderna)

For individuals who received a Pfizer-BioNTech or Moderna COVID-19 vaccine, the following groups are eligible for a booster shot at 6 months or more after their initial series:

- 65 years and older
- Age 18+ who live in long-term care settings
- Age 18+ who have underlying medical conditions
- Age 18+ who work or live in high-risk settings

For individuals who received a J&J vaccine

For individuals who received a J&J vaccine, booster shots are recommended for those who are 18 and older and who were vaccinated two or more months ago. This means that all individuals who received a J&J vaccine should receive a booster.

Mixing & Matching (heterologous series)

Both the Food and Drug Administration (FDA) and CDC support individuals to receive a booster dose that is a different vaccine type than they originally received for their primary series if they choose. CDC's recommendations now allow for this type of mix and match dosing for booster shots.

The CDC media statement is available here. An update to the CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States, which will contained much more detailed information, is expected today and will be available here.

Next week: Pfizer Pediatric Vaccine for Ages 5 through 11 Years

We expect the Pfizer pediatric vaccine to roll-out next week. See below for a detailed view of the calendar for next week:

- October 26: the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) has scheduled a meeting on Oct. 26 to inform the agency's decision-making. Information about the meeting is available here.
- **By November 1:** We expect that the FDA will likely issue an EUA for the Pfizer vaccine for 5–11 year-old children. Shipments of the product will likely begin at this time.
- **November 2–3, 10am–5pm:** ACIP meeting is scheduled. The draft agenda is not yet available. The meeting can be livestreamed here.
- November 4: We expect that administration of the 5–11 Pfizer vaccine can begin on this
 date, pending all approvals and recommendations are issued in accordance with the
 schedule above

Pfizer-BioNTech 5 through 11 year old product introduction

An Emergency Use Authorization (EUA) application for the Pfizer-BioNTech COVID-19 Vaccine for children 5–11 years old has been submitted to the Food and Drug administration (FDA) and will likely receive authorization by early November.

What is currently known about COVID-19 vaccines for children <12 years old:

- The Pfizer-BioNTech COVID-19 Vaccine for 5–11-year-olds will be a new product with <u>new packaging</u> (orange cap, see attached PRELIMINARY reference document for more details) and a new national drug code (NDC). The current product for adults and adolescents should not be used in children.
- The new product configuration will be 10-dose vials, in packages of 10 vials (100 dose total) pending FDA authorization. The product <u>can be stored for 10 weeks at 2</u> to 8°C in the refrigerator. There will also be changes to the product shipper.
- The Immunization Program will support the transfer of vaccines in smaller quantities than is available for order if shipped directly from the manufacturer.
- COVID-19 pediatric vaccines <u>will require diluent</u>, and this will be provided with ancillary supplies which are configured specific to new vaccine packaging and appropriate for use in children.

- The Public Readiness and Emergency Preparedness (PREP) Act has expanded scope of practice for pharmacists and pharmacy technicians nationwide to allow for provision of vaccinations to children ≥3 years old (please see: https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf).
 - Pharmacists, pharmacy interns, and qualified pharmacy technicians (if the pharmacy intern or technician acts under the supervision of such pharmacist and the pharmacy intern or technician is licensed or registered by his or her State board of pharmacy), may administer vaccines that the (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule. This includes influenza and FDA authorized or FDA licensed COVID -19 vaccines.
 - The PREP Act Fact Sheet explaining the COVID-19 vaccination workforce can be found <u>here</u>. The Fact Sheet described qualified persons covered to administer COVID-19 vaccines under the PREP Act Declaration and its amendments.
- The months of November and December have multiple holidays and potential for winter weather. Providers should factor this into their inventory management and clinical operations.

Assumptions regarding the COVID-19 vaccine program for children <12 years old:

- We should be ready to vaccinate children 5 through 11 years old shortly after the VRBPAC meeting on Oct 26th pending FDA authorization and ACIP recommendations.
- Pharmacies participating in the Federal Retail Pharmacy Program (FRPP) can order vaccine to select pharmacy locations increasing the number of locations children may go to get vaccinated.
- The CT Immunization Program continues to promote enrollment of CT Vaccine Program providers (CT's pediatric vaccine program) to be COVID-19 Vaccine Providers.

Moderna Ordering, Inventory Reporting, and Shelf Life Updates

- All Moderna orders approved after 10/22 will receive double ancillary kit shipments with each order in order to support administration of booster doses at a "half dose" strength
- **Terminology** –Moderna products should continue to be referenced as "Moderna 10" and "Moderna 14".
 - Moderna 10 There is very little product in the field, but it could still be available.
 - Moderna 14 most inventory will be this product.

• Inventory Reporting:

Only report unopened product in the refrigerator in whole doses

Example: Moderna 14×10 unopen vials on the shelf = 140 doses reported through inventory channels

• Do NOT count opened/punctured product. Do not count half doses or whole doses from opened/punctured product.

Wastage reporting:

- Continue to maintain reporting of wastage in whole doses up to 14 doses.
- Example: Moderna 14 If 4 doses are administered from a single vial, 10 doses should be reported as waste through currently existing channels.
- o Do NOT count half doses as waste when reporting.

Example- During a full day in a clinic, 1 primary dose is administered and 5 booster half-doses are administered from a Moderna 14 vial.

COUNT the **total** number of doses administered, regardless of volume or series and subtract this from the total number of identified doses in the vial.- For a Moderna 14 dose vial, a total of 6 people are vaccinated (1 primary and 5 booster shots); 14 - 6 = 8 doses wasted.

Vial size – number of vaccines administered = waste

Shelf life extension: Moderna continues to update data regarding extension of expired doses. A total of 78 lots have been approved for extension, and more may follow. The first available list of extended lots is provided below. These batches of Moderna vaccine have been processed for expiry extension and provide an additional 2 months. The product must be maintained in the frozen state for the extension to be applicable (extension does not apply to thawed vials). Moderna's look up tool remains the official indicator of product expiry.

Primary Lot #	NDC	Configuration	Expiration	Updated Expiry
046A21A	80777-0273-99	10	9/3/2021	11/3/2021
039A21A	80777-0273-99	10	9/4/2021	11/4/2021
008B21-2A	80777-0273-99	10	9/10/2021	11/10/2021
017B21A	80777-0273-99	10	9/14/2021	11/14/2021
020B21A	80777-0273-99	10	9/23/2021	11/23/2021
022B21A	80777-0273-98	14	9/28/2021	11/28/2021
039B21A	80777-0273-99	10	10/2/2021	12/2/2021
044B21A	80777-0273-99	10	10/6/2021	12/6/2021
046B21A	80777-0273-99	10	10/6/2021	12/6/2021
002C21A	80777-0273-99	10	10/14/2021	12/14/2021
021C21A	80777-0273-99	10	10/21/2021	12/21/2021
023C21A	80777-0273-99	10	10/24/2021	12/24/2021
024C21A	80777-0273-99	10	10/26/2021	12/26/2021

Following batches of Moderna vaccine are **NOT subject to expiry extension**. Expired lots listed below must not be used and should be discarded.

Primary Lot #	NDC	Configuration	Expiration
047A21A	80777-0273-99	10	9/1/2021
038A21A	80777-0273-99	10	9/2/2021
048A21A	80777-0273-99	10	9/5/2021
001B21A	80777-0273-99	10	9/6/2021
006B21A	80777-0273-99	10	9/6/2021
002B21A	80777-0273-99	10	9/7/2021
007B21A	80777-0273-99	10	9/8/2021
003B21A	80777-0273-99	10	9/9/2021
008B21A	80777-0273-99	10	9/10/2021
058D21A	80777-0273-98	14	9/11/2021
016B21A	80777-0273-99	10	9/13/2021
018B21A	80777-0273-99	10	9/16/2021
026B21A	80777-0273-99	10	9/17/2021
027B21A	80777-0273-99	10	9/18/2021
025B21A	80777-0273-99	10	9/19/2021
030B21A	80777-0273-99	10	9/20/2021
019B21A	80777-0273-99	10	9/21/2021
031B21A	80777-0273-99	10	9/22/2021
032B21A	80777-0273-99	10	9/24/2021
038B21A	80777-0273-99	10	9/25/2021
021B21A	80777-0273-99	10	9/26/2021
021B21A-1	80777-0273-99	10	9/26/2021
037B21A	80777-0273-99	10	10/1/2021
040B21A	80777-0273-99	10	10/2/2021
043B21A	80777-0273-99	10	10/3/2021
041B21A	80777-0273-99	10	10/4/2021
042B21-2A	80777-0273-99	10	10/5/2021
042B21A	80777-0273-99	10	10/5/2021
045B21A	80777-0273-99	10	10/8/2021
047B21A	80777-0273-99	10	10/9/2021
048B21A	80777-0273-99	10	10/9/2021
006C21A	80777-0273-99	10	10/10/2021
049E21A	80777-0273-98	14	10/11/2021
008C21A	80777-0273-99	10	10/13/2021
050E21A	80777-0273-98	14	10/13/2021
009C21A	80777-0273-99	10	10/15/2021

Recent COVID-19 and vaccine related publications

- COVID-19 Vaccination and Non–COVID-19 Mortality Risk Seven Integrated Health Care Organizations, United States, December 14, 2020–July 31, 2021
- Effectiveness of Pfizer-BioNTech mRNA Vaccination Against COVID-19
 Hospitalization Among Persons Aged 12–18 Years United States, June—September 2021

Centers for Disease Control and Prevention (CDC's) COVID-19 website updates:

- CDC Expands Eligibility for COVID-19 Booster Shots
- COVID-19 Vaccine Booster Shot
- Different COVID-19 Vaccines
- COVID-19 Vaccines for Children and Teens

Pfizer Vaccines Host "Medical Updates"

- These sessions are hosted by Pfizer and will be continuously updated to reflect new information and changes that evolve.
- Session topics, subject to change, may include: FDA indication & authorizations;
 CDC / ACIP recommendations; Packaging / presentation updates; Storage, handling & administration; Test your knowledge (Q&A scenarios for various storage & expiry conditions)
- Please click on the links below to join the sessions at the designated times. These
 sessions will be updated to reflect new information and changes that evolve. Such
 updates will be identified at the start of each session and further explained during
 each presentation.

Please click on the links below to join the sessions at the designated times. *

Date & Time	Password
Attendee link – October 25 – 5 PM ET	xUF8sKQiz76
Attendee link – October 26 – 5 PM ET	vuPhUsbD258
Attendee link – October 27 – 12 PM ET	7c2gZCqcSz8
Attendee link – October 28 – 12 PM ET	9ywEun8Mjs7
Attendee link – October 29 – 12 PM ET	cnRBrmGr324
Attendee link – November 1 – 5 PM ET	g9ZmgHaip32
Attendee link – November 2 – 5 PM ET	sJDZQERp325
Attendee link – November 3 – 12 PM ET	82qdN3PppPp
Attendee link – November 4 – 12 PM ET	Y4ZkXdh2bz7
Attendee link – November 5 – 12 PM ET	rJSpNPts332

^{*}Weblinks for future training sessions will provided at a later date.

REMINDERS

We are keeping information on many important reminders from past communications in the space below. To prevent this section from becoming too lengthy, what remains is selected carefully. All past communications are available here.

<u>Communicating the Benefits of Influenza Vaccine during COVID-19</u> Please see new handout which includes updated recommendations on co-administration of flu and COVID-19 vaccines and tips for discussing flu vaccine with patients. Check it out <u>here</u>.

Johnson & Johnson's Janssen COVID-19 Vaccine Overview and Safety | CDC

Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine: Women younger than 50 years old should especially be aware of the rare risk of blood clots with low platelets after vaccination. There are other COVID-19 vaccines available for which this risk has not been seen. If you received a J&J/Janssen COVID-19 Vaccine, here is what you need to know. Read the CDC/FDA statement.

Guidance regarding eligibility verification for booster doses of COVID-19 vaccines

As has always been the case during the COVID-19 vaccine roll out, the State of Connecticut wants to ensure that vaccine access is simple and straightforward for vaccine recipients. Providers should continue to ensure that COVID vaccines are readily available for individuals who seek them and that administration of a COVID-19 vaccine is medically appropriate and conducted in line with the ACIP guidelines.

Ensuring patients receive a COVID vaccine at the appropriate interval:

Connecticut DPH recommends that providers have a procedure for ensuring that individuals receive their booster no sooner than the minimum recommended interval. This can be accomplished in one of several ways, in order of preference:

- Verify the vaccine information, including the brand and date(s) a patient received their previous COVID-19 vaccine doses using CT WiZ; or
- Review the Centers for Disease Control and Prevention (CDC) Vaccination Card, VAMS Certificate, CT WiZ Certificate, or other documentation of the recipient's vaccination record; or
- If neither of the above are possible, ask the patient for the vaccine brand(s) and dates of previous COVID-19 doses received during the scheduling process (and including logic in scheduling systems to ensure appropriate interval).

Ensuring recommended individuals receive a COVID booster:

Connecticut DPH recognizes that the categories of individuals for whom boosters may be confusing or not immediately clear to all patients. Connecticut DPH continues to support patient self-identification and attestation as a sufficient basis for confirming that an individual is within one of the categories for whom boosters are recommended.

Additional considerations:

DPH reminds providers that there is no residency requirement to receive COVID-19 vaccines and that identification (ID) is likewise not required. Although ID may be requested from the

patient for purposes of billing, no individual should be turned away due to lack of ID and providers should endeavor to create a welcoming environment for people to seek COVID-19 vaccines.

Please verify your listings are correct on ct.gov/covidvaccine. If you need to add new clinic locations, remove a clinic location, or modify the products you offer, please email Caroline.Hou@ct.gov.

Vaccine Lot Management and Expiration

In order to minimize the number of unused expired doses and manage expired doses correctly, we encourage providers to:

- Monitor expiration dates weekly, rotate stock as needed, and follow a "first in, first out" strategy to manage inventory.
- If nearing expiration, check posted manufacturer information for the most up to date expiration/extension information for vaccine lots.
- Based on the latest expiration information and unless instructed to do otherwise, REMOVE expired vaccine from the storage unit. Do not give staff opportunity to administer expired vaccine.
 - o If expired vaccine is inadvertently is administered, it is considered a vaccine administration error and requires remediation including a VAERS report, contacting the recipient to inform them of the error, and may or may not require revaccination based on the manufacturers' guidance. Guidance on vaccine administration errors can be found in Appendix A of the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States.
- Vaccine disposal: dispose of the vaccine vial (with any remaining vaccine) and packaging as medical waste. Do NOT return vaccine in the thermal shipping container.
- Check your vaccine stock for lots expiring using the CDC's Vaccine Lot Number and Expiration Date webpage.
- Any vial of J&J that has a date prior to September 23, 2021 has now expired. There will be no more extension. J&J has an expiration date look up website.
- Request access to a new COVID-19 Vaccine Lot Number report via CDC's Vaccine
 Code Set Management Service (VCSMS). This report includes COVID-19 vaccine lot
 numbers and expiration dates provided to CDC by the vaccine manufacturers. This
 report is updated daily and can be used to support vaccine administration, inventory
 management, and jurisdiction IISs. Complete the registration form on CDC's Vaccine
 Lot Number and Expiration Date webpage to request access to the report.

Providers should dispose of expired vaccine appropriately and report the wastage in the DPH ticketing system. When reporting expired doses to the Helpdesk, please select the "Report Vaccine Wastage" ticket option, then select "Other" as the wastage reason and type "Expiration" in the text box when prompted. Please make sure that inventory is updated in Vaccine Finder, VAMS, or CT WiZ as appropriate.

Influenza Corner

The Advisory Committee on Immunization Practices *Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021–22 Influenza Season is available here.*

If a patient is eligible, both the flu and COVID-19 vaccines can be administered at the same visit, as recommended by CDC and its Advisory Committee on Immunizations Practices (ACIP).

In addition to flu vaccine, the COVID-19 vaccine can be given with other vaccines as well. Even though both vaccines can be given at the same visit, providers should follow the recommended schedule for either vaccine: If your patients haven't gotten the currently recommended doses of COVID-19 vaccine, they should get a COVID-19 vaccine as soon as possible, and ideally they should get a flu vaccine by the end of October.

Giving all vaccines for which a person is eligible at the same visit is considered a <u>best practice</u> as it increases the probability people will be up to date on recommended vaccines. It also is an important part of immunization practice, especially if a health care provider is uncertain that a patient will return for additional doses of vaccine.

Coadministration of COVID-19 and Influenza vaccines

You may administer COVID-19 and influenza vaccines without regard to timing (both live, attenuated and non-live influenza vaccines). This includes administration of COVID-19 and influenza vaccines on the same day, as well as coadministration at any time interval. (CDC | Interim Clinical Considerations: Coadministration of COVID-19 and Influenza vaccines)

With influenza season approaching, there may be compelling logistical advantages to offering patients COVID-19 and influenza vaccines on the same day, and you may encourage patients to receive these on the same day. There are no safety concerns for coadministration.

Best practices for <u>administering more than one vaccine</u>, including COVID-19 vaccines and influenza vaccines, include:

- When preparing more than one vaccine, label each with the name and dosage (amount) of vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
- Always inject vaccines into different injection sites.
 - Separate injection sites by 1 inch or more, if possible so that any local reactions can be differentiated.
 - Each muscle (deltoid, vastus lateralis) has multiple injection sites (<u>Vaccine Administration Route and Site</u>).
- If administered at the same time, COVID-19 vaccines and vaccines that might be
 more likely to cause a local injection site reaction (for example, high-dose and adjuvanted inactivated influenza vaccines) should be administered in different limbs, if possible (Pervention and Control of Seasonal Influenza with Vaccines:
 Recommendations of the Advisory Committee on Immunization Practices (ACIP)—
 United States, 2021-22).
- Inject vaccines rapidly without aspiration since aspiration is not recommended before administering a vaccine (<u>Vaccine Administration Route and Site</u>).
- There are many existing resources on administration and co-administration of vaccines relevant for healthcare providers, including:
 - o Pink Book: Vaccine Administration | CDC

- You Call The Shots: Vaccinating Adolescents (cdc.gov)
- Vaccine Administration Training Module (cdc.gov)
- Intramuscular (IM) Injection: Sites YouTube
- CDC also is developing a job aid and video for health care professionals on coadministration of vaccines.

Ensure Best Practice by Checking CT WiZ Before Vaccinating

Prior to administering any vaccine, including the COVID-19 vaccine, it is important that a recipient's prior vaccine history be referenced in the Immunization Information System (CT WiZ); best clinical practice is to verify that the recommended interval has elapsed since a previous dose of vaccine and that the preferred brand of vaccine be administered.

- If your clinic established bi-directional data exchange, you can query CT WiZ for the patient immunization record electronically from your EHR.
- Every CoVP enrolled clinic can look up the patient immunization record in the CT WiZ user interface. Those who signed the CoVP Provider Agreement and the primary and back-up vaccine coordinator already have CT WiZ access.
- If your staff need access to CT WiZ, <u>request a username</u> and select the 'Clinic Access' role. Access to CT WiZ is defined in EXECUTIVE ORDER NO. 13C.
- If you need support, please submit a Helpdesk ticket.

Report vaccine temperature excursions and vaccines wasted to the Helpdesk by following the prompts and submitting a ticket.

- Immediately report all temperature excursions in storage units containing COVID-19 vaccines. Staff will be notified in real time of the excursion and will assist you. Please store vaccines in the storage unit in a paper bag marked "do not use" until a determination about the viability of the vaccine has been made, in consultation with the manufacturer and the Immunization Program.
- Also report to the Helpdesk all COVID-19 vaccines deemed wasted or expired. This
 includes Pfizer vials from which a sixth dose cannot be extracted.

Post Notice to Patients About Reporting to CT WiZ at CoVP Clinics

All clinics enrolled in the CoVP must post the <u>Notice to Patients About Reporting to CT WiZ</u>, to let vaccine recipients know their records are being reported to CT WiZ. If you are reporting through VAMS, this data is transmitted to CT WiZ.

Replacement CDC COVID Vaccination Cards

- Recommendation: Post your procedure for recipients to request replacement cards, in a location visible to recipients at your clinic as well as on your website. If your clinic needs additional CDC COVID-19 Vaccination Cards, contact Immunizations@ct.gov and we will email you a pdf of the card for your clinic to print (note: these should not be posted on your website). Large type print cards are also available via pdf.
- Reminder: You should issue CDC COVID-19 Vaccination Cards to your vaccine recipients. DPH cannot issue a CDC card to recipients. DPH can provide the immunization record from CT WiZ. DPH's procedure is on our COVID-19 Vaccine

and DPH Immunization webpages at: <u>I lost my vaccine card, how do I get another</u> one? (ct.gov) and Request an Official Immunization Record.

Upcoming Clinic Trainings and Office Hours

- CoVPUpdate -- next meeting November 3rd
 Provides CoVP Vaccinating Providers updates on the CoVP Program and Q&A with
 DPH staff. Every other Wednesday 9:00am-10:00am; Join: CoVP Office Hours
- The CoVP Enrollment Office HoursProvides information about the CoVP enrollment process in CT WiZ and Q&A with DPH staff. Mondays 12:00pm-12:30pm; Join: CoVP CT WiZ Enrollment Office Hours
- Vaccine Storage and Handling AssessmentFor clinics who completed CoVP enrollment and received an invite to attend. Tuesdays 10:00am-11:00am & Thursdays 1:00pm-2:00pm; By invitation Only
- VAMS & CT WiZ Live Helpdesk Office Hours Clinics can ask questions about VAMS and CT WiZ functionality to DPH staff. Tuesdays
 9:00am 10:00am; Join: VAMS Live Helpdesk Office Hours

Visit: VAMS Training and CT WiZ Training for enhancement release notes and training.

Thank you for all of your ongoing work and support of our COVID-19 vaccine roll-out in Connecticut.

CT DPH Immunization Program Main P: (860) 509-7929 | Fax: (860) 706-5429 | Email: dph.immunizations@ct.gov Website: CT Immunization Program | COVID-19 Vaccine Program

If you would like to unsubscribe from these communications, please send an email to Dph.immunizations@ct.gov with the subject line "Unsubscribe from COVID-19 Program communications".