From: noreply-dphimmunizations@ct.gov <noreply@everbridge.net>
Sent: Monday, October 18, 2021 11:37 AM
Subject: COVID-19 Vaccine Program (CoVP) Provider Bulletin, Week of October 18

DEPARTMENT OF PUBLIC HEALTH

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.*

UPDATES

Please read on for important updates related to planning for the 5 through 11 year-old Pfizer product as well as for Moderna and Johnson & Johnson (J&J) booster vaccines.

The two most important things to know are:

1. Pfizer-BioNTech vaccine for 5–11 year olds will be a NEW product. You may not use existing Pfizer vaccine for this age group. We expect to introduce this product during the first week of November.
2. The Moderna booster dose is a half-dose. You may use existing vaccine that you have on hand, but it should be administered at a half-dose when used as a booster. (Note that third doses for immune compromised are still a full dose). Do not draw more than 20 doses from a single vial (do not puncture a single vial more than 20 times). We expect the Advisory Committee on Immunization Practices (ACIP) to offer final booster recommendations for both the Moderna and J&J boosters by this Thursday, so administration can begin on Friday.

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 new packaging (orange cap, see attached PRELIMINARY reference document for more details) and a new national drug code (NDC). **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 can be stored for 10 weeks at 2 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.
- More information about ordering of pediatric vaccines will be coming within the next few days.
- COVID-19 pediatric vaccines will require diluent, 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 here. 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:

- FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to meet on Oct 26th. We should be ready to vaccinate children 5 through 11 years old shortly thereafter pending FDA authorization and ACIP recommendations.
- Ordering for pediatric vaccines will begin once FDA issues the EUA, and vaccine administration will begin once the CDC Director makes a recommendation based on the ACIP recommendations.
- Vaccination providers that are most likely to vaccinate pediatric populations will be prioritized for initial doses, with provider types likely varying across communities (e.g. pediatric clinics, community health centers, and pharmacies.

- Pharmacies participating in the Federal Retail Pharmacy Program (FRPP) will be able to 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.

FDA advisory committee recommends authorization of Moderna and J&J COVID-19 vaccine booster

The FDA's VRBPAC voted unanimously to recommend the agency authorize both the Moderna and J&J booster doses. Note that the J&J booster is a full dose, while the Moderna booster is a half dose (50 ug). ACIP will be voting on whether to recommend these boosters on October 20th and 21st.

For Moderna, the booster guidance states:

- A person should receive the Moderna booster at least six months after completion of the two-dose regimen.
- Individuals 65 years of age and older.
- Individuals 18 to 64 who are at high risk of severe COVID.
- Individuals in that same age group whose work or institutional exposure puts them at a high risk for contracting COVID.

This recommendation mirrors the FDA authorization given in September to Pfizer-BioNTech.

For J&J, booster dose guidance states that all individuals 18 years and older should receive the booster dose at least 2 months after a single J&J dose primary vaccination.

Please note the following FDA VRBPAC and ACIP meeting schedule:

Moderna & J&J boosters

- **October 20-21, 10am-5pm:** ACIP meeting is scheduled. The draft agenda is now available. The meeting can be livestreamed here.

Pfizer 5-11 age expansion

- **October 26:** the FDA has scheduled a VRBPAC meeting on Oct. 26 to inform the agency's decision-making. Information about the meeting is available here.
- **November 2-3, 10am-5pm:** ACIP meeting is scheduled. The draft agenda is not yet available. The meeting can be livestreamed here.

Moderna Shelf Life Extended for Some Vaccine Lots

Please note that 78 lots of Moderna vaccine just received a shelf life extension from FDA. Moderna also has a look up website. Please check the Moderna expiration date lookup site

before disposing of presumably expired Moderna vaccine to see if it is included in this set of lots. You can also confirm all expiration dates using the QR code on the Moderna vial—see https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup for more information.

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

- Underlying Medical Conditions Associated with High Risk for Severe COVID-19: Information for Healthcare Providers
- People with Certain Medical Conditions
- Science Brief: Evidence used to update the list of underlying medical conditions that increase a person's risk of severe illness from COVID-19
- v-safe COVID-19 Vaccine Pregnancy Registry

Communicating the Benefits of Influenza Vaccine during COVID-19 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 here.

Pfizer Vaccines "Medical Updates" Tuesdays, at 5pm ET, and Thursdays, at 12pm ET.

- 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.

Oct. 19, 5pm ET - Join here. (code: 5GhYFaKfn58)

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.

Upcoming meetings for Moderna and J&J Boosters as well as Pfizer 5-11 age expansion

There are several upcoming meetings that will likely result in an approval of Moderna and J&J booster vaccines, as well as introduction of a new Pfizer 5-11 COVID Vaccine.

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.

Booster dose recommendations

COVID-19 Vaccine Providers in Connecticut may begin administration of Pfizer booster doses in line with the FDA emergency use authorization and CDC recommendations.

CDC recommends:

- People 65 years and older and residents in long-term care settings **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- People aged 50–64 years with underlying medical conditions **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- People aged 18–49 years with underlying medical conditions **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks, and
- People aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.

Note that persons who received Moderna or J&J vaccines for their primary doses are not included in the CDC recommendation currently. We expect to receive several continued updates to booster dose guidelines over the next weeks. These will include further clarification of today's recommendations; and likely include recommendations related to the Moderna and the J&J vaccines as well as potential expansion of the recommended population groups.

We encourage providers to begin outreach to those who are 65+ and at least 6 months from the second dose of the primary series of Pfizer as well as those who are under 65 and meet the CDC recommendations to encourage them to receive booster doses.

Below is a list of informational activities related to booster recommendations, as well as resource pages:

- COCA Call: What Clinicians Need to Know About the Latest CDC Recommendations for Pfizer-BioNTech COVID-19 Booster Vaccination (already aired, recording now available).
- CDC page: Pfizer-BioNTech COVID-19 Vaccine Booster Shot Updated 9/30
- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States Updated 9/27

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.

Vaccine Ordering

Providers who wish to order additional Pfizer vaccine at this time so they have adequate stocks for booster dose administration over the next days are encouraged to do so.

We encourage providers to please order only according to your anticipated COVID-19 vaccine needs for the next 10 days; vaccine supply is adequate. Given that it is difficult to estimate need, it is preferable that you place smaller doses more frequently rather than larger orders less frequently.

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.
- 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 best practice 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 administering more than one vaccine, 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. 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 (Prevention 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 (Vaccine Administration Route and Site).
- There are many existing resources on administration and co-administration of vaccines relevant for healthcare providers, including:

Pink Book: Vaccine Administration | CDC **The following are reminders about important influenza-related events coming up.** Put these dates on your calendar to keep up with flu over the course of the 2021-2022 influenza season.

- September 9 (recording now available): Webinar September 9, 2021 - 2021-2022 Influenza Vaccination Recommendations and Guidance on Coadministration with COVID-19 Vaccines
- October 7: National Foundation for Infectious Disease press conference launch
- October 7: 2021-2022 Recommendations for Influenza Prevention and Treatment in Children: An Update for Pediatric Providers
- October 12: Ad Council campaign launch
- October 15: Weekly FluView Reports for 2021-2022 begin

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, request a username 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 Notice to Patients About Reporting to CT WiZ, 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: I lost my vaccine card, how do I get another one? (ct.gov) and Request an Official Immunization Record.

Upcoming Clinic Trainings and Office Hours

- **CoVPUpdate -- next meeting October 20th**
  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 Hours**Provides 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 Assessment**For 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