California COVID-19 Vaccination Program Update

DATE: **December 18, 2020** **IZB-FY-20-21-01**

TO: **COVID-19 Vaccination Program Providers**

FROM: **Robert Schechter, M.D., Chief, Immunization Branch**
Division of Communicable Disease Control
Center for Infectious Diseases

SUBJECT: **Pfizer Vaccine**

Summary

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine (BNT162b2).On December 12, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for the use of the Pfizer-BioNTech COVID-19 vaccine in persons aged > 16 years for the prevention of COVID-19. ACIP's recommendation for use of the Pfizer-BioNTech COVID-19 vaccine under EUA should be implemented in conjunction with ACIP and CDPH interim recommendation for allocating initial supplies of COVID-19 vaccines. Recommendations will be updated as additional information becomes available.

Prioritization of Scarce Supplies

In the initial Phase 1a, immunization with COVID-19 vaccine is recommended for:

- Persons at risk of exposure to SARS-CoV-2 through their work in any role in direct healthcare or long-term care settings.
    - This population includes persons at direct risk of exposure in their non-clinical roles, such as, but not limited to, environmental services, patient transport, or interpretation.
- Residents of skilled nursing facilities, assisted living facilities, and similar long-term care settings for older or medically vulnerable individuals.

CDPH recommends sub-prioritization for immunization during Phase 1a when vaccine supplies are limited.

ACIP and CDPH will include additional populations for prioritized immunization beyond Phase 1a in the coming weeks.

Dosage and Administration

- Two doses (30 µg, 0.3 mL each) per series
- Intramuscular administration
- The recommended interval between doses is 21 days
    - The minimum interval is 17 days
    - If more than 21 days have passed since the first dose, the second dose should be given at the earliest opportunity, but the first dose does not need to be repeated.
- Both doses should be the same product (Pfizer-BioNTech COVID-19 vaccine).
    - If two doses of different authorized or licensed mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either vaccine are recommended at this time. Recommendations may be updated as further information becomes available or additional COVID-19 vaccines are authorized or licensed.

- Pfizer-BioNTech COVID-19 vaccine should be administered with no other vaccines at a minimum interval of 14 days before or after administration with any other vaccines. This is due to lack of data on safety and efficacy of the vaccine administered simultaneously with other vaccines.
    - If Pfizer-BioNTech COVID-19 vaccine is inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

As the initial doses of Pfizer vaccine have been delivered and administered this week, immunizers have observed additional volume in the vaccine vials after proper reconstitution and administration of five doses. In response, FDA has issued preliminary advice:

- "Given the public health emergency, it acceptable to use every full dose obtainable (the sixth, or possibly even a seventh) from each vial, pending our administrative solution to the issue. However, since these are preservative-free vials, any further remaining liquid that does not constitute a full dose should not be pooled from multiple vials to create one."

Vaccination of Persons with Prior SARS-CoV-2 Infection or Exposure

- Immunization should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision-making.
    - **Persons with known current SARS-CoV-2 infection:**
        - immunization should be deferred until recovery from acute illness (if person had symptoms) *and* criteria have been met to discontinue isolation.

        - No minimum interval is required between infection and immunization. However, current evidence suggests reinfection is uncommon in the 90 days after initial infection, and thus persons with documented acute infection in the preceding 90 days may defer immunization until the end of this period, if desired.
    - **Persons who previously received passive antibody therapy for COVID-19:**
        - Immunization should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses. This is based on estimated half-life of therapies and evidence suggesting reinfection is uncommon within 90 days of initial infection. There is currently no data on safety or efficacy of COVID-19 immunization in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment.
    - **Persons with a known SARS-CoV-2 exposure:**
        - In a community or outpatient setting, defer immunization until quarantine period has ended to avoid exposing healthcare personnel or other persons during immunization visit.
        - In congregate healthcare settings such as long-term care facilities, residents may be vaccinated as this would likely not result in additional exposures. Healthcare workers should employ appropriate infection prevention and control procedures.
        - In congregate settings other than healthcare such as correctional facilities and homeless shelters, residents may be vaccinated in order to avoid delays and missed opportunities for immunization. Where feasible, precautions should be taken to limit mixing of these individuals with other residents or non-essential staff.

Vaccination of Special Populations

- **Persons with underlying medical conditions**:
    - Vaccine may be administered to persons with underlying medical conditions who have no contraindications to immunization. Phase 2/3 clinical trials demonstrate similar vaccine safety and efficacy profiles in persons with underlying medical conditions, including conditions that place them at increased risk for severe COVID-19.
- **Immunocompromised persons**:
    - Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies may still receive COVID-19 vaccine unless otherwise contraindicated.
    - Individuals should be counseled about:
        - Unknown vaccine safety and efficacy profiles in immunocompromised person
        - Potential for reduced immune responses

        - Need to continue to follow all current guidance to protect them against COVID-19.
- **Pregnant women:**
    - If a pregnant woman is part of a group who is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated. A discussion with her healthcare provider can help her make an informed decision. Considerations include:
        - There are no data on safety of COVID-19 vaccines in pregnant women. Animal studies and human studies are ongoing.
        - mRNA vaccines are not live vaccines, degrade quickly by normal cellular processes, and don't enter the nucleus of the cell.
        - Pregnant women are at increased risk of severe COVID-19 disease and might be at increased risk of adverse pregnancy outcomes.
        - Level of COVID-19 community transmission.
        - Personal risk of contracting COVID-19 by occupation or other activities.
    - Pregnant women who experience fever following immunization should be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes.
    - Routine testing for pregnancy prior to receipt of a COVID-19 vaccine is <u>not</u> recommended.
- **Breastfeeding/lactating women**:
    - If a lactating woman is part of a group who is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated. A discussion with her healthcare provider can help her make an informed decision. Considerations include:
        - There are no data on safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or milk production/excretion.
        - mRNA vaccines are not live vaccines, degrade quickly by normal cellular processes, and don't enter the nucleus of the cell.
        - Level of COVID-19 community transmission.
        - Personal risk of contracting COVID-19 by occupation or other activities.

Post-Vaccination Symptoms, Adverse Reactions

- Before immunization, providers should counsel vaccine recipients about post-immunization symptoms.
- Local and systemic post-immunization symptoms
    - Fever, fatigue, headache, chills, myalgia, and arthralgia, can occur following COVID-19 immunization. Most systemic post-immunization signs and symptoms are mild to moderate in severity, occur within the first three days of immunization (the day of immunization and following two days,

with most occurring the day after immunization), resolve within 1-2 days of onset, and are more frequent and severe following the second dose and among younger persons compared to those who are older (>55 years).
        - Antipyretic or analgesic medications may be taken for treatment of post-immunization symptoms. Routine prophylaxis for the purposes of preventing symptoms is not recommended at this time.
    - Cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell are not consistent with post-immunization symptoms, and instead may be symptoms of SARS-CoV-2 or another infection.
- Vaccine providers should observe patients after immunization to monitor for the occurrence of immediate adverse reactions:
    - Persons with a history of anaphylaxis: 30 minutes
    - All other persons: 15 minutes
- Appropriate medical treatment used to manage immediate allergic reactions (including epinephrine and equipment for maintaining an airway) must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.
- CDC has issued Interim Considerations for Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites. Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Contraindications

Severe allergic reaction such as anaphylaxis to any component of the Pfizer-BioNTech COVID-19 vaccine is a contraindication to immunization.

Precautions

- Moderate-to-severe acute illness
    - Provider should conduct risk assessment and potentially defer immunization.
- Severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous).
    - This guidance is in response to reports of anaphylactic reactions in persons vaccinated outside of clinical trials.
    - Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of the vaccine.
    - Persons with a history of anaphylaxis should be observed for 30 minutes to monitor for the occurrence of immediate adverse reactions.

The following **are not contraindications nor precautions** to immunization:

- Food, pet, insect, venom, environmental, latex allergies

- Allergy to oral medications (including oral forms of injectable medications)
- Non-serious allergy to vaccines or other injectables (e.g. no anaphylaxis)
- Family history of anaphylaxis

Vaccine Safety & Monitoring

V-Safe Program

V-safe is a new smartphone-based, after-immunization health checker for people who receive COVID-19 vaccines. **V-safe** uses text messaging and web surveys from CDC to check in with vaccine recipients following COVID-19 immunization. Patients will be prompted daily for the first week post-immunization, weekly thereafter until 6 weeks post-immunization, and with additional health checks at 3, 6, and 12 months post-immunization. **V-safe** also provides second vaccine dose reminders if needed, and telephone follow up to anyone who reports medically significant (important) adverse events.

CDC is requesting that healthcare providers give patients a **v-safe** information sheet at the time of immunization and encourage them to enroll and fill out the surveys when prompted to do so. The information sheet explains **v-safe** and provides step-by-step instructions on how to sign up to participate. Vaccine recipients can use the QR code or URL on this information sheet to sign up at their convenience.

Suggested healthcare provider script for encouraging patients to participate in **v-safe:**

*CDC has created a way for you to report how you feel after COVID-19 immunization through a smartphone-based tool that uses text messaging and web surveys to check in with you. Here (or in your packet) is a **v-safe** information sheet with more details and simple instructions to sign up.*

Reporting of Suspected Vaccine Reactions or Errors

Vaccine Adverse Event Reporting System (VAERS) collects information about reactions and possible side effects that occur after vaccine is administered. Reactions may happen immediately, hours, days, or weeks after vaccination. Report a reaction even if you are not sure that it was caused by the vaccine. Providers and patients receiving vaccination can report vaccinations to the VAERS system.

EUA Fact Sheets

The EUA Fact Sheet for Recipients and Caregivers is required to be given to vaccine recipients (similar to the Vaccine Information Sheets for licensed routine vaccines). Additional languages are available on the FDA EUA webpage. If you haven't done so already, please review the Fact Sheet for Providers Administering COVID-19 Vaccine to meet the program's training requirement.

Vaccine Storage and Handling

All immunization providers participating in the COVID-19 Vaccination Program must store and handle COVID-19 vaccines under proper conditions.

Pfizer COVID-19 Vaccine

The Pfizer vaccine is shipped in a passive thermal shipper, which maintains the vaccine at an ultra-low temperature (ULT) between of -90ºC to -60ºC (-130ºF to -76ºF) with dry ice. The five-dose vials are packaged into trays, 195 vials per tray. The shipper can hold up to five trays.
Upon receipt of the thermal shipper, inspect the shipping container for damage and open the container. Review the Controlant digital data logger (DDL) imbedded in the top insulation panel to confirm the there were no temperature excursions during transport The thermal shipper contains a set of dry ice handling instructions to include PPE requirements, insulated gloves and eye protection. At this point, the provider site may move the vaccine into a ULT freezer, continue to store the vaccine in the shipping container or move the vaccine into refrigerated storage.

ULT Freezer Storage. Vaccine may be stored in an ULT freezer between -80ºC and -60ºC (-112ºF and -76ºF) until its expiration date, which might be extended as more stability data become available.

If the site has a ULT freezer, don the insulated gloves and eye protection and open the insulating panel to reveal the dry ice pod, a box or insulated bag. Remove the dry ice pod to uncover the box that holds the trays. Remove the box from the container and open the box to remove the trays. If the box cannot be moved easily, leave it in the shipping container and remove the trays. Inspect the trays for leakage and damage. Do not open the trays. Transfer the trays to the ULT freezer. The trays can remain at room temperature, 15°C to 25°C (59°F to 77°F), for no more than five minutes. After the transfer time at room temperature, the trays must remain at ULT for two hours until they can be removed again. Return the shipping container per Pfizer's instructions.

Continued Storage in the Shipping Container. Vaccine may be stored in the thermal shipper for up to 30 days, after which doses may be stored in the refrigerator for up to 120 hours (5 days). The thermal container maintains a temperature range of -90ºC to -60ºC (-130ºF to -76ºF). Storage within this temperature range is not considered an excursion from the recommended storage condition. Under federal support, dry ice will be sent for the first re-icing, which must occur within 24-hours of arrival. Additional dry ice shipments will NOT be provided and must be arranged locally.

To work with the supplies, don the insulated gloves and eye protection and open the insulating panel to reveal the dry ice pod, a box or insulated bag. Remove the dry ice pod to uncover the box that holds the trays. Remove the box from the container and open the box to remove the trays. If the box cannot be moved easily, leave it in the

shipping container and remove the trays. Inspect the trays for leakage and damage. Do not open the trays. Return the trays to the shipping container and re-ice the container per Pfizer's recommendations. Re-icing will maintain the prescribed ULT for up to five days when the container is stored at 15°C to 25°C (59°F to 77°F) and only opened twice a day for no more than three minutes at a time. Controlant monitors thermal shipper temperatures and will notify the site to re-ice depending on the temperature thresholds. At a minimum, re-ice the container every five days. Return the shipper to Pfizer by 30 days.

Watch Pfizer's storage and handling video, which demonstrates inspection and re-icing of thermal shippers.

Refrigerated Storage. The vaccine may be stored at 2ºC to 8ºC (35ºF to 46ºF) for up to 120 hours or five days. The vaccine vials should be marked with the new expiration date & hour. Return the shipping container per Pfizer's instructions.

- Pfizer-BioNTECH COVID-19 Vaccine Beyond Use Date/Time (BUD) Tracking Label for Vaccine During Refrigerator Storage

Preparing for Administration. The vaccine must be thawed for dilution before it can be administered. It will take two to three hours to thaw a frozen tray of 195 vials at refrigerated temperatures. For immediate use, the tray can be thawed in 30 minutes at room temperature. Undiluted vials may be stored at room temperature for no more than two hours. Once diluted, the vials can be stored between 2°C to 25°C (35°F to 77°F) and used within 6 hours from the time of dilution. Any vaccine remaining in vials must be discarded after 6 hours. Do not refreeze the vaccine.

- Vaccine Administration: At a Glance
- Pfizer-BioNTech COVID-19 Vaccine Pre-Vaccination Form
- Pfizer-BioNTech COVID-19 Vaccine Preparation & Administration Summary
- Pfizer-BioNTech COVID-19 Vaccine Preparation: Mixing Diluent & Vaccine

The Product Storage and Handling tab on the Pfizer-BioNTech COVID-19 Vaccine website, provides the most up-to-date information on storage and handling of their vaccine. Please familiarize yourself with the materials on the website The site contains the following: dry ice handling instructions, videos on storage and handling, preparation and administration and returning the thermal shipping container to Pfizer, safety data sheets, and checklists..

- Storage & Handling: At a Glance
- CDC's Pfizer-BioNTech COVID-19 Resources (for clinical guidance, storage & handling, and vaccine administration resources)

Temperature Monitoring

Storage unit temperatures must be checked and recorded twice daily to ensure the viability of your vaccine supply. Routine monitoring can help you quickly identify temperatures outside the recommended range and take corrective actions immediately, preventing loss of vaccines or the potential need to revaccinate.

Vaccine Temperature Excursions

Any out-of range temperature must be documented and immediately reported. Based on the details of the excursion, vaccine manufacturers can determine whether a vaccine is still viable to be administered to patients. Follow the guidance in Reporting Temperature Excursions job aid.

Vaccine Transport

Pfizer vaccine can be transported at either ULT or refrigerated temperatures. To maintain the vaccine at ULT, it must be transported as an unopened tray in the Pfizer thermal shipping container, unless transported in an active ULT shipping container powered by battery or auto DC. Otherwise the vaccine should be transported as a refrigerated product with a five-day shelf life.

- COVID-19 Vaccine Transport Log

Vaccine Redistribution

To maintain appropriate temperatures, vaccines are optimally shipped only to where they will be administered. When COVID-19 vaccines instead need to be moved, both the transporting and receiving organizations must be authorized by the California Department of Public Health (CDPH) to redistribute via a redistribution agreement.

- Guide to COVID-19 Vaccine Redistribution, Repositioning & Transfer
- Redistribution Agreement: Before You Apply
- CDC Supplemental COVID-19 Vaccine Redistribution Agreement
- Redistribution Vaccine Management Plan

Confirm with your local health department that receiving locations are authorized COVID-19 vaccination providers. Report each vaccine redistribution within 24 hours of the event.

- Report Vaccine Redistribution or Transfer

Vaccine Repositioning

Repositioning is the transport of doses for administration at another setting and return of unused doses to the original facility at the end of the day. Satellite, temporary and off-site clinics are authorized to reposition (transport) vaccines without prior authorization because ownership is not changing hands.

- Guidance for Satellite, Temporary, and Off-Site Clinics

Vaccine Transfer

Transfer is an unplanned event based on need (e.g., sudden short supply) or to prevent waste (e.g., doses will likely expire before use). Confirm with your local health department that receiving locations are approved COVID-19 vaccination providers. Report each vaccine transfer within 24 hours of the event.

- Report Vaccine Redistribution or Transfer

Reporting Vaccine Redistribution or Transfer Events

All vaccine redistribution or transfer events must be reported to CDPH within 24 hours of redistribution. It is the responsibility of the sending site to ensure the redistribution events are reported. Report electronically using the Report Vaccine Redistribution or Transfer e-form. Additionally, the sender and receiving locations must ensure updated inventory counts are reflected in their daily reporting to VaccineFinder. Additional vaccine management resources can be found on EZIZ's COVID-19 Resources.

Vaccine Shipments

Follow steps in Receiving & Storing Pfizer Vaccines.

- Do not ever reject vaccine shipments.
- Upon delivery, sites assume responsibility for ensuring that vaccines are stored in temperature-controlled environments. Immediately store vaccine vial trays in either an ultra-low-temperature freezer for longer-term storage or in the thermal shipping container, in which case consistently replenish with dry ice over the next weeks. Immediately report vaccine shipment incidents (damage, shipping issues, or Contact vaccine manufacturer or McKesson to report any shipping incidents. Then complete this Report Vaccine Shipping Incident form to report the incident and resolution.
- Pfizer vaccine ships with initial dry ice recharge and PPE. Additional dry ice will not be provided. Identify a source of dry ice pellets if planning to use the shipping container to store vaccine for more than 5 days.

Pfizer vaccines are shipped directly from the manufacturer to enrolled COVID-19 vaccine program providers. Upon transmission of approved vaccine orders to CDC, organizations will receive a confirmation email with the total doses shipping, and the anticipated delivery time window. Pfizer will also send an email when vaccines are on the way.

Pfizer tracks monitors location temperatures during transit using a Controlant Reusable RTM Logger. The DDL is embedded in the foam lid and may not be removed; the DDL does not contain a temperature display. Upon receipt, follow instructions to stop the device. A report of temperature monitoring data while vaccines were in transit will be also emailed to Controlant. It may take 2-3 hours after arrival before you get the summary report log. Limited cell reception may delay the receipt of temperature data.

Pfizer will update providers from ordering through confirmation of delivery. Once the DDL is stopped, temperature-monitoring data is no longer visible to Pfizer. If you wish to use the data logger for monitoring temperatures of doses that are stored in the thermal shipper, follow the instructions provided in the transit temperature email.

To ensure receipt of emails, check your spam and white list the email address.

Vaccine Management Resources

- A number of COVID-19 vaccine management resources are now available.
- CDC's Storage and Handling Toolkit has been updated with information on storage and handling practices for COVID-19 vaccines.

Reporting Requirements

For a summary of reporting requirements, see Reporting Requirements: At a Glance.

Enrollment in CAIR

California's Immunization Registry (CAIR) is comprised of three distinct registries: CAIR2, RIDE/CAIR San Joaquin, and SDIR/CAIR in San Diego. To participate in the COVID-19 Vaccination Program, vaccinators must be enrolled in one of California's regional registries and report administered doses daily.
Participating COVID-19 provider sites will be enrolled in CAIR as part of COVIDReadi enrollment. Providers will receive an IIS ID by email once enrollment is approved. Save this ID as it will be required when reporting doses administered to CAIR using any of the available reporting options.

Reporting Doses Administered Daily

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration, and use their best efforts to report administration data to California's Immunization Registry (CAIR) as soon as practicable and no later than 72 hours after administration.

Providers can choose the reporting option that best suits their needs: Manual data entry, submission from clinic EHR, PrepMod application (available in all three CAIR regions and includes inventory management, clinic setup and management, patient consent, and reporting), or CAIR2/Mass Vax tool.

Reporting Race and Ethnicity: As part of California's commitment to ensure that COVID-19 vaccine is equitably available, providers who administer COVID-19 vaccines in California are required to record the race or ethnicity of everyone who receives COVID-19 vaccine. Please ensure that all clinic staff record this information by whichever method is being used to submit data to your local immunization registry.

See Reporting Doses Administered for links to systems and training resources.

Reporting Doses on Hand to Vaccine Finder Daily

All COVID-19 vaccination providers must report their inventory daily into Vaccine Finder. For details on onboarding and reporting inventory, review Reporting Inventory to Vaccine Finder.

Training

Providers and key practice staff handling or administering COVID-19 vaccines are responsible for knowing all required training topics. Recent training may count towards completion.

The current listing of required training can be accessed on the CDPH COVID-19 Required Training & Resources page. Enrolled providers will be notified when new materials are released on EZIZ's COVID-19 Resources website.

Billing Notes

Enrolled providers must administer COVID-19 vaccine regardless of the vaccine recipient's coverage status or ability to pay COVID-19 vaccine administration fees. While vaccine administration reimbursement may be received from a program or plan that covers COVID-19 vaccine administration fees, providers may not seek any reimbursement, including through balance billing, from the vaccine recipient. Additional guidance is included in the following resources:

- CMS – COVID-19 Vaccine Policies & Guidance
- CMS - COVIDvax Provider Toolkit

Readiness Checklist

These resources help ensure providers and staff are prepared to store, handle, and immunize their patients.

- Readiness Checklist: Quick Start Guide
- Provider Enrollment: Next Steps
- Guide to other COVID-19 Vaccine Websites

QUESTIONS?

Contact the COVIDCallCenter@cdph.ca.gov or call (833) 502-1245, Monday through Friday from 9 am to 5 pm.