



COVID-19 Vaccine Program – What We Know So Far

Aaron Dunkel – Executive Director - KPhA

Agenda

- EUA Vaccines
 - Pfizer
 - Moderna
- Staff Vaccinations
- Long-Term Care Facility Program
- Allocations Moving Forward

Logistics

- Please put any questions in the chat box and we will get to as many as possible in the time we have
- If you would like to ask a question live please identify that to us in chat and we will call on you to unmute your line and ask your question
- We will take all questions at the end of the prepared presentation
- Please know, we will not know all of the answers to your questions. We are working in a very fluid environment but we will get answers and provide them ASAP
- Thank you for participating in our meeting today. Your questions and comments help up craft our conversations with state and federal policy makers and allow us to have a greater impact influencing our environment as we move forward

Authorized Vaccines - Similarities

- Do not administer to patients with severe allergic reaction to any ingredients in the selected vaccine
- Provider must be prepared to provide emergency care if a severe reaction occurs
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response
- May not protect all vaccine recipients
- Available data on vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy
- Data are not available to assess the effects of vaccine on the breastfed infant or on milk production/excretion

Authorized Vaccines - Similarities

- Vaccines are not interchangeable, if a patient receives one brand for first dose they must receive same brand vaccine for second dose
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967.
- Vaccination providers should review the Fact Sheet for mandatory requirements and Information to Provide to Vaccine Recipients/Caregivers and the Full EUA Prescribing Information for Requirements and Instructions for Reporting Adverse Events and Vaccine Administration Errors
- Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine.com
- Do not refreeze thawed vials

Authorized Vaccines - Similarities

- As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” (and provide a copy or direct the individual to the website www.cvdvaccine.com to obtain the Fact Sheet) prior to the individual receiving the vaccine, including:
 - FDA has authorized the emergency use of these vaccines, which is not an FDA-approved vaccine
 - The recipient or their caregiver has the option to accept or refuse the vaccine
 - The significant known and potential risks and benefits of the selected vaccine, and the extent to which such risks and benefits are unknown
 - Information about available alternative vaccines and the risks and benefits of those alternatives
- You have to provide the vaccination information to WebIZ, the Kansas Immunization Registry

Authorized Vaccines - Pfizer

- Authorized for those patients over 16
- Two Doses (0.3mL) intramuscular, three weeks apart
 - Recommend second dose within window from day 17-21
 - Do not restart series if delayed, just get them in as soon as possible
- 5 dose vials – minimum order in refrigerated boxes is 975 doses
- Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive thermal containers with dry ice.
- Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F). Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light until ready to use.
- If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice.
- Re-icing guidelines packed in the original thermal container regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage within this temperature range is not considered an excursion from the recommended storage condition.

Authorized Vaccines - Pfizer

- Thawed vials
 - Before dilution vials stored in refrigerator can be held for up to 5 days
 - Stored at room temperature vials can be stored for no more than 2 hours
- After dilution vials stored between 35 and 77 degrees F must be used within 6 hours
 - Minimize exposure to room light and avoid direct sunlight or UV light
- Diluted vaccine in vials after 6 hours must be discarded

Authorized Vaccines – Pfizer Reference Sites

- Provider Fact Sheet - <https://www.fda.gov/media/144413/download>
- Recipient Fact Sheet - <https://www.fda.gov/media/144414/download>
- Vaccine Specific FAQ - <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pfizer-biontech-covid-19-vaccine-frequently-asked-questions>
- Pfizer Info Site - <https://www.cvdvaccine.com/>

Authorized Vaccines - Moderna

- Authorized for those patients over 18
- Two Doses (0.5mL) intramuscular, four weeks apart
- 10 doses per vial – minimum order is 100 doses.
- Arrives frozen.
- Store at -25 to -15 degrees Celsius. Do not store below -40.
- Can be refrigerated between 2 and 8 degrees Celsius for up to 30 days. Unpunctured vials can be stored between 8 and 25 degrees Celsius for up to 12 hours.
- After first dose has been withdrawn the vial should be held between 2 and 25 degrees Celsius. Discard vial after 6 hours.

Authorized Vaccines – Moderna Reference Sites

- Provider Fact Sheet - <https://www.fda.gov/media/144637/download>
- Recipient Fact Sheet - <https://www.fda.gov/media/144638/download>
- Vaccine Specific Information Page - <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine>
- Moderna Info Site - <https://www.modernatx.com/covid19vaccine-eua/>

COVID-19 Vaccine Resources

- Food and Drug Administration - <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>
- CDC Vaccination Communication Toolkit - <https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html>

Staff Vaccinations

- Patient facing pharmacy staff are part of Phase 1
- Who is giving the vaccine to healthcare professionals (HCPs) varies by county
 - Call your local hospital, health department, or, if available, local safety net clinic to ask who is giving local HCP vaccinations
 - If no one knows in your area, or they tell you pharmacy staff are not part of Phase 1, let me know ASAP
- Depending on your location it might be a couple weeks before vaccine is available
 - We have heard of locations vaccinating pharmacy staff this week, or as far out as the first full week of January
 - If you are giving LTCF vaccinations or are a state test collection site and are having difficulty finding vaccine in your area please let me know

LTCF Vaccination Program

- Of 250+ facilities that originally identified a partner other than CVS or Walgreens only 27 were assigned to a preferred pharmacy partner
- Those that were selected should be hearing from the state as soon as the facility they were assigned is allotted vaccine
- For those of you that had been contacted by your local LTCF(s) and know they assigned you as their preferred pharmacy partner please email me and I can let you know if you were assigned to them or if they were assigned CVS or Walgreens

Allocations

- Allocations are made through a federal program called Tiberius
- State staff have the ability to adjust state allocations
- State allocation is adjusted based on the pharmacies that are enrolled with federal partners
- Regardless of if you are enrolled through the state or a federal partner program participant, you should receive the same allocation
- Allocations are base on population in current phase, capacity, and available doses for that allocation period
- States have some ability to adjust within priority groups

Questions and Answers

- We will get through as many questions as we can
- We will take all questions in chat and provide answers
- We will send those answers out to all registrants and will use them as the basis for an ongoing, moderated FAQ we will post to the KPhA website