ARKANSAS DEPARTMENT OF HEALTH

MEMORANDUM
#21-15

SUBJECT: **Third Dose of mRNA vaccine approved for immunocompromised persons who are fully vaccinated with an mRNA vaccine series**

ORIGINATOR **Jennifer A. Dillaha M.D., Immunizations**

EFFECTIVE DATE: **August 16, 2021**

Special Instructions:

This memorandum is to be implemented immediately by all Local Health Units (LHUs). Following U.S. Food and Drug Administration (FDA) amendment of the emergency use authorization (EUA) on August 12, 2021 for both the Pfizer-BioNTech and Moderna COVID-19 vaccine to allow for the use of an additional dose in certain immunocompromised individuals, specifically, solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise and the U.S. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommendation on August 13, 2021 for a third dose of the Pfizer-BioNTech and Moderna COVID-19 vaccine for administration to persons who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

The FDA has determined that Pfizer-BioNTech and Moderna COVID-19 vaccines are safe and efficacious in preventing COVID-19 infection and has met the criteria to amend the EUA. The known and potential benefits of this vaccine for immunocompromised persons outweigh the known and potential risks, supporting the use of Pfizer-BioNTech and Moderna COVID-19 vaccines in this population.

CDC is recommending that moderately to severely immunocompromised people receive an additional dose. This includes people who have:

- Been receiving active cancer treatment for solid tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a CAR-T- cell or hematopoietic stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response (≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Persons who have a weakened immune system other than what is listed above, should talk to their healthcare provider about their medical condition, and whether getting an additional dose is appropriate for them.
The third dose of mRNA COVID-19 vaccine should be administered **at least 28 days** after completion of the primary mRNA COVID-19 vaccine series to persons who request the vaccine. The additional mRNA COVID-19 vaccine dose should be the same vaccine product as the initial 2-dose mRNA COVID-19 primary vaccine series (Pfizer-BioNTech or Moderna). If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered. A person should not receive more than three mRNA COVID-19 vaccine doses. Proof of the person's immunosuppressed condition is not required.

According to ACIP recommendations, all COVID-19 vaccines currently authorized by the FDA may be administered with **routine** vaccines simultaneously, on same day, or at any interval.

The ADH requires written parental/guardian consent for any unemancipated minor under the age of 18 years prior to **any** dose of COVID-19 vaccine administration. This ADH policy is in place, because the currently available COVID-19 vaccines are only available through EUA granted by the FDA.

ADH Local Health Units:
The ADH follows the ACIP recommendations on use of COVID-19 vaccines. Local Health Units that have Pfizer COVID-19 vaccine available should immediately follow the guidance listed below:

- Pfizer-BioNTech COVID-19 vaccine is an FDA authorized vaccine to prevent COVID-19 for persons **12 years** and older under an Emergency Use Authorization.
- Administer Pfizer-BioNTech COVID-19 vaccine to persons 12 years and older who meet criteria for the vaccine.
- Administer Pfizer-BioNTech COVID-19 vaccine as follows:
  - **0.3 mL** (30 mcg) per dose after dilution.
  - Two-dose series.
  - Interval between Dose 1 and Dose 2 is three weeks apart (21 days).
  - May be administered with routine vaccines simultaneously, on same day, or at any interval.
  - Administer a third dose (0.3mL) to fully vaccinated persons (at their request) who are immunocompromised (who have undergone solid organ transplant or have conditions that are considered to have an equivalent level of immunocompromise.)
  - **Minimum interval between Dose 2 and Dose 3 is 28 days.**
  - **There is no maximum interval between Dose 2 and Dose 3.**

The ADH follows the ACIP recommendations on use of COVID-19 vaccines. Local Health Units that have Moderna COVID-19 vaccine available should immediately follow the guidance listed below:

- Moderna COVID-19 vaccine is an FDA authorized vaccine to prevent COVID-19 for persons **18 years** and older under an Emergency Use Authorization.
- Administer Moderna COVID-19 vaccine to persons 18 years and older who meet criteria for the vaccine.
- Administer Moderna COVID-19 vaccine as follows:
  - **0.5mL** per dose.
  - Two-dose series.
  - The interval between Dose 1 and Dose 2 is one month apart (28 days).
  - May be administered with routine vaccines simultaneously, on same day, or at any interval.
  - Administer a third dose (0.5mL) to fully vaccinated persons (at their request) who are immunocompromised (who have undergone solid organ transplant or have conditions that are considered to have an equivalent level of immunocompromise).
  - **Minimum interval between Dose 2 and Dose 3 is 28 days.**
  - **There is no maximum interval between Dose 2 and Dose 3.**

ADH should continue to instruct immunocompromised people, including those who receive an additional mRNA dose, to follow the prevention measures listed below:

- Wear a mask
- Wash your hands
- Stay 6 feet apart from others who are not in your household
- Avoid crowds and poorly ventilated indoor spaces until advised otherwise by their healthcare provider

Review the updated Pfizer-BioNTech COVID-19 and Moderna COVID-19 vaccine. Pfizer-BioNTech Fact Sheets for Healthcare Providers Administering the Vaccine (Vaccination Providers) and Pfizer-BioNTech Recipients and Caregivers, and Moderna COVID-19 Vaccine EUA Fact Sheet for Health Care Providers (fda.gov) and Moderna COVID-19 Vaccine EUA Fact Sheet for Recipients and Caregivers (fda.gov) revised on August 12, 2021.

Persons who received Johnson & Johnson's Janssen COVID-19 vaccine:

- CDC does **not** recommend additional doses of COVID-19 vaccine for persons who have received Johnson & Johnson's Janssen COVID-19 vaccine at this time. FDA and CDC are actively working to provide guidance on this issue. Studies are underway to determine whether immunocompromised people who received Johnson & Johnson's Janssen COVID-19 vaccine also have an improved antibody response following an additional dose of the same vaccine.

Continue this operational guidance until further guidance is issued. For questions, please contact the local Communicable Disease Nurse Specialist (CDNS) or Immunization Section 501- 537- 8969.