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September 24, 2021

To: Providers

RE: Pfizer Vaccine Booster Dose Authorized and Recommended

On Wednesday September 22, 2021, the Federal Drug Administration (FDA) approved a single shot of the Pfizer COVID vaccine for adults over 65 years, adults 18-64 at high risk of developing severe COVID-19, and adults 18-64 that have high occupational risk due to exposure. However, the Advisory Committee for Immunization Practice (ACIP) did not fully align with this and made the follow recommendation to the Centers for Disease Control and Prevention (CDC): A single Pfizer-BioNTech COVID-19 vaccine booster dose is recommended for persons age 65+ and LTCF residents, at least 6 months after a primary series under FDA Emergency Use Authorization.; A single Pfizer-BioNTech COVID-19 vaccine booster dose is recommended for persons aged 50-64 years with underlying medical conditions, at least 6 months after primary series under FDA Emergency Use Authorization; and A single Pfizer-BioNTech COVID-19 vaccine booster dose is recommended for persons based on individual benefit and risk who are aged 18-49 years with underlying medical conditions, at least 6 months after primary series under FDA Emergency Use Authorization.

Ultimately, the CDC Director, Rochelle Walensky, MD, MPH has issued the following recommendations, and this is what the Kansas Department of Health and Environment is authorizing COVID-19 enrolled providers to begin using as the guide for provision of booster dose vaccine for persons who have completed a series of Pfizer vaccine greater than six months ago.

- people 65 years and older and residents in long-term care settings <u>should</u> 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 <u>underlying medical conditions</u> <u>should</u> 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 <u>underlying medical conditions</u> <u>may</u> 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 <u>may</u> 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.

To be clear, all persons age 65 and greater are eligible and should receive a booster dose regardless of any condition or whether they live in a LTCF or not.

The "underlying medical conditions" referred to includes:

Cancer

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- Chronic kidney disease
- Chronic lung diseases, including COPD (chronic obstructive pulmonary disease), asthma (moderate-to-severe), interstitial lung disease, cystic fibrosis, and pulmonary hypertension
- Dementia or other neurological conditions
- Diabetes (type 1 or type 2)
- Down syndrome
- Heart conditions (such as heart failure, coronary artery disease, cardiomyopathies or hypertension)
- HIV infection
- Immunocompromised state (weakened immune system)
- Liver disease
- Overweight and obesity
- Pregnancy
- Sickle cell disease or thalassemia
- Smoking, current or former
- Solid organ or blood stem cell transplant
- Stroke or cerebrovascular disease, which affects blood flow to the brain
- Substance use disorders

Patient self-attestation is the only expectation for declaration of underlying medical conditions. A sample self-attestation form that may be used by providers is available here.

These recommendations apply only to persons who have been previously vaccinated with the Pfizer-BioNTech COVID-19 vaccine. The recommendation does not allow for providing a booster dose of Pfizer for anyone who has been previously vaccinated with Moderna or Johnson and Johnson.

Occupational or institutional setting are not specifically defined in the CDC recommendation but are intended to include healthcare workers, teachers, grocery store workers, retail workers, first responders, residents and staff of congregant settings (corrections, homeless shelters, group homes etc) and many others. Again, these decisions to receive a booster dose are based on self-attestation of the patient.

All efforts should be made to confirm completion of primary series of Pfizer vaccine using patient vaccine card, electronic medical records, KS-WebIZ or other data sources. In the absence of this documentation, patient self-attestation may be used.

Risks of myocarditis after a 3rd dose of mRNA vaccines may vary by age and sex and is <u>unknown</u> at this time. Lymphadenopathy was more common after the 3rd dose than after the 2nd dose.

Pfizer data for booster doses demonstrates safety and efficacy, **but limitations include lack of robust safety information in younger age groups.** Right now, vaccine effectiveness (VE) against severe disease and hospitalization remains high in most populations in the US, data from Israel predicts this may not be sustained. **Benefit/risk balance is most favorable for adults ≥65 years of age.** Current estimates show smaller benefits for population <65 years of age. The **American College of Obstetricians and**

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Gynecologists (ACOG) supports that pregnant individuals be eligible for booster dose as categorized under "underlying conditions".

Providers who have questions may contact the Kansas Immunization Program at kdhe.vaccine@ks.gov