

September 20, 2021

To: Providers

RE: Booster Doses of COVID-19 Are Not Yet Approved for Administration

On Friday September 17, 2021, the Federal Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted 16-2 against approving a Pfizer booster dose for individuals 16 years of age and older. Voting members were presented data from Israel, Pfizer, and FDA/Centers for Disease Control (CDC)DC. In a second vote, committee members vote 18-0 in favor of a Pfizer booster dose for adults 65+ and individuals 16+ at high risk for COVID-19. The committee ultimately voted against a universal booster due to concerns about the lack of robust data, especially safety data in younger populations. They felt that a booster dose would not significantly impact or mitigate the state of the pandemic and are looking to review additional data on effectiveness against transmissibility/longer follow up data post booster dose. **This does not clear the way for COVID-19 vaccine providers to begin administering boost doses to anyone.**

The FDA is expected to authorize or approve booster doses for Pfizer vaccine this week but is not bound by the VRBPAC recommendations. Once this step is completed, the CDC Advisory Committee on Immunization Practices (ACIP) will then consider booster doses at their meeting on Wednesday September 22 and Thursday September 23. The ACIP recommendations will likely be more specific related to length of time after initial series completion as well as specifically who can be vaccinated (age groups and identified specific high-risk groups). After this meeting the CDC Director will make a final decision to approve, amend or reject the ACIP recommendations. **It is only this final CDC Director decision that will allow for providers to begin administering booster doses.** The Kansas Department of Health and Environment will send an additional HAN at that time alerting providers.

All COVID-19 vaccine providers are reminded of responsibility for adhering to all requirements outlined in the COVID-19 Vaccine Provider Agreement signed upon enrollment. Specifically, providers must administer COVID-19 vaccines in accordance with [all program requirements and recommendations](#) of CDC, the [ACIP](#), and the U.S Food and Drug Administration ([FDA](#)). This applies to both EUA and FDA approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA (often referred to as “off-label use”) is not recommended. It would violate the provider agreement and could expose providers to the following risks:

- Administration of the product off label may not be covered under the PREP Act or the PREP Act declaration; therefore, **providers may not have immunity from claims.**

- Individuals who receive an **off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program** after a possible adverse event.
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how the USG-provided vaccines may be used in the program. **Providers giving off-label doses would be in violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program.**
- **Administration fees may not be reimbursable by payers.**

As per HAN announcement on August 18, 2021, additional doses (these are NOT considered booster doses) of Pfizer-BioNTech or Moderna COVID-19 vaccine may be administered to individuals who are moderately or severely immunocompromised and have already been fully vaccinated with the Pfizer-BioNTech or Moderna vaccines. This follows Thursday's expansion of the emergency use authorization (EUA) by the Food and Drug Administration for these mRNA vaccines, today's recommendation of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) and acceptance by the CDC Director. This EUA does not apply to those who received the Janssen/J&J vaccine as there is currently not enough data to determine if an additional dose of Janssen/J&J vaccine will improve immune response in people who are immunocompromised.

This additional is to be administered at least 28 days after the second dose and is recommended only for people who are moderately and severely immunocompromised due to a health condition or medical treatment. This includes

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-Cell or hematopoietic stem cell transplant
- Moderate or severe primary immunodeficiency
- Advanced or untreated HIV infection
- Active treatments with high-dose corticosteroids, alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers and other biologic agents that are immunosuppressive or immunomodulatory