

October 18, 2021

To: Providers

RE: Booster Doses of Moderna and Johnson & Johnson COVID-19 Vaccine Are Not Yet Approved for Administration

On Thursday October 14, 2021, the Federal Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted 19-0 in favor of a Moderna booster dose for adults 65 and older, individuals 16 - 64 at high risk for severe COVID-19 and individuals 18 – 64 with heightened job and institutional exposure has them at high risk of encounter at least 6 months after completion of a primary series of Moderna. The recommended dose for the Moderna booster is one-half the dose given during the primary series. **This booster dose has not yet been authorized by the FDA and vaccine providers SHOULD NOT begin administering Moderna booster doses to ANYONE at this time.**

On Friday October 15, 2021, the Federal Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted 19-0 in favor of a Johnson and Johnson booster dose for individuals 18 and older at least 2 months after a single primary dose of Johnson and Johnson vaccine. The recommended dose for the Johnson and Johnson booster is a full dose equal to the primary dose. **This booster dose has not yet been authorized by the FDA and vaccine providers SHOULD NOT begin administering Johnson and Johnson booster doses to ANYONE at this time.**

The FDA is expected to authorize booster doses for Moderna and Johnson & Johnson vaccine this week but is not bound by the VRBPAC recommendations. Once the booster doses have been authorized by the FDA, the CDC Advisory Committee on Immunization Practices (ACIP) will then consider its recommendations for booster doses at their meeting on Wednesday, October 20 and Thursday, October 21. The ACIP recommendations will be more specific. After ACIP makes its recommendations, the CDC Director will make a final decision to approve, amend or reject the ACIP recommendations. **It is only after this final CDC Director decision that providers should begin administering booster doses.** The Kansas Department of Health and Environment will send an additional HAN at that time alerting providers of these final steps in the regulatory process and giving the green light to begin administration of booster doses.

On Friday's VRBPAC meeting, the committee also discussed heterologous booster doses. No votes were taken and no recommendations were made. They key takeaways are as follows:

- The committee expressed varying opinions on future EUA authorization of heterologous booster doses. Some felt that this should be left up to ACIP.
- Committee members noted that those who had moderate/severe adverse reactions to their primary series or have health/safety concerns should be able to mix and match doses.
- The committee felt that heterologous booster doses will cause public confusion, especially considering the J&J booster is approved for all adults 18+ who received the J&J primary series.

- The committee was asked how much additional data would be necessary to make a decision on heterologous mixing. Overall, members felt that current data is sufficient, but a larger sample size for safety would be helpful.

All COVID-19 vaccine providers are reminded of their responsibility to adhere 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 a violation of 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 the 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.

As per the HAN announcement on September 24, 2021, booster doses of Pfizer-BioNTech may be administered to individuals 65 and older, those 16 – 64 at risk for severe COVID-19 illness and those 16 – 64 with heightened job and institutional exposure has them at high risk of encounter.