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Monovalent Moderna and Pfizer COVID-19 Vaccines No Longer Authorized as Boosters

On Aug. 31, the FDA removed emergency use authorization of the *monovalent* mRNA COVID-19 vaccines for individuals 12 years of age and older *as booster doses*. With that said, booster doses from these manufacturers and these identified age groups *can no longer be used*:

- Pfizer monovalent COVID-19 vaccine is no longer authorized for individuals 12 years of age and older
- Moderna monovalent COVID-19 vaccine is no longer authorized for individuals 18 years of age and older

These monovalent vaccines continue to be authorized for use as a *primary series* for individuals 6 months of age and older as described in the letters of authorization. Currently, the Pfizer COVID-19 vaccine remains authorized for administration of a single booster dose for individuals five through 11 years of age at least five months after completing a primary series of the Pfizer COVID-19 vaccine.

Given this FDA action, appointments for monovalent Pfizer or Moderna boosters in people 12 years of age and older must be rescheduled for when locations have the COVID-19 bivalent vaccines available. Vaccinators are now able to place orders for the Moderna COVID-19 bivalent vaccine booster for adults 18 years of age and older and the Pfizer COVID-19 bivalent vaccine booster for individuals 12 years of age and older. Orders can be placed by completing the COVID-19 Vaccine Ordering Survey and following the regular ordering process. The bivalent vaccines will begin shipping over the next few weeks.

This is a big change with very short notice to the Wisconsin Department of Health Services (DHS) and our hospitals from the FDA. WHA is aware of the impact on your vaccination programs and scheduled visits for COVID-19 boosters and has reached out to DHS with this concern. DHS will provide more information on the new bivalent vaccine boosters in the coming days.

Feel free to reach out to WHA Chief Quality Officer Nadine Allen or your contact at WHA if you have questions.

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