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**Subject:** FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID-19 Vaccines and PREP Act Update



DEPARTMENT OF PUBLIC HEALTH

**April 18, 2023**

*This communication is being sent to all key contacts at provider organizations administering COVID-19 vaccine— please read this message in its entirety. Please feel free to share it with others in your organization who may benefit from the update. Note that all our communications are archived on our [web site](#).*

Dear COVID-19 Vaccine Program (CoVP) and CT Vaccine Program (CVP) Providers,

Today, the U.S. Food and Drug Administration (FDA) amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent mRNA vaccines to simplify the vaccination schedule for most individuals. This action includes authorizing the current bivalent vaccines (original and omicron BA.4/BA.5 strains) to be used for all doses administered to individuals 6 months of age and older, including for an additional dose or doses for certain populations.

**The monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.**

- **Most individuals, depending on age, previously vaccinated with a monovalent COVID-19 vaccine** who have not yet received a dose of a bivalent vaccine may receive a single dose of a bivalent vaccine.
- **Most individuals who have already received a single dose of the bivalent vaccine** are not currently eligible for another dose. The FDA intends to make decisions about future vaccination after receiving recommendations on the fall strain composition at an FDA advisory committee in June.
- **Individuals 65 years of age and older who have received a single dose of a bivalent vaccine** may receive one additional dose at least four months following their initial bivalent dose.
- **Most individuals with certain kinds of immunocompromise who have received a bivalent COVID-19 vaccine** may receive a single additional dose of a bivalent COVID-19 vaccine at least 2 months following a dose of a bivalent COVID-19 vaccine, and additional doses may be administered at the discretion of, and at intervals determined by, their healthcare provider. However, for immunocompromised individuals 6 months through 4 years of age, eligibility for additional doses will depend on the vaccine previously received.
- **Most unvaccinated individuals** may receive a single dose of a bivalent vaccine, rather than multiple doses of the original monovalent mRNA vaccines.
- **Children 6 months through 5 years of age who are unvaccinated** may receive a two-dose series of the Moderna bivalent vaccine (6 months through 5 years of age)

OR a three-dose series of the Pfizer-BioNTech bivalent vaccine (6 months through 4 years of age). Children who are 5 years of age may receive two doses of the Moderna bivalent vaccine or a single dose of the Pfizer-BioNTech bivalent vaccine.

- **Children 6 months through 5 years of age who have received one, two or three doses of a monovalent COVID-19 vaccine** may receive a bivalent vaccine, but the number of doses that they receive will depend on the vaccine and their vaccination history.

The full FDA press release can be found [here](#). The [Advisory Committee on Immunization Practices \(ACIP\)](#) will be meeting tomorrow from 11-3pm.

### **Use of Current Monovalent mRNA (Pfizer-BioNTech and Moderna) COVID-19 Vaccines**

As of today, the monovalent mRNA (Pfizer-BioNTech and Moderna) COVID-19 vaccines are NO LONGER authorized for use in the United States for any age. This change is NOT due to any safety concerns, but rather in anticipation of the new simplified schedule that will be released later this week. Providers should do the following:

- Remove all monovalent Pfizer-BioNTech and Moderna mRNA COVID-19 vaccine currently in inventory to reduce the risk of accidental administration.
- Report all removed monovalent mRNA doses as waste to the CT WiZ [Helpdesk](#).
- Dispose of the vaccine vial (with any remaining vaccine) and packaging as medical waste. Do NOT return vaccine.

Providers can continue to utilize Novavax and Janssen COVID-19 vaccines as indicated in the [clinical considerations for COVID-19 vaccines](#).

### **Public Readiness and Emergency Preparedness (PREP) Act**

HHS has released a [fact sheet](#) about an upcoming amendment to the COVID-19 PREP Act declaration. This will be the eleventh amendment to the declaration and seeks to clarify issues around provider liability protections.

### **Key changes under the upcoming amended declaration include:**

- **Extending coverage for COVID-19 vaccines, seasonal influenza vaccines, and COVID-19 tests.** PREP Act immunity from liability will be extended through December 2024 to pharmacists, pharmacy interns, and pharmacy technicians to administer COVID-19 and seasonal influenza vaccines (to those individuals three and over, consistent with other requirements), and COVID-19 tests, regardless of any USG agreement or emergency declaration.
- **Extending coverage through December 2024 for Federal agreements.** This includes all activities related to the provision of COVID-19 countermeasures that are 1) provided based on a Federal agreement (including the vaccines and treatments purchased and provided by the USG), or 2) directly conducted by the USG, including by Federal employees, contractors or volunteers.

- **Ending of coverage for certain activities.** Once products are no longer distributed under a USG agreement, PREP Act coverage will no longer extend to the following activities:
  - COVID-19 vaccination by non-traditional providers (e.g., recently retired providers and students); and
  - COVID-19 vaccinations across state lines by licensed providers and pharmacists and pharmacy interns.
- **Ending of coverage for routine childhood vaccinations.** Once there is no emergency in effect, PREP Act coverage will no longer extend to all routine childhood vaccinations by pharmacists, pharmacy interns, and pharmacy technicians.

As always, thank you for your ongoing support and effort with the COVID-19 vaccine rollout.

For the CT DPH Immunization Program, visit: [Contact Us](#)

For the COVID-19 webpage, visit: [COVID-19 Vaccine Program](#)

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