

# EXHIBIT 5

August 16, 2022

## CDC Fall Vaccination Operational Planning Guide – Information for the Fall Vaccine Campaign, Including Upcoming Bivalent COVID-19 Vaccine Booster Doses

### Overview

On June 30, 2022, the U.S. Food and Drug Administration (FDA) [advised manufacturers](#) seeking to update their COVID-19 vaccines to add an Omicron BA.4/5 spike protein component to the current vaccine composition to create a bivalent booster vaccine. This operational planning guide includes details about the anticipated bivalent COVID-19 booster.

Pending potential FDA Emergency Use Authorizations (EUAs) for new bivalent COVID-19 boosters developed by Pfizer-BioNTech and Moderna in or around September 2022, CDC's Advisory Committee on Immunization Practices (ACIP) will convene to discuss potential recommendations. Once scheduled, [ACIP meeting information is announced on the CDC website](#). Administration of any new bivalent COVID-19 boosters can begin only after CDC's official recommendations.

The bivalent COVID-19 vaccine will be administered as a single booster dose to those who previously completed a primary series of COVID-19 vaccine. It is anticipated that bivalent COVID-19 vaccine booster doses may initially be authorized for people ages 12 years and older (Pfizer-BioNTech) and for people ages 18 years and older (Moderna), followed by younger pediatric age groups. It is also anticipated that the bivalent COVID-19 vaccines will **only** be authorized as a single dose in people who have completed a primary vaccination series but would not vary by number or type of prior booster doses received.

At publication of this guide, the U.S. Government (USG) has procured 175 million doses of bivalent COVID-19 vaccine for distribution and administration. This is part of a planned fall and early winter campaign that will include primary (prototype) and booster (bivalent) vaccines intended to maximize availability and uptake across age groups to ensure population protection against circulating strains. It is expected that many COVID-19 vaccination providers will offer bivalent booster doses, but not all providers are expected to continue carrying primary series COVID-19 vaccines. Providers planning to continue offering primary series COVID-19 vaccines will need to store both original (i.e., prototype vaccine) and new formulations.

### BACKGROUND INFORMATION

On June 28, 2022, FDA's independent experts on the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to publicly discuss whether a change to the current vaccine strain composition of COVID-19 vaccines for booster doses is necessary for the 2022 fall and winter seasons. The advisory committee voted in favor of including a SARS-CoV-2 Omicron component in COVID-19 vaccines that would be used for boosters in the United States beginning in fall 2022. FDA subsequently clarified intent to authorize bivalent boosters including a BA.4/5 valence specifically.

Pfizer-BioNTech and Moderna have both developed bivalent COVID-19 vaccine booster doses. The USG has arranged to purchase Pfizer-BioNTech and Moderna bivalent booster doses, provided the vaccines are authorized by FDA and recommended by CDC. The USG has purchased enough booster doses to ensure a robust and complete national vaccination campaign through the fall and early winter. The new vaccines will have the same storage and handling parameters as the original vaccine products:

#### [Pfizer-BioNTech COVID-19 Vaccines](#)

- Ultra-cold freezer storage (-90°C to -60°C) until expiry
- NO FREEZER STORAGE
- Refrigerate (2°C to 8°C) up to 10 weeks without puncturing

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### Moderna COVID-19 Vaccines

- NO ULTRA-COLD FREEZER STORAGE
- Freezer storage (-25°C to -15°C) until expiry
- Refrigerate (2°C to 8°C) up to 30 days without puncturing

Pfizer-BioNTech bivalent COVID-19 vaccine is expected to be packaged in 6-dose vials in cartons of 10 vials each (60 doses total), with a minimum order quantity of 300 doses. Moderna bivalent vaccine will be packaged in 5-dose vials in cartons of 10 vials each (50 doses total), with a minimum order quantity of 100 doses. **Once punctured, each vial must be used within 12 hours.** Similar to existing Moderna and Pfizer-BioNTech (gray cap) products, vials must be discarded ≤12 hours after the first puncture. Ancillary supplies will be provided, including a variety of 1-inch and 1.5-inch needles and syringes. An ancillary opt-out continues to be available for all non-diluent kits.

## PROJECTED LAUNCH PLAN

Doses of each vaccine will be made available under thresholds rather than allocations. This means that at the start of each new order period, doses available for ordering will be replenished up to the threshold for that order period (i.e., with each subsequent threshold, the full number of doses will be available to order). Currently, planning is for a rollout that includes pre-ordering to enable vaccine to be shipped immediately following EUA.

Prior to EUA, there will be a pre-ordering period consisting of two waves, with an initial pre-EUA threshold for each vaccine in Wave 1 followed by a threshold increase in Wave 2. A post-EUA threshold for each vaccine will be refreshed following EUA(s) and CDC recommendation(s) to ensure that each authorized product is able to continuously flow to sites and to ensure no interruption in product availability. Details and a summary table are below.

Jurisdictions will have the opportunity and are encouraged to order enough bivalent vaccines to meet the anticipated demands of their communities.

### Pre-EUA Thresholds

- Doses of each bivalent vaccine will be made available for jurisdictions, federal entities, and pharmacies to pre-order. Thresholds for jurisdictions will be determined on a pro rata basis. **Threshold numbers are anticipated to be posted in Tiberius for planning purposes at the same time this guide is published.** Pre-orders will occur in two waves for each vaccine — Wave 1 and Wave 2 (timeline below subject to change).
  - Wave 1 pre-ordering of Moderna and Pfizer-BioNTech bivalent vaccines will start on or about August 17 at 10:00 AM EDT and end on or about August 24 at 9:00 AM EDT.
  - Wave 2 pre-ordering of Moderna and Pfizer-BioNTech bivalent vaccines will start on or about August 24 at 10:00 AM EDT (with a threshold expansion) and end on or about August 30.
- Additional details regarding the timing of pre-ordering for Moderna and Pfizer-BioNTech pediatric bivalent vaccines will be updated based on available information. It is expected that at least one bivalent vaccine for children ages 11 years and younger may be authorized within a short time following the authorization(s) of bivalent vaccines for people ages 12 years and older. Sites should plan to manage necessary freezer and refrigerator space when developing their overall fall vaccine plans.
- Jurisdictions should begin to prioritize which sites would be first to receive doses based on various considerations (e.g., vaccinating those at highest risk for severe COVID-19 disease, such as long-term care facility residents, persons ages 65 years and older, and people with certain medical conditions; ensuring

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vaccine equity; feasibility of sites efficiently implementing the vaccine program; operating hours conducive to receiving and administering initial shipments). Jurisdictions should order sufficient vaccine during Waves 1 and 2 to cover the initial anticipated demand.

- Doses that are pre-ordered will begin being processed for delivery following EUA. Expected delivery schedules will be dependent on the actual EUA date and whether it falls before or after Labor Day.

There will be a **sufficient but finite supply** of bivalent COVID-19 vaccines, which should be directed to providers with expected demand among eligible patients.

Due to the minimum order quantity, jurisdictions should consider internal distribution and hub & spoke operations to maximize ultra-cold freezer and refrigerator space and avoid wasting vaccine. Dashboards will be developed within Tiberius that will enable jurisdictions to view their order thresholds and optimally prioritize providers to receive initial shipments.

The public will be directed to [Vaccines.gov](https://www.vaccines.gov) to find providers offering bivalent COVID-19 vaccine. After receiving their initial vaccine orders, providers are asked to report their inventory to [Vaccines.gov](https://www.vaccines.gov) as soon as possible.

### **Post-EUA Thresholds**

After the EUA is issued, orders will reopen against the remaining threshold. Orders placed after EUA will be delivered following pre-orders and will arrive in sequence, noting initial launch may stretch the usual delivery windows. Additional information on weekly thresholds after the initial set of thresholds for each vaccine will be forthcoming.

The following summary table provides **estimated** dates based on Pfizer-BioNTech and Moderna bivalent COVID-19 vaccines each receiving an EUA around or after September 1, 2022. Additional details regarding the vaccine ordering timeline and delivery of vaccine shipments will be updated when available.

| <b>Estimated Date<br/>(all subject to change)</b> | <b>Action/Event</b>  | <b>Comments</b>  |
|---|--|--|
| <i>Pre-EUA</i>                                    |  |  |
| 8/11  | Thresholds posted for planning (pro rata per jurisdiction)     | Posted in Tiberius   |
| 8/17  | Pfizer-BioNTech (12+) and Moderna (18+) pre-ordering begins    | Wave 1 – start on or about August 17 at 10:00 AM EDT and end on or about August 24 at 9:00 AM EDT<br><br>Wave 2 – start on or about August 24 at 10:00 AM EDT (with a threshold expansion) and end on or about August 30 |
| 8/24  | All-awardee call (Pfizer and Moderna in attendance)            |  |
| <i>Post-EUA</i>                                   |  |  |
| 9/5   | Labor Day (no deliveries)                                      |  |
| EUA Day   | Ordering re-opens for each vaccine on their respective EUA Day |  |

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| Estimated Date<br>(all subject to change) | Action/Event                                  | Comments |
|---|---|----------|
| TBD (pending EUA)                         | ACIP meeting, CDC recommendations             |          |
| TBD (pending EUA)                         | First deliveries of vaccine arrive            |          |
| TBD (pending EUA, ACIP)                   | Post-ACIP all-awardee call                    |          |
| TBD                                       | COCA call                                     |          |
| TBD                                       | Thresholds posted (pro rata per jurisdiction) |          |

## CONSIDERATIONS FOR JURISDICTIONS

To enhance readiness to launch the bivalent booster program and begin administering vaccine, jurisdictions should identify providers who will receive the bivalent doses. Also, jurisdictions will need to balance making primary series vaccine accessible to those who would like to receive it while avoiding distributing inventories across too many sites and seeking to minimize vaccine loss.

Jurisdictions and providers are **strongly encouraged to adopt strategies to minimize unnecessary wastage**, however, **they should not miss any opportunities to vaccinate every eligible person** who requests a vaccination, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose in the vial.

Bivalent COVID-19 vaccines will be made available to jurisdictions, pharmacies, and federal entities through pro rata thresholds. Jurisdictions should create a distribution plan in coordination with local health departments and other partners and determine which sites will receive vaccine product, incorporating the considerations listed below.

### Considerations for selecting sites to receive the initial doses include:

- Location and access to a range of populations (e.g., urban and rural, communities that may be disproportionately impacted by COVID-19) and ensuring that distribution to these groups is equitable to the extent possible.
- Ability to reach eligible [persons at highest risk for severe COVID-19](#) (e.g., older adults, long-term care facility residents, people with certain medical conditions).
  - It is expected that people who have completed any COVID-19 vaccine primary vaccination or any number of prior COVID-19 vaccine booster doses will be able to receive a bivalent COVID-19 vaccine booster dose, if eligible based on age and interval since last dose.
- Ability to handle 100-dose & 300-dose product configurations, depending on whether the jurisdiction has plans in place for redistribution.
- Ability to administer both Pfizer-BioNTech bivalent and Moderna bivalent vaccines to meet anticipated community demand.
- Ability to efficiently vaccinate within 12 hours once a vial is opened. Sites should consider vial size and the expected demand when planning and scheduling individuals for vaccination, especially early in the program, to optimize supply.
- Ability to manage inventory to ensure availability of primary series doses, in addition to bivalent booster doses, in their local area when feasible.
- Overall readiness (e.g., staffing, training, scheduling capabilities).

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Jurisdictions will be responsible for assuring primary vaccines remain available especially in populations where uptake of the primary series is lower, such as children. **It is anticipated that the bivalent COVID-19 vaccines will only be authorized as a single dose in people who have completed a primary vaccination series.** The type and number of COVID-19 boosters that people have previously received is not expected to matter for the purposes of eligibility for bivalent COVID-19 boosters.

In order to continue offering primary series vaccines in addition to bivalent boosters, providers will need to keep multiple COVID-19 vaccine products in their inventory throughout the fall. CDC recommends providers offer simultaneous administration of all age-appropriate doses of vaccines for children, adolescents, and adults for whom no contraindications exist at the time of the healthcare visit. As the demand for seasonal flu vaccines will also increase during this time, providers may have some concerns regarding vaccine storage space. To better maintain vaccine storage space, providers are encouraged to:

- Manage inventory to ensure availability of primary series doses, in addition to bivalent booster doses.
- Assess storage space to determine freezer and refrigerator capacity before placing orders for vaccine, taking into account anticipated flu vaccine inventory as appropriate.
- Check expiry dates on inventory and dispose of expired vaccine according to state and local regulations.
- Reduce vaccine ordering, reduce inventory, and place orders on an “as-needed” basis. In most instances, vaccine orders of existing COVID-19 vaccines can be delivered within 24-48 hours.
- Zero out old inventory in [Vaccines.gov](https://www.vaccines.gov), and ensure the publicly posted amount reflects actual inventory on hand. This will help to reduce confusion and assist the public in identifying a location where they can receive a vaccine.

| READINESS CHECKLIST                  |  |
|--------------------------------------|--|
| Main Theme                           | Key Activities for Readiness and Response  |
| <b>Supply and Ordering Readiness</b> | <ul style="list-style-type: none"> <li><input type="checkbox"/> Determine which provider locations will receive initial vaccine supply, balancing equitable access with vaccination capacity and consideration of initial demand.</li> <li><input type="checkbox"/> Finalize a list of providers and sequence of provider activation for the first week of vaccine deliveries. Jurisdictions will submit pre-orders for providers to facilitate delivery of initial orders.</li> <li><input type="checkbox"/> Review CDC and manufacturer materials regarding product configuration, shipping, storage, dosing, dosing intervals, and adverse event profiles as they become available.</li> <li><input type="checkbox"/> Optimize vaccine use by ordering supply to minimize unnecessary accumulation of inventory and wastage while also ensuring no vaccination opportunity is missed.</li> <li><input type="checkbox"/> Plan for internal redistribution (e.g., within a jurisdiction) to reduce wastage and improve access.</li> <li><input type="checkbox"/> Manage and accurately report on-hand product inventory to inform tracking near-expiry and redistribution.</li> </ul> |
| <b>Provider Readiness</b>            | <ul style="list-style-type: none"> <li><input type="checkbox"/> Ensure providers are enrolled to reach the key populations; identify providers who are not yet COVID-19 vaccination providers and facilitate their enrollment, especially providers who can fill a geographic gap in access and providers who care for people who are at increased risk for developing severe outcomes.</li> <li><input type="checkbox"/> Ensure providers or other on-location staff are equipped and trained to respond to possible severe allergic reactions, like anaphylaxis.</li> <li><input type="checkbox"/> Encourage providers to offer COVID-19, influenza, or other routine vaccines, as feasible, to additional eligible persons (e.g., family members, community members).</li> </ul>  |

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|--|---|
|  | <ul style="list-style-type: none"> <li><input type="checkbox"/> Ensure providers are aware of resources to help support coadministration of COVID-19 vaccines and other vaccines, including influenza vaccines, during a visit.</li> <li><input type="checkbox"/> Reinforce how providers are required to report certain adverse events following COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) and support providers in encouraging enrollment in v-safe.</li> <li><input type="checkbox"/> Encourage providers who are not able to offer COVID-19 vaccination to refer their patients to nearby vaccination providers.</li> </ul>  |
| <p><b>IT Systems, Reporting and Monitoring</b></p> | <ul style="list-style-type: none"> <li><input type="checkbox"/> Ensure electronic systems, including immunization information systems (IISs), are prepared to report and track vaccine administration.</li> <li><input type="checkbox"/> Remember that the Special Project Provider label is required for COVID-19 vaccine ordering. Inclusion of this flag on the provider record indicates that the jurisdiction has signed the agreement with the provider to receive COVID-19 vaccines.</li> <li><input type="checkbox"/> Once the vaccination program begins, continue to leverage Tiberius dashboards to monitor the program.</li> </ul>  |
| <p><b>Communications</b></p>                       | <ul style="list-style-type: none"> <li><input type="checkbox"/> Create a communication plan that outlines strategies, audiences, and products that will be used to promote COVID-19 vaccination of unvaccinated key populations and populations recommended for bivalent booster vaccination.</li> <li><input type="checkbox"/> Understand existing data, attitudes, and perceptions regarding COVID-19 vaccination (including co-administration with influenza vaccine) in terms of demand, provider types, and locations where vaccination would be preferred. Share these data with local jurisdictions and partners to help shape messages.</li> <li><input type="checkbox"/> Develop communications products for providers, pharmacies, and the public that align with federal messaging and ensure communication materials are culturally and linguistically appropriate.</li> <li><input type="checkbox"/> Leverage partnerships to help mobilize providers and promote COVID-19 bivalent booster vaccination messaging.</li> <li><input type="checkbox"/> Engage and educate partners and trusted messengers (e.g., healthcare professionals, community leaders, faith leaders and faith-based organizations) as soon as possible.</li> </ul> |