

**Bulletin:** Updates on Maryland's COVID-19 Vaccine Plan

**To:** All COVID-19 Vaccine Providers Registered in ImmuNet, including but not limited

to Hospitals, Federally Qualified Health Centers (FQHC), and Local Health

Departments

From: Webster Ye, Assistant Secretary, Maryland Department of Health (MDH)

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- Please review the latest <u>Vaccination Matters Order (06/27/2022)</u> and <u>Nursing Home Matters Order (08/26/2022)</u>. We encourage every provider to make use of every resource to ensure a successful vaccination campaign.
- All COVID-19 vaccine providers are required to administer COVID-19 Vaccine according to the following updated guidance.
- This document updates and supersedes the past COVID-19 vaccine bulletin, dated July 27, 2022 and earlier bulletins. This bulletin will be updated as needed going forward.

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# Updates & Recommendations | September 2, 2022

#### • UPDATES:

On August 31, 2022, the <u>U.S. Food and Drug Administration</u> amended the emergency use authorization (EUA) for Pfizer COVID-19 vaccines for individuals 12 years and older and Moderna COVID-19 vaccines doses for individuals 18 years and older. FDA approved the administration of a single dose of the updated bivalent booster formula in these populations to be administered at least two months after the individual's last dose (either booster or primary series).

On September 2, 2022, the U.S. Centers for Disease Control and Prevention recommended the use of updated COVID-19 bivalent boosters from Pfizer-BioNTech for people ages 12 years and older and from Moderna for people ages 18 years and older.

(Please see Section 1. Vaccine Eligibility for more information)

Please note: With the amendment to the EUA for these populations, the monovalent mRNA COVID-19 vaccines are no longer authorized as booster doses for individuals 12 years of age and older. The Pfizer-BioNTech and Moderna monovalent COVID-19 vaccines should only be administered as a primary series for individuals in this age group.

#### • RECOMMENDATIONS:

We strongly urge Marylanders to get vaccinated and stay up to date on their vaccines.

Marylanders who are unvaccinated or not up to date on their vaccines remain at the greatest risk of contracting and spreading COVID-19 and highly contagious variants, hospitalization, and death.

Please see the <u>CDC website</u> for further information regarding staying up to date with vaccinations. Marylanders can check if they are up to date by using <u>this tool</u>.

MDH strongly recommends that the following high-risk individuals should maintain their immunity by getting booster doses as soon as possible:

- Individuals aged 50 years and older;
- All eligible immunocompromised individuals; and
- Individuals that live in <u>long-term care settings</u>, those that have <u>underlying medical</u> <u>conditions</u>, and those that work or live in <u>high-risk settings</u> or in communities with high transmission rates.

It is important for providers, including retail pharmacies, not to miss any opportunity to vaccinate every eligible person who presents for a COVID-19 vaccine, either for a primary series or booster dose.

Individuals may self-attest to eligibility. Providers shall not turn away any individual who self-attests to eligibility for a booster or additional dose. Please see Section 1, Vaccine Eligibility for more information.

# 1. Vaccine Eligibility (Updated September 2, 2022)

### • Primary Series:

All Marylanders 6 months and older are eligible to receive a primary series of COVID-19 Vaccine (monovalent formula).

Please note: Those aged 6 months to 17 are only eligible to receive the Pfizer-BioNTech COVID-19 Vaccine (monovalent formula) or Moderna COVID-19 Vaccine (monovalent formula) authorized for that population under the expanded Emergency Use Authorization. Please see the <u>FDA</u> and <u>CDC</u> statements for more information.

MDH strongly supports COVID-19 Vaccines for all eligible children and adolescents, and encourages providers to make appointments available to this population immediately. Providers should develop their own procedures for handling parental consent of these populations. Please see the CDC webpage for children and teens and clinical considerations for more information.

#### Booster Dose:

Upon request, all providers shall administer a booster dose of any FDA approved or authorized COVID-19 Vaccine after the appropriate length of time from the primary series. Please see the CDC website for more information.

(See below for timing and formula for specific COVID-19 Vaccine types.)

### Moderna & Pfizer-BioNTech COVID-19 Vaccine (Monovalent) primary series:

Pfizer- BioNTech COVID-19 Vaccine (Monovalent) Booster Dose:

Individuals **5 years to 11 years of age** are eligible for a single booster dose of Pfizer-BioNTech COVID-19 Vaccine (Monovalent) **at least 5 months** after their Pfizer-BioNTech Monovalent primary series.

Please note: A booster dose is not currently recommended for individuals in this age group who have received the Moderna COVID-19 vaccine (Monovalent) as their primary series.

#### Moderna & Pfizer- BioNTech COVID-19, Bivalent Booster Dose:

Individuals **18 years of age and older** are eligible for a single booster dose of the **Moderna COVID-19 Vaccine**, **Bivalent** if it has been **at least two months** since they have completed primary vaccination or received their last booster dose with any authorized or approved monovalent COVID-19 vaccine.

Individuals 12 years of age and older are eligible for a single booster dose of the **Pfizer-BioNTech COVID-19 Vaccine**, **Bivalent** if it has been at least two months since they have completed primary vaccination or received their last booster dose with any authorized or approved monovalent COVID-19 vaccine.

<u>Janssen (J&J) COVID-19 primary series</u>: Individuals 18 years and older are eligible for a booster dose of either Pfizer-BioNTech COVID-19 Vaccine, Bivalent or Moderna COVID-19 Vaccine, Bivalent **at least two months** after receiving their primary or last booster dose.

Providers are reminded that they may not turn away any individual requesting a booster dose for failure to "show proof" of eligibility.

Patients should talk to their healthcare providers to determine individual benefits and risks of receiving a booster dose, including any specific contraindications, such as previous reactions to the vaccine.

# • Additional Dose for Immunocompromised Individuals:

All vaccine Providers shall offer an additional dose of COVID-19 Vaccine (Pfizer-BioNTech COVID-19 Vaccine (Monovalent)/Moderna COVID-19 Vaccine (Monovalent)) to individuals in light of the following considerations:

The CDC approved the FDA amendment of the emergency use authorizations for the Pfizer-BioNTech and Moderna COVID-19 Vaccines to allow specific individuals 5 years of age and older with compromised immune systems to receive a third additional vaccine dose at least 28 days after the second dose as part of a 3-dose initial primary mRNA series.

Patients should talk to their healthcare providers to determine if they need an additional dose and what the timing of that dose should be.

As required by the MDH <u>Nursing Home Matters</u> and <u>Vaccination Matters Orders</u>, those that reside in Nursing Homes, Assisted Living Programs, Developmental Disabilities Group Homes, and Residential Drug Treatment Centers shall be offered the opportunity for an additional/booster dose.

# Booster Doses for Immunocompromised individuals (5 years of age and older)

Individuals who received an additional dose are eligible to receive a booster dose. The timing, dosage, and formula depends on the individual's age. (See above). <u>Please see the CDC website for more information.</u>

#### • Self-Attestation:

Any Marylander who presents to a provider that they are eligible for an additional dose or a booster dose shall be allowed to self-attest that eligibility. Providers shall follow <u>CDC guidelines</u> when developing their own procedures to allow for self-attestation of patient eligibility.

However, providers shall not turn away any individual who self-attests to eligibility for an additional dose or booster dose. Failure of an individual to "show proof" of eligibility shall not be a reason that a provider does not administer an additional or booster dose.

Providers should continue to report any doses they administer in the same manner that they report first and second doses to ensure that vaccine records are reported into ImmuNet within 24 hours of administration. ImmuNet is able to track all dose vaccine administrations in Maryland.

# 2. Residency and Priority Group Eligibility Determinations

- A COVID-19 Vaccine provider may not refuse an individual a vaccine or additional/booster dose based on their citizenship or immigration status.
- Non-discrimination: MDH complies with applicable Federal and State civil rights laws and prohibits discrimination on the basis of race, color, religion or creed, sex, age, ancestry or national origin, marital status, physical or mental disability, sexual orientation and gender identity, genetic information, socioeconomic status, and/or any other protected status. The Maryland Department of Health prohibits the exclusion and favorable/unfavorable treatment of any individual in the aforementioned protected categories based on an individual's medical knowledge of and/or experience with a vaccine's efficacy, longevity, reduced side effects, or any other characteristic associated with the performance of an administered COVID-19 vaccination. An individual's protected status shall have no bearing on the type of vaccine an individual receives.

### 3. Vaccine Operations

• All COVID-19 Vaccine Providers who administer any formula of COVID-19 Vaccine shall register in ImmuNet to be able to receive or order COVID-19 vaccine at

https://www.mdimmunet.org/ Please refer to this guide for instructions on how to register.

Please note that registered Vaccines for Children (VFC) providers must register separately and sign the COVID-19 vaccine provider agreement before receiving and administering COVID-19 vaccine.

• All COVID-19 Vaccine providers shall submit their orders for COVID-19 vaccine directly through ImmuNet each Thursday between 8am and 4pm. Please review this document for instructions on how to place a COVID-19 Vaccine order in ImmuNet.

Please contact <a href="mdh.covidvax@maryland.gov">mdh.covidvax@maryland.gov</a> if you have any questions.

Providers can check the status of their COVID-19 order in ImmuNet. Please see <u>this</u> <u>guide</u> for information on how to check your ImmuNet COVID-19 Vaccine order.

All local health departments, subject to vaccine availability, shall act as centralized storage and distribution of COVID-19 vaccines to providers in their community who request smaller allotments of vaccine.

All COVID providers must regularly review and update their COVID-19 Vaccine
inventory in ImmuNet. This review and update should be done by each individual
provider (each provider with a COVID PIN) and not at the healthcare system level.
 MDH strongly recommends an inventory review on a twice a week, if not daily, basis.

Using this guide, log into ImmuNet and update the current inventory you have in your facility/office.

 All COVID-19 Vaccine Providers are required to have a digital data logger (DDL) to monitor temperatures in your COVID vaccine storage unit(s) effective Friday, September 30, 2022, per the CDC.

This requirement is effective immediately for all newly registering COVID providers and effective September 30, 2022 for all existing COVID providers as DDLs are the "gold standard" for monitoring storage temperatures for all vaccines ensuring temperature excursions are detected, including the length of time a temperature is out of range, making them one of the most advanced devices to ensure vaccines are stored correctly and protected from unnecessary waste. For more information, please see the CDC's Vaccine Storage and Handling Toolkit.

**Expiration**: Providers should visit the manufacturer's website to check the expiration dates of any vaccine in their inventory. Please check your inventory to confirm expiration dates. Once expired, please report the doses expired and dispose of the

- expired vaccine with your medical waste (eg. red sharps container). Do not dispose of the expired vaccine in your normal trash.
- **Pfizer-BioNTech COVID-19 Vaccines/COMIRNATY:** Further information regarding dosage, vial size and differing vial cap colors, and further administration guidance can be found on the <u>CDC website</u> and <u>FDA website</u>.
- Moderna COVID-19 Vaccines/Spikevax: Further information regarding dosage and administration timing, vial size and differing vial cap colors, and further administration guidance can be found on the <u>CDC website</u> and <u>FDA website</u>.
- Novavax COVID-19 Vaccine/Adjuvanted: Further information regarding dosage and administration timing, vial size, and further administration guidance can be found on the <u>CDC website</u> and <u>FDA website</u>.
- Janssen COVID-19 Vaccine (Johnson & Johnson): Further information regarding dosage and administration timing, vial size, and further administration guidance can be found on the CDC website and FDA website.
- All hospital providers shall, subject to the availability of vaccine supply, offer COVID-19 Vaccine to any eligible inpatients being discharged from a hospital admission to a nursing home, assisted living program, or other post-acute care facility (such as a rehabilitation center).

### 4. CovidVax.Maryland.gov

- All providers who administer vaccines to the general public and wish to be listed on
  the website shall submit their vaccination site details (vaccine appointment registration
  webpage and a phone number that directs callers to staff accepting appointment
  registrations) to fosie.joseph-norton@maryland.gov.
- All registered COVID-19 vaccine providers in ImmuNet that are offering vaccination clinics will be listed on this page.

### 5. Wastage/At-risk Vaccines

• To avoid missed vaccine administration opportunities, vaccine providers may follow the CDC updated wastage policy, found below in Appendix 1, with the understanding that the emphasis on reducing vaccine wastage by providers remains. Please continue to follow best practices to use every dose possible while minimizing the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated.

- For further guidance, please refer to the current <u>Vaccination Matters Order</u> and/or <u>Provider Guidance for Avoiding Waste of COVID-19 Vaccine Doses</u> documents (subject to update).
- Providers should report all COVID-19 Vaccine wastage and vaccine storage unit temperature excursions via the PROPs Provider Portal- the only system for recording COVID-19 wastage and temperature excursions events. The wastage history summary page provides all wastage events previously submitted, as well as updated information for providers documenting new wastage, expired and temperature excursion events.

**NOTE:** For Pfizer-BioNTech (COMIRNATY): If a provider is unable to access a sixth dose, the sixth dose must be reported as wastage as "other". Please review the guidelines before disposing of any COVID-19 Vaccine doses.

#### 6. Provider to Provider Transfers

- Providers can contact <a href="mailto:mdh.covidvax@maryland.gov">mdh.covidvax@maryland.gov</a> at any time to initiate a provider-to-provider transfer. MDH will facilitate the transfer by providing contact information for community providers to initiate a transfer. A provider to provider transfer can be for a smaller amount of doses than currently available through direct ordering via ImmuNet.
- A provider who has been allocated doses from Maryland may transfer doses to another approved COVID-19 Vaccine provider using the Transfer Marketplace (PROPS Provider Portal > Transfer Marketplace tile) or through a direct provider-to-provider transfer. The receiving vaccine provider must have completed the CDC provider agreement and the CDC redistribution agreement.
- Providers must keep records of what doses have been transferred and must complete a
  transfer via the PROPS Provider Portal (Transfer Marketplace tile > Transfer Form).
   Vaccine transfers facilitated via the Transfer Marketplace are auto-recorded and do not
  require additional follow-up from the provider. Providers do not need to complete a
  transfer form for vaccines transferred via the Transfer Marketplace. The form will ask
  to/from, date, type (1st or 2nd) and amount.
- Both the transferring and receiving provider are responsible for ensuring that their part
  of the transfer is executed correctly, i.e. transfer paperwork, chain of custody, storage
  and handling.
- Receiving providers must have the proper reporting mechanism in place and are responsible for reporting the vaccinations to ImmuNet.

Further information will be provided as it becomes available. If you have any questions, please contact <a href="mailto:mdh.covidvax@maryland.gov">mdh.covidvax@maryland.gov</a>.

# **Appendix 1: CDC Statement on Wastage (as of May 11, 2021)**

# Take every opportunity to vaccinate every eligible person

- Over a hundred million people are fully vaccinated in the United States, and many more have received at least one COVID-19 vaccination.
- Our goal is to increase vaccine confidence and for everyone who wants to be vaccinated to have every opportunity to be fully vaccinated once they become eligible.
- CDC and our partners are doing everything possible to minimize the amount of vaccine that goes unused.
- Vaccine wastage may increase as the vaccine rollout continues because:
  - o more providers, including smaller provider sites, are now receiving vaccine,
  - o vial sizes for some vaccines have increased,
  - o vaccine vials may be opened without every dose being used
- To ensure providers do not miss an opportunity to vaccinate every eligible person, CDC recommends:
  - Providers follow <u>clinical best practice for vaccination as well as best practices when managing inventory</u> to maximize vaccination and minimize dose wastage.
  - Providers should not miss any opportunities to vaccinate every eligible person who presents at a vaccination site, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose.
    - Consider establishing and promoting standing vaccination days or half-days to increase likelihood of larger numbers of people presenting for vaccination on the same day.
    - Vaccinate family members or friends who accompany patients to medical visits even if they are not established patients at the vaccinating practice
    - Continue outreach to employers or other community partners that have a large membership or network to arrange vaccination events.
    - As a contingency plan, vaccine providers should attempt to contact additional persons (i.e., from a waitlist or through personal contacts of persons being vaccinated) to use as many vaccine doses as possible.
    - Once punctured, multidose vials must be used within:
      - 12 hours (Moderna)
      - 6 hours (Pfizer-BioNTech (COMIRNATY))
      - 2 hours (J&J/Janssen)
    - The more Americans who get vaccinated the fewer COVID-19 cases, hospitalizations, outbreaks, and deaths that will occur.
- CDC remains committed to helping jurisdictions and sites manage inventory and creating additional strategies to minimize vaccine wastage, including increased use of walk-in clinics.