

**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)

**Date:** July 27, 2022

- Please review the latest <u>Vaccination Matters Order (06/27/2022)</u> and <u>Nursing Home Matters Order (06/27/2022)</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 June 20, 2022 and earlier bulletins. This bulletin will be updated as needed going forward.

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## Updates & Recommendations | June 27, 2022

#### • UPDATES:

On July 19, 2022, the <u>U.S. Centers for Disease Control and Prevention (CDC)</u> recommended the use of the <u>Novavax COVID-19 Vaccine</u>, Adjuvanted for individuals 18 years of age and older for a primary vaccination series. This vaccine received emergency use authorization (EUA) from the U.S. Food and Drug Administration on July 13, 2022. (Please see Section 3. Vaccine Operations for more information)

### • **RECOMMENDATIONS**:

We strongly urge Marylanders who are unvaccinated to get vaccinated and receive booster doses at the appropriate interval.

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.

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

- o 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.

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 using this tool.

It is important for providers, including retail pharmacies, not to miss any opportunity to vaccinate every eligible person who presents at vaccine clinics.

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

All Marylanders 6 months and older are eligible to receive a COVID-19 Vaccine.
 Please see the CDC webpage for children and teens and clinical considerations for more information.

Please note: Those aged 6 months to 17 are only eligible to receive the Pfizer-BioNTech COVID-19 Vaccine or Moderna COVID-19 vaccine 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.

#### Booster Dose:

Upon request, all providers shall administer a first or second booster dose of any FDA approved or authorized COVID-19 Vaccine after the appropriate length of time after the primary series. (See below for timing for specific COVID-19 Vaccine types.)

## **Moderna & Pfizer-BioNTech primary series:**

#### First Booster Dose:

Individuals 5 years and older are eligible for a first booster dose of a FDA approved or authorized COVID-19 Vaccine at least 5 months after the primary series.

#### Second Booster Dose:

The following individuals are eligible for a **second booster dose** of either Moderna or Pfizer-BioNTech COVID-19 Vaccine **at least 4 months** after the first booster dose:

- a) Individuals 50 years or older
- b) Immunocompromised individuals 12 years or older

This may also apply to the above individuals (50 years or older, immunocompromised) that received a Janssen (J&J) primary dose followed by a booster of Pfizer-BioNTech or Moderna COVID-19 vaccine.

Please note individuals 5 to 17 years of age are only eligible for booster doses if they received the Pfizer-BioNTech COVID-19 Vaccine as their primary series and should only receive the Pfizer vaccine for their booster.

Please see the CDC website for more information.

**Janssen (J&J) COVID-19 primary series:** Individuals 18 years and older are eligible for:

- a) First booster dose of any FDA approved or authorized COVID-19 Vaccine at least 2 months after the primary dose
- b) Second booster dose of either Pfizer-BioNTech or Moderna COVID-19 Vaccine at least four months after a primary and booster dose of Janssen (J&J).

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/Moderna) 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 dose.

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

Patients who received an additional dose are eligible to receive their first booster dose three months after completing their 3-dose primary series and a second booster dose four months after the first booster, for a total of 5 doses. <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 (Updated July 27, 2022)

 All COVID-19 Vaccine Providers who administer COVID-19 Vaccine shall register in ImmuNet to be able to receive or order COVID-19 vaccine at <a href="https://www.mdimmunet.org/">https://www.mdimmunet.org/</a> 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 <u>mdh.covidvax@maryland.gov</u> 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 <u>guide</u>, 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 Vaccine/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 Vaccine/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 <u>CDC website</u> and <u>FDA website</u>.
- 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 PROPS Provider Portal is now the only system for recording COVID-19 wastage and temperature excursions events. The wastage history summary page provides visibility into all wastage events previously submitted, as well as updated information for providers documenting new wastage, expired and temperature excursion events.

**NOTE:** For providers that have received 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="math.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 provider and the 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.