

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: January 7, 2022

- Please review the latest <u>Vaccination Matters Order (12/15/2021)</u> and <u>Nursing Home Matters Order (12/16/2021)</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 January 04, 2022 and earlier bulletins. This bulletin will be updated as needed going forward.

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<u>Updates & Reminders | January 7, 2022</u>

• UPDATES:

- Please see updated booster eligibility (Section 1, Vaccine Eligibility).
- On January 7, 2022, the U.S. Food and Drug Administration amended the emergency use authorization (EUA) for the Moderna COVID-19 Vaccine to shorten the time between the completion of primary vaccination of the Moderna COVID-19 Vaccine and a booster dose to at least five months.
- o On January 3, 2022, U.S. Food and Drug Administration amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine to:
 - Expand the use of a single booster dose to include use in individuals 12 through 15 years of age.
 - Shorten the time between the completion of primary vaccination of the Pfizer-BioNTech COVID-19 Vaccine and a booster dose to at least five months.
 - Allow for a third primary series dose for certain immunocompromised children 5 through 11 years of age.

• REMINDERS:

- 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.
- Marylanders who are still unvaccinated remain at the greatest risk of contracting and spreading COVID-19 and highly contagious variants, hospitalization, and death. We strongly urge Marylanders who are unvaccinated to get vaccinated.
- All COVID-19 vaccine providers shall continue to prioritize Marylanders who are
 65 and older.
- COVID-19 Vaccine and the Flu Shot can be administered at the same time.
 All COVID-19 vaccine providers are encouraged to promote the flu shot.

1. Vaccine Eligibility (Updated January 7, 2022)

• All Marylanders 5 and older are eligible to receive a COVID-19 vaccine. Please see the CDC website for more information.

Please note: Those aged 5 to 11 are **only eligible to receive the Pfizer-BioNTech COVID-19 vaccine** authorized for that population (Orange vial) under the expanded Emergency Use Authorization. Please see the <u>FDA</u> and <u>CDC</u> statements for more information

MDH strongly supports use of the Pfizer-BioNTech COVID-19 vaccine in children and adolescents 5 to 17 years of age, 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:

For those individuals 18 years and older who completed their primary series, all providers shall administer upon request a 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.)

We strongly recommend that the following high-risk individuals maintain their immunity by getting a booster shot as soon as possible:

- Individuals aged 65 years and older;
- 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.

Moderna & Pfizer-BioNTech primary series: Individuals 18 years and older are eligible for a booster dose of any FDA approved or authorized COVID-19 vaccine **at least 5 months** after the primary series.

Individuals 12 to 17 years of age are eligible for a booster dose of the Pfizer-BioNTech COVID-19 Vaccine at least 5 months after completion of the primary series

<u>Janssen (J&J) COVID-19 primary series</u>: Individuals 18 years and older are eligible for a booster dose of any FDA approved or authorized COVID-19 vaccine **at least 2 months** after the primary dose.

Due to the inherent nature of COVID-19, including the emergence of new variants, previously vaccinated individuals may be at high risk of exposure to COVID-19. Providers

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

Please note that the dosage for the Moderna booster dose is smaller than the doses in the Moderna primary series. Providers should see the <u>FDA's Moderna guidance</u> for more details.

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:

All 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 with compromised immune systems to receive a third additional vaccine dose at least 28 days after the completion of the 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 Nursing Home Matters and Vaccination Matters Orders, 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

Individuals who received an additional dose are eligible to receive a booster dose five months after receiving their additional dose. Please see the CDC website for more information.

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 third dose vaccine administrations.

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 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 mdh.covidvax@maryland.gov 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.

Please Note: Starting Thursday January 6, 2022 Pfizer formulated for the 5-11 population will be available for direct ordering. Providers wishing to order this vaccine should follow the directions above.

All local health departments, subject to vaccine availability, shall act as centralized storage and distribution of pediatric Pfizer doses to providers in their jurisdiction upon request to providers that request less than 300 Pfizer doses. Local health departments shall provide centralized regional ultra-cold storage capacity and disaggregate trays into smaller doses (minimum 2 vials).

- All COVID-19 Vaccine Providers shall: Register in ImmuNet to order vaccine at https://www.mdimmunet.org/ Please refer to this <u>guide</u> for instructions on how to register.
- 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.

- If you do not have any doses of a particular lot in ImmuNet, zero out the inventory.
- If the inventory that you have for a particular lot does not match what is in ImmuNet, add or subtract to get to the correct amount.
- If the inventory that you have for a particular lot is not in ImmuNet, add it.
- Pfizer-BioNTech (COMIRNATY) formulated for 12 plus population: Per federal guidance, all vials of Pfizer-BioNTech (COMIRNATY) contain 6 vaccine doses. Providers that are unable to get a sixth dose from each vial will need to report the sixth dose as wastage using the process outlined in Section 4, Wastage. Additional Pfizer-BioNTech (COMIRNATY) details can be found here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html
- **Pfizer-BioNTech formulated for 5-11 population:** Per federal guidance, the Pfizer COVID-19 vaccine for this population comes in a separate vial with an orange cap containing 10 doses.
- **Moderna:** Per updated federal guidance, Moderna will only ship vials containing the larger 15 vaccine doses (but are indicated as 14 dose vials). Providers should note the vial size of the vials they have in their inventory before administering doses. Requests will be filled in installments of 140. Additional Moderna details can be found here: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html
- 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 on this <u>form</u> 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.
- **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 shall submit their vaccination site details (vaccine appointment registration webpage and a phone number that directs callers to staff accepting appointment registrations) to john.fickel@maryland.gov and joan.kelly@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> (amended 09/08/2021) 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 to: https://www.marylandvfc.org/covid-19-vaccine-excursion-expiration-reporting-form/.

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 <u>mdh.covidvax@maryland.gov</u> 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. 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 request here at:

https://app.smartsheet.com/b/form/52e75f3d4514499cb0fd7110bd4000a7

- 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 mdh.covidvax@maryland.gov.

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.