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: **August 18, 2021**

- Please review the latest Vaccination Matters Order (08/18/2021). 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 COVID-19 vaccine bulletin (Week 27), dated June 11, 2021 and earlier bulletins. This bulletin will be updated as needed going forward.**

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Updates & Reminders

- **REMINDER**: All COVID-19 vaccine providers shall continue to prioritize Marylanders who are 65 and older.

  All local jurisdictions are reminded that homebound seniors should receive priority for vaccines.

- As access to COVID-19 vaccine increases, it is important for providers not to miss any opportunity to vaccinate every eligible person who presents at vaccine clinics. Please see Section 6 and Appendix 1 for further details.

- **Provider Updates:**

  - Today we learned that booster doses of the Pfizer and Moderna mRNA COVID-19 vaccines will be available for all U.S. adults beginning next month. The Maryland Department of Health (MDH) is actively planning for booster vaccine administration and asks that all Maryland healthcare providers also prepare. (Federal release here)

  - **Booster/Supplemental Shots:**

    All Providers should offer additional shots of COVID-19 vaccine (Pfizer/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.

    Patients should talk to their healthcare providers to determine if they need an additional dose and what the timing of that dose should be. CDC does not recommend additional doses for any other population at this time.

    Providers should develop their own procedures to determine if patients are eligible. Please see the CDC's website for more information.

    Providers should continue to report any third 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.

1. Vaccine Eligibility

- All Marylanders 12 and older are now eligible to receive a COVID-19 vaccine. All COVID-19 vaccine providers shall continue to prioritize Marylanders who are 65 and older.

  Please note: Those aged 12 to 17 are **only eligible to receive the Pfizer-BioNTech COVID-19 vaccine** based on the amended Emergency Use Authorization to expand its use in adolescents 12 to 15 years of age. Please see the FDA and CDC statements for more information.

  MDH strongly supports use of the Pfizer-BioNTech vaccine in adolescents 12 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.**

2. Residency and Priority Group Eligibility Determinations

- **A COVID-19 vaccine provider may not refuse an individual a vaccine based on their citizenship or immigration status.**

- **Non-discrimination:** The Maryland Department of Health 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 COVID-19 vaccine orders directly through ImmuNet each Friday 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.

  With this move to direct orders, MDH will no longer provide allocation details in this provider bulletin. Providers can check the status of their COVID-19 order in ImmuNet.

Please see this guide for information on how to check your ImmuNet COVID-19 vaccine order.

- All COVID-19 Vaccine Providers shall: Register in ImmuNet to order vaccine at: https://phpa.health.maryland.gov/OIDEOR/IMMUN/Pages/quick_ref_guides.aspx

- **Pfizer:** Per updated federal guidance, all vials of Pfizer 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 details can be found here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

- **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

- **Johnson & Johnson COVID-19 Vaccine:**

    i. All vaccine providers who receive J&J vaccine **shall**:

        1. Comply with the FDA emergency use authorization conditions and recommendations;

        2. Develop internal use and administration guidelines for offering the J&J vaccine in conjunction with any other allocated vaccine as clinically appropriate and based on the availability of vaccine.

    ii. Per the FDA, the shelf life of properly refrigerated (36℉ to 46℉) Johnson and Johnson COVID-19 vaccines has been extended from three months to four-and-a-half months. Providers should visit the manufacturer's website to check the expiration dates of any vaccine in their inventory.

- **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 wesley.huntemann@maryland.gov."
- All registered COVID-19 vaccine providers in ImmuNet that are offering vaccination clinics will be listed on this page.

5. Second Doses

- Helping unvaccinated Marylanders seeking vaccination become fully vaccinated (i.e., getting both shots in a two dose regimen or getting single dose regimens) remains a priority.
- Providers are required to ensure that second dose appointments are scheduled and doses allocated to those appointments. Providers are responsible for managing their vaccine inventory to fulfill second dose appointments per the CDC-recommended schedule.
- To the extent possible, a provider shall schedule an individual's second dose at the time of the first dose at the appropriate time interval from the 1st dose. For more information, please see the CDC second dose information.

6. 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 Vaccination Matters Order and/or Provider Guidance for Avoiding Waste of COVID-19 Vaccine Doses 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: 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.

7. Provider to Provider Transfers

- A provider who has been allocated doses from Maryland may transfer doses to another 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:
    - more providers, including smaller provider sites, are now receiving vaccine,
    - vial sizes for some vaccines have increased,
    - 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 clinical best practice for vaccination as well as best practices when managing inventory 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)
            - 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.

Appendix 2

Maryland
DEPARTMENT OF HEALTH

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

August 18, 2021

Dear Colleague:

Today we learned that booster doses of the Pfizer and Moderna mRNA COVID-19 vaccines will be available for all U.S. adults beginning next month. The Maryland Department of Health (MDH) is actively planning for booster vaccine administration and asks that all Maryland healthcare providers also prepare. (Federal release here)

Last Friday, August 13, 2021, CDC's independent Advisory Committee on Immunization Practices (ACIP) recommended that people with moderately to severely compromised immune systems receive an additional dose of mRNA COVID-19 vaccine following their initial 2-dose vaccination series. ACIP's recommendation follows the decision by the U.S. Food and Drug Administration (FDA) on August 12th to amend Pfizer-BioNTech and Moderna's COVID-19 vaccine Emergency Use Authorizations (EUAs) in support of this allowance.

Patients have been advised to talk to their healthcare providers to determine if they need an additional dose and what the timing of that dose should be. Providers should develop their own procedures to determine if patients are eligible. Please see the CDC's website for more information.

People who are recommended for an additional dose include those who have:

- Been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response

A full list of conditions can be found on CDC's website. The use of serologic testing to determine immune response is not recommended at this time. **The additional dose of an mRNA COVID-19 vaccine should be the same vaccine as the initial series and administered at least four weeks after completing a primary mRNA COVID-19**

vaccine series. While vaccination is likely to increase protection in this population, even after vaccination, people who are immunocompromised should continue to follow current prevention measures (including wearing a mask, staying 6 feet apart from others they do not live with, and avoiding crowds and poorly ventilated indoor spaces) to protect themselves and those around them against COVID-19 until advised otherwise by their healthcare provider.

All administered doses of COVID-19 vaccines must be reported to ImmuNet per the CDC Provider Agreement and within 24 hours per the Maryland Department of Health's Amended Vaccination Matters Order (attached). This requirement applies to all additional doses of mRNA vaccines administered to immunocompromised persons.

If you recommend that your patient receive an additional dose of an mRNA vaccine but you are not a COVID-19 vaccine provider, your patient can self-attest and receive the additional dose wherever vaccines are offered. This will help ensure there are no additional barriers to access for this vulnerable population receiving a needed additional dose. As we receive additional updates, MDH will continue to provide information regarding vaccine administration to immunocompromised individuals to local health departments, pharmacies, health centers, and all vaccine providers.

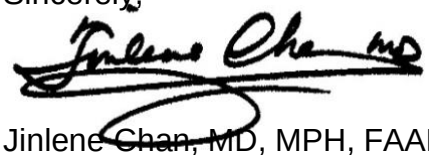
Please be aware that CDC does **not** recommend additional doses for any other population at this time. Additionally, this amendment only applies to mRNA COVID-19 vaccines and **does not apply** to the J&J/Janssen vaccine. Vaccine providers should continue to administer COVID-19 vaccine in accordance with the updated EUAs per the COVID-19 vaccine provider agreement.

Below is a list of resources related to the recommendation:

- Updated Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States
- New web page for consumers
- New web page for healthcare providers
- Updated **Pfizer** EUA Fact Sheet for HCPs
- Updated **Pfizer** EUA Fact Sheet for Vaccine Recipients and Caregivers
- Updated **Moderna** EUA Facts Sheet or HCPs
- Updated **Moderna** EUA Fact Sheet for Vaccine Recipients and Caregivers

Thank you for everything that you have done and are continuing to do to ensure all Marylanders have access to COVID-19 vaccines.

Sincerely,



Jinlene Chan, MD, MPH, FAAP
Deputy Secretary for Public Health Services

MDPCP
MARYLAND PRIMARY CARE PROGRAM

Appendix 3

Maryland
DEPARTMENT OF HEALTH

3rd COVID-19 Vaccine Dose for Immunocompromised Patients:

Guide for Primary Care Practices

BACKGROUND

On August 12, the FDA amended the emergency use authorizations (EUAs) for both the Pfizer and Moderna COVID-19 Vaccine to allow for the use of an additional dose in certain immunocompromised individuals.

CDC followed by recommending a 3rd dose of mRNA vaccine for these individuals with moderate to severe immune compromise.

List of Conditions Considered Moderate to Severe Immunocompromised (from CDC guidance)

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.
- *Others determined by providers' clinical judgement*

KEY POINTS

1. **TIMING:** The 3rd dose should be administered at least 28 days after the 2nd mRNA COVID vaccine dose

2. **USE THE SAME PRODUCT, WHEN POSSIBLE:** People should receive a 3rd dose of the same mRNA product as their first two doses when feasible. If not feasible, a different mRNA product is allowed

3. **NO INDICATIONS CURRENTLY FOR THOSE WHO RECEIVED J&J:** A 3rd dose is currently only recommended for immunocompromised people who received an mRNA vaccine, not those who received the J&J vaccine as their first shot. Further research is being done as to if there is an improved immune response with additional doses for those who received J&J.

4. **CONTINUE TO EMPHASIZE OTHER PREVENTION MEASURES:** Immunocompromised people should continue other prevention measures as well, including masking, distancing, and avoiding crowded indoor spaces. Additionally, close contacts of immunocompromised people should be encouraged to be vaccinated.

5. **NO SCRIPT NEEDED:** Patients do not need a referral from their provider to receive a 3rd dose. Self-attestation of moderate to severe immunocompromise is sufficient.

6. **SEROLOGIC TESTING NOT INDICATED:** The use of serologic testing to determine immune response is not recommended at this time. Providers' clinical judgement of the patient's general level of immune competence is sufficient.

IMPLEMENTATION

Use your EHR to create an eligible patient outreach list

Use your EHR to generate a list of your patients with moderate to severe immune compromise who received 2 mRNA vaccines, and contact these patients to recommend vaccination with a 3rd dose appointment. This list can be generated by including:

- Patients with organ transplant diagnoses and other conditions causing immune incompetence
- Patients currently taking immunosuppressive medications
  - You can use either of these lists as starting points, however note that neither is an exhaustive list

Use the CRISP Vaccine Tracker to Determine Vaccine Type and Dates

Use the CRISP Vaccine Tracker to understand which type of COVID-19 vaccine your patient previously received, and when.

Order additional vaccine in ImmuNet as needed

You may use existing vaccine inventory to administer 3rd doses to patients. If you need additional vaccine doses, you can place an order in ImmuNet.

1. See this ImmuNet Ordering Guide for instructions on how to place a COVID-19 vaccine order in ImmuNet.
   a. *Note: only practices currently registered in ImmuNet as a COVID-19 vaccinator and reporting data to ImmuNet are eligible to order*
   b. Orders can be placed Friday, August 20 from 8am-4pm, or Thursdays beginning August 26
2. Email mdh.covidvax@maryland.gov with any ordering issues

Vaccinate and Bill for Vaccine Administration

Use CPT codes:

- 0003A for the 3rd dose of Pfizer
- 0013A for the 3rd dose of Moderna