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: **September 24, 2021**

- Please review the latest Vaccination Matters Order (09/08/2021) and Nursing Home Matters Order (09/08/2021). 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 past COVID-19 vaccine bulletin, dated September 2, 2021 and earlier bulletins. This bulletin will be updated as needed going forward.**

TABLE OF CONTENTS

Updates & Reminders (09/24/2021) 2

1. Vaccine Eligibility (Updated September 24, 2021) 3
2. Residency and Priority Group Eligibility Determinations 4
3. Vaccine Operations (Updated September 24, 2021) 5
4. CovidVax.Maryland.gov 6
5. Wastage/At-risk Vaccines 6
6. Provider to Provider Transfers (Updated September 24, 2021) 7

Updates & Reminders (09/24/2021)

- **REMINDERS**:
    - **It is important for providers, including retail pharmacies, not to miss any opportunity to vaccinate every eligible person who presents at vaccine clinics.** Please see Sections 1 and 6 for further details.
    - **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 Maryalnders 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.
- **UPDATES:**
    - **On September 23, 2021, the Centers for Disease Control & Prevention (CDC) issued new recommendations for certain individuals who received the Pfizer-BioNTech vaccine, recommending a one booster dose six (6) months after completion of the primary two-dose series. (See Appendix 1).**

      Individuals may self-attest to eligibility. Providers shall not turn away any individual who self-attests to eligibility for a booster or additional dose if immunocompromised. Please see Section 1, Vaccine Eligibility for more information.
    - **Maryland strongly encourages all COVID-19 Vaccine Providers to reach out to previously vaccinated individuals to encourage them to consider their eligibility for a booster (Pfizer) or additional doses of COVID-19 vaccine (Pfizer/Moderna, if immunocompromised).**
    - On Monday, August 23, 2021, the FDA gave full approval for Comirnaty, the brand name for the Pfizer-BioNTech's COVID-19 Vaccine, mRNA, for use as a two-dose series for individuals **16 years of age and olde**r.

      Comirnaty is the official brand name of the Pfizer-BioNTech COVID-19 vaccine that was under FDA Emergency Use Authorization (EUA). Comirnaty may be used under the EUA for individuals aged 12 through 15 years, and for the administration of a third dose in certain immunocompromised individuals (see Section 1. Vaccine Eligibility below).

1. **Vaccine Eligibility (Updated September 24, 2021)**

- All Marylanders 12 and older are 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 (COMIRNATY) 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 (COMIRNATY) COVID-19 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.**

- **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.

  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.

- **Booster Dose (Updated September 24, 2021):**

  All Providers shall offer a booster dose of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer primary series to individuals in light of the following considerations, based on the CDC's September 23, 2021 recommendations:

  - people 65 years and older and residents in long-term care settings,
  - people aged 50–64 years with underlying medical conditions,
  - people aged 18–49 years with underlying medical conditions based on their individual benefits and risks, and

- people aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting based on their individual benefits and risks.

Patients should talk to their healthcare providers to determine individual benefits and risks of receiving a booster dose. For further clinical information, please see Appendix 2.

NOTE: COVID-19 vaccines are not interchangeable. Providers should make every effort to determine which vaccine was received as the first dose to ensure completion of the vaccine series with the same product.

- **Self-Attestation (Updated September 24, 2021):**

  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 to that eligibility. Providers shall follow CDC guidelines 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 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 September 24, 2021)

- 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 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-BioNTech (COMIRNATY):** Per updated 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

  Per the FDA, the shelf life of properly stored (between -90°C to -60°C (-130°F to -76°F)) cartons and vials of the Pfizer-BioNTech (COMIRNATY) COVID-19 vaccine with an expiration date of August 2021 through February 2022 printed on the label may remain in use for three months beyond the printed date as long as authorized storage conditions have been maintained. This does **not apply** to vials dated July 2021 or earlier.

  Note: Frozen vials stored at -25°C to -15°C and refrigerated vials (2°C to 8°C) are **NOT** eligible for extension.

- **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.

- Please check your inventory to confirm expiration dates. Once expired, please report the doses expired on this form 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 wesley.huntemann@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 2, 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 (amended 09/08/2021) 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-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 (Updated September 24, 2021)

- Providers can contact mdh.covidvax@maryland.gov 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 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 Media Statement on ACIP Booster Recommendations (as of September 23, 2021)

Media Statement

For Immediate Release
Thursday, September 23, 2021

Contact: CDC Media Relations
(404) 639-3286

CDC Statement on ACIP Booster Recommendations

Today, CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendation for a booster shot of the Pfizer-BioNTech COVID-19 vaccine in certain populations and also recommended a booster dose for those in high risk occupational and institutional settings. The Food and Drug Administration's (FDA) authorization and CDC's guidance for use are important steps forward as we work to stay ahead of the virus and keep Americans safe.

This updated interim guidance from CDC allows for millions of Americans who are at highest risk for COVID-19 to receive a Pfizer-BioNTech COVID-19 booster shot to help increase their protection.

CDC recommends:

- people 65 years and older and residents in long-term care settings **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- people aged 50–64 years with underlying medical conditions **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- people aged 18–49 years with underlying medical conditions **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks, and
- people aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.

Many of the people who are now eligible to receive a booster shot received their initial vaccine early in the vaccination program and will benefit from additional protection. With the Delta variant's dominance as the circulating strain and cases of COVID-19 increasing significantly across the United States, a booster shot will help strengthen protection against severe disease in those populations who are at high-risk for exposure to COVID-19 or the complications from severe disease.

CDC will continue to monitor the safety and effectiveness of COVID-19 vaccines to ensure appropriate recommendations to keep all Americans safe. We will also evaluate with similar urgency available data in the coming weeks to swiftly make additional recommendations for other populations or people who got the Moderna or Johnson & Johnson vaccines.

The following is attributable to Dr. Walensky:

As CDC Director, it is my job to recognize where our actions can have the greatest impact. At CDC, we are tasked with analyzing complex, often imperfect data to make concrete recommendations that optimize

health. In a pandemic, even with uncertainty, we must take actions that we anticipate will do the greatest good.

I believe we can best serve the nation's public health needs by providing booster doses for the elderly, those in long-term care facilities, people with underlying medical conditions, and for adults at high risk of disease from occupational and institutional exposures to COVID-19. This aligns with the FDA's booster authorization and makes these groups eligible for a booster shot. Today, ACIP only reviewed data for the Pfizer-BioNTech vaccine. We will address, with the same sense of urgency, recommendations for the Moderna and J&J vaccines as soon as those data are available.

While today's action was an initial step related to booster shots, it will not distract from our most important focus of primary vaccination in the United States and around the world. I want to thank ACIP for their thoughtful discussion and scientific deliberation on the current data which informed my recommendation.

###

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CDC works 24/7 protecting America's health, safety and security. Whether disease start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC responds to America's most pressing health threats. CDC is headquartered in Atlanta and has experts located throughout the United States and the world.

Appendix 2: 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-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.