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 25, 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 past COVID-19 vaccine bulletin, dated August 18, 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.

- **Vaccine Updates:**

  - On Monday, August 23, 2021, the Food and Drug Administration (FDA) gave full approval for Comirnaty, 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 still be used under the EUA to prevent COVID-19 in individuals aged 12 through 15 years, and for the administration of a third dose in certain immunocompromised individuals (see Section 1. Vaccine Eligibility below).

    With this announcement, the Maryland Department of Health (MDH) encourages providers to reach out to any remaining unvaccinated patients, address any lingering hesitancy issues, and recommend vaccination. For more information, please see the attached Clinician's Letter, dated August 24, 2021.

  - 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 Comirnaty (manufactured by Pfizer-BioNTech) 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.

- **Provider Updates:**

  - Booster doses of the Comirnaty COVID-19 vaccines will be available for all U.S. adults beginning next month. MDH is actively planning for booster vaccine administration and asks that all Maryland healthcare providers also prepare. (Federal release here)

1. **Vaccine Eligibility (Updated August 25, 2021)**

- 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 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 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.**

- **Booster/Supplemental Shots:**

  All Providers should offer additional shots of COVID-19 vaccine (Comirnaty/Moderna) to individuals in light of the following considerations:

  The CDC approved the FDA amendment of the emergency use authorizations for the Comirnaty 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.

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

- 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

- **Comirnaty:** Per updated federal guidance, all vials of 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 Comirnaty 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°F to 46°F) 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 <u>shall</u>**, 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 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.

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 (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.

Maryland
DEPARTMENT OF HEALTH
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

August 25, 2021

Dear Colleague:

On Monday, August 23, 2021, the Food and Drug Administration (FDA) approved Comirnaty (COVID-19 Vaccine, mRNA) for use as a two-dose series for individuals 16 years of age and older. Comirnaty has been known as the Pfizer-BioNTech COVID-19 vaccine that was available for use under FDA Emergency Use Authorization (EUA). This vaccine may still be used under the EUA to prevent COVID-19 in individuals aged 12 through 15 years, and for the administration of a third dose in certain immunocompromised individuals.

Comirnaty (the fully approved vaccine) and the Pfizer-BioNTech COVID-19 Vaccine (under EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or efficacy concerns. Therefore, providers can use doses distributed under the EUA to administer the vaccination series for those seeking the approved vaccine. The Fact Sheet for health care providers administering provides additional information about both the approved and authorized vaccine. Providers should continue to use the vaccines on their shelves.

Providers are responsible for adhering to all requirements outlined in the CDC COVID-19 Vaccination Program Provider Agreement. The Centers for Disease Control & Prevention (CDC) has notified Maryland that providers must administer COVID-19 vaccines in accordance with all program requirements and recommendations of the CDC, the Advisory Committee on Immunization Practices, and the FDA. This applies to both EUA and FDA approved COVID-19 vaccines. Accordingly, “off-label use” (including administration to children under 12 years old) of these products is not recommended. Off-label use would violate the provider agreement and could expose providers to the following risks:

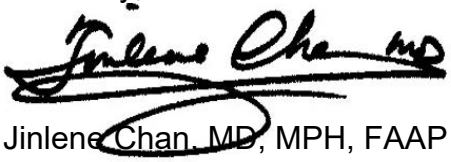
- Administration of the product off-label may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
- Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how the USG-provided vaccines may be used in the program. Providers giving off-label doses would be in violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program.

- Administration fees may not be reimbursable by payers.

Based on CDC Vaccine Confidence data, approximately 10% of the unvaccinated Maryland population reports that they probably will get vaccinated or are unsure. With the full licensure of the Pfizer vaccine, confidence in the vaccine may rise and cause an increase in demand for the vaccine. We encourage you to reach out to your unvaccinated patients, address any lingering hesitancy issues, and recommend vaccination.

The Advisory Committee on Immunization Practices will be meeting on August 30 to discuss their recommendations for the use of Comirnaty. We will keep you informed of any changes in recommendations.

Sincerely,



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Deputy Secretary for Public Health Services