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To: Maine Immunization Program Providers
From: Maine Immunization Program
Subject: COVID commercialization
Date: September 11, 2023

PRE-ORDER SHIPMENTS

Thank you for placing pre-book orders. These will continue to be filled over the next couple weeks as vaccine becomes available for distribution. Once pre-orders are filled and additional allocations are received, we will open for routine ordering.

FDA ANNOUNCEMENT

Today, the U.S. Food and Drug Administration (FDA) [authorized and approved](#) updated COVID vaccines. The updated vaccines made by Pfizer-BioNTech and Moderna, were formulated to target variants that are currently circulating, and include a monovalent (single) component that corresponds to the Omicron variant XBB.1.5. Additionally, the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices will meet tomorrow (Sept. 12), to discuss clinical recommendations on who should receive an updated vaccine, as well as further considerations for specific populations such as immunocompromised and older individuals. Updated recommended schedules and clinical considerations will be available following the ACIP meeting.

PROVIDER INVENTORY

- **VFC PROVIDERS**

VFC Providers will need to update their COVID-19 inventory in ImmPact, complete with reconciliation by Friday, September 15 to show that the provider site has wasted out their remaining doses of bivalent COVID-19 vaccine. MIP staff will begin the process of zeroing out bivalent COVID-19 inventory. The newly authorized COVID-19 vaccine will be added to your order set and available for regular ordering as allocations from Federal CDC become available.

- **COVID-19 ONLY PANDEMIC PROVIDERS**

Pandemic providers will be completely disenrolled from the Maine Immunization Program upon the Federal Drug Administration (FDA) authorization of commercial COVID-19 vaccine (anticipated September 11, 2023). If providers wish to continue administering COVID-19 vaccine through our program, please reach out to the following email: MEAdultVaccine@maine.gov to assess your continued eligibility to participate.

BRIDGE ACCESS PROGRAM

Providers wishing to become enrolled with the Bridge Access Program will need to update their COVID-19 inventory in ImmPact, complete with reconciliation by Friday, September 15 to show that the provider site has wasted out their remaining doses of bivalent COVID-19 vaccine. MIP staff will begin the process of zeroing out bivalent COVID-19 inventory. MIP staff will order Bridge Access Program vaccine on provider's behalf throughout the entirety of the Bridge Access Program (expected end date: December 31, 2024). Please email: MEAdultVaccine@maine.gov to request the newly authorized COVID-19 vaccine. All Bridge Access Program documentation must be completed prior to orders being placed. Information on enrollment and vaccine administration reimbursement will be sent out to all providers who have expressed interest, in the coming days.

DISPOSAL OF BIVALENT COVID-19 VACCINE

Upon the FDA authorization of the updated COVID-19 vaccines, the bivalent COVID-19 vaccine will no longer be recommended for use. **Bivalent COVID-19 vaccine must be disposed of IMMEDIATELY following FDA authorization.**

Any vaccine that is no longer recommended by the FDA should be disposed of as regulated medical waste. Providers are required to report wastage, including doses disposed of due to expiration. The bivalent COVID-19 vaccine will not count towards your provider site's preventable wastage.

Moving forward, post authorization of the new monovalent COVID-19 formulation, vaccine should NOT be disposed of. It is anticipated that all newly authorized COVID-19 vaccines will be returned to the third-party distributor (McKesson). Staff must not discard MIP-supplied vaccine unless specifically directed by MIP. In the event of a cold chain failure, staff are immediately required to contact the vaccine manufacturer(s) to determine vaccine viability.

Vaccine loss must be documented in ImmPact no later than five days past the date of the incident(s). All vaccine returns to McKesson must occur within six months of the loss.

Should you have any questions, please contact the Maine Immunization Program at (207) 287-3746 or email: ImmunizeME.DHHS@maine.gov.