Maine Immunization Program
COVID-19 Commercialization Weekly Update – 9/1/2023

Commercialization is the transition of COVID-19 medical countermeasures—vaccines, treatments, and test kits—previously purchased by the U.S. Government (USG) to established pathways of procurement, distribution, and payment by both public and private payers. This guide summarizes the HHS Commercialization Transition Guide, HHS Bridge Access Program Fact Sheet, and Maine Immunization Program guidance as the USG prepares to stop distributing COVID-19 vaccines and vaccines transition to the commercial market. Updated topics highlighted below, are all subject to change. Sections include:

- Fall Transition Timeline
- Sunsetting of the Federal COVID-19 Vaccination Program
- Commercialization of COVID-19 Vaccines
- Anticipated Vaccination Schedule for the Fall

Topic	Guidance	Effective Date
Section 1	**Fall Transition Timeline**	
NEW UPDATES 9/1/2023	**September 7 or 8** • First allocations provided, pre-ordering for updated COVID-19 vaccines begins (pre-orders will not be fulfilled until day 3) **Day 0 (TBD, estimated to be week of Sept. 11)** • Updated COVID-19 vaccines are approved/authorized by FDA. • Once new EUA is released, COVID-19 Provider Agreements will no longer be valid. • Sites without a Maine Immunization Program Provider Agreement will be disenrolled. **Day 1** • ACIP out-of-cycle meeting occurs. **Day 2** • Pre-ordering process ends; ordering process begins. • Vaccine pre-orders begin to ship out. • CDC vaccine price list updated to reflect COVID-19 contracts. **Day 3** • Vaccine pre-orders begin to be delivered.	

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Section 1	**Fall Transition Timeline**	
Updated 8/25/23	**Week of July 31, 2023** • CDC set vaccine thresholds to -0- in anticipation of decreased vaccine demand. • Providers were encouraged to place necessary orders to maintain their COVID-19 inventory while current vaccines are still authorized. **August 3 – mid Sept.** • States begin to plan for the closeout of USG COVID-19 Program and transition to VFC program, implementation of the Bridge Access Program, and the availability of the new COVID-19 formulation. **TBD (expected mid Sept.)** • FDA decisions and amendments to Emergency Use Authorization (EUAs)/Biologics License Applications (BLAs). Approve new products, and de-authorize current products. • Concurrently, USG will discontinue distribution of current COVID-19 vaccine composition • ACIP discussion on COVID-19 and CDC recommendation • Maine Immunization Program works on VFC enrollment of COVID-19 providers **TBD (expected mid Sept.)** • Fall vaccine availability for administration begins for VFC and Bridge Access Program • Providers will dispose of any remaining supply of de-authorized COVID-19 vaccines	

Topic	Guidance	Effective Date
Section 2	**Sunsetting of the Federal COVID-19 Vaccination Program**	**TBD**
Ordering	**Post Sunset of the Federal COVID-19 Vaccination Program** Plan to transition to traditional pathways for ordering and distribution of COVID-19 vaccines. ***Vaccine:*** Providers should begin planning to incorporate COVID-19 vaccine into their ordering with standard vaccine supply procurement processes for the practice or organization. ***Ancillary Kits:*** Kits are not provided as part of routine vaccine ordering. Therefore, any COVID-19 vaccine ordered privately or through publicly funded COVID-19 vaccine programs (Vaccines for Children Program and Bridge Access Program) will NOT ship with ancillary kits. Providers should look at ancillary supplies and consider needs post-commercialization to ensure they have adequate supply of ancillary supplies budgeted and planned to purchase.	
Billing	Providers should continue planning to transition COVID-19 vaccine billing to traditional pathways for payment of COVID-19 vaccine administration. Planning includes making sure billing practices and systems are updated. COVID-19 vaccine will be provided to VFC enrolled providers at no cost, along with all other pediatric routine vaccinations. VFC providers may not bill for the cost of the vaccine. It is allowable to bill a reasonable administration fee, provided that no patient is denied state supplied vaccine for inability to pay. If the patient is VFC eligible you may not bill for more than $21.58 for the administration fee.	
Program Requirements	Any COVID-19 Vaccination Program Provider who plans to continue administering COVID-19 vaccinations MUST complete the Maine Immunization Program Provider Agreement. To inquire about enrollment, providers should contact the Maine Immunization Program at: ImmunizeME.DHHS@maine.gov. VFC enrolled providers will be required to offer all routine ACIP recommended vaccines, in addition to the COVID-19 vaccine. Until commercialization occurs and the USG announces the end of the COVID-19 Vaccination Program, COVID-19 Vaccination Program providers must continue to comply with all program requirements outlined in the Provider Agreement to ensure patients seeking vaccination during this transition period can receive vaccine without barriers, to the greatest extent possible, with vaccine provided by the federal government. What does this mean for Providers? • Providers should adhere to the COVID-19 Vaccination Provider Agreement, particularly as it pertains to patient access. • Providers should continue to offer COVID-19 vaccines during this transitional time. • Providers maintain a COVID-19 vaccine supply. • Patients should **NOT** be denied based on insurance coverage status or provider network status. • Patients should **NOT** be charged for an office visit or any other fee if the only service provided is COVID-19 vaccination.	

Topic	Guidance	Effective Date
	***Reporting Doses Administered**:* Continue to document vaccine administration into ImmPact within 24 hours of administration and report doses administered as soon as practicable and no later than 72 hours.	
	Reporting & Disposal of Nonviable Vaccine: Continue to report all nonviable doses in ImmPact; dispose of all vaccines following practice protocols. Providers should maintain their inventories of EUA and/or BLA vaccines until vaccine exceeds its shelf life or the FDA announces a change to EUAs and/or BLAs, whichever occurs first.	
	Vaccine Replacement Procedure: When commercialization occurs, any preventable wastage of COVID-19 vaccine over the allowable 5% threshold, will be subject to the Vaccine Replacement Procedure.	Fall 2023
Section 3	**Commercialization of COVID-19 Vaccines**	
COVID-19 Agreements	CDC's COVID-19 Provider Agreement and all related reporting requirements will no longer be valid.	Fall 2023
	Reporting Doses Administered: Providers are required to report doses administered as required in Maine Immunization Program's Provider Agreement. All MIP-supplied doses must be entered into the client record within five days of administration.	
Access and Eligibility	***Pediatric Populations:*** Vaccines will be made available through the Vaccines for Children (VFC) Program for all children from birth through 18 years of age.	Fall 2023
	Adult Populations: Because a national Vaccines for Adults (VFA) Program, modeled after the childhood VFC Program, has not been enacted into law as a permanent solution, **limited** supply of COVID-19 vaccine will be made available through the HHS Bridge Access Program (BAP)—only to public health departments, FQHCs, and Indian Health Service providers—serving uninsured adults (19 years and older) to prevent loss of access. Vaccines for privately insured adults will be purchased following established mechanisms for non-COVID-19 vaccines.	Fall 2023 – December 2024

	Select provider sites will have access to COVID-19 vaccines for adults 19+ without insurance (uninsured individuals) coverage once COVID- 19 vaccines become commercially available. This will bring to a closure the previously enacted federal pandemic COVID-19 vaccine program. Moving forward, the Bridge Access Program doses provided through publicly funded COVID-19 programs will only be for eligible adults (uninsured individuals). Adult populations with insurance coverage will no longer be eligible to receive monovalent COVID-19 vaccines authorized this fall. It is important that clinics assess patient populations served to ensure adequate vaccine supply is available and patients continue to access COVID-19 vaccines. Screening and documentation must occur with each vaccine administration.	Fall 2023

Topic	Guidance	Effective Date
	The HHS Bridge Access Program for COVID-19 Vaccines and Treatments will create a unique public-private partnership that will help maintain access to COVID-19 care for uninsured/under-insured adults. The program has two major components: • Public Health Component: Distribution of vaccines to FQHCs, IHS, Public Health Departments, and HRSA-supported health centers using Section 317 funding; HRSA will also provide support directly to its networks of health centers to support delivery of both vaccines and treatments. • Pharmacy Component: This will be a new, CDC-funded partnership with select pharmacy chains that will enable pharmacies to continue offering free COVID-19 vaccinations and treatments to uninsured and under-insured adults through their network or retail locations as has been done during the COVID-19 Public Health Emergency.	

Topic	Guidance	Effective Date
Products & Formulations		

Manufacturer	Age Indication	CDC Description	Storage
Moderna	Two presentations: • 6M – 11Y • 12Y+	Single dose vials 10-pk.	- Shipped as frozen products - Storage and handling will be the same as previous Moderna presentations
Novavax	• 12Y+	5-dose Multi-dose vials 2-pk.	- Shipped as refrigerated product - Storage and handling will be the same as original Novavax
Pfizer	Three presentations: • 6M – 4Y (requires diluent)	3-dose vials, yellow cap 3 x 0.3mL doses (after 1.1mL saline dilution)	- Ships at ultra-low temperatures but expect a shift for commercial Comirnaty: wholesalers may ship it at 2° to 8° C for both vials and prefilled syringes - Storage and handling will be the same as bivalent Pfizer
	• 5-11Y (no diluent)	single-dose vials, blue cap 0.3 mL dose	
	• 12Y+ (no diluent)	single-dose vials, gray cap 0.3 mL dose	

Topic	Guidance	Effective Date
Section 4	**Anticipated Vaccination Schedule for the Fall**	
	Detail on the current recommended vaccine schedules for each age group can be found on the CDC website. An updated recommendation for all age groups is expected in mid to late September after anticipated FDA regulatory authorizations or approvals of an updated COVID-19 vaccine composition. We anticipate that providers will be able to order and receive updated COVID-19 vaccines shortly thereafter.	Mid to late September

Resources:

- Commercialization Transition Guide (HHS)
- Fact Sheet: Bridge Access Program for COVID-19 Vaccines and Treatments (HHS)
- COVID-19 Commercialization (HHS)
- Bridge Access Program (CDC)

Please contact the Maine Immunization Program at (207) 287-3746 or email ImmunizeME.DHHS@maine.gov with any questions.

Post Sunset of the Federal COVID-19 Vaccination Program: Vaccine ordering will follow more traditional pathways for purchasing vaccines