Maine Immunization Program
COVID-19 Commercialization Weekly Update 10/6/2023

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**	

Updated 10/6/2023	**Novavax now authorized by FDA**
	• October 3rd, the Food and Drug Administration (FDA) announced that it had authorized Novavax's updated COVID-19 vaccine. This authorization now adds a third option for individuals 12 years and older for the newly updated COVID-19 shot this fall and winter.
	• Novavax's updated shot has been redesigned to target the XBB strains of the virus, similar to Moderna and Pfizer's, however, Novavax is a non-mRNA vaccine.
	
	Disposal and Reporting
	• All previous stocks of Novavax vaccine will need to be removed from storage units immediately, even if they are not expired.
	  ○ Once all doses are accounted for, they will need to be deleted from inventory in ImmPact.
	  ○ Dispose **all unauthorized Novavax vaccine** into medical waste.
	  ○ Report all disposed inventory as wastage.
	• The newly updated Novavax COVID-19 vaccine is not yet available to order, but a notification will be sent to providers when the new formulation is available for ordering.
	• Novavax will host Office Hours to assist in educating providers on Novavax and data surrounding the new fall strain. Please join this Friday, October 6 at 2:00 EST and use the following link to register: https://novav.ax/officehours.	

Topic	Guidance	Effective Date
Section 1	**Fall Transition Timeline**	
Updated 9/29/23	**VFC COVID-19 vaccine distribution** • **Routine COVID-19 ordering is now open through ImmPact for enrolled Vaccines for Children (VFC) provider.** • **COVID-19 and routine vaccine orders should be placed separately.** • **Possibility for delays in vaccine shipments.** • **Vaccine orders will be shipped when vaccine is available at the depot. We will continue to fill orders as more vaccine becomes available.** **Bridge Access Program (BAP) Updates** • **BAP providers may not charge an administration fee to patients receiving BAP COVID-19 vaccine if they are receiving reimbursement for administration through Maine's BAP.** • **Providers receiving BAP vaccine may not transfer vaccine to another facility that is NOT an enrolled BAP provider.** • **BAP FAQs** • **Check vaccines.gov for list of participating provider sites** **Updated Reference Materials** • Updated Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States • Interim 2023-2024 COVID-19 Immunization Schedule for Persons 6 Months of Age and Older • COVID-19 Vaccination Recommendations Infographic • COVID-19 Vaccination Recommendations Infographic (Immunocompromised) • COVID-19 Vaccine Product Information	

<table>
<tr><th>Topic</th><th>Guidance</th><th>Effective Date</th></tr>
<tr><td>Section 1</td><td>Fall Transition Timeline</td><td></td></tr>
<tr><td>Updated 9/15/2023</td><td>

Early this week, FDA and ACIP authorized the newly updated COVID-19 vaccine.

Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula): individuals ages 6 months and older
Moderna COVID-19 Vaccine (2023-2024 Formula): individuals ages 6 months and older
Note that FDA has not yet authorized or approved an updated Novavax vaccine for 2023-2024. As a result, the existing Novavax vaccine may still be administered at this time if it is determined that the individual should not wait for a 2023-2024 Novavax COVID-19 vaccine.

Bivalent mRNA COVID-19 Vaccines Are No Longer Authorized

Remove all bivalent mRNA COVID-19 vaccines from storage units immediately, even if they are not expired.
MIP staff have deleted all bivalent mRNA COVID-19 vaccine listings from the available vaccine inventory from your site in ImmPact.

<table>
<tr><th></th><th></th><th></th></tr>
<tr><td>ModernaTX Inc.</td><td>12y+; SDV; 10pk</td><td>80777-0102-95</td></tr>
<tr><td>Pfizer Inc.</td><td>12y+; SDV; 10pk</td><td>00069-2362-10</td></tr>
<tr><td>Pfizer Inc.</td><td>Peds 5y-11y; SDV; 10pk</td><td>59267-4331-02</td></tr>
<tr><td>Pfizer Inc.</td><td>Peds 6m-4y; MDV3; 10pk</td><td>59267-4315-02</td></tr>
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- **Novavax vaccine is still under review by the FDA**
  - Providers can continue to administer this vaccine at this time if it is determined that the individual should not wait for a 2023-2024 Novavax COVID-19 vaccine.
- **Pre-ordering is ongoing**
  - Preorders for the presentations below 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.

Manufacturer	Presentation	Unit of Sale NDC
ModernaTX Inc.	12y+; SDV; 10pk	80777-0102-95
Pfizer Inc.	12y+; SDV; 10pk	00069-2362-10
Pfizer Inc.	Peds 5y-11y; SDV; 10pk	59267-4331-02
Pfizer Inc.	Peds 6m-4y; MDV3; 10pk	59267-4315-02

  - Preorders for Moderna's pediatric presentation for children 6m-11y will also be filled.

- Updated recommended schedules and clinical considerations are expected to be available in the coming days.
- **Bridge Access Program**
  - Enrollment into the Bridge Access Program has begun for select provider sites
  - Due to the limited quantities of COVID-19 vaccination available through Maine's Bridge Access Program and the overwhelming response from our providers, at this time we are only able to accommodate enrollments from **FQHCs, IHS, and Public Health Departments.**
  - We will be reassessing the available doses at the beginning of the new year and will reach out if we are able to enroll your site at that time. The Bridge Access Program is a temporary program and will only continue through December 31, 2024.
  - For more information on commercialization and the Bridge Access Program please see the **COMMERICALIZATION OF COVID-19 VACCINE FAQs** document.

Topic	Guidance	Effective Date
Section 1	Fall Transition Timeline	
Updated 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.	

Topic	Guidance	Effective Date
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.** • **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.	
Accessand 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.	

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<tr><td>Products & Formulations</td><td>
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<tr><th>Manufacturer</th><th>Age Indication</th><th>CDC Description</th><th>Storage</th></tr>
<tr><td>Moderna</td><td>Two presentations:
• 6M – 11Y
• 12Y+</td><td>Single dose vials
10-pk.</td><td>- Shipped as frozen products

- Storage and handling will be the same as previous Moderna presentations</td></tr>
<tr><td>Novavax</td><td>• 12Y+</td><td>5-dose
Multi-dose vials
2-pk.</td><td>- Shipped as refrigerated product
- Storage and handling will be the same as original Novavax</td></tr>
<tr><td rowspan="3">Pfizer</td><td>Three presentations:
• 6M – 4Y (requires diluent)</td><td>3-dose vials, yellow cap
3 x 0.3mL doses
(after 1.1mL saline dilution)</td><td rowspan="3">- 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</td></tr>
<tr><td>• 5-11Y (no diluent)</td><td>single-dose vials, blue cap
0.3 mL dose</td></tr>
<tr><td>• 12Y+ (no diluent)</td><td>single-dose vials, gray cap
0.3 mL dose</td></tr>
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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