

# Commercialization at a Glance: Provider Transition Guide



## California COVID-19 Vaccination Program

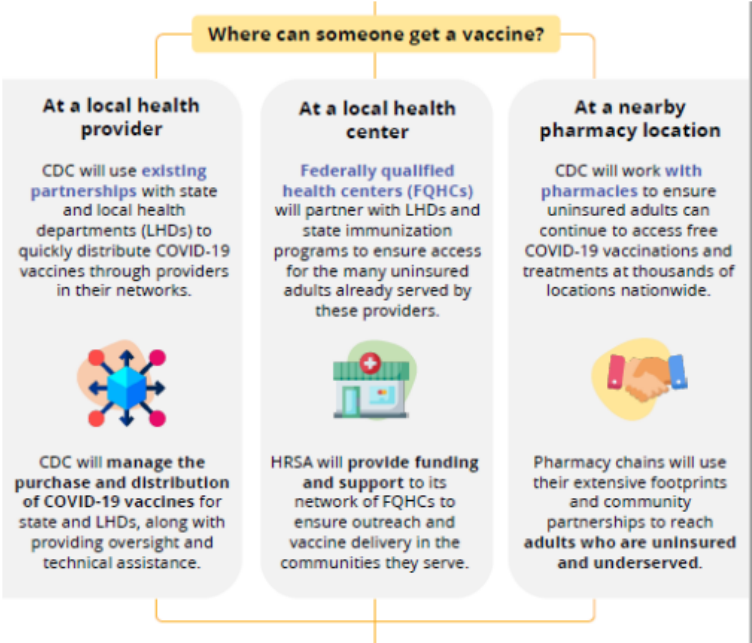
Commercialization is the transition of COVID-19 medical countermeasures—vaccines, treatments, and test kits—previously purchased by the U.S. Government (USG) to established pathways of procurement, distribution, and payment by both public and private payers. This guide summarizes the [HHS Commercialization Transition Guide](#), [HHS Bridge Access Program Fact Sheet](#), and CDPH guidance as the USG prepares to stop distributing COVID-19 vaccines and vaccines transition to the commercial market. Updated topics highlighted below. 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	
	<p data-bbox="506 932 695 954"><b>Week of July 31, 2023</b></p> <ul data-bbox="800 906 1730 1013" style="list-style-type: none"> <li>• CDC set vaccine thresholds to -0- in anticipation of decreased vaccine demand</li> <li>• Providers were asked to order a 2-month vaccine supply to last until new products are approved by FDA</li> <li>• Vaccine doses can still be ordered by States, but the processes, timing, and cadence for ordering processing will change. Based on doses ordered, we ask CDC for allocations, wait 1-3 days for doses, then transmit orders to CDC.</li> </ul> <p data-bbox="459 1094 695 1117"><b>August 3-Early September</b></p> <ul data-bbox="800 1036 1730 1182" style="list-style-type: none"> <li>• Providers may still submit additional Small Orders if needed. But these are NOT sent to CDC. These are fulfilled locally/TPR.</li> <li>• Larger orders are now only available to LHDs/MCEs.</li> <li>• ALL healthcare providers are advised to begin planning, prebooking or procuring COVID-19 vaccine doses for privately insured individuals.</li> <li>• States begin to plan closeout of USG COVID-19 Program, and implementation of much smaller Bridge Access Program, and addition of COVID-19 vaccines to VFC Programs.</li> </ul> <p data-bbox="449 1263 695 1305"><b>TBD (expected early to mid-September)</b></p> <ul data-bbox="800 1208 1730 1354" style="list-style-type: none"> <li>• FDA decisions and amendments to Emergency Use Authorizations (EUAs) / Biologics License Applications (BLAs). Approve new products, and de-authorized current products.</li> <li>• Concurrently, USG WILL discontinue distribution of current COVID-19 vaccine composition.</li> <li>• Advisory Committee on Immunization Practices (ACIP) discussion on COVID-19 epidemiology and vaccine effectiveness and CDC recommendation.</li> <li>• CDPH and LHDs work on BAP provider enrollment, and prepare for COVID-19 ordering for BAP Provider and VFC Providers</li> </ul> <p data-bbox="407 1386 695 1451"><b>TBD (ACIP Recommendation + 2 weeks=Late September/Early October)</b></p> <ul data-bbox="800 1393 1730 1468" style="list-style-type: none"> <li>• Fall vaccine availability for administration begins across all eligible age groups, with corresponding vaccine supply based on insurance coverage, and eligibility (for providers participating in VFC or CA's Bridge Access Program)</li> <li>• Providers will dispose of any remaining supply of de-authorized COVID-19 vaccines</li> </ul>	

Topic	Guidance	Effective Date
Section 2	<b>Sunset of the Federal COVID-19 Vaccination Program</b>	TBD
<b>Ordering</b>	<p>Providers should maintain vaccine supply and ancillary kits to continue administration of vaccinations—until the sunset of the federal COVID-19 Vaccination Program—to anyone who is eligible and seeking vaccination.</p> <p>Standard Routine order review and approval in myCAvax for current bivalent COVID-19 formulations will close <b>Wednesday, August 2, 2023</b>. Therefore, providers should plan to order <b>by Monday July 31, 2023</b>, about a 2-month supply of product to last until the new formulation is available this fall. After this date, there will be the opportunity to submit additional Small Orders to be filled locally or by the TPR if needed (process, including frequency of order submission, is yet to be determined). Ancillary supplies for these small vaccine orders will continue to be provided.</p> <p style="text-align: center;"><b>Post Sunset of the Federal COVID-19 Vaccination Program</b></p> <p>Plan to transition to traditional pathways for ordering and distribution of COVID-19 vaccines.</p> <p><b>Vaccine:</b> Providers should begin planning to incorporate COVID-19 vaccine ordering with standard vaccine supply procurement processes for the practice or organization. Planning includes assessing patient population by insurance coverage type, age, and COVID-19 vaccination status to determine how much vaccine supply they will need.</p> <p><b>Ancillary Kits:</b> 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 vaccine. 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.</p>	8/2/2023
<b>Billing</b>	Providers should begin planning to transition COVID-19 vaccine billing to traditional pathways for payment of COVID-19 vaccines. Planning includes making sure billing practices and systems are updated.	
<b>Program Requirements</b>	<p>COVID-19 Vaccination Program providers must continue to comply with all program requirements outlined in the <a href="#">Provider Agreement</a> until the USG announces the end of the COVID-19 Vaccination Program 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?</p> <ul style="list-style-type: none"> <li>• Providers should adhere to the <a href="#">COVID-19 Vaccination Provider Agreement</a>, particularly as it pertains to patient access.</li> <li>• Providers should continue to offer COVID-19 vaccines during this transitional time.</li> <li>• Providers maintain a COVID-19 vaccine supply.</li> <li>• Patients should <b>NOT</b> be denied based on insurance coverage status or provider network status.</li> <li>• Patients should <b>NOT</b> be charged for an office visit or any other fee if the only service provided is COVID-19 vaccination.</li> </ul>	

Topic	Guidance	Effective Date
	<b>Reporting Doses Administered:</b> Continue to document vaccine administration in your medical record systems within 24 hours of administration and report doses administered to CAIR as soon as practicable and no later than 72 hours.	
	<b>Reporting Inventory to VF:</b> Continue to report inventory to VaccineFinder at least monthly by the second Wednesday of each month. (After the transition, providers will only be encouraged to report inventory to VaccineFinder as the public will continue to be directed to <a href="https://www.vaccines.gov">Vaccines.gov</a> to find COVID-19 providers.)	
	<b>Reporting &amp; Disposal of Nonviable Vaccine:</b> Continue to report all nonviable doses in myCAVax; 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.	
<b>Section 3</b>	<b>Commercialization of COVID-19 Vaccines</b>	
<b>COVID-19 Agreements</b>	CDC’s <a href="#">COVID-19 Provider Agreement</a> and <a href="#">COVID-19 Vaccine Redistribution Agreement</a> and all related reporting requirements will no longer be valid or in force.	Fall 2023
	<b>Reporting Doses Administered:</b> By <a href="#">California law</a> , providers are required to report doses administered and race/ethnicity using My Turn or their EHR connected to CAIR (CAIR2 or RIDE). Document vaccine administration in your medical record systems within 24 hours of administration and report doses administered to CAIR as soon as practicable and no later than 72 hours.	
<b>Access and Eligibility</b>	CDC will provide access to COVID-19 vaccines for individuals without insurance (uninsured individuals) coverage once COVID-19 vaccines become commercially available.  Unlike the federal COVID-19 Vaccination Program, doses provided through publicly funded COVID-19 programs will only be for eligible individuals. Pediatric and 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 for and patients continue to access COVID-19 vaccines. Screening and documentation must occur with each vaccine administration.	Fall 2023
	<b>Pediatric Populations:</b> Vaccines will be made available through the Vaccines for Children (VFC) Program for eligible children from birth through 18 years of age. Vaccines for privately insured patients will be purchased following established mechanisms for non-COVID-19 vaccines.	Fall 2023
	<b>Adult Populations:</b> Because a national Vaccines for Adults (VFA) Program, modeled after the childhood VFC Program, has not been enacted into law as a permanent solution, <b>limited</b> supply of COVID-19 vaccine will be made available through the HHS Bridge Access Program (BAP)—only to providers serving uninsured/underinsured adults through public health departments,	Fall 2023 – December 2024

Topic	Guidance	Effective Date
	<p>Federally Qualified Health Centers (FQHCs)/Rural Health Centers, tribal clinics, Indian Health Services sites, and additional providers deemed eligible by LHDs. Vaccines for privately insured adults will be purchased following established mechanisms for non-COVID-19 vaccines. (See <a href="#">BAP Requirements at a Glance</a> for details.)</p>	
	 <p><b>Where can someone get a vaccine?</b></p> <ul style="list-style-type: none"> <li><b>At a local health provider</b>            CDC will use existing partnerships with state and local health departments (LHDs) to quickly distribute COVID-19 vaccines through providers in their networks.            CDC will manage the purchase and distribution of COVID-19 vaccines for state and LHDs, along with providing oversight and technical assistance.         </li> <li><b>At a local health center</b>            Federally qualified health centers (FQHCs) will partner with LHDs and state immunization programs to ensure access for the many uninsured adults already served by these providers.            HRSA will provide funding and support to its network of FQHCs to ensure outreach and vaccine delivery in the communities they serve.         </li> <li><b>At a nearby pharmacy location</b>            CDC will work with pharmacies to ensure uninsured adults can continue to access free COVID-19 vaccinations and treatments at thousands of locations nationwide.            Pharmacy chains will use their extensive footprints and community partnerships to reach adults who are uninsured and underserved.         </li> </ul>	
<p><b>Products &amp; Formulations</b></p>	<p>COVID-19 vaccines are now considered routine vaccines and follow <a href="#">ACIP's Recommended Adult Immunization Schedule</a> for administration. The following are anticipated presentations for commercial COVID-19 vaccines.</p> <p><b>Commercialized Moderna (Spikevax)</b></p> <ul style="list-style-type: none"> <li>Presentations:             <ul style="list-style-type: none"> <li>Ages 12+ (single-dose vials 0.5 mL injection volume; prefilled syringes 0.5 mL injection volume)</li> <li>Ages 6month-11years (single-dose vials 0.25 mL injection volume)</li> </ul> </li> <li>Minimum Order: 10 doses (Note: May be larger if purchasing through a wholesaler. One wholesaler told us their minimum order will be likely 60 doses.)</li> <li>Storage (vials and prefilled syringes): Long-term frozen storage (9 to 12 months from date of manufacture); refrigerated storage for up to 30 days; normal room temperature for up to 24 hours</li> <li>Offering returns: Yes</li> </ul>	

Topic	Guidance	Effective Date
	<p><b>Commercialized Novavax (coming soon?)</b></p> <ul style="list-style-type: none"> <li>• Presentation: Ages 12+ (5-dose multi-dose vials 0.5mL injection volume)</li> <li>• Minimum Order: 10 doses, 2 vials</li> <li>• Storage: Refrigerated expiry 9 months from date of manufacture</li> <li>• Offering returns? Yes, up to 100% for opened and unopened vials</li> </ul> <p><b>Commercialized Pfizer &amp; Comirnaty</b></p> <ul style="list-style-type: none"> <li>• Three presentations: <ul style="list-style-type: none"> <li>• Pfizer COVID-19 Vaccine, 6 months – 4 years: Requires diluent (1.1 mL normal saline). 3 dose multidose vials. Yellow cap. 0.3 mL injection volume.</li> <li>• Pfizer COVID-19 Vaccine, 5 years – 11 years: No diluent required. Single dose vials. Blue cap. 0.3 mL injection volume.</li> <li>• Comirnaty, 12 years+: No diluent required. Single dose vials. Gray cap. 0.3 mL injection volume.</li> </ul> </li> <li>• Minimum order <ul style="list-style-type: none"> <li>• 6 months-4 years: 30 doses</li> <li>• 5 years – 11 years: 10 doses (government supplied vaccine), 100 doses private purchase</li> <li>• 12 years+: 10 doses (government supplied vaccine), 100 doses private purchase</li> </ul> </li> <li>• Storage: <ul style="list-style-type: none"> <li>○ Long-term storage at ultracold temperatures, if vaccine was received at ultracold temperatures; expiry (12 to 18 months from date of manufacture)</li> <li>○ Short-term storage (10 weeks) at refrigerated temperatures (most wholesalers have said they plan to ship this way)</li> </ul> </li> <li>• Returns Offered? Yes</li> </ul>	
<p><b>Ordering</b></p>	<p><b>All providers will order COVID-19 vaccines through traditional pathways for procurement, distribution, and payment for both privately insured and public payers.</b> Order sufficient supply to meet patient demand according to insurance coverage type, age, and COVID-19 vaccination status.</p> <p><b>Ancillary Kits:</b> No kits will be provided though Pfizer-BioNTech will provide diluent with its commercial vaccine.</p> <p><b>Redistribution:</b> Redistribution of COVID-19 vaccines provided through the Bridge Access Program or VFC is not an allowed routine practice. Carefully consider how COVID-19 vaccines are currently ordered and distributed. Vaccines must be ordered and delivered directly where doses will be administered.</p>	<p>Fall 2023</p>

Topic	Guidance	Effective Date
	See Appendix for vaccine ordering pathways post sunset.	
	<b>VFC-Eligible Pediatric Populations:</b> Pediatric COVID-19 vaccines will be available for ordering through the CA VFC Program for eligible children under 19 years of age. Vaccines will be added to VFC’s vaccine ordering system, MyVFC Vaccines. See <a href="#">How to Order VFC Vaccines</a> .	
	<b>Bridge Access Program-Eligible Adult Populations: Limited</b> doses of COVID-19 vaccines will be available to providers serving uninsured and underinsured adults through public health departments, Federally Qualified Health Centers (FQHCs)/Rural Health Centers, tribal clinics, Indian Health Services sites, and additional providers deemed eligible by LHDs. Participating providers will order vaccine through myCAvax. (See <a href="#">EZIZ’s BAP website</a> for details and resources.)	Sep 2023
	<b>FQHCs:</b> HRSA will provide operations funding to FQHCs to support ongoing COVID-19 vaccination efforts. FQHCs will receive vaccine through the State’s Bridge Access Program to ensure access to vaccines for uninsured adults.	
<b>Billing</b>	All providers will use traditional pathways of payment for both privately insured and public payers. Providers need to make sure billing practices and systems are updated. Billing and reimbursement for eligible public payers follows requirements listed in the relevant <a href="#">VFC Provider Agreement</a>   <a href="#">Addendum</a> and Bridge Access Program Provider Agreement (TBD).	Fall 2023
<b>Expected Patient Expenses</b>	When the transition occurs, most Americans should continue to pay nothing out-of-pocket for COVID-19 vaccines; for COVID-19 treatments such as Paxlovid and Lagevrio, out-of-pocket expenses may be similar to costs one may incur for other drugs and treatments through traditional coverage. (See <a href="#">HHS Letter to Manufacturers</a> .)	Fall 2023
<b>PREP Act</b>	In accordance with the recent PREP Act Amendment 11, neither the end of the COVID19 public health emergency on May 11, 2023, nor the discontinuation of USG COVID-19 vaccine distribution, affect the protections of the PREP Act declaration for COVID-19 vaccines. The <a href="#">PREP Act and the PREP Act Declaration</a> issued by the Secretary of the U.S. Department of Health and Human Services authorize and provide liability protections to licensed providers and others identified in the declaration to administer COVID-19 vaccines authorized or approved by FDA, including COVID-19 vaccines authorized for administration to children.	
<b>Section 4</b>	<b>Anticipated Vaccination Schedule for the Fall</b>	
	Detail on the current recommended vaccine schedules for each age group can be found on the <a href="#">CDC website</a> . 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 jurisdictions and providers will be able to order and receive updated COVID-19 vaccines shortly thereafter.	Mid to late September

## Resources:

- [Commercialization FAQ Webpage](#) (CDPH)
- [Commercialization Transition Guide](#) (HHS)
- [Fact Sheet: Bridge Access Program for COVID-19 Vaccines and Treatments](#) (HHS)
- [COVID-19 Commercialization](#) (HHS)
- [Bridge Access Program](#) (CDC)

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

