

Requirements at a Glance

Updated 9/11/24: The California Bridge Access Program (CA BAP) has been extended for existing BAP provider locations to ensure uninsured and underinsured adults aged 19 years and older have access to no-cost COVID-19 vaccines! There are no changes to provider agreements or patient eligibility. Providers must continue to report doses administered to CAIR; CA BAP locations no longer need to be displayed on Vaccines.gov. There is no open enrollment at this time. The 2024-25 COVID-19 vaccines will be available for ordering in myCAVax by the end of September. Local health departments will continue to review and approve adult COVID-19 vaccine orders.

Topic	Requirements & Guidance	Resource Links
Primary Documents	<ul style="list-style-type: none"> • Provider Participation Agreement • Provider Operations Manual (and Startup Worksheet for new providers) • COVID-19 Vaccine Provider FAQs 	
Key Roles	<ul style="list-style-type: none"> • Organization Vaccine Coordinator (completes Section A enrollment for parent company) • Vaccine Coordinator (completes Section B enrollment in myCAVax for affiliated locations) • Vaccinators and providers 	
Vaccine Products & Presentations	<p>COVID-19 vaccines are considered routine. Refer to the COVID Vaccine Product Guide for packaging & billing codes, storage limits, administration, and use-by limits.</p> <p>CDC's Pfizer at a Glance, Moderna at a Glance and Novavax at a Glance are being updated for 2024-25 vaccine products.</p>	<p>COVID Vaccine Product Guide</p> <p>COVID-19 Vaccine Timing Guide</p>
Required Training	<p><i>Vaccinators, clinicians, vaccine coordinators, and other staff who store, handle, or administer COVID-19 vaccine must complete the required vaccine product training before receiving shipments to ensure they are prepared to maintain vaccines under proper conditions. (Provider Agreement #7J)</i></p> <p>Program Training. Staff completing the BAP Provider Agreement will complete the required program training in myCAVax before enrollment. Program training prepares sites to incorporate requirements into clinic protocols and identifies key resources for use on the job.</p> <p>Product Training. Any staff who store, handle, or administer COVID-19 vaccines must complete COVID-19 Vaccine Product Training—only for products your location will order—prior to receiving</p>	<p>Required Vaccine Product Training</p> <p>Vaccine Eligibility Guidelines</p> <p>Eligibility Based on Insurance Status</p>

Topic	Requirements & Guidance	Resource Links
	<p>vaccine shipments. This training teaches staff to prepare, administer, store, and handle each vaccine product and report adverse events to VAERS.</p> <p>Eligibility Screening & Documentation. Train staff who conduct eligibility screening using the Eligibility Based on Insurance Status and Eligibility Screening Record job aids (see right).</p>	<p>317 Eligibility Screening Record for Adult Patients</p>
	<p>Vaccine Administration</p>	
<p>Standing Orders</p>	<p>Standing orders enable eligible healthcare professionals to assess patient vaccine status and administer needed vaccinations without examination or direct order from the attending provider, which can save time and reduce missed opportunities for vaccination. See Licensees Authorized to Administer Vaccines in California and CDC templates at right.</p> <p>CDC’s standing order templates are being updated for 2024-25 vaccine products.</p>	<p>Moderna 6M-4Y 5Y+</p> <p>Novavax 12Y+</p> <p>Pfizer-BioNTech 6M-4Y 5Y+</p>
<p>Pre-vaccination Screening</p>	<p>Federal emergency funding for COVID-19 vaccines ends with commercialization, but most adults will have access to COVID-19 vaccine at no cost through their insurance plan or State programs.</p> <p>My Turn offers screening, eligibility checks, and appointment scheduling for the public. If the patient indicates they don’t have insurance while making an appointment, My Turn will only display locations that offer COVID-19 vaccines at no cost for the insured.</p> <p>CDC also provides a COVID-19 screening form (available in English and other languages) to assist with patient screening.</p>	<p>Screening Questions in Multiple Language (My Turn)</p> <p>Pre-vaccination Screening Checklists (CDC)</p>
<p>Patient Visit Checklist</p>	<p>Participating providers must incorporate this checklist into practice protocols:</p> <ul style="list-style-type: none"> • Confirm eligibility: recipient is uninsured/underinsured and 19 years of age or older. • Distribute EUA Fact Sheet for Recipients BEFORE administration. • Prepare/administer vaccines and observe recipient per EUA Fact Sheet for HCPs and ACIP Recommended Adult Immunization Schedule (or CDPH Timing Guide). • Request recipient’s mobile number and email (see Health Officer Order). • Report administration data daily using My Turn (or EHR/EMR connected to CAIR). • Report any adverse events to VAERS. • Complete vaccination record card per practice protocols. 	

Topic	Requirements & Guidance	Resource Links
	<ul style="list-style-type: none"> Schedule next appointment (if recommended). Recommend Digital Vaccination Record. 	
Eligibility Screening & Documentation	<p><i>COVID-19 vaccines will be administered to any individual aged 19 years and older who is uninsured or underinsured. Insured patients, including patients covered by Medicare and Medi-Cal, are NOT eligible for COVID-19 vaccines provided through the Bridge Access Program (hereafter referred to as BAP). Staff will consult the Eligibility Based on Insurance Status table as needed to determine specific vaccine eligibility for patients. Eligibility screening will be conducted prior to the administration of vaccine doses. Verification of eligibility may be obtained verbally from the individual. All staff, including front office and billing staff, will be knowledgeable of BAP eligibility. (P.A. #1)</i></p> <p>Eligibility screening must be conducted prior to administration to ensure doses only go to eligible adults.</p> <p>COVID-19 vaccines must be administered to any adults 19 years and older who are uninsured or underinsured (CDC defines for BAP only as “a person who has health insurance, but the insurance does not include any vaccines; a person whose insurance covers only selected vaccines; a person whose insurance does not provide first-dollar coverage for vaccines”).</p> <p>Insured patients, including patients covered by Medicare and Medi-Cal, are NOT eligible for COVID-19 vaccines provided through the Bridge Access Program (BAP).</p> <p>Administration data (including eligibility category 317) must be documented in CAIR.</p> <p>How to screen for BAP eligibility.</p> <p>Ensure staff, including front office and billing staff, are knowledgeable of the Eligibility Based on Insurance Status table and follow these 317 Eligibility Screening and Documentation Requirements:</p> <ol style="list-style-type: none"> Screen prior to administration of any 317-funded vaccine (e.g., Vaccines for Adults and Bridge Access Programs). Eligibility is self-reported, and verification of eligibility may be obtained verbally. Document patient’s eligibility, including screening date, whether eligible for VFA and/or BAP, and which criterion is met. Use a compliant recordkeeping system: CAIR and your EHR/EMR, or CAIR and the 317 Eligibility Screening Record. (See CAIR Requirement for Documenting 317-Funded Vaccines for instructions.) Communicate patient eligibility. 	<p>Eligibility Based on Insurance Status</p> <p>317 Eligibility Screening & Documentation Requirements</p> <p>317 Eligibility Screening Record for Adult Patients Spanish</p> <p>CAIR Requirement for Documenting 317-Funded Vaccines</p> <p>Vaccine Eligibility Guidelines</p> <p>Free Vaccines for Adults Poster Spanish</p>

Topic	Requirements & Guidance	Resource Links
	Ensure protocols are in place so vaccinators know when to use 317-funded vaccines versus private vaccines.	
Fact Sheets for Recipients & Caregivers	<p><i>Before administering COVID-19 vaccine, an approved EUA fact sheet or vaccine information statement (VIS) will be provided as required to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. (P.A. #4)</i></p> <p>COVID-19 VISs: CDC will publish a Vaccine Information Statement this fall. Currently, providers are required by law to provide EUA fact sheets to vaccine recipients or their caregivers for all uses of Novavax and when Moderna or Pfizer vaccines are given to children 6 months through 11 years of age. For recipients who are 12 or older receiving Pfizer or Moderna vaccine, a provider may use the manufacturer’s package insert (COMIRNATY Patient Package Insert or SPIKEVAX Patient Package Insert), written FAQs, or any other document (including provider-produced information materials) to inform patients about the benefits and risks of that vaccine. See COVID-19 Vaccine Resources for package inserts and EUA fact sheets.</p>	<p>COVID-19 Vaccine Resources</p> <p>for package inserts & EUA fact sheets</p>
Vaccine Administration per ACIP & FDA	<p><i>COVID-19 vaccines will be administered in compliance with the most recent immunization schedule, dosage, and contraindications established by the Advisory Committee on Immunization Practices (ACIP) and in compliance with all applicable requirements as set forth by the U.S. Food and Drug Administration (FDA), including but not limited to requirements in any Emergency Use Authorization (EUA) fact sheet that covers COVID-19 vaccine. (P.A. #2)</i></p> <p>The Advisory Committee on Immunization Practices provides guidance to CDC; recommendations adopted by CDC are published in the Morbidity and Mortality Weekly Report (MMWR).</p> <p>Follow the CDPH Timing Guide (or ACIP Recommended Adult Immunization Schedule when updated) as well as ongoing guidance in the interim clinical considerations for use of COVID-19 vaccines authorized and approved.</p> <p>Manufacturer Emergency Use Authorization (EUA) fact sheets can be found on FDA’s website.</p> <p>To minimize administration errors, refer to the Vaccine Administration Checklist.</p>	<p>MMWR (CDC)</p> <p>Interim Clinical Considerations for Use of COVID-19 Vaccines (CDC)</p> <p>EUA Fact Sheets (FDA)</p> <p>COVID-19 Vaccine Timing Guide</p> <p>Vaccine Administration Checklist</p>

Topic	Requirements & Guidance	Resource Links
Coadministration	Routine administration of all age-appropriate vaccine doses simultaneously (i.e., administering more than one vaccine on the same clinic day or “coadministration”) is recommended for children, adolescents, and adults if there are no contraindications at the time of the healthcare visit. However, there are additional considerations if administering an orthopoxvirus vaccine. See CDC coadministration guidance.	Coadministration of COVID-19 Vaccines (CDC)
Reporting Doses Administered	<p><i>Within 24 hours of administering a dose of COVID-19 vaccine to a BAP-eligible patient, administration data will be recorded in the recipient’s permanent medical record and submitted to the State’s Immunization information System (CAIR2 or Healthy Futures/RIDE) no later than 72 hours; providers must ensure that the proper vaccine eligibility category of “317” is applied. (P.A. #5)</i></p> <p>By California law, 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 (including eligibility category of 317) to CAIR as soon as practicable and no later than 72 hours.</p>	Reporting Race & Ethnicity
Digital Vaccine Record (DVR)	<p>The California Department of Public Health has created a system to allow Californians to access their Digital Vaccine Record (DVR) to replace lost or otherwise unavailable paper records and provide an additional form of portable and reliable vaccine verification. The DVR is generated using patient data from the California Immunization Registry (CAIR).</p> <p>Providers may direct their patients to the portal for digital proof of vaccination for COVID-19 and other vaccines.</p>	DVR Portal
Reporting to VAERS	<i>Vaccine administration records will be maintained in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS). (P.A. #4)</i>	https://vaers.hhs.gov/
Billing & Reimbursement	<p><i>Patients immunized with BAP-supplied vaccines will not be billed for the cost of the vaccine nor be charged an administration fee. All systems will be checked to ensure patients are not charged and vaccine cost will not be billed. (P.A. #3)</i></p> <p>Ensure systems and protocols are updated so patients are not charged, and vaccine cost is not billed.</p>	
Patient Recordkeeping	<i>The patient's recorded BAP 317 eligibility status and all records related to the Bridge Access Program will be retained for three (3) years. If requested, patient records will be made available to CDPH. Records include, but are not limited to, vaccine administration documentation, billing records, and</i>	

Topic	Requirements & Guidance	Resource Links
	<p><i>medical records that verify receipt of vaccine. Release of such records will be bound by federal and state privacy laws. (P.A. #6)</i></p>	
	<p>Vaccine Management</p>	
<p>Fact Sheets for HCPs</p>	<p><i>The location will comply with requirements for COVID-19 vaccine management and reporting including the following: Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer’s package insert, Fact Sheet for Healthcare Providers Administering the Vaccine, and guidance in CDC’s Vaccine Storage and Handling Toolkit and COVID-19 Addendum. (P.A. #7A)</i></p> <p>Follow vaccine preparation instructions provided in the vaccine product’s EUA Fact Sheet for Healthcare Providers, which supersede package inserts. Proper preparation and administration help to ensure patients receive sufficient protection after vaccination and minimize revaccination efforts due to administration errors. Do not prepare or administer vaccines without first checking the expiration date. Do not prepare or administer vaccine past the manufacturer expiration date or use-by date.</p>	<p>EUA Fact Sheets for HCPs (FDA)</p> <p>EUA Fact Sheets for Recipients & Caregivers (CDC)</p> <p>EUA Fact Sheets for HCPs (FDA)</p>
<p>Storage Equipment</p>	<p><i>The location will comply with requirements for COVID-19 vaccine management and reporting including the following: Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer’s package insert, Fact Sheet for Healthcare Providers Administering the Vaccine, and guidance in CDC’s Vaccine Storage and Handling Toolkit and COVID-19 Addendum. (P.A. #7A)</i></p> <p>Storage units. Use purpose-built or pharmaceutical-grade units designed for storage of biologics, including vaccines. If not an option, commercial or household standalone units are acceptable. If necessary, combination units may be used—but frozen vaccines must be stored in a standalone freezer. Never store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit. Set up storage units to minimize administration errors: group vaccines by funding source and label shelf space or baskets as pediatric, adolescent, and adult.</p> <p>Data loggers. Storage units must be equipped with a digital data logger; devices with a buffered probe provide more accurate readings. For ultra-cold storage units, device must use an air probe or a probe designed for UL temperatures. Keep a backup device on hand for transports and should primary devices fail. Devices must have a current and valid Certificates of Calibration Testing. Set up devices carefully to ensure you are notified if temperatures drift outside recommended ranges.</p>	<p>Vaccine Storage and Handling Toolkit & COVID-19 Addendum</p> <p>Preparing Vaccine Storage Units</p> <p>Setting Up Vaccine Storage Units</p> <p>Data Logger Setup & Use</p>

Topic	Requirements & Guidance	Resource Links
Vaccine Management Plan	<p>Vaccine management plan. How will you protect vaccines during a power safety shutoff or encroaching fire? The vaccine management plan documents how your staff should perform routine storage and handling tasks and respond to vaccine-related emergencies. Review and update it annually, or more frequently if changes occur.</p>	<p>Vaccine Management Plan</p>
Ordering Vaccine	<p><i>Order vaccines according to the BAP ordering guidance; providers who have not ordered vaccines in a period longer than 6 months may be terminated from the Bridge Access Program. (P.A. #8)</i></p> <p>Ordering of COVID-19 vaccines now follows guidelines for routine vaccines. Submit vaccine order requests in myCAvax. Vaccines ship to the location’s shipping address in myCAvax; routine redistribution is not allowed. For technical questions, look for the Knowledge Center link in myCAvax.</p> <p>Ordering Cadence. Weekly. See ordering cadence for BAP-supplied vaccines.</p> <p>Minimum Order Quantities. Carton size.</p> <p>Ancillary Kits. No kits are supplied with vaccine.</p> <p>Small Orders/TPR. Small Orders and Third-Party Redistributor (TPR) will NOT be available for BAP-supplied vaccines.</p> <p>Vaccine Marketplace. Providers will NOT use Marketplace for BAP-supplied vaccines.</p>	<p>Weekly Ordering Cadence Calendar</p>
Ordering - Reporting Doses Administered & on Hand	<p><i>The total number of patients immunized with COVID-19 vaccines and current inventory on hand will be reported to the California Department of Public Health (CDPH) according to the BAP reporting guidelines. (P.A. #6)</i></p> <p>As with other routine vaccines, report the total number of doses administered (since the previous order) and inventory (doses on hand) in myCAvax on each vaccine order. Providers are accountable for all BAP-supplied vaccines upon receipt and must be able to provide documentation to support their numbers. Providers must report vaccine accountability numbers with each order to receive vaccines.</p>	
Vaccine Distribution	<p>Because the Public Health Emergency has ended, COVID-19 vaccine distribution will no longer be expedited. Distribution of COVID-19 vaccines now follows guidelines for routine vaccines. CDC uses its contract with McKesson to fulfill orders and centrally distribute Moderna and Novavax vaccines. Pfizer-BioNTech vaccine will ship directly from the manufacturer.</p> <p>Moderna and Novavax vaccines will be shipped by McKesson.</p>	<p>Weekly Ordering Cadence Calendar</p>

Topic	Requirements & Guidance	Resource Links
	<ul style="list-style-type: none"> COVID-19 vaccine orders will follow same shipping timelines for routine vaccines (shipping approximately within 3 days of order receipt at McKesson). Moderna (SPIKEVAX®) vaccine ships frozen between -50°C and -15°C (-58°F and 5°F). Novavax vaccine ships like other routine refrigerated vaccines at temperatures between 2° to 8°C (36° to 46°F). <p>Pfizer vaccines will ship directly from Pfizer</p> <ul style="list-style-type: none"> Will be shipped on dry ice on ultra low temperature conditions. CDC contract stipulates vaccines must be delivered within 15 days of order receipt by CDC. For vaccines with diluent (6m-4y) diluent will be shipped separately and will arrive at the same time of before vaccines arrive. 	
<p>Critical Systems & Senders</p>	<p>Primary Vaccine Coordinators receive critical emails regarding order confirmations, advance shipment notices of vaccine and ancillary kits, and temperature monitoring alerts. Add these critical senders to your contact list, or work with your IT staff to have these addresses included in your organization’s email whitelist, to ensure emails are not filtered to Spam or Junk folders.</p>	<p>Critical Systems & Senders</p>
<p>Vaccine Management Checklist</p>	<p>Providers must incorporate this checklist into practice protocols:</p> <ul style="list-style-type: none"> Store and handle vaccines in compliance with Vaccine Storage and Handling Toolkit. Record storage unit temperatures twice daily on a temperature log (see sample log). Report temperature excursions daily in myCAvax. Rotate stock weekly to ensure vaccines soon to expire are used first. Monitor and comply with COVID-19 vaccine expiration dates. After puncture, use labels or alternate method for marking use-by date/time. Remove spoiled, expired, and deauthorized vaccine IMMEDIATELY to prevent administration errors. Report all nonviable vaccines in myCAvax; report deauthorized vaccine products as “Waste” and use “Other” to add comment “deauthorized”. As with other routine vaccines, return nonviable vaccine to McKesson. Report transfer of excess supply or short-dated doses within 24 hours. 	

Topic	Requirements & Guidance	Resource Links
<p>Receiving & Storing Vaccines</p>	<p><i>The location will comply with requirements for COVID-19 vaccine management and reporting including the following: Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer’s package insert, Fact Sheet for Healthcare Providers Administering the Vaccine, and guidance in CDC’s Vaccine Storage and Handling Toolkit and COVID-19 Addendum. (P.A. #7A)</i></p> <p>Refer to the Provider Operations Manual (POM) for product-specific guidance. Apply CDC storage and BUD tracking labels (see Labels and BUD Guidance by product) when storing product to reduce administration errors.</p> <p>Receiving. Never refuse vaccine shipments. Verify shipments & contents upon arrival for signs of damage, temperature excursions during transit, and discrepancies between packing slip, order, and shipper contents. Store vaccines properly in their original packaging; label with beyond-use date/time per manufacturer; rotate stock to ensure vaccines soon to expire are used first.</p> <p>Reporting shipment incidents. Report shipment incidents for vaccine products in myCAvax when discovered. For technical questions, look for the Knowledge Center link in myCAvax. (See Reporting Shipment Incidents for details.)</p> <p>Storing vaccine. Vaccines must be stored under storage temperatures defined by product in EUA Fact Sheets for HCPs and CDC’s Vaccine Storage & Handling Toolkit & COVID-19 Addendum. See COVID-19 Vaccine Product Guide for summary chart.</p> <p>Returning shippers. See Pfizer Return Instructions.</p>	<p>COVID-19 Vaccine Product Guide</p> <p>Vaccine Storage & Handling Toolkit & COVID-19 Addendum</p> <p>Provider Operations Manual</p> <p>Pfizer Return Instructions</p> <p>Reporting Shipment Incidents</p>
<p>Temperature Monitoring</p>	<p><i>Monitor and record vaccine storage unit temperatures twice daily following guidance in CDC’s Vaccine Storage and Handling Toolkit and COVID-19 Addendum. (P.A. #7B)</i></p> <p>Record data logger’s current, MIN, and MAX readings twice daily on your temperature logs for refrigerated, frozen, or ultra-cold vaccines, or use this COVID-19 Temperature Log or the Universal Temperature Log (both include step-by-step instructions). Post refrigerated and frozen temperature logs on corresponding storage units to prevent recording errors.</p> <p>Staff training. Ensure staff are trained to operate your data loggers and download any temperature data file in the event of an excursion; refer to device’s product guide. Train staff not to ignore alarm alerts; if temperature alarms go off repeatedly, do not disconnect the alarm until it has been confirmed as a false alarm.</p>	<p>COVID-19 Temperature Log</p> <p>Universal Temperature Log</p>

Topic	Requirements & Guidance	Resource Links
Reporting Temperature Excursions	<p><i>Respond to and report temperature excursions following CDPH guidance. (P.A. #7C)</i></p> <p>Report temperature excursions in myCAvax. For technical questions, look for the Knowledge Center link in myCAvax. If an alarm goes off, take action immediately (COVID-19 Temperature Log includes step-by-step instructions):</p> <ul style="list-style-type: none"> • Label exposed vaccines DO NOT USE so vaccines are not administered. • Complete the Temperature Excursion Worksheet to gather data manufacturers will need to determine viability, then contact the manufacturer. • Contact the manufacturer to determine if vaccines may be administered. • Report temperature excursions daily in myCAvax. • Do not administer vaccines until the manufacturer resolution is determined. 	Temperature Excursion Worksheet
Vaccine Preparation	<p>Never miss a vaccination opportunity! Vaccinate every eligible person who presents at a vaccination site! CDC recommends this guidance to minimize wasted vaccine:</p> <ul style="list-style-type: none"> • Always check expiration & beyond use dates before preparation and administration. • Prepare vaccine according to the manufacturer fact sheet. • Don't exceed the number of doses in the fact sheet. • Never use partial doses (pool) from two or more vials to obtain a dose of vaccine. • Administer COVID-19 vaccines in the correct site and route. <p>To minimize administration errors, refer to the Vaccine Administration Checklist.</p>	Vaccine Administration Checklist
Managing Expiration & Beyond-Use Dates	<p><i>Monitor and comply with COVID-19 vaccine expiration and beyond-use dates; never administer expired vaccine. (P.A. #7D)</i></p> <p>Discard vaccine after the earlier of the expiration or beyond-use date. Apply CDC BUD tracking labels (see Labels and BUD Guidance by product) to prevent administration of expired vaccine.</p> <p>Expiration Dates. Expiration dates may be extended as more data come in. To determine expiration dates:</p> <ul style="list-style-type: none"> • <i>Moderna:</i> Scan QR code on product • <i>Novavax:</i> Expiry checker • <i>Pfizer-BioNTech:</i> Check the date on the product/carton, or for thawed products refer to the written use-by date 	Novavax expiry checker

Topic	Requirements & Guidance	Resource Links
	<p>Beyond-Use Dates. Vaccines may have a shortened beyond-use date (BUD) as specified in the EUA Fact Sheet for HCPs and documented in CDC’s Toolkit COVID-19 Addendum. The BUD replaces the manufacturer’s expiration date. If the vaccine has no beyond-use date, use the expiration date.</p> <p>Before puncture, manufacturer-shortened expiration dates may apply if storing unpunctured vials under conditions other than coldest recommended temperatures; apply storage labels so vaccines aren’t administered past these use-by dates/times. After first puncture, multidose vials have a shortened use-by date/time for punctured vials; label vial with puncture date/time. Do not administer after the use-by date/time.</p>	
<p>Vaccine Transport</p>	<p>Carefully package and transport vaccines following guidance in CDC’s Vaccine Storage & Handling Toolkit & COVID-19 Addendum. Transport containers must be equipped with data loggers and comply with CDC guidelines. Report temperature excursions during transport in myCAvax; do not report as shipment incidents because vaccines weren’t shipped.</p> <p>It is critical that providers have plans in place for vaccine-related emergencies:</p> <ul style="list-style-type: none"> • Vaccines may remain inside a nonfunctioning unit as long as appropriate temperatures are maintained; monitor your data logger to determine when action should be taken. • Having an on-site generator(s) prevents the need to transport vaccines to an alternative storage facility during a power outage. • Emergency situations can arise outside of normal business hours; staff must be trained to implement emergency operation plans or access your facility if necessary. • Ensure your facility has the resources on hand and know how to safely pack vaccines for transport during emergencies. • Styrofoam™ or hard-sided insulated containers are only to be used in an emergency. • Document your routine & emergency protocols in your vaccine management plan or use the COVID-19 Vaccine Management Plan. 	<p>Vaccine Transport Log</p>
<p>Reporting Vaccine Transfers</p>	<p><i>Never routinely redistribute BAP-supplied vaccines; report emergency/unplanned vaccine transfers following CDPH guidance. (P.A. #71)</i></p> <p>Report vaccine transfers in myCAvax within 24 hours. For technical questions, look for the Knowledge Center link in myCAvax. Transfer is the transport of vaccines in response to an emergency</p>	

Topic	Requirements & Guidance	Resource Links
	<p>or other unplanned event. Locations may transfer excess inventory or doses soon to expire—only to other approved BAP provider locations.</p>	
<p>Vaccine Redistribution</p>	<p><i>Never routinely redistribute BAP-supplied vaccines; report emergency/unplanned vaccine transfers following CDPH guidance. (P.A. #7I)</i></p> <p>As with other routine vaccines, redistribution is not allowed now that minimum order quantities are standard sizes. Vaccines must be ordered and delivered directly to administration sites. Order accordingly.</p>	
<p>Vaccine Wastage</p>	<p>Never miss a vaccination opportunity because of fear of vaccine wastage!</p> <p>Multi-dose vials are a challenge for providers, and CDC is aware that the limitations of available presentations may result in more waste. Moderna and Pfizer-BioNTech vaccines are available as single-dose vials; Novavax is working to supply single-dose vials, but they may not be here by fall 2023.</p> <p>Do your best to follow clinical and inventory management best practices for vaccination to maximize vaccinations and minimize dose wastage where possible.</p>	
<p>Reporting Nonviable Doses</p>	<p><i>Report the number of doses of COVID-19 vaccine and adjuvants that were unused, spoiled, expired, or wasted following CDPH guidance. (P.A. #7F)</i></p> <p>Report spoiled, expired, or wasted vaccine in myCAvax.</p> <p>Spoiled: Vaccines are considered spoiled if manufacturers determine vaccines were exposed to out-of-range temperatures and may not be used. (Consistent and accurate temperature monitoring minimizes spoiled vaccines.)</p> <p>Expired: Vaccines are considered expired if beyond the manufacturer expiration date or beyond-use date/time as identified in product EUA fact sheet. (Careful vaccine management helps to minimize expired vaccines.)</p> <p>Wasted: Vaccines are considered wasted if deauthorized, drawn but not administered, left in open vials but doses not administered, lost or unaccounted, or if you are unable to draw the last dose. <i>Tip:</i> Report deauthorized vaccine products as “Waste” and use “Other” to add comment “deauthorized”. (Careful vaccine management and administration minimizes waste.)</p>	

Topic	Requirements & Guidance	Resource Links
<p>Returning Nonviable Doses</p>	<p><i>Return all nonviable vaccine to McKesson following CDPH guidance. (P.A. #7G)</i></p> <p>Wasted vaccines: Dispose of all products following practice protocols (may be disposed of in pharmaceutical waste containers or comingled pharmaceutical/Sharps containers).</p> <p>Updated 2023-24 COVID-19 vaccines: Return all spoiled/expired vaccines to McKesson; a return shipping label will be sent to attach to the shipping container. Clearly label the outside of the shipping container "Non-viable Vaccine enclosed" and return to this address:</p> <p>MCKESSON SPECIALTY CAR VACCINE: VFC -OBV 8745 FOREST HILL IRENE SUITE 105 OLIVE BRANCH, MS 38654</p>	
<p>Borrowing Vaccine</p>	<p><i>Never borrow BAP-supplied vaccines to supplement private stock, or vice versa. (P.A. #7H)</i></p> <p>Locations must order and stock sufficient supply to serve BAP-eligible and private recipients. Set up storage units to prevent errors: Label vaccines by funding source and group (pediatric, adolescent, and adult) to minimize administration errors.</p>	<p>Setting Up Vaccine Storage Units</p>
<p>Vaccine Management Recordkeeping</p>	<p><i>Preserve all records related to COVID-19 vaccine management (e.g., vaccine temperature logs, invoices, and packing slips) for a minimum of 3 years. (P.A. #7E)</i></p> <p>Records include vaccine transport logs and data logger certificates of calibration testing.</p>	
<p>Summary of Reporting Requirements</p>	<ul style="list-style-type: none"> • Report vaccination data daily to CAIR using My Turn or an EHR/EMR connected to CAIR (unless already reporting to CAIR manually.) • Report doses spoiled, expired, or wasted before return to McKesson. • Report shipment incidents when discovered for vaccine product, including temperature excursions, damage, or packing slip discrepancies. • Report temperature excursions daily (if any) and quarantine affected vaccines; contact vaccine manufacturer to determine if doses may be administered. • Report transfer events within 24 hours. 	

Topic	Requirements & Guidance	Resource Links
	Other Requirements and Guidance	
Updating Vaccines.gov	CDC sunset the federal Bridge Access Program in August of 2024. BAP locations no longer need to be displayed on Vaccines.gov.	
Site Visits	<p><i>Authorized CDPH representatives will be permitted to visit the location to review compliance with all BAP policies and procedures; provider agrees to implement and complete corrective actions identified during the visit. (P.A. #10)</i></p> <p>Providers agree to periodic compliance visits. Site visits help ensure compliance with program requirements, including administration, documentation, accountability, and vaccine management.</p> <p>Site visits are educational opportunities designed to improve compliance, highlight best practices and lessons learned, and reveal challenges for future program improvement efforts.</p>	
Fraud & Abuse	<p><i>The location will operate in a manner intended to avoid fraud and abuse of COVID-19 vaccines supplied through the Bridge Access Program.</i></p> <p>Fraud is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.</p> <p>Abuse is defined as provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the program or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. (P.A. #9)</p>	
Agreement Expiration	<i>The term of this agreement is valid from enrollment through December 31, 2024, or until vaccine supply doses are completely depleted. COVID-19 vaccines supplied through the Bridge Access Program may continue to be administered until their expiration date. (P.A. #11)</i>	
Agreement Termination	<i>I understand that either the CDPH Immunization Branch or my location/organization may terminate this agreement at any time. If the agreement is terminated, any unused COVID-19 vaccines will be properly returned to the CDPH Immunization Program, which administers the Bridge Access Program. (P.A. #12)</i>	

Topic	Requirements & Guidance	Resource Links
<p>PREP Act Protections</p>	<p>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 PREP Act and the PREP Act Declaration 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.</p>	