Welcome to California COVID-19 Vaccination Program Friday Provider Office Hours



Friday, October 22, 2021



Housekeeping

Reminder to Panelists:



Please mute yourself when not speaking.

Please monitor the Q&A panel for questions you may be able to answer.

Reminder to Participants:



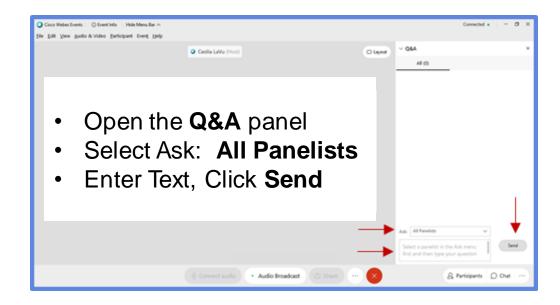
Please access today's slides and archived presentations at: https://eziz.org/covid/education/



Provider Office Hours Q&A

During the session, please use the Q&A panel to comment or ask a question:

Q&A Panel





Today's Poll

Do you have a volunteer program that can mobilize medical professionals (e.g., retired nurses) and other support volunteers to assist with vaccine administration?

- a. Yes
- b. No



Agenda: Friday, October 22, 2021

No.	Item	Speaker	Time (AM)		
1	Welcome, Announcements & Poll	Leslie Amani (Moderator)	9:00 – 9:05		
2	Vaccine Administration	Amy Pine (CDPH)	9:05 – 9:10		
4	CalVaxGrant	Nisha Gandhi (CDPH)	9:10 – 9:15		
5	Clinical Update	Caterina Liu, M.D. (CDPH)	9:15 – 9:25		
	Q&A		9:25 – 9:30		
6	Storage & Handling	Kate McHugh (CDPH)	9:30 – 9:35		
7	Data Quality	Jennifer Womack (CDPH)	9:40 – 9:45		
8	Vaccine Management	Eric Norton (My Turn) and Claudia Aguiluz (CDPH)	9:45 – 9:55		
9	Wrap Up & Resources	Leslie Amani (Moderator)	9:55 – 10:00		
	Q&A				



Announcements

Leslie Amani, CDPH



- Alerts
- Program Enrollment
- My Turn Onboarding
- Reporting Requirements
- Patient Resources
- Archived Communications
- Education & Support Materials
- More to explore!



California COVID-19 Vaccination Program

ENHANCED BY Google

Program Updates

Program Enrollment

My Turn Onboarding

Vaccine Management

Vaccine Administration

Reporting Requirements

Archived Communications

Patient Resources

Provider Support

COVID Call Center

Email: For Program Info Phone: (833) 502-1245 Hours: Mon-Fri, 8AM-6PM

myCAvax Help Desk

Email: For Technical Support Phone: (833) 502-1245,

option 2

Vaccines

Manufacturer Contacts

My Turn

Email: For Onboarding, Technical Support

Help Desk: (833) 502-1245,

option 4

Mon-Fri: 7AM-7PM Sat-Sun: 8AM-1PM

Program Updates

If you need assistance with accessing documents on this website, email covidcallcenter@cdph.ca.gov or call (833) 502-1245 Mon-Fri 8 AM-6 PM.

Program Support and Education

- COVID-19 Vaccination Program FAQs Updated 10/14
- Connect with Vaccine Experts Provider Office Hours Every Friday
- myCAvax Training
- · Weekly Webinars and Training Calendar

Alerts:

Pre-Order Pfizer Vaccine for 5-11 Years of Age

Catch-up pre-ordering is available through Friday, October 22 at 5:00 PM.

- Pre-Orders Available in myCAvax!
- · Pre-Ordering and Anticipated Delivery Schedule

CalVaxGrant Deadline Extended to December 17!

 There's still time to apply for Grants Up to \$55,000 for Support of Small Practices

What barriers do you foresee in administering booster doses in the next month?

Please email CovidCallCenter@cdph.ca.gov with your response. You're feedback is appreciated!

- COVID-19 Vaccine Eligibility Chart | Summary of Related Guidance and Requirements
- · Are You Ready for Expanded Booster Doses? Provider Readiness Checklist
- · CDPH Town Hall on Booster Dose Readiness | Slides

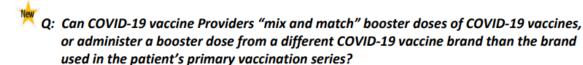
Now Enrolling Providers of Pediatric Services

- Benefits for Primary Care Providers
- · Find Information on How to Enroll



COVID-19 Vaccine Provider FAQs

- Answers to Provider questions
- Updated weekly: Last updated 10.21.2021
- Currently in its 42nd iteration!



A: The following information is subject to recommendation by CDC's Advisory Committee on Immunization Practices (ACIP) and the Western States Scientific Safety Workgroup (WSSSW): The FDA amended the emergency use authorizations (EUAs) for COVID-19 vaccines to allow for administration of a booster dose from a different COVID-19 vaccine brand than the original brand used in the patient's primary vaccination series. For the FDA news release, please visit FDA Booster Doses for Moderna and Janssen Vaccines.



Q: Can COVID-19 vaccine Providers pre-order the Pfizer pediatric product for 5-11-year-olds in myCAvax?

A: Yes. In anticipation of the Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 vaccine for children aged 5-11, Standard Orders of pediatric COVID-19 vaccine are available for pre-order in myCAvax until 5pm on October 22, 2021. Once the initial pre-order rollout period is complete, Providers will be able to submit routine pediatric orders for additional vaccine supply. For detailed information, please visit COVID-19 Vaccine for 5-11-year-olds. To view pre-ordering cadence calendars for Providers and Local Health Jurisdictions, please visit Pediatric Vaccine Ordering Cadence Calendar.

California COVID-19 Vaccination Program Provider FAQs

For Prospective, Newly Enrolled, and Current California COVID-19 Vaccine Providers.

Providers may also visit California COVID-19 Vaccination Program for information and updates.

Directions: Click on a category to be directed to related FAQs.

Contents

New and Updated FAQs	
Pediatric Providers	
Vaccine Program Management	
Provider Enrollment	
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COVID-19 Vaccination Program Webinars and Training for Providers

Week of October 25, 2021

Tuesday 10/26

What's New in mvCAvax

Vaccine Administrator / VA

12:30 pm - 1:00 pm

PW: myCAvax2021!

Assistant Training

1:00 pm - 2:00 pm PW: myCAvax2021!

Thursday 10/28	Friday 10/29					
Introduction to My Turn Onboarding 4:00 pm - 5:00 pm						
Clinic Manager Training 10:00 am – 12:00 pm						

Note: Calendar subject to change

View On
Demand

Combined

Office Hours

and Events

myCAvax

My Turn

• Intro to My Turn Onboarding (v. 9/24/21)

My Turn and myCAvax Office

Monday 10/25

myCAvax Vaccine Order

Request with Q&A

Onboarding

Hours

12 pm – 1 pm

PW: Immunize2020!

10:00 am - 10:30 am

PW: myCAvax2021!

Introduction to My Turn

12:00 pm – 1:00 pm

 My Turn Flu Functionality Review (v. 10/1/21)

 Provider 101 Account Enrollment (v. 8/27/21)

Vaccine Marketplace (v. 8/26/21)

What's New in myCAvax (v. 9/28/21)

· What's New in myCAvax for Reactivated Providers (v. 9/8/21) • Clinic Manager Training (v. 10/14/21)

Provider Office Hours

9:00 am - 10:00 am

PW: Immunize2021!

· Vaccine Administrator / VA Assistant Training (v. 10/14/21)



Website: www.eziz.org/covid, FAQs

General email: covidcallcenter@cdph.ca.gov

CDPH Provider Call Center: 1-833-502-1245, 8am-6pm

My Turn email: myturnonboarding@cdph.ca.gov

myCAvax Help Desk Email: myCAvax.HD@accenture.com

Vaccine Administrator / VA

Assistant Training 1:00 pm - 2:00 pmPW: myCAvax2021!

Phone: (833) 502-1245, option 2

Wednesday 10/27

My Turn Flu Functionality

10:00 am - 11:30 am

Onboarding (My Turn &

myCAvax) Office Hours

1:00 pm – 2:00 pm

Review



Last updated: 10/21/21



Ambassador Program Virtual Training The Ambassador Program is a new learning resource that provides support when talking with friends, family members, and neighbors about COVID-19 vaccination.

Ambassador Program Training in Spanish

Virtual training introduces 5 animated videos, messages to share, and provides basic information on COVID-19.

Wednesday, November 3 at 6:30 (Spanish) Register here!

For more information, contact: yumi.sera@cdph.ca.gov



Upcoming 30 Conversations in 30 Days Webinars

Talking to Parents about COVID-19 Vaccination for School-Aged Children: Thursday, November 11 at 12:00PM – 1:00PM Register here!

Speaker: Dr. Eric Ball, Pediatrician

Talking about COVID-19 Vaccination and Fertility & Pregnancy: Thursday, November 18 at 12:30PM – 1:30PM Registration link coming soon!

• Speakers: Dr. LaTanya Hines and Dr. Michael Policar, OB-GYNs





Community Conversations

Community Conversations is a series of videos where medical experts connect with real people across California to address questions related to COVID-19, including the vaccine, additional shots, and efforts to keep schools safe.



COVID-19 Community Conversation with KDYA-AM Gospel 1190 AM

CDPH recently partnered with KDYA-AM Gospel 1190 AM The Light radio station to host a "Community Conversation" about COVID-19 vaccines.

Watch and share the video.

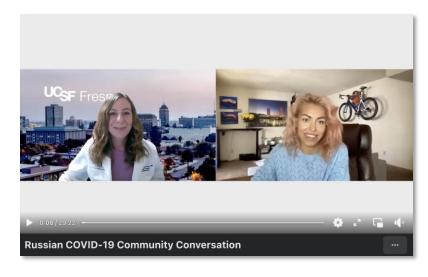


COVID-19 Community Conversation with Russian American Media (in Russian)

CDPH recently partnered with Russian American Media to host a "Community Conversation" in Russian about COVID-19 vaccines.

Watch and share the video.

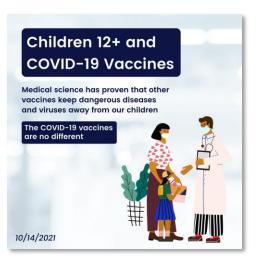






COVID-19 Vaccine Messaging for Parents





- Shareable social media posts and graphics to help promote
 COVID-19 vaccine for children ages 12 and older
 - Uses messages that parents said were the most compelling and convincing reasons, informed by polling from the <u>de Beaumont</u> <u>Foundation</u>.
 - Children, Schools, and Vaccines: Communicating to Parents <u>poll</u> <u>summary</u>
- Messaging and graphics will be updated in accordance with new guidance on pediatric vaccines.

Urgency & Strategies for Improving Young Adult COVID-19 Immunization Rates

Young adults have the lowest COVID-19 vaccine rate of all adults. We all have an important role in promoting COVID-19 vaccines among young adults. We invite you to learn from young adult leaders about strategies to increase vaccine uptake among this unique population.

Wednesday, October 27 from 12-1 PM PT Register Now!

Speakers:

- Judy Klein, President, Unity Consortium
- Ethan Lindenberger, Immunization Advocate, Unity Consortium Co-Lead for Teen Advisory Board
- Chynna Lloyd, West Program Coordinator, Young Invincibles
- Francine Rios-Fetchko, Research Analyst, Latinx Center of Excellence, University of California, San Francisco (UCSF)
- Charles E. Irwin, Jr., MD, Director, Division of Adolescent & Young Adult Medicine, UCSF Benioff Children's Hospitals, UCSF; Director, Adolescent and Young Adult Health National Resource Center

Webinar Objectives:

- Understand the main reasons young adults are not getting vaccinated
- Identify the influences on young adults' vaccine beliefs and behaviors
- Identify strategies and messages that public health organizations can use to motivate young adults to get vaccinated





Today's Poll

Do you have a volunteer program that can mobilize medical professionals (e.g., retired nurses) and other support volunteers to assist with vaccine administration?

a. Yes

b. No



Vaccine Administration

Amy Pine, CDPH



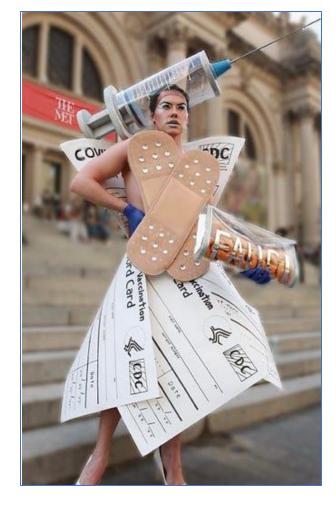
Doses Administered to Date (10/20/21)

51,603,064 doses administered!

• **80.1%** of 12+ population has received at least one dose and 72.3% are fully vaccinated!

Age Group	Fully Vaccinated	Total with at Least One Dose	Still Unvaccinated
12-17 years	58.2%	66.1%	34%
18-49 years	70.3%	78.5%	21.5%
50-64 years	80.2%	87.5%	12.5%
65+ years	74.8%	82.2%	17.8%

• 1,651,243 booster doses have been administered



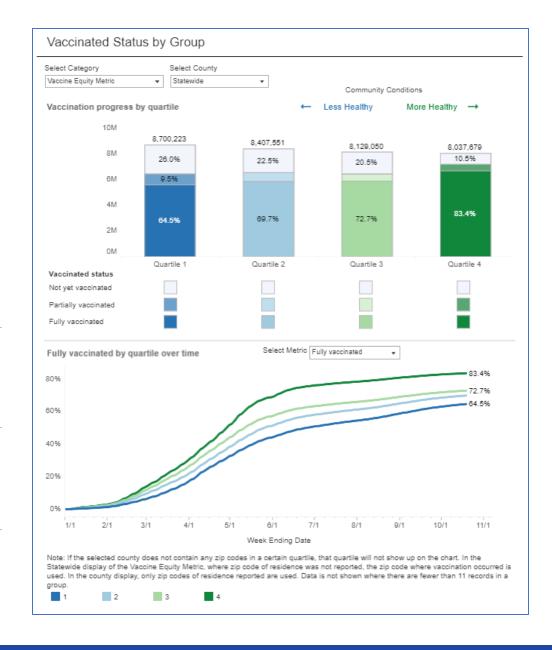
Brendan McCann designed a science-themed Met Gala dress - He wore the dress made of vaccine cards and Band-Aids with a Fauci purse and a syringe headpiece.



Vaccine Equity Metric

Vaccinations by VEM Quartile						
	Doses Administered	11,862,826	23.41%			
VEM Quartile 1	Fully Vaccinated	5,618,950	64.58%			
	Partially Vaccinated	828,516	9.52%			
	1+ Dose Administered	6,447,466	74.11%	4		
VEM Quartile 4	Doses Administered	14,084,525	27.79%			
	Fully Vaccinated	6,705,960	83.43%			
	Partially Vaccinated	492,670	6.13%			
	1+ Dose Administered	7,198,630	89.56%	4		
	Doses Administered	-2,221,699	-4.38%			
VEM Quartile	Fully Vaccinated	-1,087,010	-18.85%			
Delta	Partially Vaccinated	335,846	3.39%			
	1+ Dose Administered	-751,164	-15.45%	•		

#relentlessincrementalism





CalVaxGrant

Nisha Gandhi, CDPH



Latest CalVaxGrant Status

- Application deadline EXTENDED to Dec 17th or until funding is spent. First come, first served!
- Skilled Nursing Facilities and Home Health
 Agencies now eligible. Visit <u>PHC website</u> for a
 full list of who's eligible.
- 1,624 applications approved.



\$26.6 million in funding requested

\$10.4 million in funding remaining

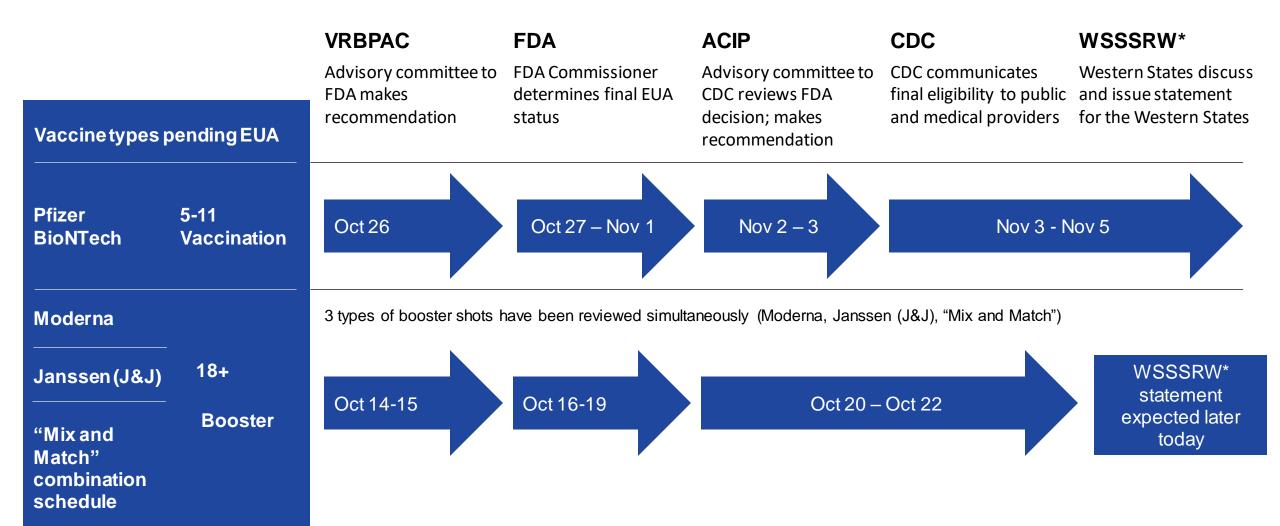


Clinical Update

Caterina Liu, M.D., CDPH



Anticipated pipeline of vaccine EUA authorizations¹



^{1.} Subject to change; may be updated as additional information becomes available



Booster Update

- On 10/20/21, FDA expanded EUA for Moderna and Janssen to include a booster dose following the primary series. In addition, the FDA updated the EUA to allow for heterologous booster administration (also referred to as "Mix-and-Match").
- On 10/21/21, CDC's Advisory Committee on Immunization Practices (ACIP) voted to recommend Moderna and Janssen/Johnson & Johnson boosters.
- CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed the ACIP's recommendation for a booster shot of COVID-19 vaccines in certain populations.

CDC Expands Eligibility for COVID-19 Booster Shots

Media Statement

For Immediate Release: Thursday, October 21, 2021 **Contact:** <u>Media Relations</u> (404) 639-3286

Today, CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendation for a booster shot of COVID-19 vaccines in certain populations. The <u>Food and Drug Administration's (FDA) authorization [7]</u> and CDC's recommendation for use are important steps forward as we work to stay ahead of the virus and keep Americans safe.

For individuals who received a Pfizer-BioNTech or Moderna COVID-19 vaccine, the following groups are eligible for a booster shot at 6 months or more after their initial series:

- · 65 years and older
- Age 18+ who live in <u>long-term care settings</u>
- Age 18+ who have <u>underlying medical conditions</u>
- Age 18+ who work or live in high-risk settings

For the nearly 15 million people who got the Johnson & Johnson COVID-19 vaccine, booster shots are also recommended for those who are 18 and older and who were vaccinated two or more months ago.

There are now booster recommendations for all three available COVID-19 vaccines in the United States. Eligible individuals may choose which vaccine they receive as a booster dose. Some people may have a preference for the vaccine type that they originally received and others, may prefer to get a different booster. CDC's recommendations now allow for this type of mix and match dosing for booster shots.

Millions of people are newly eligible to receive a booster shot and will benefit from additional protection. However, today's action should not distract from the critical work of ensuring that unvaccinated people take the first step and get an initial COVID-19 vaccine. More than 65 million Americans remain unvaccinated, leaving themselves – and their children. families, loved ones, and communities—vulnerable.

Available data right now show that all three of the <u>COVID-19 vaccines approved or authorized in the United States</u> continue to be <u>highly effective</u> in reducing risk of severe disease, hospitalization, and death, even against the widely circulating <u>Delta variant</u>. Vaccination remains the best way to protect yourself and reduce the spread of the virus and help prevent new variants from emerging.

The following is attributable to Dr. Walensky:

"These recommendations are another example of our fundamental commitment to protect as many people as possible from COVID-19. The evidence shows that all three COVID-19 vaccines authorized in the United States are safe – as demonstrated by the over 400 million vaccine doses already given. And, they are all highly effective in reducing the risk of severe disease, hospitalization, and death, even in the midst of the widely circulating Delta variant."

Read <u>CDC statement</u>



Interim Clinical Considerations for Moderna and Janssen COVID-19 Vaccine Booster Doses

- Final clinical guidance will be posted on the CDC webpage
- Indications for COVID-19 vaccine booster doses
- Heterologous (mix-and-match) booster doses
- COVID-19 vaccine booster administration
- Fully vaccinated definition
- Coadministration with other vaccines
- Contraindications and precautions



Indications for a Booster Dose Following mRNA COVID-19 Primary Series



- The following recipients of an mRNA primary series <u>should receive</u> a single mRNA COVID-19 vaccine booster dose ≥ 6 months after completion of primary series
 - ≥65 years
 - ≥18 years and reside in long-term care settings
 - Aged 50-64 years with certain underlying medical conditions*
- The following recipients of an mRNA primary series <u>may receive</u> a single mRNA COVID-19 vaccine booster dose ≥6 months after completion of primary series based on their individual risks and benefits
 - Aged 18-49 years with certain underlying medical conditions*
 - Aged 18-64 years at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting
- In general, the same product that was used for the primary regimen should be used for the booster.



Individual Risk-Benefit Assessment for People Who "May Receive" mRNA Booster Dose

- Individual risk factors for SARS-CoV-2 infection
 - Risk of exposure (occupational and institutional settings)
 - Risk for infection (time since completion of primary series)
- Potential impact of SARS-CoV-2 infection
 - Risk for severe infection (underlying conditions)
 - Risk associated with a person's circumstances (living with/caring for at-risk individuals or consequences of inability to meet obligations due to infection)
- Potential benefits of booster
 - Reduced risk of infection, including severe infection
- Potential risks of booster
 - Rare risks of serious adverse events (myocarditis, pericarditis, anaphylaxis)
 - Common risks of transient local and systemic symptoms





Indications for Booster Dose Following Janssen COVID-19 Primary Dose

 People aged ≥18 years who received a single dose Janssen primary series should receive a single Janssen COVID-19 booster dose at least 2 months after completing their primary series



Heterologous (Mix-and-Match) Booster Dose



- The same product that was used for the primary regimen should be used for the booster.
 - If that is not available or another product is preferred, heterologous boosting with a single dose of any of the authorized COVID-19 vaccine boosters is acceptable
- Heterologous dosing may be considered for the booster dose only.
 - All doses of the primary series and additional dose (if indicated for moderately to severely immunocompromised people who received 2 doses of mRNA vaccine) should utilize the same vaccine product.
- Individual benefit-risk assessment may inform which booster product to use.
 - Availability of booster product
 - Risk profile of vaccine boosters, including rare events





Additional Considerations for Heterologous (Mix-and-Match) Booster Dose

- Interval should follow the interval recommended by the primary series
 - People who received a single dose Janssen primary series can receive a mRNA
 COVID-19 booster dose at least 2 months after completing primary series
- If Moderna vaccine booster is used, the booster dose and volume should be utilized (50µg in 0.25ml)
 - Pfizer-BioNTech and Janssen booster doses are the same dose as primary vaccine
 - If an individual who is moderately to severely immunocompromised received a primary dose of Janssen vaccine and receives a booster dose using Moderna, the 50µg dose should be used





Administration of COVID-19 Vaccines

Vaccine	Primary series/dose		Additional dose in immunocompromised *		Booster dose+				
	Dose (volume)	N doses (interval)	Age (y)	Dose (volume)	N doses (interval since primary series)	Age (y)	Dose (volume)	N doses (interval since primary series)	Age (y)
Pfizer- BioNTech	30 μg (0.3 ml)	2 (21 d)	≥12	30 μg (0.3 ml)	1 (≥28 d)	≥12	30 μg (0.3 ml)	1 (≥6 m)	≥18§
Moderna	100 μg (0.5 ml)	2 (28 d)	≥18	100 μg (0.5 ml)	1 (≥28 d)	≥18	50 μg (0.25 ml)	1 (≥6 m)	≥18§
Janssen	5 × 10 ¹⁰ VP (0.5 ml)	1 (N/A)	≥18	(se	ee booster dose)		5 × 10 ¹⁰ VP (0.5 ml)	1 (≥2 m)	≥18

N = number, y = years, ml = milliliters, m = months, d = days, μg = micrograms, VP= viral particles



⁺ Moderately to severely immunocompromised people

[§] Minimum authorized age group

[&]quot;Booster interval based on homologous dosing (booster product is the same as primary series). Heterologous (mix-and-match) booster interval is dependent on the recommendation for the primary series

Definition of "Fully Vaccinated" is Unchanged

 For public health purposes, people who have completed a primary vaccine series (i.e., 2-dose mRNA vaccine series or a single dose of the Janssen vaccine) are considered fully vaccinated ≥2 weeks after completion of the primary series





Coadministration with Other Vaccines

- COVID-19 vaccine booster dose (Pfizer-BioNTech, Moderna, or Janssen) may be given with other vaccines, without regard to timing.
- This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day.
- If multiple vaccines are administered at a single visit, administer each injection in a different injection site.





Contraindications Related to Allergy

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine
- Known polysorbate allergy is a contraindication to Janssen COVID-19 and a precaution to mRNA COVID-19 vaccination
 - People with a contraindication to the mRNA COVID-19 vaccines (including a known allergy to polyethylene glycol [PEG]) have a precaution to Janssen COVID-19 vaccine



Upcoming FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting



- VRBPAC Meeting on Pfizer COVID-19 Vaccines for Children 5-11y/o
 - October 26, 5:30 AM − 2 PM PT (8:30 AM − 5 PM ET)

Followed by:

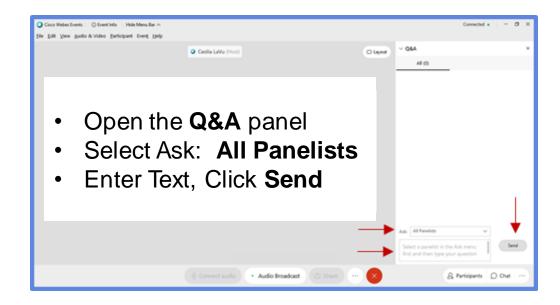
- CDC's Advisory Committee on Immunization Practices (ACIP)
 - November 2-3, 7 AM 2 PM PT
 - More information here
- Western States Scientific Safety Review Workgroup
 - Date TBD
 - More information here



Provider Office Hours Q&A

Please use the Q&A panel to comment or ask a question:

Q&A Panel





Storage & Handling

Kate McHugh, CDPH



COVID-19 Vaccine Presentations

		a	
	Purple Cap	Gray Cap	Orange Cap
Age	12+	12+	5 - <12
Formulation	PBS / Sucrose	Tris / Sucrose*	Tris / Sucrose*
Diluent Required	YES (1.8mL)	NO (DO NOT DILUTE)	YES (1.3 mL)
Dosage	30 mcg	30 mcg	10 mcg
Doses per Vial	6 doses	6 doses	10 doses
Injection Volume	0.3 mL	0.3 mL	0.2 mL
Storage in ULT Freezer (-90°C to -60°C)	Up to 9 months	Up to 6 months*	Up to 6 months*
Storage in Refrigerator (2°C to 8°C)	Up to one month	Up to 10 weeks*	Up to 10 weeks*
Storage in Freezer (-25°C to -15°C)	Up to 2 weeks	N/A	N/A
Status	ON MARKET	NOT YET APPROVED	NOT YET APPROVED



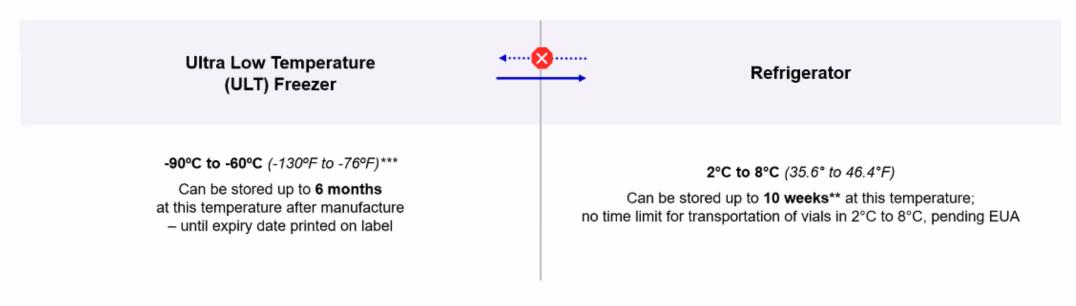


^{*}Regardless of storage condition, vaccines should not be used after 6 months from the date of manufacture printed on the vial and cartons.



PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

Detailed Storage Options for New Formulation – Pediatric 5-11 YO (orange cap vaccine)



NOTE: Once the vaccine has been thawed, it should not be re-frozen (i.e., if vial cartons are delivered at 2°C to 8°C, vaccine needs to stay at 2°C to 8°C). All thaw times for Tris/Sucrose are still under review pending results from stability studies. Tris/Sucrose vials cannot be stored in freezers at -25°C to -15°C.

*The BioNTech-Pfizer COVID-19 Vaccine shipment may arrive at the POU at a range of frozen and ultra-low-temperatures. However, when the POU receives the formulation, this end user should only store the vaccine using two storage options: (1) Ultra Low Temperature (ULT) Freezer and (2) Refrigerator. BIONTECH

^{***}Could also be known as Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA) in select markets



^{**}Projected storage allowance is subject to change based on upcoming data.

Pfizer COVID-19 Vaccine for 5-to-11-year-olds

- Packaged as Pfizer COVID-19 Vaccine.
- Expecting shipments to begin around November 1.
- Ancillary kits:
 - Week 1 ancillary kits and minimum order will be 300 doses
 - Week 2 ancillary kits and minimum order will be 100 doses
 - 10mL vials of normal saline as diluent.
 - You cannot use one vial of diluent to dilute multiple vials of vaccine. Remaining saline must be discarded.
- Shipper is smaller and disposable.
 - Cannot be used for storage
 - Only data logger needs to be returned



Pfizer COVID-19 Vaccine for 5-to-11-year-olds

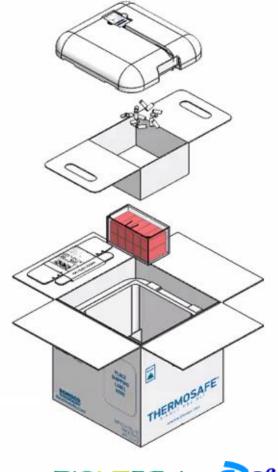
- You <u>cannot</u> use the current formulation on the shelves to administer to children ages 5-11.
- You will need to wait to receive the formulation approved for children ages 5-11.
- If you serve both individuals 12+ and under 12 at your clinic, it will be important to pay attention when administering the vaccine to check that you are using the correct product.



New Single-Use Shipper

	Kan Canadanatanat	
Key Considerations*		
Controlant Logger/ Monitoring	Real-time Data Monitoring	
Pack Options	10-pack	
Shipper Duration	3 Days	
External Dimensions	410 X 412 X 477mm	
Shipper Return	Not Applicable – Destroyed per procedure	
Controlant Logger Return	Returned without Shipper in provided return envelope	
Thermal System	Dry Ice – 10kg	
POU Considerations	Lightweight Not reusable Not designed for on-site storage Vials must be transferred to ULT or refrigerator upon receipt Differentiated from Medium ULT through nomenclature & Pfizer Global Supply brochure	







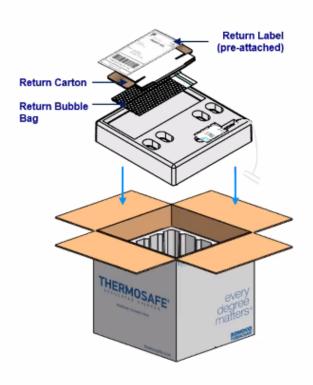


*Note: Pfizer does not recommend storing the Pediatric doses in the Medium ULT

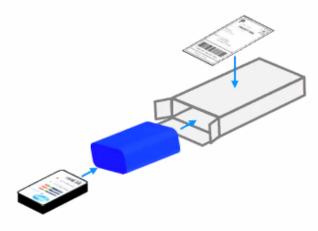


Single-Use Shipper Logger Return Process*

POU will receive vaccines in Single-Use Shipper with Logger Return Kit embedded within lid of shipper



- POU removes Logger from thermal shipper and places it inside of Bubble Bag
 - POU places Bubble Bag into Return Carton
 - Return Label applied to Return Carton (or may come pre-attached)



*Single-Use Thermal Shipper will not be returned, solely the Logger

3 Logger Return Carton collected at POU or dropped off for return to Controlant Service Center



Partners Include:

- FedEx
- UPS
- U.S. Postal Service







Moderna COVID-19 Boosters

Booster dose vials are the same formulation/NDC* as the primary series.
 It is <u>not</u> a different product.

Primary Series Dose: 0.5mL

Booster Dose: 0.25mL

Vial Size		Unit of Use NDC* (Vial)	Number of Primary Series Doses Per Vial	Number of Booster Doses Per Vial
5.5 mL	80777-273-99	80777-273-10	10 (maximum 11)	Maximum 20
7.5 mL	80777-273-98	80777-273-15	14 (maximum 15)	Maximum 20

Note: For both NDCs*, vials can be punctured a **maximum** of 20 times. The stopper in the vial has only been studied to successfully withstand up to 20 punctures.

*National Drug Code



More information to come...

We are awaiting further guidance from CDC on:

- Moderna waste
- Moderna detailed administration
- Ordering for Moderna and Janssen (J&J)



Moderna Booster Ancillary Supplies

- Due to the small size of the dose, 1mL syringes must be used for accurate measurements.
 - Moderna recommends using low-dead volume needles/syringes.
- If you are going to use Moderna currently in inventory for booster doses, you may have to supply your own 1mL syringes.
- CDC will ship double ancillary supplies for new Moderna shipments with all 1mL syringes.





Moderna COVID-19 Vaccine Shelf-life Extension

- This week Moderna started to update the expiration dates of the vaccine that received the shelf-life extension.
- They are updating the expiration lookup checker slowly. It may take several weeks for them to finish updating it.
- <u>Vial Expiration Date Lookup | Moderna COVID-19 Vaccine (EUA)</u>
 <u>(modernatx.com)</u>
- Continue to keep any vaccine that has not had its lot number updated quarantined.
- Currently, there is no published complete list of extended lot numbers.



Data Quality

Jennifer Womack, CDPH



Data Quality Reminders

- Make sure to update your inventory in Vaccine Finder!
 - As we prepare for J&J boosters make sure your inventory is up-to-date.
 - See job aids: <u>Reporting Inventory to VaccineFinder</u>, <u>VaccineFinder</u>
 <u>Updates</u>
- Report your expired vaccine in myCAvax!
 - See job aid: Reporting Doses Spoiled, Expired, or Wasted
- Data Strike Team will be reaching out to providers who have not reported inventory since September.
- Provider inventory will be reviewed when approving orders.



Vaccine Management

Eric Norton, My Turn and Claudia Aguiluz, CDPH



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What's New on My Turn: Release 19 (10/20)

My Turn Public



Incorporate all 15 flu Vaccines

Six additional flu vaccines added to the system. Residents can choose any of the vaccines available in CA, pending resident eligibility

Updated Screening Page

- Reorder screening page to add "Are you scheduling your first vaccination?" at start of flow
- ✓ To minimize confusion, residents will not be directed to the group scheduling flow if they are not scheduling their first vaccine

My Turn Clinic



Edit Vaccine Records

- ✓ Users can single or bulk update Additional Dose, Booster Dose, and flu records
- Users can only bulk update records of the same vaccine type

Added flu Products & Presentations

✓ All 15 flu brands and presentations supported for clinic setup, walk-in creation, and vaccine administration



My Turn Booster Dose Functionality Dates

(Available 10/25*)

Moderna

Single

booster dose

6 months

(minimum) following primary series completion

Ages

- 18 64 at high risk of severe COVID-19
- 18 64 with frequent institutional or occupational exposure
- o 65 and older

Janssen

Single

booster dose

2 months

(minimum) following primary single-dose completion

Ages

18 and older

Pfizer

Single

booster dose

6 months

(minimum) following primary series completion

Ages

- 18 64 at high risk of severe COVID-19
- 18 64 with frequent institutional or occupational exposure
- o 65 and older

(Available 10/26*)

Mix-and-Match Booster Dose

- Single booster dose of FDA-authorized COVID-19 vaccine
- Following primary series completion
- Can be administered regardless of different primary series

Continue to wait for regulatory approvals before administering doses in arms



REMINDER: My Turn Flu Live Support (Ends 10/28)

Providers: Q: Do you want to use My Turn to create and manage flu clinics?

A: Yes? Great, take advantage of the live support resources available until Oct 28th!

Next Steps	Details	Support
myCAvax Pre-Requirement for All Providers (wanting to stand-up a flu clinic)	 Clinics must enroll in the California COVID-19 Vaccination Program as a clinic location using the myCAvax website (even if you will be providing just flu vaccine). 	Live, Virtual Trainings & Office Available through 10/28
My Turn Requirement for Providers NEW to My Turn	Must follow Option 2 below	
My Turn Requirement for Providers REGISTERED & already using My Turn	 N/A, can create flu clinics immediately Regardless, if you're creating flu clinics for yourself or partnering with schools to create them 	

Support:

(1) My Turn-Flu Mass Vaccination Clinics Website



(2) Option 2: Enrollment Kit for Flu Vaccine; A resource kit for prospective and enrolling providers info



(3) My Turn Onboarding and Training Session Schedule and Registration Links





What's New on myCAvax: Release 18 (10/21)*

Changes for Providers

Enrollments

- ✓ Block autofill during Section B Enrollment
- Org Coordinator changes CEO/CMO email on the 'Responsible Officers' page? a new E-Signature email request is generated

Viewing Waste events

- On the 'Waste Events' tab, Organization Coordinators can view all waste events for all locations within their organization.
- Location Coordinators can view all waste events for all the locations they're affiliated with.

✓ Vaccine Marketplace

Only locations with an active status can request excess doses.

For Providers

California COVID-19 Vaccination Program Update



New Release October 21, 2021

Enhancement Details for Providers

The myCAvax system will have new functionalities available tomorrow. We are making many of these enhancements in response to user feedback. They have an impact on Providers, especially those newly enrolling, and Local Health Departments/MCEs. Please review what is changing based on your role in the system:

Waste Events

View Waste Events

On the 'Waste Events' tab, Organization Coordinators will be able to view all waste events for all locations within their organization. Also, Location Coordinators will be able to view all waste events for all the locations they're affiliated with.

Account/Case Changes

Vaccine Marketplace

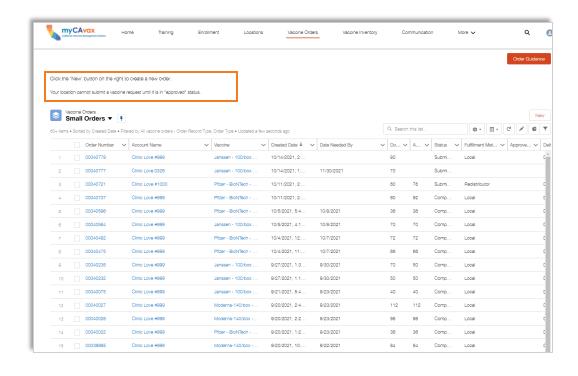
When filling out the 'New Vaccine Marketplace: Request Excess Doses' section, only active location accounts in the 'Location Name' lookup will show. Both active and inactive locations can post excess doses to share. A tool tip will display in 'Location Name' field: "All locations regardless of status can post their excess or short-dated COVID vaccine. Only locations with an active status can request excess doses."

The text at the top of the 'Vaccine Marketplace' page will be updated to indicate how to proceed if you have excess doses or

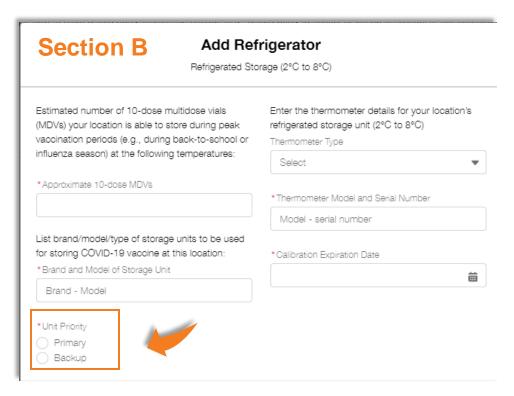


What's New on myCAvax: Release 18 (10/21)*

Changes for Providers



✓ 'Vaccine Orders' tab on Community view directs users to new button to create a new order



- Providers can mark up to two primary storage units of the same type
- ✓ Replaced 'Primary' field with 'Unit Priority'



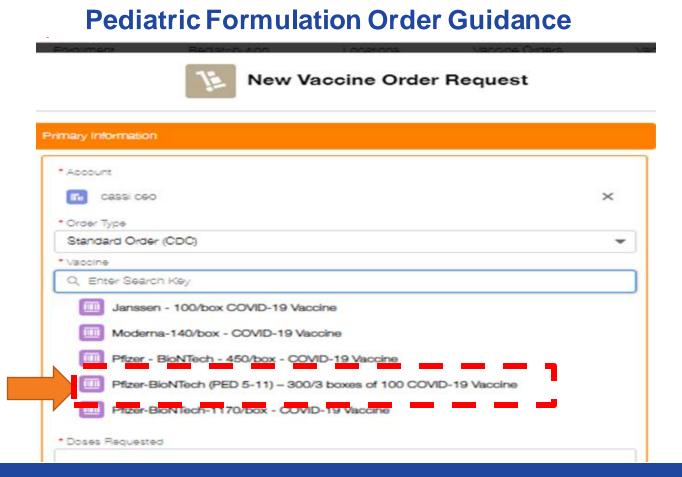
Ages 5-11 Pediatric Pfizer Vaccine

While awaiting formal FDA approval of the ages 5-11 pediatric vaccine ...

PRE-ORDER

- CDC is allowing pre-ordering of Pfizer's Pediatric COVID 19 vaccines during an initial rollout week.
 - o Pre-order available 10/19 to 10/22, by 5 pm
 - Min Order Qty 300 doses/increments of 300
- Approved orders submitted to CDC in 3 waves, based on CDC supply allocations, starting 10/21, 10/22, and 10/25
- Once transmitted, orders will be ship after FDA EUA approval, arriving between 11/1- 11/8
- Pfizer Shipment email notifications will alert you when doses begin to ship.

CHECK YOUR EMAIL!





Ages 5-11 Pediatric Pfizer Vaccine

While awaiting formal FDA approval of the ages 5-11 pediatric vaccine ...

UP NEXT

Post pre-ordering rollout

- Standard Orders
 - Minimum Quantity will change to 100 doses per order
- Small Orders (< 100 doses) for local and TPR redistribution
- Details will be forthcoming

REMINDER

Current inventory of Pfizer 12+ formulation cannot be used in 5-to-11-year-olds.

Pediatric Formulation Order Guidance

	Current Formulation	Future Formulations		
Description	Dilute Prior to Use	Do Not Dilute	Dilute Prior to Use	
Age Group	12 years and older	12 years and older	5 to <12 years*	
Vial Cap Color	PURPLE	GRAY	ORANGE	
Dose	30 mcg	30 mcg	10 mcg	
Injection Volume	0.3 mL	0.3 mL	0.2 mL	
Fill Volume (before dilution)	0.45 mL	2.25 mL	1.3 mL	
Amount of Diluent* Needed per Vial	1.8 mL	NO DILUTION	1.3 mL	
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)	
Storage Conditions				
ULT Freezer (-90°C to -60°C)	9 months	6 months	6 months	
Freezer (-25°C to -15°C)	2 weeks	N/A	N/A	
Refrigerator (2°C to 8°C)	1 month	10 weeks	10 weeks	

CHECK YOUR EMAIL!



Pfizer 1170 Ordering

Pfizer 1170 will **not be available** for order & delivery during a temporary blackout period. To prevent potential delays and ensure timely delivery of vaccine prio to the ordering and shipping blackout:



Provider submits all order requests.

Approved orders will be delivered week of Nov 1st



LHD approves ordering requests; CDPH transmits to CDC





Order Blackout begins
Oct 29th and ends Nov
4th for Pfizer only



Pfizer 1170 Deliveries Paused Nov. 2nd – 9th



APPENDIX



Pre-Order Week Cadence for Providers: Pfizer Pediatric COVID-19 Vaccine (5-11 Years)

Monday	Tuesday	Wednesday	Thursday	Friday	
October 18	19	20	21	22	
	Pediatric Pre-Orders by 5pm (300 doses minimum)	Pediatric Pre-Orders Catch-up (300	doses minimum)		
Routine Orders by 5pm		Routine Catch-up Orders by 5pm			
25	26	27	28	29	
Routine Orders by 5pm (last chance to receive Pfizer 1170 before pause in delivery)		Routine Catch-up Orders by 5pm (delayed delivery for Pfizer 1170)			
November 1	2	3	4	5	
Wave 1 Pediatric Deliveries (pending ACIP approval)		Wave 2 Pediatric Deliveries (pending ACIP approval)		Wave 3 Pediatric Deliveries	
Routine Orders by 5pm		Routine Catch-up Orders by 5pm		(pending ACIP approval)	
(delayed delivery for Pfizer 1170)	Pfizer 1170 delivery paused Nov 2–9				
8 Wave 3 Pediatric Deliveries (pending ACIP approval)	9	10	11	12	
Small Orders by 5pm		Small Order Catch-up by 5pm			
Routine Orders by 5pm		Routine Catch-up Orders by 5pm			
Pfizer 1170 delivery paused Nov 2-	-9				



What's New on My Turn: Release 19 (10/20)

My Turn Public

Booster Updates

- ✓ Split booster and additional dose
 - Updated copy and vaccine rules

Flu

✓ Incorporate all 15 flu vaccine brands

General Enhancements

- ✓ Reorder screening page to improve group scheduling experience
- ✓ Limit clinic search address to California addresses only
- ✓ User friendly error message for expired clinic links
- ✓ Add optional middle name field to patient booking
- ✓ New CDC question: history of Guillain-Barré syndrome
- ✓ Updating COVID flow also to separate personal and contact information from CDC questions for better user experience

My Turn Clinic

Priorities

- ✓ Supporting additional flu products
- ✓ IIS flu sending records
- ✓ Pregnancy warning banner
- ✓ Minor consent provider handoff
- ✓ Separating additional dose and booster

General Enhancements

- ✓ Create middle name field and suffix on walk-in
- ✓ EUA quick link in Vaccine Administrator flow
- ✓ Make state address field 2 letter code picklist on walk-in UI
- ✓ New CDC question: history of Guillain-Barré syndrome
- ✓ Ability to filter clinic list views by date range, physical address
- ✓ Automate nasal spray and free flu tagging
- ✓ Edit Single / Bulk Functionality for flu, AD, Booster



What's New on myCAvax: Release 18 (10/21)

Enrollment: Section A

- Only CDPH / System Admin can update the Provider Organization on the Location Application. LHDs / Providers are not allowed
 - Updates to the Provider Organization and Application Number on the Location Application will be reflected in the Location Account's Parent Organization. New Organization Coordinator will be added to the Location Account's Account Team Member section and Related Contacts. Location Coordinator will be added to the new Organization account's Account Team Members section. Location Coordinator's contact Account Name will be updated to the new organization
- ✓ Home and Enrollment Page
 - Updated 'Redistribution Plan Job Aid' link
 - Before User's Training begins, all buttons in the subsequent sections will be greyed out and labeled either 'Start' or 'Setup Locations'
- ✓ Relabeled 'Request E-Signatures' page to 'E-Signatures' Requested'

✓ Updated Enrollment buttons and display of toast notification when E-Signature is sent to CEO / CMO. If an Organization Coordinator changes CEO / CMO email address on the 'Responsible Officers' page, the system will generate a new E-Signature email request once Coordinator clicks 'Request E-Signature' button

Enrollment: Section B

- ✓ Updated Enrollment buttons and display of toast notification when E-Signature is sent to Location Coordinator
- ✓ Relabeled 'Request E-Signatures' page to 'E-Signatures' Requested'
- Block autofill
- Updated tool tip for 'Primary and Backup COVID-19 Vaccine Coordinator' roles on 'Vaccination Coordinators' page
- ✓ Replaced 'Primary' field with 'Unit Priority' and added 'Primary' and 'Backup' Radio buttons to Program Provider Capacity Form for Location Coordinator. 'Unit Priority' and 'Thermometer Model and Serial Number' fields is visible on related list view on Location Application and Account. Removed validations to require at least one and no more than two primary storage units of the same type



What's New on myCAvax: Release 18 (10/21) - cont.

Vaccine Transfer

Relabeled 'Order Comments' to 'Internal Comments' on internal Vaccine Order layout for LHD. Added 'Internal Comments' field and mapped comments made in the 'Vaccine Accept / Reject' pop-up to the 'Internal Comments' field on the Internal Vaccine Transfer layout for LHD

Account / Case Changes

Updated the text at the top of Vaccine Marketplace page for community users. Only display Active Location accounts in Location Name lookup if user is requesting excess doses. Added a tool tip to Location Name field to provide guidance to proceed

Shipment

LHD can update Lot Number and Lot Expiration Date on the Distribution Shipment Record Type

Allocation

 Display products with the COVID-19 record type. Flu products will not be displayed in the Bulk Allocation Template

User Interface

'Vaccine Orders' tab on Community view to direct users to new button to create a new order

Waste Events

Coordinators can view all Waste events for all locations within their organization. Location Coordinators can now see all Waste events for locations they are affiliated with on the Waste events tab



myCAvax – Known Issues & Workarounds



Known Issue

Location Application (Section B) Enrollment Interface Action Misalignment

- When a Provider navigates to the enrollment interface for the location application (Section B) the action available may be misaligned to the current status of the location application.
 - For example, a user may see the update option when the location application's DocuSign has been returned.



Providers can manually refresh the page and the correct action should appear.



Wrap-Up & Resources

Leslie Amani, CDPH



Where can I go for additional help?

Type of Support	Description	Updated 9.23.21
COVID-19 Provider Call Center	The COVID-19 Call Center for Providers and Local Health Departments is dedicated to medical provide their COVID-19 response, specifically addressing questions about State program requirements, enrollm distribution, including the Vaccine Marketplace. • Email: covidcallcenter@cdph.ca.gov	
	 Phone: (833) 502-1245, Monday through Friday from 8AM-6PM 	
Enrollment Support	For Provider enrollment support, please contact myCAvax Clinic Operations at	
/ * \	Email: myCAvaxinfo@cdph.ca.gov	
	Dedicated staff provide up-to-date information and technical support on the myCAvax system.	
myCAvax Help Desk	Email: myCAvax.HD@Accenture.com	
\Box	 Phone: (833)-502-1245, option 2, Monday through Friday 7AM-7PM, Saturday and Sunday 8AM-1PM 	Л
	For training opportunities: https://eziz.org/covid/education/	
My Turn Clinia Haln Dook	For onboarding support (those in the process of onboarding): myturnonboarding@cdph.ca.gov	
My Turn Clinic Help Desk	For technical support with My Turn Clinic for COVID-19 and flu vaccines: MyTurn.Clinic.HD@Accentur	e.com or
	(833) 502-1245, option 4: Monday through Friday 7AM-7PM, Saturday and Sunday 8AM-1PM.	
	For job aids and demo and training opportunities: https://eziz.org/covid/myturn/	
CalVaxGrant Program	For questions and support around CalVaxGrant, contact the program's administrator, Physicians for a F	Healthy California.
Support	Email: <u>calvaxgrant@phcdocs.org</u>	
/ V \ cabbait	• Phone: (916) 551-2565	



Hear it? Clear It.

If you see or hear of any vaccine-related rumors within the communities you serve, share them with our Trust and Safety team via the CDPH Rumors Inbox.



Trust and Safety Team

Our shared mission is to reduce COVID-19 vaccine hesitancy and increase vaccination across the State of California.



How You Can Help

You are critical in our effort to provide Californians accurate and timely information around COVID-19 vaccination.



Monitor What You See and Hear

Monitor online media and what you hear in your local communities for potential rumors and inaccurate information.

If found, report it to rumors@cdph.ca.gov

<u>Contac</u>



Public Call Center

Public COVID-19 Call Center

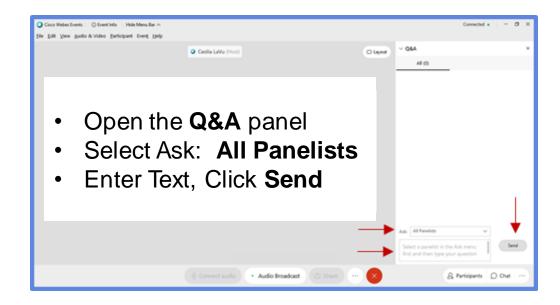
- Phone: (833) 422-4255: M-F 8AM-8PM; S-S 9AM-5PM
- For general COVID questions, including vaccines, scheduling vaccination appointments through My Turn, return to school, testing, etc.



Provider Office Hours Q&A

Please use the Q&A panel to comment or ask a question:

Q&A Panel





Thank you!



Monday: My Turn & myCAvax Office Hours Link

Monday, October 25, at 12:00 PM

Audio Conference: 415-655-0001 Access Code: 145 995 8782 Session Number: 145 995 8782 Session Password: Immunize2020!

Next Friday: Provider Office Hours Link

Friday, October 29, at 9:00 AM

Audio Conference: 415-655-0001 Access Code: 145 195 9307 Session Number: 145 195 9307 Session Password: Immunize2021!



Provider Office Hours Q&A

Please use the Q&A panel to comment or ask a question:

Q&A Panel

