

Providers of Adolescent Services: What to Expect After Enrolling in the CA COVID-19 Vaccination Program

California Department of Public Health
Tuesday, May 25, 2021



Housekeeping



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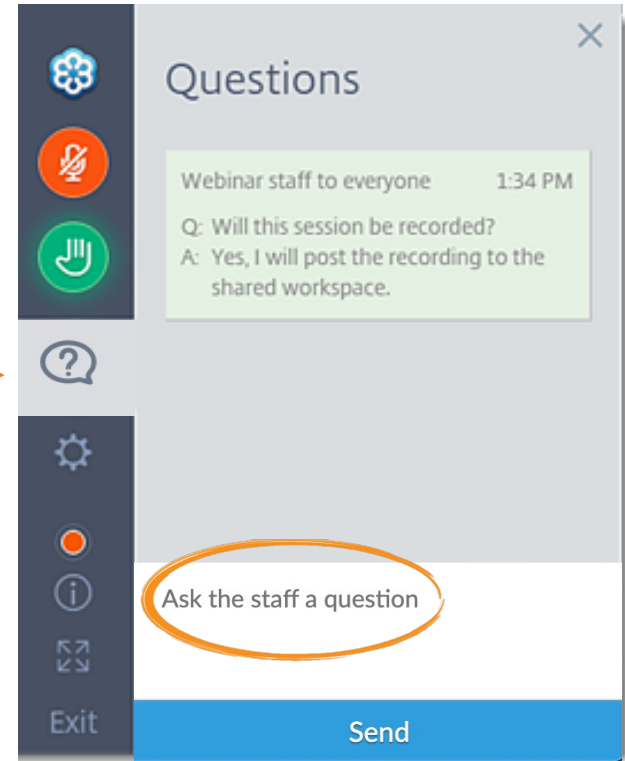
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Questions & Answers

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Webinar Objectives:

- Describe clinical guidance for vaccinating adolescents with COVID-19 vaccine.
- Provide operational guidance and considerations for vaccinating adolescents with COVID-19 vaccine.
- Describe storage and handling requirements for participating in the CA COVID-19 Vaccination Program.
- Share resources for providers and patients.



Agenda

- **Clinical Guidance on use of COVID-19 Vaccine in Adolescents**, Tom Boo, MD, FAAFP
- **Next Steps After Enrollment**, Nisha Gandhi, MPH
- **Storage & Handling of Pfizer COVID-19 Vaccine**, Kate McHugh
- **Next Steps After Ordering Vaccine**, Claudia Aguiluz
 - **Billing and Reimbursement**, Mark Lane
 - **My Turn Overview**, Eric Norton
- **Resources**
- **Questions & Answers**

Moderator: Leslie Amani

We Appreciate Your Feedback!

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Clinical Guidance on Use of Pfizer COVID-19 Vaccine in Adolescents

Tom Boo, MD, FAAP

Medical Officer, CDPH Immunization Branch

Adolescents Now Eligible for COVID-19 Vaccine

- Emergency Use Authorization for Pfizer-BioNTech vaccine extended to persons 12-15 years of age May 10, 2021
 - Fact sheets for providers and recipients and caregivers have been updated.
- ACIP and Western States Scientific Safety Review Work Group voted to recommend Pfizer-BioNTech for all people 12+

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **Pfizer-BioNTech COVID-19 Vaccine**, for active immunization to prevent COVID-19 in individuals 12 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.3 mL each) 3 weeks apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.covidvaccine.com.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.



California families need more trusted physician practices providing COVID-19 vaccination

- Health Care Providers are patients' most trusted source of vaccine information.
 - Clearly recommend COVID 1Z to patients!
- Focus is shifting away from community mass-vaccination efforts toward medical practices.
- Increasingly, medical practices should give COVID-19 shots.
- Trust & continuity!
- Particularly important in children
- Barriers are decreasing, though not eliminated.

Clinical Considerations for Adolescents

- Interim Clinical Considerations updates for Use of COVID-19 Vaccines (CDC)
 - Dose volume and timing for vaccination of 12-15 y/o are the same as for adults:
 - 0.3ml per dose, given 21 days apart
 - Information re: fainting risk with administration of injections; higher in adolescents
 - Procedures should be in place to avoid injury from fainting.
 - Parents and guardians can enroll adolescents (ages 12 and older) in v-safe and complete health check-ins on their behalf after COVID-19 vaccination.
 - Restrictions on the co-administration of other vaccines are removed.
- 1-inch needles provided in ancillary kits for adolescent COVID-19 vaccination
 - While CDC Pink Book references 5/8" to 1" 22- to 25-gauge needle for intramuscular injection in 11-18-year-olds, 1" needles are preferred to ensure intramuscular administration.

Reports of Myocarditis After Vaccination

- CDC and health departments are investigating a handful of reports of mild myocarditis in young vaccine recipients.
- Unclear whether vaccine-attributable
- All vaccine safety databases and programs on alert
- Communications to Health Care Providers to raise awareness
- No change in CDC, ACIP, AAP, CDPH recommendations

Co-administration of COVID-19 Vaccine

FDA-authorized COVID-19 vaccines and other vaccines **may now be administered without regard to timing**, per CDC guidance. Includes simultaneous administration of COVID-19 vaccine on the same day or administration within 14 days of another vaccine.

- Unknown whether reactogenicity is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines.
- When deciding whether to co-administer, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of disease, and the reactogenicity profile of the vaccines.
- If multiple vaccines are administered at a single visit, administer each injection in a different injection site, i.e., spaced on same limb or on different limbs.

Co-administration with COVID-19 Vaccine

American Academy of Pediatrics also supports co-administration of routine childhood and adolescent immunizations with COVID-19 vaccines

- For adolescents behind on or due for immunizations
- For adolescents at increased risk from vaccine-preventable diseases

Avoid the back-to-school rush and vaccinate now!

COVID-19 vaccination provides an opportunity for catch-up on other vaccines like Tdap, HPV, & MenACWY.



CDPH Minor Consent Guidance

Persons younger than 18 years must have parental or guardian consent given by a legally authorized representative (parent or guardian). An emancipated minor may consent for him/herself.




Allowable Consent:


- Parent/guardian accompanies the minor in person
- If the parent/guardian cannot accompany the minor, a signed written consent is acceptable. Phone or video consent is also possible. The consent must verify the parent/guardian has been provided the [Pfizer EUA Fact Sheet](#).

Sample Consent/Permission Slip

Found on
CDPH website
& in My Turn

COVID-19 Home Protect Your Health Get Latest Guidance See the Numbers Learn More

 State of California—Health and Human Services Agency
California Department of Public Health


GAVIN NEWSOM
Governor

TOMÁS J. ARAGÓN, M.D., Dr.P.H.
State Public Health Officer & Director

May 13, 2021

TO: To all Californians

SUBJECT: Pfizer Vaccine Minor Consent Guidance

Background

Administration of COVID-19 vaccines to as many Californians as possible is critical to control the pandemic. Based on evidence of safety and efficacy, the U.S. Food and Drug Administration (FDA) has now reduced the minimum age for its Emergency Use Authorization of Pfizer COVID-19 vaccine from 16 years of age down to 12 years.

In an ongoing clinical trial, two doses of this vaccine given three weeks apart has been shown to prevent illness, hospitalization, or death from COVID-19. The duration of protection against COVID-19 is currently unknown. More information on the risks and benefits of the Pfizer vaccine can be found on the [Pfizer COVID-19 Vaccine Benefits and Risks Fact Sheet](#).

Options for Consent

Persons younger than 18 years must have parental or guardian consent given by a legally authorized representative (parent or guardian). An emancipated minor may consent for him/herself. Currently, only the Pfizer vaccine has received Emergency Use Authorization for people 12 years of age and older.

Allowable consent includes:

- Parent/guardian accompanies the minor in person.
- If the parent/guardian cannot accompany the minor, a signed written consent is acceptable. The parent/guardian must sign the consent and the parent/guardian has been provided the [Pfizer EUA Fact Sheet](#).
- Phone or video consent is possible if the parent/guardian confirms that they have read the [Pfizer EUA Fact Sheet](#) or the [Fact Sheet](#) is read to the parent/guardian.

To learn more about risks, benefits, and side effects of the Pfizer vaccine, visit the CDPH website [Get the Facts on Vaccines \(ca.gov\)](#) and/or read the U.S. Food and Drug Administration's [Fact Sheet for Recipients and Caregivers](#).

Download the Sample Consent Form:

- Editable Word Doc template
- Fillable PDF form

Pfizer-BioNTech COVID-19 Vaccine Consent For Individuals Under 18 Years of Age [Clear form](#)

Section 1: Information about the child to receive Pfizer-BioNTech COVID-19 Vaccine (please print):

Child's Name (Last, First, Middle) _____ Date of Birth (mm/dd/yyyy) Age _____

Street Address _____ City _____ State _____ Zip _____

Phone Number _____

Section 2: Information on the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine (Pfizer Vaccine).

Currently the U.S. Food and Drug Administration (FDA) has authorized emergency use of the Pfizer Vaccine to prevent COVID-19 in individuals 12 years of age and older. The FDA has not yet approved licensure of vaccine to prevent COVID-19. To learn more about risks, benefits, and side effects of the Pfizer vaccine, read the U.S. Food and Drug Administration's [Fact Sheet for Recipients and Caregivers](#).

Section 3: Consent.

I have reviewed the information on risks and benefits of the Pfizer Vaccine in Section 2 above and understand the risks and benefits. I agree that:

1. I reviewed this consent form and have read and understand the "Fact Sheet for Recipients and Caregivers" about the potential risks and benefits of the Pfizer Vaccine.
2. I have the legal authority to consent to have the child named above vaccinated with the Pfizer Vaccine.
3. I understand I am not required to accompany the child named above to the vaccination appointment and, by giving my consent below, the child will receive the Pfizer Vaccine whether or not I am present at the vaccination appointment.
4. I understand that as required by state law (Health and Safety Code, § 120440), all immunizations will be reported to the California Immunization Registry (CAIR2). I understand the information in the child's CAIR2 record will be shared with the local health department and State Department of Public Health, shall be treated as confidential medical information, and shall be used only to share with each other or as allowed by law. I may refuse to allow the information to be further shared and can request the CAIR2 record be locked by visiting the [Request to Lock My CAIR Record](#) web form.

I GIVE CONSENT for the child named at the top of this form to get vaccinated with the Pfizer-BioNTech COVID-19 Vaccine and have reviewed and agree to the information included in this form.

Name (Last, First, Middle) _____

Signature _____ Date _____

Address if different from above _____

Phone Number if different from above _____

Next Steps After Enrollment

Nisha Gandhi, MPH

Adult Immunization Coordinator, CDPH Immunization Branch

Enrollment Steps

- ✓ Step 1: Review Program Requirements including CDC Provider Agreement
- ✓ Step 2: Immunization Information System (IIS)
- ✓ Step 3: Storage & Handling Guidelines
- ✓ Step 4: Enrollment Worksheet
- ✓ Step 5: Responsible Officers
- ✓ Step 6: Complete Required Training
- ✓ Step 7: CDC Provider Agreement in myCAvax

Provider Enrollment: Before You Enroll

California COVID-19 Vaccination Program



Providers with an active license in California and who possess and administer vaccines are eligible to enroll in the California COVID-19 Vaccination Program. To receive State doses, local providers, medical groups, health systems, multi-county entities, pharmacies, and [HRSA community health centers](#) will enroll in myCAvax. Your application will be reviewed and verified by CDPH prior to approval.

Section A: Provider Requirements & Legal Agreement

Organization Coordinator is the Point of Contact who enrolls the provider organization in myCAvax. This role will complete Section A, identify affiliated locations (under the same CEO) who are to receive or administer COVID-19 vaccines, register with VaccineFinder and determine whether Organization or Locations will report inventory daily, and monitor all program communications.

Who signs? Organization's Chief Medical Officer (or equivalent medical official) and Chief Executive Officer (or chief fiduciary/legal official) must agree to the conditions of program participation and DocuSign the CDC Provider Requirements & Agreement on behalf of your Organization.

Section B: Provider Profile Information

Each location must have an **on-site** primary and backup **Location Coordinator**, typically filled by vaccine coordinators. This role will enroll the provider location in myCAvax; receive vaccines, monitor temperatures, and manage vaccine inventory; receive emails regarding allocations, shipments, and temperature monitoring; may be delegated to report inventory to VaccineFinder; and may transport vaccines for mass vaccination clinics. The Location Coordinator completes Section B and submits the application to CDPH for review.

Who signs? Medical or Pharmacy Director (or Vaccine Coordinator) responsible for location's adherence to CDC Provider Agreement terms must DocuSign Section B.

Step 1: Review Program Requirements

Review [CDC Provider Agreement](#) to ensure your facility can meet all program requirements. Go to [Program Enrollment](#) to review Steps to Participation (in the TPA Network) to ensure you are willing to participate in order to receive vaccine. (Providers of pediatric services may opt out.)

Step 2: Enroll in IIS

Each vaccination location must be enrolled in the California Immunization Registry (CAIR) and have their own unique IIS Registry ID (e.g., CAIR Org Code); locations may not share the Organization's IIS ID. If your facility is not currently enrolled, please [enroll in your local registry](#) now. If your location is already enrolled in CAIR2/SDIR/RIDE and has its own unique IIS ID, do not enroll again; use your existing CAIR Org Code.

Next Steps

- Once a Provider is approved, you will receive an email describing the COVID-19 Program details.
- Providers will be able to update account information in myCAvax as needed.
- Information on VaccineFinder will be sent to the Organization Contact.

Pfizer Minimum Order


- Currently, Pfizer COVID-19 vaccine has a minimum order and increment of 1,170 doses.
- Coming soon, incremental ordering of 450 doses for smaller providers
 - Only ~35% of the nationwide allocation




Vaccine Ordering

- **myCAvax is the main vaccine ordering system for most enrolled providers.**
 - Submit order requests weekly.
 - Request in increments of 1,170 doses.
 - Coordinate smaller orders through your LHD (filled via “redistribution”).
 - Report # of doses administered and on-hand inventory with your request.
- LHDs and the Third-Party Administrator (TPA) will approve most requests as they are submitted.
 - When order is approved, you will receive email confirmation.



 New Vaccine Order Request

Primary Information

* Account
 Queen1 ×

* Vaccine

* Doses Requested




* Doses Administered


* How many doses in this order will be used for dose 2?

Comments/Extra Quantity Justification

Inventory Information

Inventory Detail

Lot Number	Quantity	Expiration Date	Action
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Lot Number	Quantity	Expiration Date	Action
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Lot Number	Quantity	Expiration Date	Action
<input type="text"/>	<input type="text"/>	<input type="text"/>	

 Add Row

Cancel

Save as Draft

Save & Submit

Storage & Handling of Pfizer COVID-19 Vaccine

Kate McHugh

Preparedness Field Assignee, CDPH

Vaccine Management

To protect the potency of COVID-19 vaccines, Providers must:

- ✓ Store and handle COVID-19 vaccines in accordance with the EUA, manufacturer guidance, and CDC's [Vaccine Storage & Handling Toolkit](#).
- ✓ Monitor and comply with COVID-19 vaccine expiration dates.
- ✓ Monitor and comply within vaccine storage temperature parameters required by the manufacturer.
- ✓ Use labels, or alternate method for marking thaw time and beyond-use date on vaccine vials after thawing or mixing with diluent. (See [EZIZ](#) for links to beyond use date labels.)
- ✓ Report all nonviable vaccines ([waste](#)) daily and comply with guidance for disposal.

Pfizer-BioNTech COVID-19 Vaccine Storage & Handling

- 6-dose vial, reconstituted with 1.8 ml of diluent (provided)
- Must be used within 6-hours of reconstitution
- 2-dose regimen at 21 days (+/- 4d)
- Storage
 - Ultra-low temperatures (-60°C to -80°C) until the published expiration date (approximately 6 months)
 - Standard frozen storage (-25°C to -15°C) for 14 days
 - Refrigerated storage (2°C to 8°C) for one month (31 days)





How Long Can I Store Pfizer Vaccine Without an ULT Freezer?

Your Storage Unit(s)	Shelf Life
Thermal shipper, standard freezer, and refrigerator	75 days
Standard freezer and refrigerator	45 days
Standalone standard freezer only	14 days
Standalone refrigerator only	31 days (1 month)

Temperature Monitoring

Daily Tasks

- Read CURRENT, MIN, and MAX refrigerator and freezer temperatures twice per day – when the clinic opens and before it closes – even if using digital data loggers.
- Document temperatures on your temperature logs ([EZIZ temperature log](#)) and keep your printed log on the outside of your refrigerator.
- See next slide for instructions on temperature excursions.

Biweekly Tasks

- Review, certify, and sign that temperatures were recorded twice daily and corrective actions were taken.
- Download and review data files at the end of every two-week reporting period to look for missed excursions or temperature trends that might indicate performance issues with vaccine storage units.

Important: Temperature logs must be saved for three years as outlined in the CDC provider agreement.

Temperature Excursions

- Vaccine is sensitive to temperature change.
- Most temperature excursions happen during transport. Closely follow transport guidance for each vaccine, found in the CDC [Storage & Handling Toolkit](#).
- Must use digital data logger (DDL) for storage and transport.
 - If vaccine experiences a temperature excursion, you will need data from DDL to determine vaccine viability.
- Never refreeze thawed vaccine. If you experience an excursion and the vaccine thawed, place in refrigerator.
- Never transport vaccine on dry ice as this will make the vaccine too cold.
 - Exception: Transporting Pfizer vaccine stored in original thermal shipper



Vaccine Management Plan

- Providers are highly encouraged to develop your own location-specific COVID-19 Vaccine Management Plan.
 - Should be printed and kept in accessible place for all staff to access in case of emergency
- Template plan includes:
 - Staff contact information
 - Emergency contact information (for maintenance, utilities, etc.)
 - Storage unit information and maintenance/data logger calibration information
 - Roles, responsibilities, and daily/weekly/monthly tasks
 - Emergency plan
 - And more!

Vaccine Management Plan

California COVID-19 Vaccination Program



Maintain a vaccine management plan for routine and emergency situations to protect vaccines and minimize loss due to negligence. The Vaccine Coordinator and Backup are responsible for implementing the plan.

Instructions: Complete this form and make sure key practice staff sign and acknowledge the signature log whenever your plan is revised. Ensure that all content is up to date. Keep the plan near storage units and available for review by CDC or program staff during site visits.

Section 1: Important Contacts

Office/Practice Name		COVID-19 PIN			
Address					
	Role	Name	Title	Phone #	E-mail
Provider of Record					
Organization Coordinator					
Location Coordinator (Vaccine Coordinator)					
Backup Location Coordinator					
Immunization Champion (optional)					
Receives vaccines					
Stores vaccines					
Handles shipping					
Issues					
Monitors storage unit temperatures					

Emergency & Support Contacts

Service	Name	Phone #	Alt Phone #	E-mail
COVID Call Center		(833) 502-1245		
Utility Company				
Building Maintenance				
Building Alarm Company				
Refrigerator/Freezer Alarm Company				
Refrigerator/Freezer Repair				
Point of Contact for Vaccine Transport				
Dry Ice Company (if storing Pfizer in thermal shippers)				

California COVID-19 Vaccination Program

IMM-1362 (5/6/21)

Next Steps After Ordering Vaccine

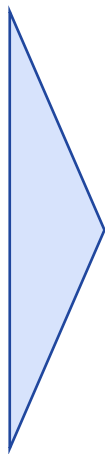
Claudia Aguiluz

Vaccines for Children Program Manager, CDPH Immunization Branch

Vaccine Management: Shipments

Preparing to receive vaccine shipments

- System notifications
- Updated information
 - Practice Hours
 - Vaccine Coordinators & Contact Information



Receiving, inspecting and storing shipments (Direct from LHD)

- Staff training
- Shipments (vaccines AND ancillary kits)
 - Inspect, store and report
 - Proper equipment, temperature monitoring AND entering receipt of doses in myCAVax

Pfizer-BioNTech COVID-19 Vaccine Delivery Checklist

COVID-19 vaccine (Pfizer) requires ultra-cold temperatures during shipment and will arrive in a thermal shipping container with dry ice. To unpack the vaccine, staff will need proper personal protective equipment (PPE) and should know how to handle dry ice safely. Training materials from the manufacturer, including videos, are available at www.cdc.gov/covid-19. Use the following checklist to ensure the vaccine is received, stored, and handled appropriately.

1. Vaccine will be delivered by FedEx or UPS.

2. Examine the shipping container for signs of physical damage.

- If the thermal shipping container appears damaged – STOP. Contact Pfizer with questions or concerns.
- If the thermal shipping container appears to be in good condition, continue to Step 3.

3. Place the thermal shipping container on the floor to unpack (may weigh up to 40 pounds).

4. The thermal shipping container contains dry ice.

Before opening:

- Collect PPE, including goggles and insulated gloves.
- Place the thermal shipping container in an area with proper ventilation. A leak in a confined area may create an oxygen deficient environment and result in suffocation.

5. Open the thermal shipping container.

6. Press and hold the "Stop Shipment" button on the temperature monitoring device (TMD) for 3 seconds.

- This triggers an e-mail report from the manufacturer on the temperature status of the container during transit. The report will be sent to the provider (facility) e-mail address associated with the order.
- The LED indicator light on the TMD will change from blinking to a solid light.

7. Proceed based on the color of the LED indicator light.

- **Green:** Vaccine can be unpacked. Continue to step 8.
- **Red or no color:** STOP! Wait for the status report on the vaccine.
- Contact the manufacturer immediately if the status report indicates a temperature excursion has occurred.
- Continue to step 8 if the vaccine can be used.

8. Wearing PPE, continue to unpack the shipping container following the manufacturer's guidance. Materials outlining the unpacking process can be found inside the container immediately after opening the lid.

- Inspect the tray(s) of vaccine for damage. Ensure the correct number of trays were delivered.
- Place the tray(s) inside the vials upright in the storage unit.
- If storing vaccine at ultra-cold temperatures between -80°C (-112°F and -90°F), do NOT open the tray(s) or touch the vials. Return tray to ultra-cold storage within 8 minutes.
- If storing the vaccine at freezer temperatures between -20°C and -15°C (-13°F to -5°F), the vaccine may be stored for up to 2 weeks.
- Vials stored in the freezer may be returned one time to ultra-cold temperature storage (-80°C to -60°C [-112°F to -50°F]).
- Once returned to ultra-cold storage, the 2-week time limit is suspended.
- If storing the vaccine at refrigerator temperatures between 2°C and 8°C (36°F and 46°F), the vaccine must be used within 1 month (31 days).
- Thawed vaccine cannot be refrozen.
- Dispose of the dry ice according to the manufacturer's directions.

9. If using the thermal shipping container to store vaccine*, replenish the container with dry ice pellets (sized 10 mm to 16 mm) within 24 hours of delivery. Unless you have opted out of receiving dry ice when the order was placed, dry ice will be provided for the first re-icing. Close the container using packing tape.

10. Respond to the manufacturer's status report email regarding ongoing temperature monitoring of the thermal shipping container.

- If storing vaccine in an ultra-cold freezer or refrigerator, click on the link to opt out of ongoing temperature monitoring.
- If storing vaccine in the thermal shipping container, an additional e-mail will be sent. Add additional contacts to be notified of the temperature status of the container. Include after-hours phone numbers.

* CDC recommends using the thermal shipping container for temporary storage only.
* Dry ice will not be provided for Pfizer-BioNTech COVID-19 vaccine orders.

05/20/2021 (continued) Contact the vaccine manufacturer at 1-800-435-1985. Additional information is available at www.cdc.gov/covid-19.

Ancillary Kits

Federally supplied ancillary kits include:

- Diluent (for Pfizer)
- Needles
- Syringes
- Alcohol prep pads
- Vaccination record cards
- Small quantity of PPE (face shields and surgical masks)

Kits correspond to quantity ordered. An order of 1,170 doses of Pfizer will receive a kit with enough supply for 1,170 doses.

ALL THE KITS Vaccine Administration: Needle Gauge and Length

Vaccines must reach the desired tissue to provide an optimal immune response and reduce the likelihood of injection-site reactions. Needle selection should be based on the:

- Route
- Age
- Gender and weight for adults (19 years and older)
- Injection site

The following table outlines recommended needle gauges and lengths. In addition, clinical judgment should be used when selecting needles to administer injectable vaccines.

Route	Age	Needle gauge and length	Injection site
Subcutaneous injection	All ages	23-25-gauge 5/8 inch (16 mm)	Thigh 12 in out
	Neonate, 28 days and younger	22-25-gauge 5/8 inch (16 mm) ¹	Vastus ant.
	Infants, 1-12 months	22-25-gauge 1 inch (25 mm)	Vastus ant.
Intramuscular injection	Toddlers, 1-2 years	22-25-gauge 1-1.25 inches (25-32 mm)	Vi
	Children, 3-10 years	22-25-gauge 5/8-1 inch (16-25 mm)	Deltoid muscle of arm ¹
		22-25-gauge 5/8-1 inch (16-25 mm)	Deltoid muscle of arm ¹
		22-25-gauge 1-1.25 inches (25-32 mm)	Vastus lateralis muscle of anterolateral thigh
	Children, 11-18 years	22-25-gauge 5/8-1 inch (16-25 mm)	Deltoid muscle of arm ^{1,2}
Adults, 19 years and older	<ul style="list-style-type: none"> • 130 lbs (60 kg) or less • 130-152 lbs (60-70 kg) • Men, 152-260 lbs (70-90 kg) • Women, 152-200 lbs (70-90 kg) • Men, 260 lbs (118 kg) or more • Women, 200 lbs (90 kg) or more 	22-25-gauge 1 inch (25 mm) ¹	Deltoid muscle of arm ^{1,2}
		1-1.5 inches (25-38 mm)	
		1-1.5 inches (25-38 mm)	
		1.5 inches (38 mm)	
		1.5 inches (38 mm)	

May be administered into the upper outer triceps area if necessary.
If the skin is stretched tightly and subcutaneous tissues are not bunched.
Preferred site.
Some experts recommend a 1.5 inch needle for men and women weighing less than 60 kg. If used, skin must be stretched tightly and subcutaneous tissues must not be bunched.
For ventral lateral muscle in the anterolateral thigh can also be used. Ideal adolescents and adults will require a 1- to 1.5-inch (25-38 mm) needle to ensure intramuscular administration.

Source: Advisory Committee on Immunization Practices General Best Practice Guidelines for Immunization.
www.cdc.gov/vaccines/imz/aci-recs/general-recs/administration.html

Alcohol Prep Pad
STERILE & DISINFECTANT
KILLS GERMS
1.2 in x 2.6 in
50 pads per box
N95 x 58-204

Alcohol Prep Pad
STERILE & DISINFECTANT
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50 pads per box
N95 x 58-204

COVID-19 Vaccination Record Card
Please keep this record card, which includes medical information about the vaccines you have received.
For facts, consulte esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

Last Name: _____ First Name: _____ SSN: _____

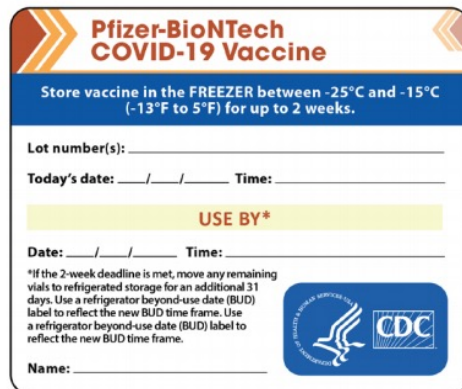
Date of birth: _____ Patient number (medical record or ID number): _____

Vaccine	Product Name/Manufacturer Lot Number	Date	Healthcare Professional or Clinic Site
1 st Dose COVID-19		mm / dd / yy	
2 nd Dose COVID-19		mm / dd / yy	
Other		mm / dd / yy	
Other		mm / dd / yy	

Vaccine Management: Inventory

Key activities:

- Inventory reporting (daily)
- Inventory expiration tracking
- Temperature monitoring
 - Documenting temperature excursions & contacting vaccine Manufacturers
- Waste event reporting (spoiled, expired, wasted doses)
- Emergency vaccine transfers



**Pfizer-BioNTech
COVID-19 Vaccine**

Store vaccine in the FREEZER between -25°C and -15°C
(-13°F to 5°F) for up to 2 weeks.

Lot number(s): _____


Today's date: ____/____/____ Time: _____

USE BY*

Date: ____/____/____ Time: _____

*If the 2-week deadline is met, move any remaining vials to refrigerated storage for an additional 31 days. Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame. Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame.

Name: _____





Vaccine Management: Reporting

3 key systems to remember:

1



Report doses administered daily to the California Immunization Registry (CAIR); [My Turn](#) automatically reports doses administered to CAIR.

2



[Report doses spoiled, expired, or wasted](#) daily; dispose of following guidance provided.

[Report shipment incidents](#) daily for vaccine product or kits, including temperature excursions, damage, or packing slip discrepancies.

[Report temperature excursions](#) daily and quarantine affected vaccines; contact vaccine manufacturer to determine if doses may be administered.

Report redistribution and transfer events daily. (See [redistribution](#) and [transfer](#) job aids.)

3

VaccineFinder

[Report inventory to VaccineFinder](#) daily once you receive vaccines using a browser and Internet connection.

Patient Visit

Participating providers must incorporate these steps into practice protocols:

- Do not ask for citizenship or photo ID in order to receive COVID-19 vaccine.
- Distribute [EUA Fact Sheet for Recipients](#) before administration.
- Distribute v-safe Program information.
- Prepare & administer vaccines and observe recipient per [EUA Fact Sheets](#).
- Report doses administered daily to CAIR (My Turn or EHR).
- Procure supplies and [prepare for potential anaphylaxis](#).
- Report any adverse events to [VAERS](#).
- Schedule 2nd appointment (if applicable).
- Provide Vaccination Record Card; encourage recipient to photograph it.
- Encourage registration for [v-safe](#) for appointment reminders (recommended).



COVID-19 Vaccine Administration

Billing and Reimbursement

Mark Lane, Director of Center for Economic Services (CES) Publications and Resources



General Information



- Federal government has purchased the COVID-19 vaccine with taxpayer dollars.
- Physicians who participate in the CDC COVID-19 Vaccination Program contractually agree to administer regardless of an individual's ability to pay/coverage.
- Both public and private payors are required to cover the vaccine administration without any patient cost sharing.
- Physicians will be reimbursed for vaccine administration, but may not seek reimbursement from vaccine recipients, including for CPT 99072 (PPE, cleaning supplies, etc.)
- Uninsured or those without coverage for the vaccine can also receive it at no cost and providers may submit for reimbursement through Provider Relief Fund.



AMA CPT Guidance

- In accordance with new vaccine-specific product CPT codes, new vaccine administration codes were created.
 - New vaccine administration CPT codes are specific to the manufacturer and the first vs. second dose
 - Include actual work of administration of the vaccine, all counseling provided, updating patient record

Manufacturer	National Drug Code	Vaccine Serum CPT	1 st Admin CPT	2 nd Admin CPT
Pfizer	59267-1000-1	91300	0001A	0002A
Moderna	80777-273-10	91301	0011A	0012A
Janssen (Johnson & Johnson)	59676-0580-05	91303	0031A	N/A

- Because the federal government is supplying the vaccine itself at no cost, physicians should not bill for the vaccine itself at this time.

Claim Submission and Reimbursement



Medicare Summary (Fee-For-Service and Medicare Advantage)

- CMS carved out COVID-19 vaccine administration benefit from Medicare Advantage plans and will reimburse under Medicare fee-for-service (FFS) system.
- Patient cost sharing – **Not permitted.**
- Submit claims to Noridian with patient's original Medicare ID number (not MA ID number).
- Claims should include vaccine administration CPT code only. Physicians should not bill for vaccine itself.
- Dates of service on or after March 15, 2021 – \$40 for each dose required.

Claim Submission and Reimbursement



Medi-Cal (FFS and Managed Care)

- DHCS carved out COVID-19 vaccine administration benefit from Medi-Cal managed care plans and will reimburse under Medi-Cal FFS system.
- Patient cost sharing – **Not permitted.**
- Submit claims to Medi-Cal FFS with patient's Medi-Cal benefit ID number (not Medi-Cal managed care number).
- Claims should include vaccine administration CPT code only. No vaccine serum codes
- Dates of service on or after March 15, 2021 – \$40 for each dose required.
- <https://www.dhcs.ca.gov/provgovpart/Pages/PAVE.aspx>

Claim Submission and Reimbursement



Commercial Health Plans and Insurers

- Patient cost sharing – **Not permitted.**
- Claims should include vaccine administration CPT code only. Do not bill for vaccine itself.
- Submit claims to plan or delegated group as you normally would, unless notified otherwise by plan/delegated group.
- Plans cannot shift financial responsibility of vaccine administration to delegated groups unless the RBO has requested in writing plan delegate this function.
- In-network physicians will be reimbursed at their contracted rate.
- Out-of-network providers must be reimbursed at a “reasonable rate,” which CMS suggests is the Medicare rate (\$40 per shot).

Claim Submission and Reimbursement



ERISA Plans

- CARES Act requires self-funded plans to cover administration of COVID19 vaccines with no patient cost sharing for in- or out-of-network providers during national public health emergency.

Uninsured Patients

- Physicians will be reimbursed for administering COVID19 vaccine through the Provider Relief Fund, administered by the U.S. Health Resources and Services Administration.
- For more information on COVID-19 vaccine administration claim submission for uninsured individuals, [HRSA website](https://www.hrsa.gov/covid19/uninsured/). (coviduninsuredclaim.linkhealth.com)

My Turn Overview

Eric Norton
My Turn Project Manager

My Turn is a platform that allows LHDs and Providers an all-in-one application for public eligibility, public scheduling, clinic management, dose administration and reporting, and walk-in registration for vaccine clinics.



TYPES OF CLINICS

- Walk-In
 - Fully Closed for clinic's use
 - Public Clinic visible to general population
- Scheduled
 - Visible to public on My Turn
- Coded
 - Visible on My Turn only to patients with an individual code or master code



GENERAL FEATURES

- Automatic Dose Reporting
 - Hourly updates to CAIR
- User Account Management
- Patient Info
- Manage Appointments
- Receive email and SMS appointment reminders



REPORTING

- Access and Run:
 - Clinic Reports
 - Appointment Reports
 - Patient Reports
 - Vaccines Administered
 - Clinic Capacity Report
- Export Reports



MY TURN VOLUNTEER

- Volunteer Registration
- Recruit, Vet and Match Support
- Request Medical and General Support Volunteers
- At no cost, value added application for those who are utilizing My Turn Clinic.

Options as a Pediatric Provider

Requirement: Submit vaccination records to IIS

EHR Submits to IIS

Option 1:

EHR able to send data to CAIR for child and parent

Continue using EHR as long as it can send data to the IIS

EHR Does NOT Submit to IIS

Option 2:

EHR able to send data to CAIR for child, not parent

For Child: Use existing EHR

For Parents: Use My Turn Clinic Walk-in functionality**

- Indefinitely open for pediatrician
- Can be shown publicly on My Turn walk-in page (see right)

Option 3:

No EHR system – Use My Turn for parent and child

For Parents and Children: Use My Turn Clinic Walk-In functionality for recording the administration of vaccines and reporting to the IIS

Optional:
Advertise to public?

Other:

Advertise and open to the public

Track 1 - My Turn Solution: Clinic appointments are made visible on My Turn Public**

Track 2 - My Turn EHR : EHR track for EPIC or Cerner providers; leverage API functionality to make appointments visible on My Turn Public

**A full-service My Turn support team is available for pediatric providers needing to onboard onto My Turn. For more information on this specialized support service please reach out to the CMA Onboarding Team at: VaccineNetwork@cmadocs.org

Resources

Stay informed!

Provider Resources on eziz.org/covid

Frequent Content Updates:

- 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

The state of California signed a Third Party Administrator (TPA) contract with Blue Shield of California to help the state optimize and accelerate COVID-19 vaccine allocation and distribution equitably, efficiently, and safely throughout the state. The TPA is working closely with local health departments to identify facilities that have the capacity to properly maintain COVID-19 vaccine and meet additional federal and state requirements.

Providers currently enrolled or in the process of enrolling in the California COVID-19 Vaccination Program can access program-related resources and communications on this website.

Program Education and Support

- Provider Office Hours and myCAvax Training Sessions
- COVID Call Center and Vaccine Manufacturers' Contact Info
- Guide to Other COVID-19 Vaccine Related Websites
- Frequently Asked Questions Updated 5/20

Alerts:

Providers of Pediatric Services

- How to Enroll in the California COVID-19 Vaccination Program: Recorded Webinar | Enrollment Steps | Begin Enrollment at myCAvax
- What Clinicians Need to Know About Pfizer Vaccination of Adolescents (Archived CDC Webinar)
- Statements from Western States Scientific Review Workgroup and AAP 5/12

myCAvax Users: We Need Your Feedback

- Please take the survey for your user type: **Provider** or **LHD/MCE** by 7:00 p.m. on May 26.

TPA Information

- TPA-Direct Allocation Process and Cadence
- Changes to requirements for non-TPA-contracted pediatricians, individual practitioners and small group practices for participation in the COVID-19 Vaccine Program
- TPA and My Turn Presentations at Provider Office Hours
- Third Party Administrator (TPA) Site-Level Direct Allocation Process 3/26

Vaccine Updates:

- Updates: Interim Clinical Considerations for Use of COVID-19 Vaccines 5/14
- FDA Authorizes Pfizer Vaccine for EUA in Adolescents 5/10
- Inventory Tips for 14-Dose Moderna Vials 4/30
- Johnson & Johnson Vaccine and Thrombosis with Thrombocytopenia Syndrome

Provider Support

COVID Call Center

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

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: (415) 621-9494
Sun-Sat, 7AM-7PM

Clinic Translation Line:
(833) 980-3933.
M-F 8AM-8PM,
Sun-Sat 8AM-5PM

Third Party Administrator

Email: [For Allocations, TPA Agreement, General Questions](#)

Provider FAQs

- Answers to questions on the hottest topics
- Updated weekly: Last updated 05.20.2021
- Currently in its 20th iteration!

➡ **Q: Do Providers need to be enrolled in the Vaccines for Children (VFC) Program to enroll in the California COVID-19 Vaccination Program?**

A: No. All Providers with pediatric populations aged 12-17 who meet the requirements of the program and agree to the CDC COVID-19 Vaccination Program Provider Agreement may enroll in the California COVID-19 Vaccination Program. To review program requirements, please visit [Steps to Enrollment for Providers of Pediatric Services](#).

➡ **Q: What is the difference between the California COVID-19 Vaccination Program and the Vaccines for Children (VFC) Program?**

A: Each program has its own separate enrollment and ordering processes, provider management systems, and call centers. To learn more about each program, please visit [Vaccines for Children \(VFC\)](#) and [California COVID-19 Vaccination Program](#).

➡ **Q: Is the Pfizer COVID-19 vaccine dosage the same for children aged 12-17 and adults?**

A: Yes. The Pfizer COVID-19 vaccine dosage is the same for children aged 12-17 and adults. Please refer to the [Pfizer-BioNTech COVID-19 Vaccine EAU Fact Sheet](#) for further information.

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.](#)

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Training and Resources

- [Program and Vaccine Product Training](#)
- [Enrollment Next Steps](#)
- [Readiness Checklist](#)
- [Vaccine Management at a Glance](#)
- [Vaccine Administration at a Glance](#)
- [Reporting at a Glance](#)

myCAvax 101 Training:
Account Enrollment

Wednesday, May 26

10:00 – 11:00AM

[Click here to join session](#)

Password: myCAvax2021!

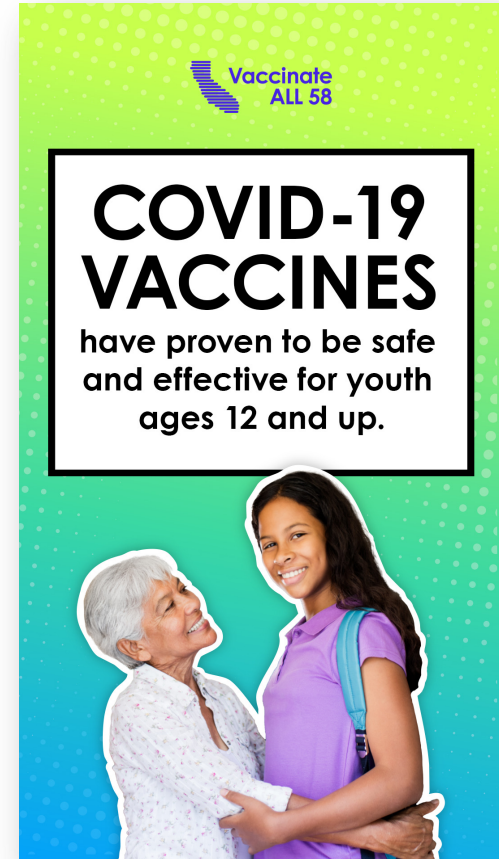


Vaccine Administration Resources





- [CMS COVID-19 Insurers Toolkit](#)
- [CMA's COVID-19 Vaccine Toolkit for Medical Practices](#)
- [DHCS COVID-19 Medi-Cal Response webpage](#)
- DMHC [APL 20-039](#) and [CMS interim final rule](#)
- CMA's Member Resource Center (800) 786-4262

Educational Materials for Parents & Patients

- [Vaccinate All 58 \(VA58\) Communication Toolkit](#) updated with adolescent resources
 - [Q&A for Parents and Adolescents \(Spanish\)](#)
 - [Talking Points \(Spanish\)](#)
- [How to Talk to Your Patients about COVID-19 Vaccine](#) (CDC)
- [COVID-19 Vaccine for Preteens and Teens](#) flyer (CDC)
- COVID-19 Vaccine fact sheet for lower-literacy audience
[English](#) | [Spanish](#) | [Portuguese](#)

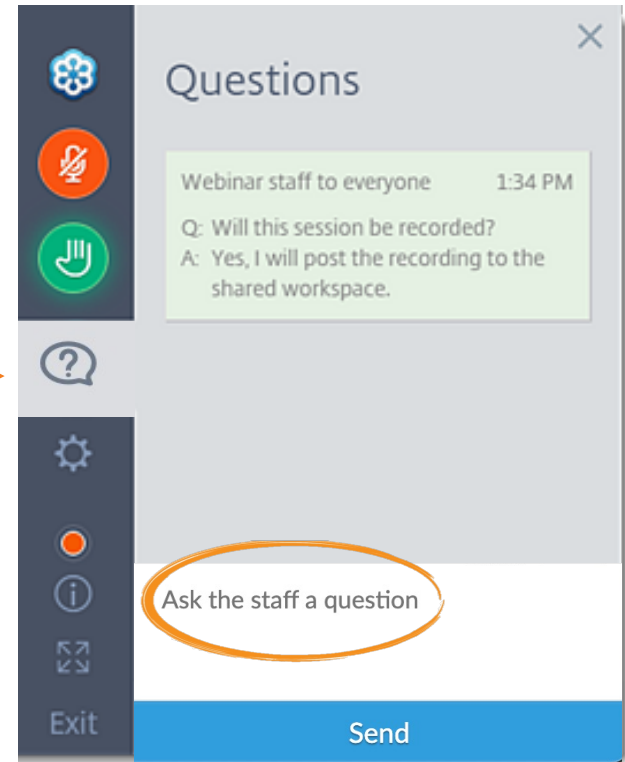


Where can I go for support?

Type of Support	Description
 COVID-19 Call Center for Providers/LHJs	<p>The COVID-19 Call Center for Providers is dedicated to medical providers in California and their COVID-19 response, specifically addressing questions about State program requirements, enrollment, and vaccine distribution.</p> <ul style="list-style-type: none">• Email: covidcallcenter@cdph.ca.gov• Phone: (833) 502-1245 (Monday through Friday from 8AM–8PM)
 CMA Enrollment Support	<p>To receive assistance with the enrollment process, contact CMA:</p> <ul style="list-style-type: none">• Email: VaccineNetwork@cmadocs.org
 myCAvax Help Desk	<p>Dedicated staff provides up-to-date information and technical support through myCAvax help desk: myCAvax.HD@Accenture.com or (833) 502-1245, option 2.</p>
 My Turn / My Clinic Help Desk	<p>For Onboarding (those in the process of onboarding): myturnonboarding@cdph.ca.gov For Technical Support: MyTurn.Clinic.HD@Accenture.com; (415) 621-9494: Daily (including Saturdays and Sundays) 7AM–7PM For job aids and demo and training opportunities: https://eziz.org/covid/myturn/</p>

Questions & Answers

Submit questions via GoToWebinar
"Questions" pane.



Special Thanks to:

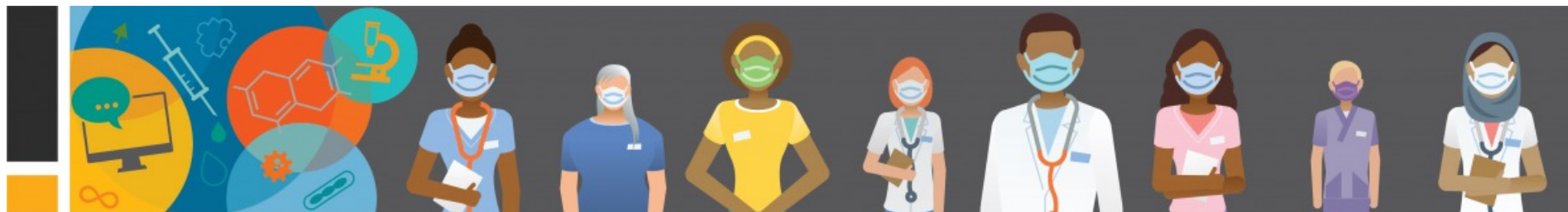
Today's Presenters: Tom Boo, MD, Kate McHugh,
Nisha Gandhi, MPH, Claudia Aguiluz, Eric Norton, and
Mark Lane

Content Support: Troy Parrish, Edgar Ednacot, EdD, MPH,
& Jane Grey, MPH

Webinar Support: Victoria Travis & California Medical
Association



Thank you for your commitment to protect the health and well-being of all Californians!



And for joining today's webinar!

