

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

Friday, July 22, 2022



Vaccinate ALL 58

Together we can end the pandemic.

Provider Office Hours Q&A

During today's session, please use the Q&A panel to ask your questions so our subject matter experts can respond directly.



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 Attendees:



Today's session is being recorded. Access today's slides and archived presentations at:
<https://eziz.org/covid/education/>



If you have post-webinar questions, please email leslie.amani@cdph.ca.gov

Agenda: Friday, July 22, 2022

No.	Item	Speaker	Time (AM)
1	Welcome & Announcements and Poll	Leslie Amani (Moderator)	9:00 – 9:05
2	Vaccine Administration Data	Elizabeth Reosti (CDPH)	9:05 – 9:10
3	Clinical Update	Priyanka Saxena, D.O., M.P.H (CDPH)	9:10 – 9:20
Q&A			9:20 – 9:30
4	Storage & Handling	Kate McHugh (CDPH)	9:30 – 9:35
5	Vaccine Management	Eric Norton (My Turn) and Daniel Conway (myCAvax)	9:35 – 9:45
6	Wrap Up & Resources	Leslie Amani (Moderator)	9:45 – 10:00
Q&A			

Announcements

Leslie Amani, CDPH

Vaccine Timing Guide: Pediatric/Adolescent/Adult

COVID-19 Vaccine Timing–Pediatric			
Routine Schedule			
Age*	Vaccine	Primary Doses	Booster Dose
6 months–4 years	Pfizer–Infant/Toddler	1st Dose → 3–8 weeks → 2nd Dose → ≥8 weeks → 3rd Dose	
6 months–5 years	Moderna–Infant/Toddler	1st Dose → 4–8 weeks → 2nd Dose	
5–11 years	Pfizer–Pediatric	1st Dose → 3–8 weeks → 2nd Dose → ≥5 months → Booster	
6–11 years	Moderna–Pediatric	1st Dose → 4–8 weeks → 2nd Dose	
Schedule if Moderately or Severely Immunocompromised			
Age*	Vaccine	Primary Doses	Booster Dose
6 months–4 years	Pfizer–Infant/Toddler	1st Dose → 3 weeks → 2nd Dose → ≥8 weeks → 3rd Dose	
6 months–5 years	Moderna–Infant/Toddler	1st Dose → 4 weeks → 2nd Dose → ≥4 weeks → 3rd Dose	
5–11 years	Pfizer–Pediatric	1st Dose → 3 weeks → 2nd Dose → ≥4 weeks → 3rd Dose → ≥3 months → Booster	
6–11 years	Moderna–Pediatric	1st Dose → 4 weeks → 2nd Dose → ≥4 weeks → 3rd Dose	

* See schedules for children in transition from a younger to older age group: [Pfizer](#) | [Moderna](#).
 ^ An 8-week interval may be preferable for some people, especially for males 12–39 years.
 View [Interim Clinical Considerations for Use of COVID-19 Vaccines](#) for details. Schedule is subject to change.

California COVID-19 Vaccination Program IMM-1396 (7/20/22) Page 1 of 3

COVID-19 Vaccine Timing–Adolescent/Adult			
Routine Schedule			
Age	Vaccine	Primary Doses	Booster Doses
12–17	Moderna–Adol/Adult	1st Dose → 4–8 weeks → 2nd Dose	
12+	Pfizer/Adol/Adult	1st Dose → 3–8 weeks → 2nd Dose → ≥5 months → 1st Booster	2nd Booster
18+	Moderna–Adol/Adult	1st Dose → 4–8 weeks → 2nd Dose → ≥5 months → 1st Booster	2nd Booster
18+	Janssen (J&J) Pfizer/Moderna preferred*	1st Dose → ≥2 months → 1st Booster	2nd Booster
18+	Novavax	1st Dose → 3–8 weeks → 2nd Dose	

1st Booster: Ages 12–17: Pfizer
 18+: Moderna/ Pfizer (mRNA preferred) or J&J*
 2nd Booster: Ages 50+: Moderna/Pfizer
 18–49: Not currently recommended.
 (If received J&J for primary and 1st booster, may consider receiving a 2nd booster of mRNA vaccine.)

^ An 8-week interval may be preferable for some people, especially for males 12–39 years.
 * Although use of mRNA COVID-19 vaccines is preferred, the Janssen vaccine may be offered in [some situations](#).
 View [Interim Clinical Considerations for Use of COVID-19 Vaccines](#) for details. Schedule is subject to change.

California COVID-19 Vaccination Program IMM-1396 (7/20/22) Page 2 of 3

18+	Novavax	1st Dose → 3 weeks → 2nd Dose
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* Although use of mRNA COVID-19 vaccines is preferred, the Janssen vaccine may be offered in [some situations](#).
 View [Interim Clinical Considerations for Use of COVID-19 Vaccines](#) for details. Schedule is subject to change.

California COVID-19 Vaccination Program IMM-1396 (7/20/22) Page 3 of 3

Minor Consent Guidance: English & Spanish



Q

I am looking for

I am a

Programs

A-Z Index

[Home](#) | [Programs](#) | [Center for Infectious Diseases](#) | [Division of Communicable Disease Control](#) | [COVID-19 Vaccine Minor Consent Guidance](#)

[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

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

July 18, 2022

TO: All Californians

SUBJECT: COVID-19 Vaccine Minor Consent Guidance

Related Materials: [Safe Schools for All Hub](#) | [Get the Facts on COVID-19 Vaccines, Boosters, and Additional Doses](#) | [COVID-19 Vaccines Home Page](#) | [More Languages](#)



GAVIN NEWSOM
Governor

COVID-19 Vaccine Consent For Individuals Under 18 Years of Age

Section 1: Information about the child to receive a COVID-19 Vaccine (Pfizer-BioNTech COVID-19 Vaccine or Moderna Vaccine)

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

Street Address _____ City _____

Phone Number _____

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

The U.S. Food and Drug Administration (FDA) has authorized emergency use of the Pfizer-BioNTech COVID-19 Vaccine and the Moderna Vaccine to prevent COVID-19 in individuals ages 6 months and older. The U.S. Food and Drug Administration (FDA) has not yet approved licensure of vaccine to prevent COVID-19 for any individual age of 16. Please read the Fact Sheets for Recipients and Caregivers that the U.S. Food and Drug Administration (FDA) has approved. There are different fact sheets for different age groups.

Section 3: Consent.

I have reviewed the information on risks and benefits of the COVID-19 Vaccine (Pfizer-BioNTech COVID-19 Vaccine or Moderna Vaccine) and understand the risks and benefits. I agree that:

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

I GIVE CONSENT for the child named at the top of this form to get vaccine or the Moderna 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 _____ Relationship to Child _____

Consentimiento de la vacuna Pfizer-BioNTech COVID-19 para individuos menores de 18 años

Sección 1: Información sobre el niño que recibe la vacuna Pfizer-BioNTech COVID-19 (letra de imprenta):

Nombre del niño (apellido, primer y segundo nombre) _____ Nacimiento (mm/dd/aaaa) _____ Edad _____

Calle _____ Ciudad _____ Estado _____ Código Postal _____

Teléfono _____

Sección 2: Información sobre los riesgos y beneficios de la vacuna Pfizer-BioNTech COVID-19 (vacuna Pfizer).

En la actualidad, la Administración de Drogas y Alimentos de EE. UU. ha autorizado el uso de emergencia de la vacuna Pfizer en individuos de 5 años en adelante. La FDA aún no ha aprobado la licencia de la vacuna para prevenir COVID-19 en menores. Para más información sobre los riesgos, beneficios y efectos secundarios de la vacuna Pfizer, lee la [Hoja de datos para destinatarios y cuidadores](#) de la Administración de Drogas y Alimentos; aquí está la versión específica para los destinatarios de la vacuna de 5 a 11, y aquí está la versión para los menores de 12 a 17 años.

Sección 3: Consentimiento

He revisado la información sobre los riesgos y beneficios de la vacuna Pfizer en la previa sección 2 y entiendo los riesgos y beneficios. Estoy de acuerdo en que:

- Revisé el consentimiento y leí y entendí la "Hoja de datos para destinatarios y cuidadores" sobre los posibles riesgos y beneficios de la vacuna Pfizer.
- Tengo la autoridad legal para autorizar que el niño previamente mencionado reciba la vacuna Pfizer.
- Entiendo que no es un requisito acompañar al mencionado niño a su cita de vacunación y, al dar el siguiente consentimiento, el niño recibirá la vacuna Pfizer, esté yo presente o no en la cita de vacunación.
- Entiendo que la ley estatal (Código de Salud y Seguridad, § 120440) requiere que todas las inmunizaciones sean reportadas al Registro de Inmunización de California (CAIR2).
- Entiendo que la información del niño en el registro CAIR2 será compartida con los departamentos de salud locales y el Departamento de Salud Pública de CA, como información médica confidencial, y sólo será utilizada para compartir mutuamente o como lo permita la ley. Puedo negarme a permitir que dicha información sea compartida posteriormente y puedo pedir que se bloquee el registro de CAIR2 completando el formulario del internet [Pedido para bloquear mi registro CAIR](#).

YO CONSENTO que el niño mencionado al comienzo de este formulario reciba la vacuna Pfizer-BioNTech COVID-19 y he revisado y estoy de acuerdo con la información incluida en este formulario.

Nombre (apellido, primer y segundo nombre) _____

Firma _____ Fecha _____

Dirección (de ser diferente a la previa) _____

Teléfono (de ser diferente a la previa) _____

Summary of Resources: Preparing for Infant/Toddler

Preparing for Under 5 Vaccination | 4

Summary of Resources

-  **Product Training & Resources**
 - [COVID-19 Vaccine Product Training](#)
 - [COVID-19 Vaccine Product Guide](#) (PDF)
 - [COVID-19 Vaccine Timing by Age](#) (PDF)
-  **Intramuscular (IM) Injections**
 - Babies: [PDF](#) | [Video](#)
 - Giving All the Doses [Under 12 Months](#) | [12 Months and Older](#) (PDF)
 - [Infants 11 months of age and younger](#) (PDF)
 - [Children 1 through 2 years of age](#) (PDF)
 - [Children 3 through 6 years of age](#) (PDF)
-  **Proficiency**
 - Skills Checklist for Vaccine Administration [job aid](#) (PDF)
 - Injection Safety [job aid](#) (PDF)
 - [Vaccine Administration Checklist](#) (PDF)
 - [Responding to Administration Errors](#) (PDF)
 - [Preventing Administration Errors](#) (PDF)
-  **Patient Care**
 - [Recommending COVID-19 Vaccination: Clinical Talking Points for Providers of](#)
 - [Tips to Ease Anxiety During Vaccination: Babies & Toddlers](#)
 - [How to Hold Your Child During Vaccination](#)
-  **Operations**
 - Receiving & Storing [Pfizer](#) | [Moderna](#) job (PDF)
 - [Add new vaccines](#) to VaccineFinder (PDF)
 - [Expanding Vaccination Capacity](#) (PDF)
 - [Requesting COVID-19 Vaccination Staff](#) (PDF)
 - [COVID-19 Vaccine Reimbursement](#) (PDF)

California COVID-19 Vaccination Program IMM-1432 (6/17/22)

Included in:

Vaccinate ALL 58

2 | 3 | 4

Preparing for Infant/Toddler Vaccinations

Whenever new vaccine products are introduced into your practice's supply, ensure staff are properly trained on what's new and reinforce the storage and handling basics staff already know. This guide addresses training issues and setup required to support new pediatric vaccine products.

#1. Review Clinical, Safety, and Efficacy Talking Points

We'll share findings from the clinical trials once data are available. In the meantime, [review clinical talking points for parents](#) and start talking to families about COVID-19 vaccines now!

#2. Complete the COVID-19 Product Training

CDC's training for any new vaccine products will be posted [here](#) once released by CDC. In the meantime, review FDA's EUA Fact Sheets for each product you'll administer.


To ensure everyone is proficient with any new products in your inventory, CDC requires that everyone storing, handling, administering, or managing COVID-19 vaccines complete the [COVID-19 Vaccine Product Training](#).

CDC training is broken down into separate *Preparation & Administration* and *Storage & Handling* summaries so staff and clinicians can review the training appropriate to their roles and print them for reference.

Bookmark the [COVID-19 Vaccine Product Guide](#) as a quick reference.

#3. Review Timing for Doses by Age

Ensure staff know how to identify which vaccine is for which age group. [This chart](#) includes two schedules (routine and for moderately and severely immunocompromised) for primary and booster doses.



California COVID-19 Vaccination Program IMM-1432 (6/17/22)

Product Updates

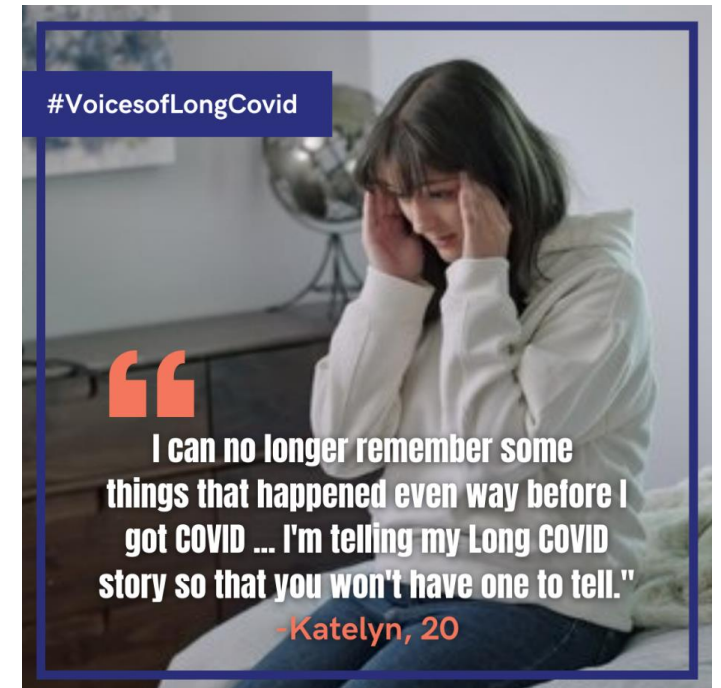
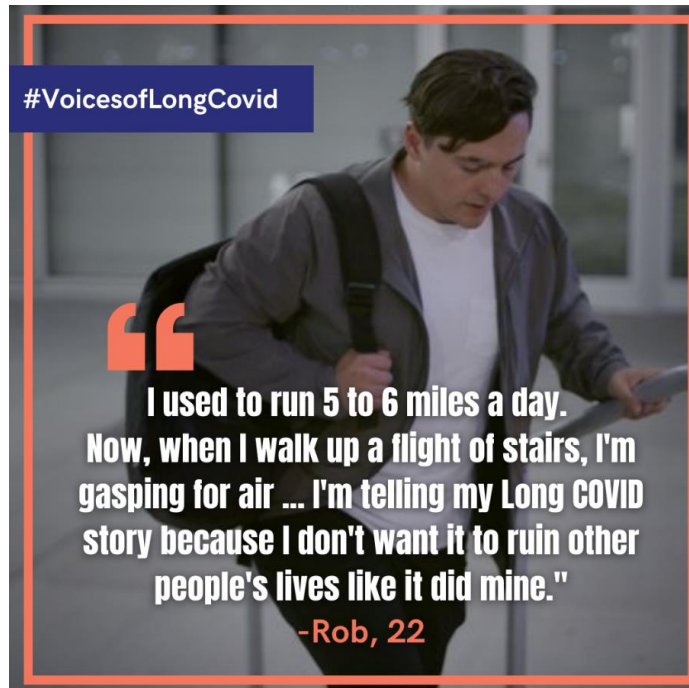
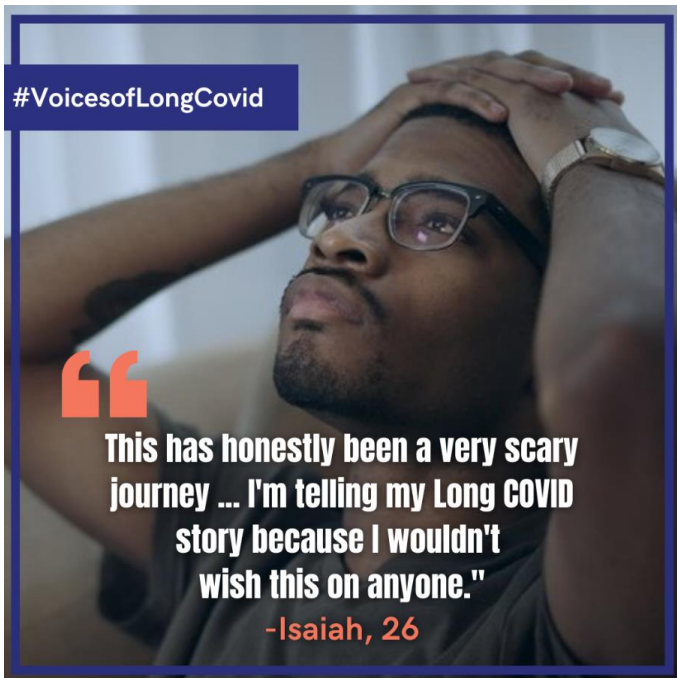
CDC and the California Department of Public Health are updating job aids and communications for the following product authorizations:

- Pfizer-BioNTech COVID-19 boosters for children 5-11Y ([recommended](#))
- Pfizer-BioNTech COVID-19 primary vaccine series for 6M-4Y ([Fact Sheet](#))
- Moderna COVID-19 primary vaccine series doses for 12Y+, boosters for 18Y+ ([Fact Sheet updated](#))
- Moderna COVID-19 primary vaccine series for 6M-5Y ([Fact Sheet](#))
- Moderna COVID-19 primary vaccine series for 6-11Y ([Fact Sheet](#))

COVID Call Center will keep sites posted as new pediatric products or boosters are authorized by FDA and recommended by the Advisory Committee on Immunization Practices (ACIP), CDC, and Western States Scientific Safety Review Workgroup (WSSSRW).

Long COVID Videos and Social Media Posts

- Video Assets in English and Spanish
- Social Media Messaging



Pfizer COVID-19 Vaccine Updates & Trainings

Date & Time (linked)	Password
Tuesday, July 26 - 12PM	BVqKcg25GQ4
Wednesday, July 27 - 9AM	aU7BRQ8tTZ7
Thursday, July 28 - 9AM	W9jxbB6MnT4
More sessions listed! NOTE: All times listed here are PDT.	

Audience:

Providers and immunization staff

Session Topics Include:

- New vaccine presentation (**Maroon Cap**) for individuals 6 months through 4 years of age
- FDA approvals, authorizations - including recent authorizations
- **Gray Cap**, Comirnaty®
- Use of each vaccine presentation, including storage, handling, preparation, and administration

VA58 Trust & Safety Team Updates

The VA58 Trust & Safety Team reports on trending narratives about COVID-19, delivers biweekly briefings, and develops comprehensive resources to increase awareness around mis-, dis-, and mal-information, as well as the State's capacity to counter it.

BIWEEKLY BRIEFINGS

Biweekly briefings provide partners with the top COVID-19 vaccine mis/dis topics and trends, and invitees receive a copy of the report post-briefing.

To be added to the invite, email
rumors@cdph.ca.gov.

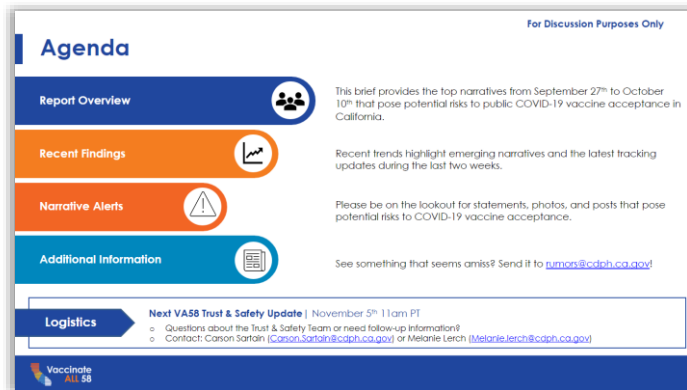
RUMORS INBOX

The Rumors Inbox serves as a tip line for our partners to submit the COVID-19 rumors they're hearing online and within their communities to our team. We incorporate the submissions into our team's reporting.



Report COVID-19 Vaccine Rumors to:

rumors@cdph.ca.gov



RECENT TOPICS & RESOURCES

Mis/Dis/Mal-information: Children are at low risk and do not require ineffective COVID-19 vaccines

Trusted Resources: [Why COVID-19 Vaccines are Important for Children \(aap.org\)](#), [Children and COVID-19: State-Level Data Report \(aap.org\)](#), [Frequently Asked Questions about COVID-19 Vaccination for Children and Teens | CDC](#), [Why Children and Teens Should Get Vaccinated Against COVID-19 | CDC](#)

Mis/Dis/Mal-information: COVID-19 vaccines increase the risk of reproductive and fetal abnormalities

Trusted Resources: [COVID-19 Vaccines for People Who Would Like to Have a Baby | CDC \(Spanish\)](#), [More Evidence That COVID-19 Vaccines Do Not Cause Infertility | NIH COVID-19 Research](#), [COVID-19 Vaccination Considerations for Obstetric–Gynecologic Care | ACOG](#)

COVID-19 Vaccine Billing & Reimbursement Resources

Document last updated: 12/23/2021

Reimbursement and Billing Information

PATIENT COST SHARING – Since the federal government is supplying the vaccine itself at no cost, vaccination providers are only able to be reimbursed for administering the vaccine. There should be no patient cost sharing for all payers for vaccine administration regardless of whether the service is provided by an in-network or out-of-network provider.

Medicare Fee-For Service
The Centers for Medicare and Medicaid Services (CMS) will reimburse COVID-19 vaccine administration services for Medicare fee-for-service enrollees through Noridian, the Medicare Administrative Contractor.

For the most up-to-date information, please see CMA's COVID-19 Vaccine webpage at www.cmadoocs.org/covid-19/vaccine.

COVID-19 Vaccine Provider FAQs

- Answers to provider questions
- Updated weekly: last updated 07/21/2022
- Currently in its 81st iteration!



What is the Physicians for a Healthy California KidsVaxGrant 2.0 program?

A: The KidsVaxGrant 2.0 Program, administered by Physicians for a Healthy California (PHC) and funded by the California Department of Public Health (CDPH), is a grant opportunity for COVID-19 vaccine Providers of pediatric services. Providers can receive up to \$35,000 for COVID-19 Vaccination Program enrollment and expansion of infant/toddler vaccination services. For detailed eligibility criteria, please visit [PHC KidsVaxGrant](#).



Q: Will the Novavax COVID-19 vaccine be available to order through the CA COVID-19 Vaccination Program?

A: On July 13, 2022, the [FDA authorized emergency use](#) of the Novavax COVID-19 vaccine. On July 19, 2022, [CDC's Advisory Committee on Immunization Practices \(ACIP\)](#) and the Western States Scientific Safety Review Workgroup (WSSSRW) recommended the Novavax vaccine as a 2-dose series for persons ages 18 years and older. CDPH will continue to provide updates regarding Novavax COVID-19 vaccine ordering. For further Novavax information, visit [Fact Sheet for Healthcare Providers: Novavax Emergency Use Authorization](#). The CDPH [COVID-19 Vaccine Timing Guide](#) has been updated with Novavax guidance.

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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[Provider FAQs on EZIZ, Updated Weekly](#)



Vaccinate ALL 58

COVID-19 Vaccination Program Webinars and Training for Providers

Week of July 25, 2022

Note: Calendar subject to change

	Monday 7/25	Tuesday 7/26	Wednesday 7/27	Thursday 7/28	Friday 7/29
myCAvax	My Turn and myCAvax Office Hours 12:00 pm – 1:00 pm				
Combined Office Hours and Events	Vaccine Order Request with Q&A 10:00 am – 10:30 am	Pfizer BioNTech COVID-19 Vaccine Training & Education* 12:00 pm – 1:00 pm PW: BVqKcg25GQ4	Pfizer BioNTech COVID-19 Vaccine Training & Education* 9:00 am – 10:00 am PW: aU7BRQ8tTZ7	Pfizer BioNTech COVID-19 Vaccine Training & Education* 9:00 am – 10:00 am PW: W9jxbB6MnT4	Provider Office Hours 9:00 am – 10:00 am
<i>* Pfizer topics vary by day and include the latest information about use of each vaccine presentation, including storage, handling, preparation, and administration; recent medical updates and FDA authorizations, healthcare provider resources, and a Q&A session.</i>					
View On Demand	<ul style="list-style-type: none">Intro to My Turn Onboarding (v. 1/4/22)Latest Features in My Turn (*Requires My Turn Login)	<ul style="list-style-type: none">Latest Features in myCAvax for Providers (*Requires myCAvax Login)myCAvax Release Notes for LHJs and CDPH Users (*Requires myCAvax Login)COVID-19 Crucial Conversations Archived Webinars and Slides		<ul style="list-style-type: none">Provider 101 Account Enrollment: Section A: Organization Application (v. 10/21/21)Provider 101 Account Enrollment: Section B: Location Application (v. 10/21/21)Provider Office Hours and MCE Office Hours Archived Sessions	

Help

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
Phone: (833) 502-1245

Poll: CDPH Appreciates Your Feedback!

How would you rate your overall satisfaction with the services and information provided by the CDPH COVID-19 Vaccine Team to support your work in the CA COVID-19 Vaccination Program?

Examples: Office hours, webinars, call centers, job aids, FAQs, flyers/posters, weekly wrap-ups

- ☐ Very Satisfied
- ☐ Satisfied
- ☐ Neither Satisfied nor Unsatisfied
- ☐ Unsatisfied
- ☐ Very Unsatisfied

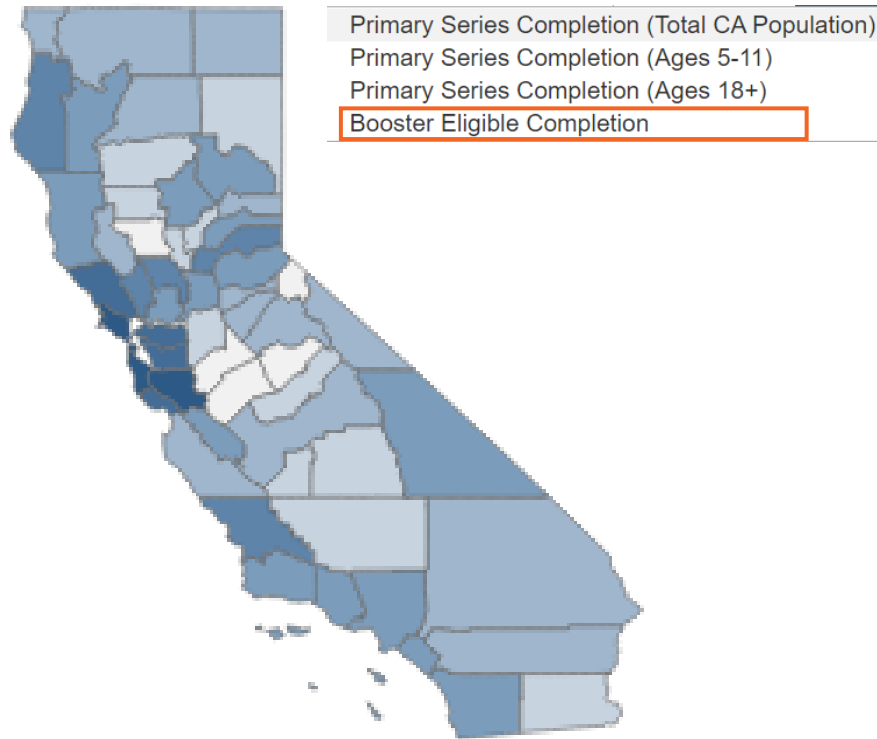


Vaccine Administration Data

Elizabeth Reosti, CDPH

Vaccine Administration Summary

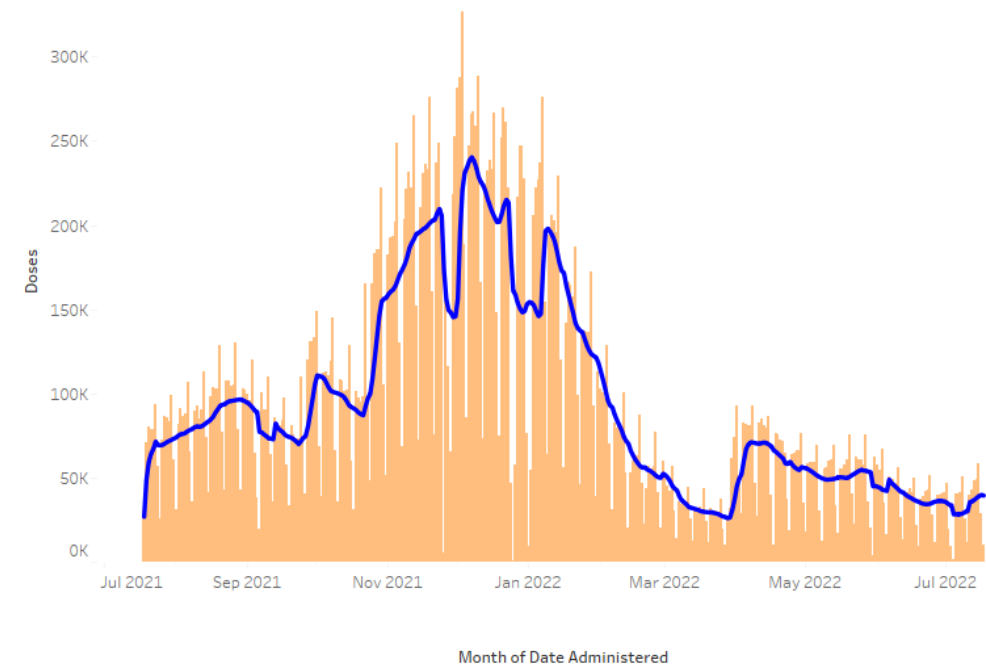
as of July 18, 2022



78,156,577

Total Doses Administered:

Daily Doses Administered: **Statewide**



Trends in Vaccine Administration

as of July 18, 2022

New Eligibility Groups Driving Demand

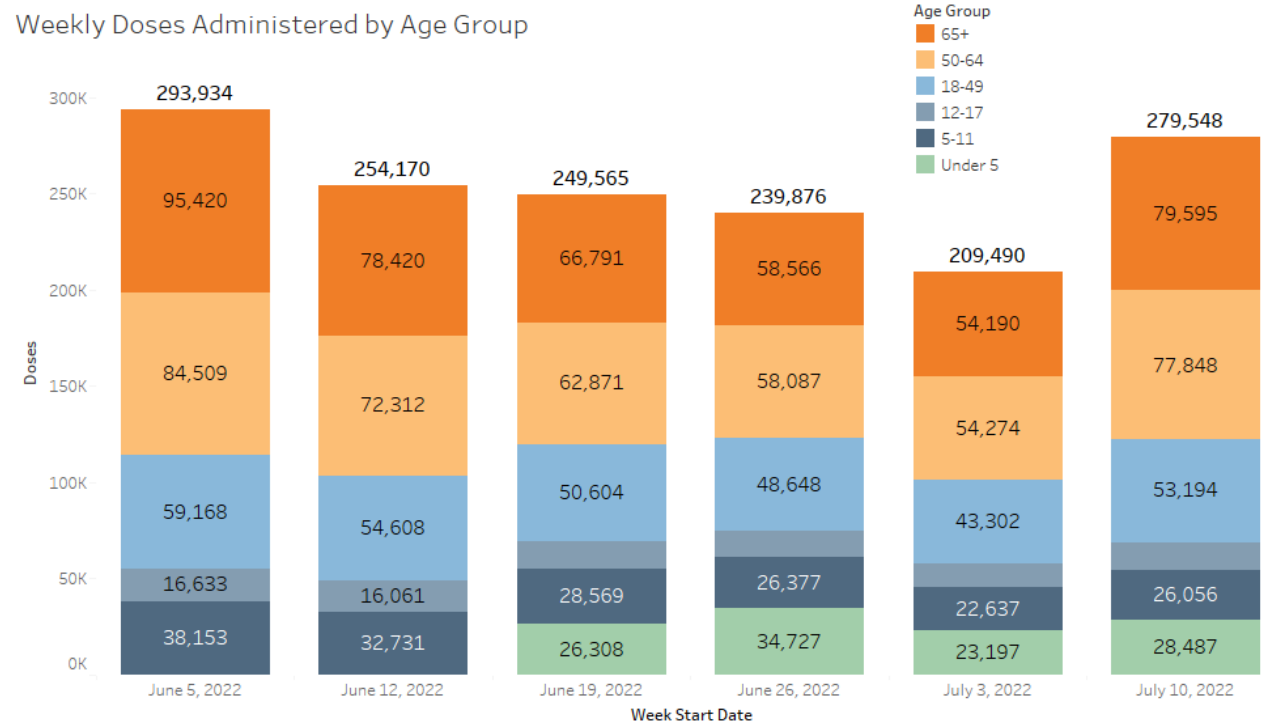
- Primary series among under 5
- First boosters among 5-11-years-old
- Second boosters among 50+ years-old

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age

For Immediate Release: June 17, 2022

Weekly Doses Administered by Age Group

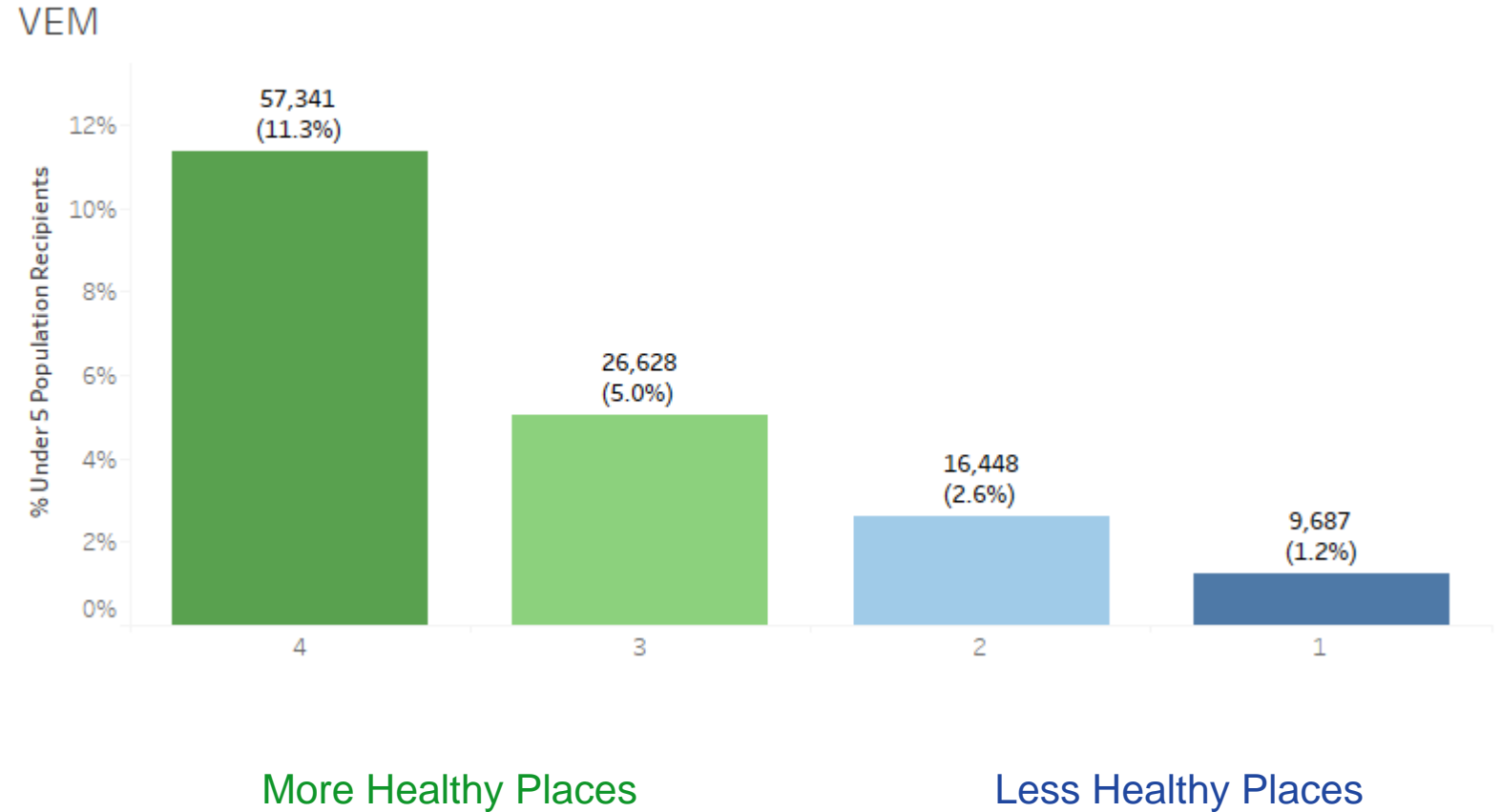


Percent change from previous week	- 14%	- 2%	- 4%	- 13%	+ 33%
5-11	- 14%	- 13%	- 8%	- 14%	+ 15%
12-17	- 3%	- 10%	- 7%	- 12%	+ 21%
18-49	- 8%	- 7%	- 4%	- 11%	+ 23%
50-64	- 14%	- 13%	- 8%	- 7%	+ 43%
65+	- 18%	- 15%	- 12%	- 7%	+ 47%
Under 5			+ 32%	- 33%	+ 23%

Infant/Toddler Vaccinations

as of July 18, 2022

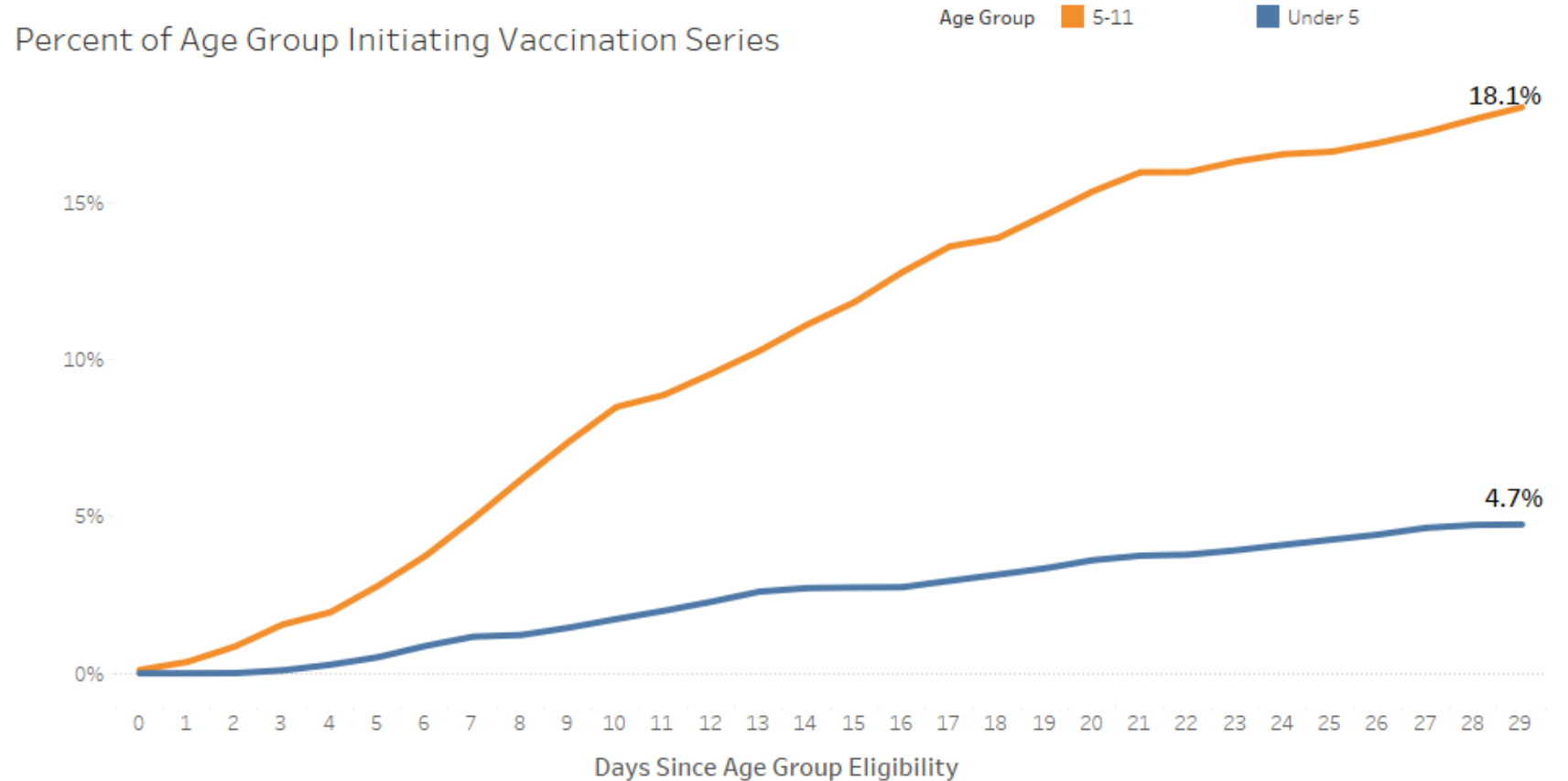
Disparities in
vaccination coverage
rates by Vaccine
Equity Metric Quartile
after first four weeks
of eligibility



Infant/Toddler Vaccinations

as of July 18, 2022

Slower rollout over the first 29 days of eligibility for youngest eligibility group

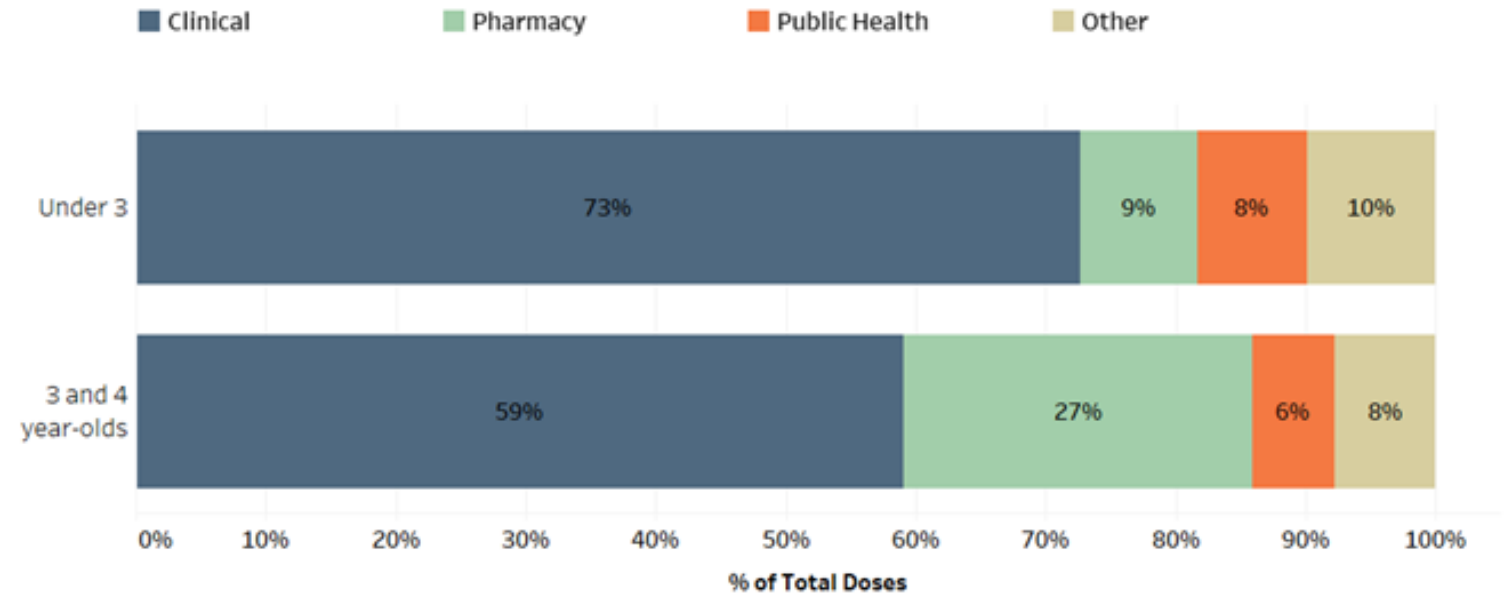


Infant/Toddler Vaccinations

as of July 18, 2022

- Clinical providers increasingly important for reaching younger ages
- Reduced role of pharmacies for youngest age groups

Under 5 Doses by Age and Provider Type



Data Summary

as of July 18, 2022

Latest Metrics

78.2 Million doses administered

280K doses administered in previous week (+33% point change)

28K new Infant/Toddler recipients (+23% point change)

System Updates

- Vaccination data for children under 5 years of age added to all dashboards
- 4th doses included in overall dose count, but not currently displayed in immunization status

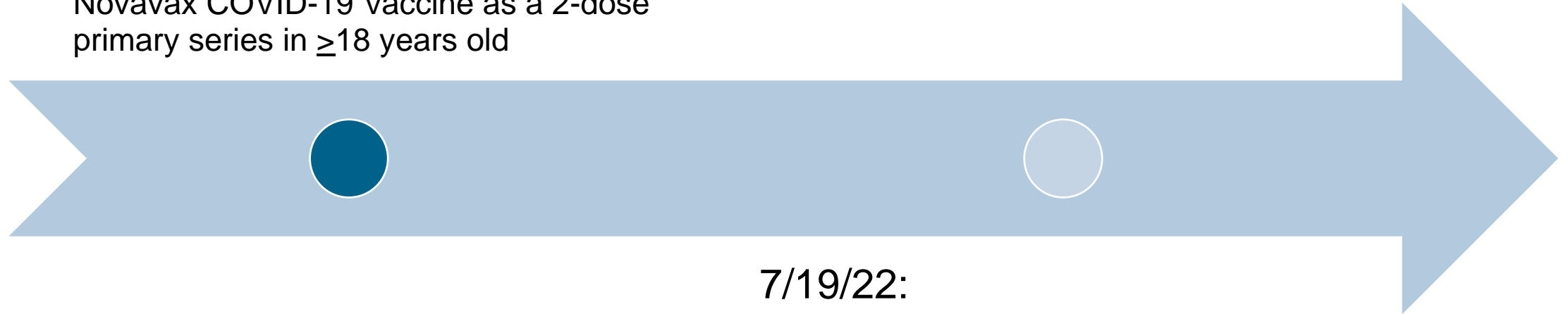
Clinical Update

Priyanka Saxena, D.O., M.P.H, CDPH

Novavax COVID-19 Vaccine Updates

7/13/2022:

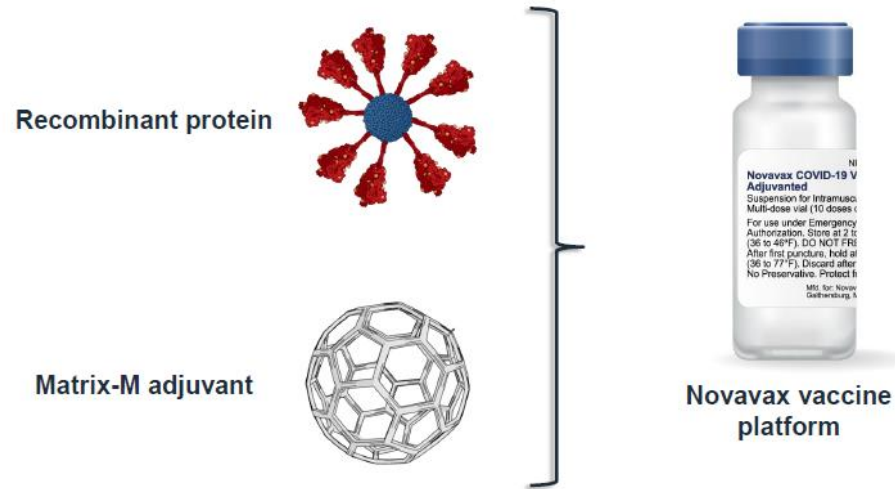
- FDA Authorized Emergency Use of Novavax COVID-19 Vaccine as a 2-dose primary series in ≥ 18 years old



7/19/22:

- ACIP and CDC recommend Novavax for adults
- Western States Scientific Safety Review Workgroup met to discuss Novavax

Novavax (NVX-Co2373)



- Novavax (NVX-Co2373) contains the SARS-CoV-2 recombinant spike protein and Matrix-M adjuvant.
- Granted Emergency Use Listing (EUL) by the WHO in December 2021
- Approved for use in 39 countries

GRADE Evidence

- Novavax phase III randomized controlled trial (RCT) (Dunkle 2022, additional data obtained from manufacturer)
- Persons ages ≥ 18 years in the United States and Mexico
- Data evaluated: Data cut-off September 27, 2021; median follow-up: 2.5 months
 - Study enrollment and efficacy follow-up occurred during December 27, 2020, to September 27, 2021, and mainly when the Alpha variant of SARS-CoV-2 was predominant
- Full analysis set: 19,963 vaccine; 9,982 placebo
- Per-protocol set: 17,272 vaccine, 8,385 placebo
 - No immunologic or virologic evidence of prior SARS-CoV-2 infection, no major protocol deviations

Outcome 1: Symptomatic Lab-confirmed COVID-19

Studies with Unvaccinated Comparator (n=1)

Population	Events/Vaccine ^a (n/N)	Events/Placebo ^a (n/N)	Vaccine efficacy (95% CI)
Primary Outcome ^b			
Ages ≥18 years	17/17272	79/8385	89.6% (82.4%, 93.8%)
Ages 18–64 years	15/15228	75/7417	90.3% (83.1%, 94.4%)
Ages ≥65 years	2/2044	4/968	76.3% (-29.1%, 95.7%)
Any comorbidity ^c (18–64 years)	6/6957	38/3451	92.2% (81.5%, 96.7%)
Any comorbidity ^c (≥65 years)	1/1125	3/580	82.8% (-64.9%, 98.2%)

a. 19,963 and 9,982 persons were randomized to vaccine and placebo

b. Cases diagnosed ≥7 days post dose 2 among persons without evidence of prior SARS-CoV-2 infection

c. Comorbidities: obesity, chronic kidney disease, chronic lung disease, cardiovascular disease, diabetes mellitus type 2

CI: confidence interval

Adverse Reactions

- Most frequently reported solicited local adverse events were tenderness and injection-site pain.
- Most common solicited systemic adverse events were headache, myalgia, fatigue, and malaise.
- Severe local reactions (grade ≥ 3) were infrequent.
- Frequency of serious adverse events were similar in groups receiving vaccine (1.0%) and placebo (1.1%).

Summary: Cases of Myocarditis and/or Pericarditis Following Novavax Vaccination, Doses Administered & Reporting Rates

Setting	Cases	Doses administered	Reporting rate** (cases/million doses administered)
Novavax COVID-19 Vaccine clinical trials ¹	4–6*	41,546	96–144
Sponsor submission of post-marketing reports in Australia, Canada, EU, New Zealand & South Korea ²	36	744,235	48
Australia post-marketing reports ³	15	160,000	94

¹ Total expanded safety population approximated from FDA EUA [Novavax Letter of Authorization](#) July 13, 2022: Study 1 = 26,151; Study 2 ≈ 10,800; Study 3 + 4 ≈ 5500. Precise denominators requested of the sponsor.

² Lee L. FDA review of effectiveness and safety of Novavax COVID-19 vaccine in adults ≥18 years of age. June 7, 2022. <https://www.fda.gov/media/159004/download>.

³ <https://www.tga.gov.au/periodic/covid-19-vaccine-safety-report-30-06-2022#section-1865>. Of these 15 cases reported in Australia, 3 were likely to represent myocarditis; 12 were likely to represent pericarditis.

*Includes a 16-year-old vaccine recipient from the adolescent safety data set; 4 = cases in temporal relationship without alternative etiology, 5 = cases in temporal relationship, with or without alternative etiology, 6 = all cases in vaccine recipients in clinical trials, regardless of temporal relationship or alternative etiology

**Reporting rate calculated as: (# cases)/(# doses administered*1,000,000)

Summary of GRADE

Outcome	Importance	Design (# of studies)	Findings	Evidence Type
Benefits				
Symptomatic lab-confirmed COVID-19	Critical	RCT (1)	Novavax COVID-19 vaccine is effective in preventing symptomatic COVID-19 during a period of Alpha variant predominance	1
Hospitalization due to COVID-19	Critical	RCT (1)	Severe COVID-19 evaluated as a surrogate for this critical outcome. Novavax COVID-19 vaccine is effective in preventing severe COVID-19.	3
Death due to COVID-19	Important	RCT (1)	No events occurred in the study included in the review of evidence.	No events
Asymptomatic SARS-CoV-2 infection	Important	No studies	No systematically collected data on outcome not available in study included in the review of evidence.	No data
Harms				
Serious adverse events	Critical	RCT (1)	SAEs were balanced between vaccine and placebo arms.	1
Reactogenicity	Important	RCT (1)	Severe reactions were more common in vaccinated; any grade ≥ 3 reaction was reported by 16.3% of vaccinated vs. 4.0% of placebo group	1

Evidence type: 1=high; 2=moderate; 3=low; 4=very low

Novavax COVID-19 Vaccine Preparation & Administration



Age indication:
18 years and older



Dose: 5 mcg SARS-CoV-2rS
50 mcg Matrix-M™ adjuvant



Injection volume:
0.5 mL



Preparation:
Do not dilute



Doses per vial:
10 doses

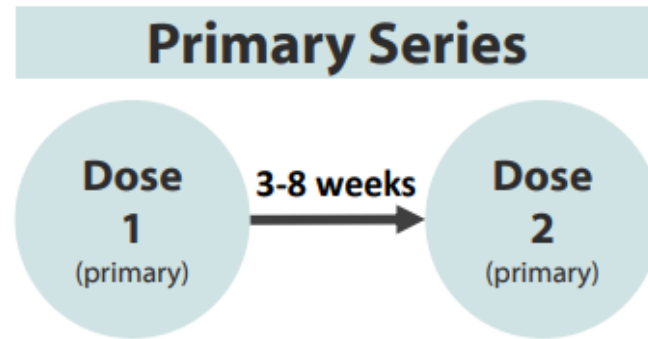


Injection route/site:
Intramuscular/deltoid

Novavax COVID-19 Vaccination Schedule

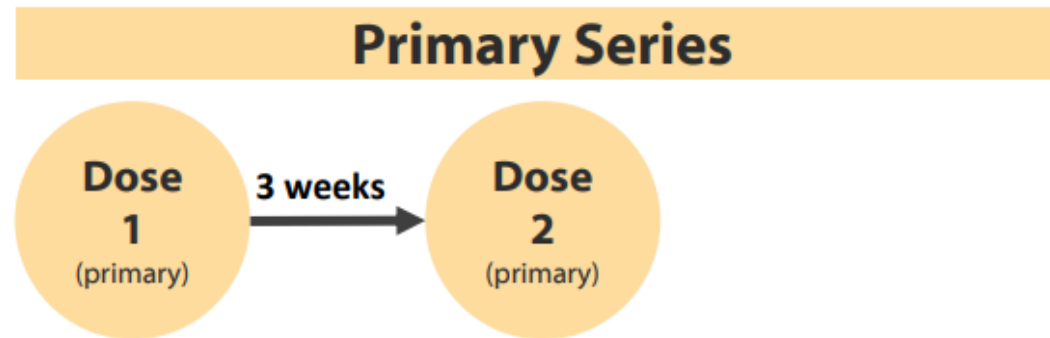
People who are **NOT** moderately or severely immunocompromised

Novavax
(18 years and
older)



People who **ARE** moderately or severely immunocompromised

Novavax
(18 years and
older)



Extended Interval Between Dose 1 & 2

- No specific data on extended interval between dose 1 & 2 of Novavax
- Evidence of benefits of an extended interval in mRNA recipients
 - The small risk of myocarditis and/or pericarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses
 - Vaccine effectiveness may be increased
- Therefore an 8-week interval may be used between dose 1 & 2 to potentially reduce the risk of myocarditis and/or pericarditis

Mixed Primary Series

- The **same** vaccine product should be used for all doses in the primary series.
- There are limited data on the safety and efficacy of a mixed primary series composed of any combination of Moderna, Novavax, and Pfizer-BioNTechCOVID-19 vaccines.
- If a mixed primary series is inadvertently administered
 - The series is complete, and doses do not need to be repeated
 - This is considered an error; report to the Vaccine Adverse Event Reporting System (VAERS)

Novavax COVID-19 Vaccine

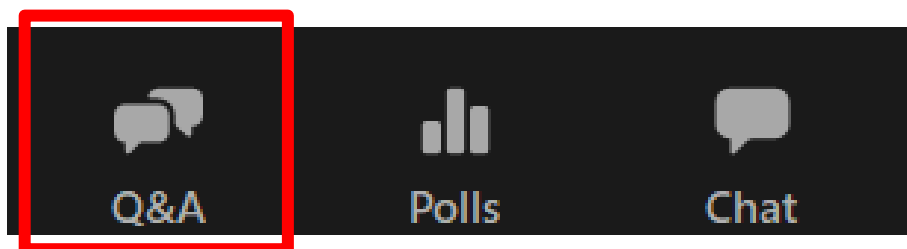
To learn more about Novavax COVID-19, please view the:

[CDC Recommendation: Novavax COVID-19 Vaccine for Adults](#)

[Fact Sheet for Healthcare Providers: Novavax Emergency Use Authorization](#)

Provider Office Hours Q&A

During today's session, please use the Q&A panel to ask your questions so our subject matter experts can respond directly.



Storage & Handling

Kate McHugh, CDPH

Novavax Storage and Handling

- 10 dose multi-dose vials
- Cap color: Royal Blue
- Refrigerated storage (2°C to 8°C) until expiration date
 - The first vials to be shipped will have a nine-month expiry date
 - Expiration dates can be found on: novavaxcovidvaccine.com
- Do not freeze
- Injection volume: 0.5 mL
- No diluent required
- Storage after puncture
 - Hold the vial between 2° to 25°C (36° to 77°F) for up to 6 hours
 - Discard the vial 6 hours after the first puncture
- EUA: [Novavax HCP Fact Sheet 07132022 \(fda.gov\)](https://www.fda.gov/emergency-preparedness-response-recovery/clinical-trials-authorized-emergency-use-authorization-eua-novavax-covid-19-vaccine)

Novavax Label²



Pfizer Pediatric 5 Years -11 Years Expiry

- Pfizer vaccines for ages 5 years -11 years currently being shipped have an expiry date of end of September
- Pfizer will not be shipping vaccines that have less than 30 days to expiry
- It does not sound as if there are any plans for a shelf-life extension in the immediate future
 - If your Pfizer Pediatric 5 years -11 years expires, please discard it
- CDPH will share more information once received.

Administration Errors

- Steps include:
 - Notifying patient
 - Refer to CDC's [revaccination information](#) to determine if revaccination is necessary
 - Contacting CAIR to determine how this dose should be entered
 - Reporting to VAERS (required)
 - Implement actions to determine why the error occurred and to ensure it does not happen again
- Manufacturers can help determine if vaccine was viable
 - Moderna: 1-866-MODERNA (1-866-663-3762)
 - Pfizer: Call 800-438-1985
 - Janssen: 1-800-Janssen (1-800-526-7736)
- CDPH clinical team: COVIDVaccineClinical@cdph.ca.gov

Vaccine Management

Eric Norton, My Turn, and Daniel Conway, myCAvax

My Turn and myCAvax Office Hours Cadence Reminder



The My Turn and myCAvax office hour session has been moved to a bi-weekly cadence. The next session will be held on Monday, July 25th.

To register for the webinar, click [here](#).

My Turn Release 29 Overview



New updates for Clinic Managers and Vaccine Administrators will launch July 27th.



Public

- ✓ Removing flu – The flu vaccine supplies will be zeroed out to remove nasal spray and flu shot tags.
- ✓ In-home vaccination and transportation page updates will be made to reflect guidance for under 5 patients.
- ✓ Error messaging will be updated for better user experience and accessibility.

Clinic

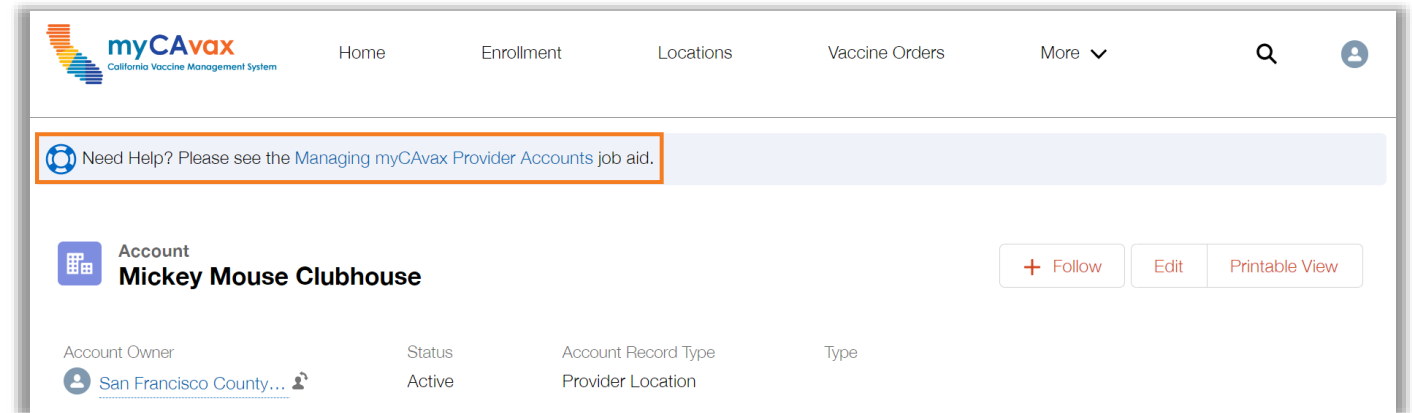
- ✓ Opt-out will be available for SMS/Email on the Walk-In flow.
- ✓ There will be a tool tip on the Vaccine Inventory Lot Number field to encourage accurate entries.
- ✓ "Cross Street 1" and "Cross Street 2" will be concatenated for CAIR2.

Managing myCAvax Provider Job Aid in myCAvax



The [Managing myCAvax Provider Accounts](#) job aid explains how Providers can edit their organization and location accounts including account name, address, storage capacities, available hours to receive shipments, and temporary closure.

Providers must, however, reach out to the Provider Call Center to update any account-related coordinators, contacts, and IIS Identifier.



Providers may access the [Managing myCAvax Provider Accounts](#) job aid from the **Account** page. This job aid is also available in the [Knowledge Center](#).

Novavax Ordering



- We have put all of the product details into myCAvax and will be opening ordering for Novavax next week.
- Allocations for LHJs/MCEs will be uploaded into myCAvax by Monday.
- Minimum order is 100 doses.

APPENDIX

myCAvax – Upcoming Enhancements - *Updated 7/18*



Enhancements

Soon to Be Links on the CDC Product Training Page




- ✓ Pfizer
 - ✓ Vaccine Preparation and Administration - 6 months through 4 years
 - ✓ Storage and Handling - 6 months through 4 years
- ✓ Moderna
 - ✓ Vaccine Preparation and Administration – 6 months through 5 years
 - ✓ Vaccine Preparation and Administration – 12 – 100+
 - ✓ Storage Handling – 6 months and older



Timeline

- ✓ Estimated Implementation: 8/11/2022

Slide Icon Key

Icon	Meaning
	This is to label slides that are referencing upcoming or existing functionality and how to use it in the system.
	This is to label slides that include important system reminders.
	This is to label slides that include tips and best practices to improve your system experience.

myCAvax Release Roadmap

RECENTLY DEPLOYED

June 16th (R27.0)

Orders

- ✓ LHDs to Move Small Orders to Standard Orders
- ✓ Order Page Layout Changes
- ✓ New order cancelation 'Status Reason' options
- ✓ Update Audit History for Orders/Transfers
- ✓ Add 'Doses Requested' to Standard Order Screen

Account

- ✓ Storing DocuSign at the Location Application

Community

- ✓ Add Knowledge Center article to account page
- ✓ Change Flow Title for Multiple Flows

Other

- ✓ Auto-Deactivate Licenses
- ✓ Default tab display on opening of records
- ✓ Remaining email templates to Lightning

IN PROGRESS

July 14th (R28.0)

Orders

- ✓ Order Fulfillment Updates to allow multiple lots and general UI enhancements
- ✓ Allow CDPH and LHD users to update additional details on the Shipment Records such as quantity, product, expiration date, etc.
- ✓ Validate Shipping Hours
- ✓ Set Flags for Temporary Closure on Vaccine Order Review page

Account

- ✓ Temporary Closure for Location Accounts
- ✓ Add VFC Regions to Accounts
- ✓ Add Calibration Expiration date to Storage Unit List

Community

- ✓ Update Thermometer Type options
- ✓ Add Data Logger as Shipment Incident Type

Site Visits

- ✓ Provider Category
- ✓ VFC Assigned Pin

Other

- ✓ Put LHD Dashboard on LHD Homepage

UPCOMING

August 11th (R29.0)

Orders

- ✓ Draft Order Enhancements

Account

- ✓ Provider initiated Disenrollment
- ✓ Disenrollment due to inactivity

Other

- ✓ Start of Contact enhancements to remove duplicate contacts
- ✓ Sharing Rule enhancements for accounts, storage units, etc.

My Turn Public Product Roadmap

RECENTLY DEPLOYED

July 7th (R28.4)

Release 28.4

- ✓ Moderna Pediatric 6-years-11-years two dose series
- ✓ Moderna Adolescent 12-years-17-years two dose series
- ✓ In-home vaccination and transportation page updates to reflect guidance for under 5 patients
- ✓ [Continued] Failure Point Notification – setting up monitoring tools throughout system to flag (potential) issues
- ✓ [Continued] Analysis – Consider walk-in and bulk upload appointments for clinic's Public Portal capacity and availability

CURRENT

July 27th (R29)

Release 29

- ✓ Moderna Pediatric/Adolescent 6-17 years Additional Dose rollout
- ✓ Translations refresh
- ✓ Update eligibility chart to CDC link
- ✓ Display number of locations on Select a Location page
- ✓ Pfizer Infant/Toddler (6 mos.-4 yrs.) second dose reminder communications
- ✓ [Testing] Custom flows for vaccine type
- ✓ [Delivery] Failure Point Notification – setting up monitoring tools throughout system to flag (potential) issues
- ✓ [Testing] Consider walk-in and bulk upload appointments for clinic's Public Portal capacity and availability

UPCOMING

August 24th (R30)

Release 30

- ✓ SMS opt in
- ✓ [Testing] Custom flows for vaccine type
- ✓ [Delivery] Update error messaging for better user experience and accessibility
- ✓ [Continued] Failure Point Notification – setting up monitoring tools throughout system to flag (potential) issues
- ✓ [Testing] Consider walk-in and bulk upload appointments for clinic's Public Portal capacity and availability

My Turn Clinic Product Roadmap

RECENTLY DEPLOYED

July 7th (R28)

Release 28.4

- ✓ Moderna Pediatric 6-years-11-years two dose series
- ✓ Moderna Adolescent 12-years-17-years two dose series ★
 - ✓ Add Vaccine Supply & Inventory
 - ✓ Bulk Walk-In Upload
 - ✓ Clinic Creation Setup
 - ✓ Walk-in Flow Update
 - ✓ Vaccine Administrator Flow Update
 - ✓ Single/Bulk Update
 - ✓ Appointment/IIS Tab Filter Update
 - ✓ Dashboard Homepage Update

CURRENT

July 27th (R29)

Release 29

- ✓ [Walk-In] Adding tool tips to the Homeless questions
- ✓ [Vaccine Inventory] Entering Lot Numbers correctly
- ✓ [CAIR2] Concatenate "Cross Street 1" and "Cross Street 2"
- ✓ [Clinic Creation] Pfizer Infant/Toddler 6m-4yrs checkbox visible
- ✓ [IIS Tab] Update filters to mimic the Appointment tab Filters
- ✓ Moderna Infant/Toddler/Pediatric/Adolescent 6m-17years Additional Dose
 - ✓ Walk-In flow
 - ✓ Vaccine Administration flow
 - ✓ Single/Bulk Edit update
 - ✓ Clinic Creation Setup
 - ✓ Vaccine Supply & Inventory
 - ✓ Bulk Walk-In Upload
 - ✓ Appointment/IIS Tab Filters

UPCOMING

August 24th (R30)

Release 30

- ★ ✓ [SMS/Email] Opt-out on the Walk-In flow
- ✓ [Walk-In Flow] Make the second Homelessness question optional
- ✓ Monkey Pox Flow
 - ✓ Clinic Creation Setup
 - ✓ Walk-In flow
 - ✓ Vaccine Supply & Inventory
 - ✓ Appointment/IIS tab filters
 - ✓ Vaccine Administration flow
 - ✓ Single Edit

Wrap-up

Leslie Amani, CDPH

Additional Support

Type of Support

Description

Updated 6.6.22



COVID-19 Provider Call Center

The COVID-19 Call Center for Providers and Local Health Departments is dedicated to medical providers in California and their COVID-19 response, specifically addressing questions about State program requirements, enrollment, and vaccine 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



myCAVax Help Desk

Dedicated staff provide up-to-date information and technical support on the myCAVax system.

- Email: myCAVax.HD@Accenture.com
- Phone: (833)-502-1245, option 3, Monday through Friday 8AM–6PM

For training opportunities: <https://eziz.org/covid/education/>



My Turn Clinic Help Desk

For **onboarding support** (those in the process of onboarding): myturnonboarding@cdph.ca.gov
For **technical support** with My Turn Clinic for COVID-19 and flu vaccines: MyTurn.Clinic.HD@Accenture.com or (833) 502-1245, option 4: Monday through Friday 8AM–6PM

For job aids, demos, and training opportunities: flu at <https://eziz.org/covid/myturn/flu/> and COVID at <https://eziz.org/covid/myturn/>



Archived Communications

For archived communications from the COVID-19 Provider Call Center about the California COVID-19 Vaccination Program visit

- Website: [EZIZ Archived Communications](#)

Public COVID-19 Call Center



- Contact Information:

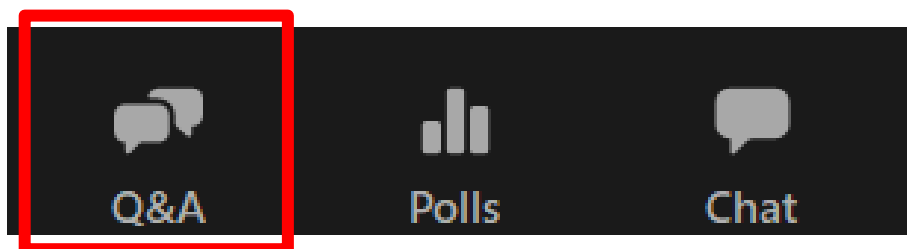
Phone: 833.422.4255: M-F 8AM-8PM; S-S 9AM-5PM

- For questions about general COVID questions, including COVID-19 vaccines, scheduling vaccination appointments through My Turn, school-related question, masking, testing, and more.



Provider Office Hours Q&A

During today's session, please use the Q&A panel to ask your questions so our subject matter experts can respond directly.



Thank you!



Monday

My Turn myCAvax Office Hours

Next session: Monday, July 25, 12PM

Reminder: Now Bi-weekly

Friday

Provider Office Hours

Next session: Friday, July 29, 9AM