Welcome to the California COVID-19 Vaccination Program Multi-County Entities Updates

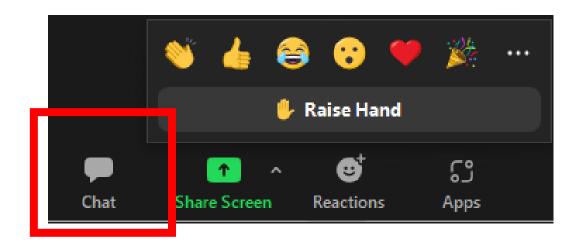


Wednesday, July 20, 2022



Q&A and Discussion

During today's session, please use the chat panel or use the raise your hand feature to ask your questions.







Housekeeping



Reminder! Please mute yourself when not speaking to avoid feedback and background noise.



Please introduce yourself by adding your name, role and organization into the chat.



This session is being recorded. Slides and recording will be available on https://eziz.org/covid/education/



Agenda: Wednesday, July 20, 2022

No.	Item	Speaker	Time (AM)	
1	Welcome & Announcements	Leslie Amani (Moderator)	9:00 – 9:05	
2	Therapeutics Update	Alan Hendrickson (CDPH)	9:05 – 9:10	
3	COVID-19 Vaccine Clinical Update and Poll	Lily Horng, M.D. (CDPH)	9:10 – 9:20	
4	COVID-19 Vaccine Storage & Handling Update	Kate McHugh (CDPH)	9:20 – 9:25	
5	COVID-19 Vaccine Management	Maria Volk (CDPH)	9:25 – 9:35	
	Q&A and Discussion			
6	Wrap-up & Resources	Leslie Amani (Moderator)	9:55 – 10:00	



Announcements

Leslie Amani, CDPH



For Discussion



Data question:

 What is your estimated population of Under 5-years-old in your health system catchment?

Operations questions:

- How are you integrating COVID-19 immunizations into routine primary care for pediatrics, especially Under 5-years-old?
- What are barriers to integrating COVID-19 immunizations into routine primary care for pediatrics, especially Under 5-years-old?



VA58 Bi-weekly Information Digest

This briefing will help you keep up with campaign information.

Digests are released every two weeks and are organized around a specific theme with a focus on actionable insights.

Issue #6 link: Parent Education: Part 1

Discusses:

- What we all should know about the new vaccines for kids under 5.
- Why vaccines are important for this age group.
- Talking points and tips to better engage with parents.



Updated Talking Points and Test to Treat

Tips for Talking About COVID-19 English & Spanish



Test to Treat English & Spanish





Updated Assets

Available in English and



Spanish





Virtual Backgrounds



Virtual Backgrounds for Kids 6 months+









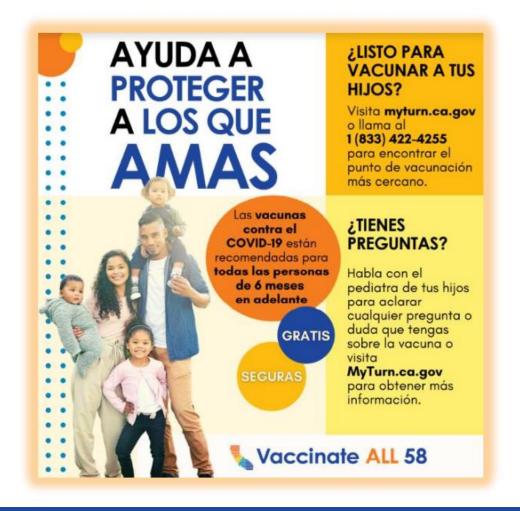


Social Assets

Click for English



Click for Spanish





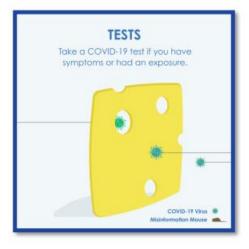
SMARTER Protective Layers



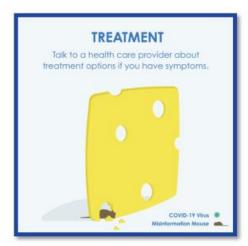


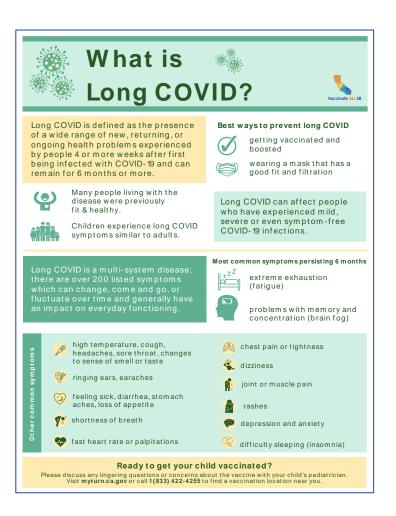






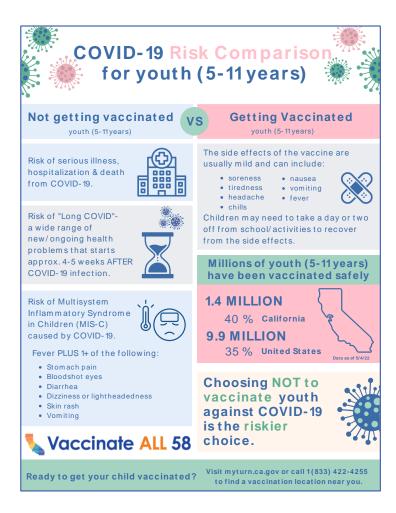








Long COVID in Kids Risk Comparison for Teens



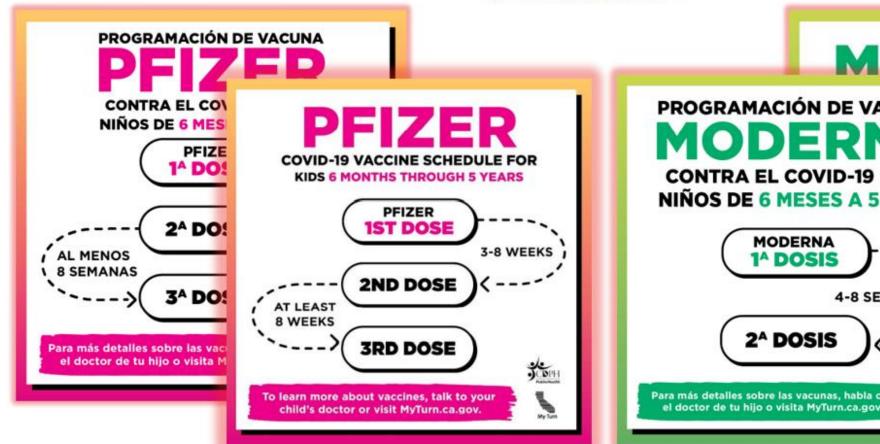
Risk Comparison for Youth

Infant Toddler Toolkit

Available in English and Spanish Vaccine Schedule

Available in English and Spanish

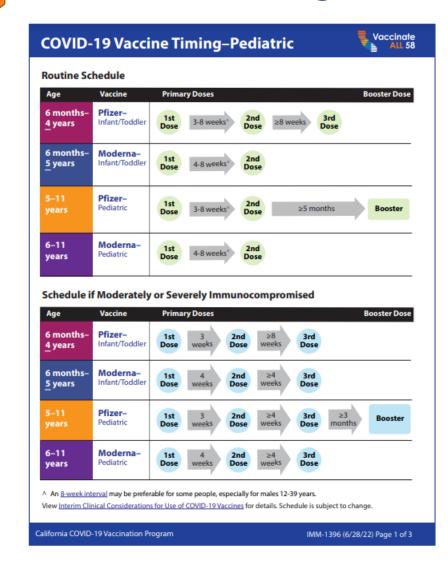
6 months +

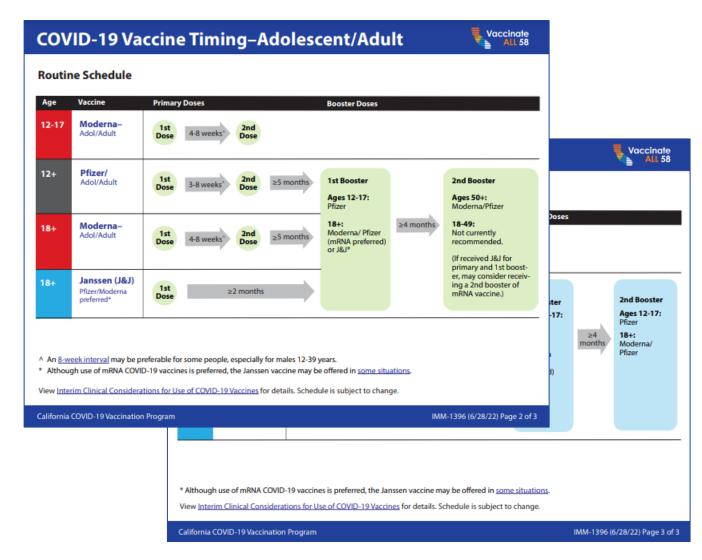






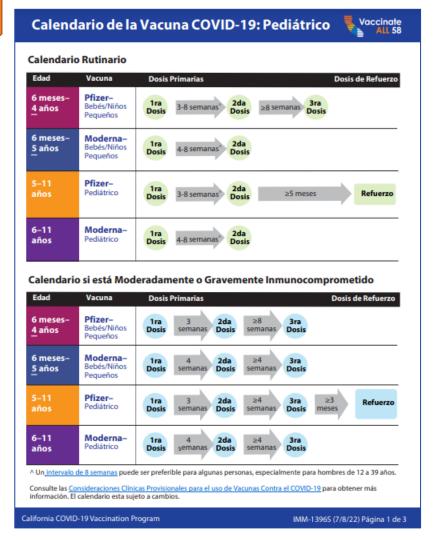
Vaccine Timing Guide: Pediatric/Adolescent/Adult

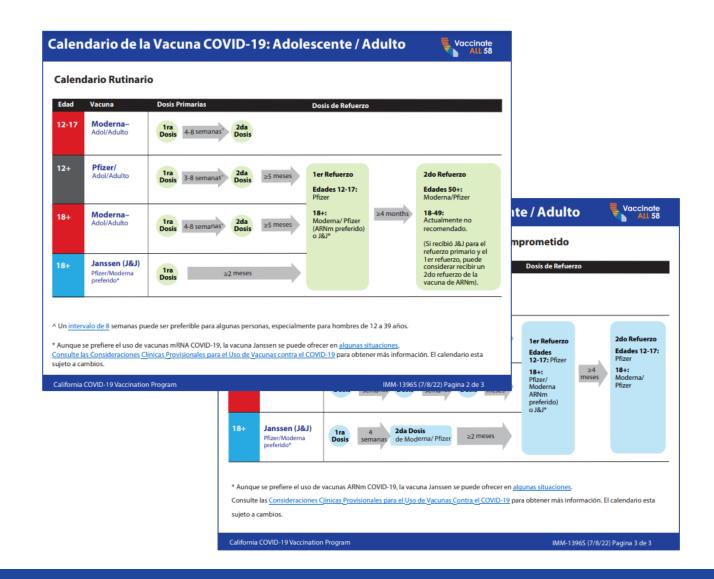




Calendario de la Vacuna: Pediátrico/Adolescente/Adulto







Moderna COVID-19 Vaccines/mRNA 6 Mos.- 17 Yrs.



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



July 8, 2022

IZB-FY-22-23-01

TO: California Providers of Pediatric Services

FROM: Robert Schechter, M.D., Chief
Center for Infectious Diseases

Division of Communicable Disease Control, Immunization Branch

SUBJECT: Moderna COVID-19 Vaccines, mRNA for children 6 months through

17 years: Preliminary information

HIGHLIGHTS

- Moderna COVID-19 Vaccine is recommended for children 6 months through 17 years of age as a two-dose primary series at varying doses according to age span, given 4-8 weeks apart (<u>CDPH COVID-19 Vaccine Timing</u>). The vaccine is also authorized for administration of an additional dose at least 4 weeks following the second dose to individuals 6 months through 17 years of age with certain kinds of immunocompromise.
- The vaccines for the pediatric age groups are supplied in multiple dose vials with different colored caps and label borders, depending on the age group (<u>CDPH COVID-19</u> <u>Vaccine Product Guide</u>). Formulations for age groups should not be used interchangeably.
- Under initial standards, unopened vials may be stored frozen between -50°C to -15°C (-58°F to 5°F) until the published expiration date or for up to 30 days at 2°C to 8°C (36°F to 46°F) prior to first use.
- The information sheet about the V-safe smartphone safety monitoring system should be provided to parent/guardians, who should be encouraged to participate.
- This letter is intended to provide information common to all formulations of pediatric Moderna COVID-19 vaccine, as well as point out age-specific differences, and links to CDC, CDPH, FDA, and other resources.

Immunization Branch / Division of Communicable Disease Control 850 Marina Bay Parkway, Bidg. P. 2nd Floor, Richmond, CA 94804 (510) 620-3737 + FAX (510) 620-3774 + Internet Address: www.getimmunizedca.org



Letter to Providers of Pediatric Services
From Dr. Robert Schechter,

Center for Infectious Diseases

Division of Communicable Disease Control

Immunization Branch

July 8, 2022



Translated Materials: Moderna Fact Sheets

Translations of the Moderna Fact Sheet for Recipients and Caregivers for 6 months through 5 years of age

Fact Sheet	Vaccine Recipient Group	Language
HOJA INFORMATIVA PARA RECEPTORES Y CUIDADORES AUTORIZACIÓN DE USO DE EMERGENCIA DE LA VACUNA CONTRA EL COVID-19 DE MODERNA PARA PREVENIR LA ENFERMEDAD DEL CORONAVIRUS 2019 (COVID-19) EN NIÑOS DE 6 MESES A 5 AÑOS (June 17, 2022)	6 months - 5 years of age	Español (Spanish)
给受种人和监护人的情况说明书针对6个月到5岁的个体预防2019冠状病毒病(COVID-19)的现代 COVID-19 疫苗紧急使用授权(June 17, 2022)	6 months - 5 years of age	中文 (Chinese, Simplified)
수혜자와 간병인을 위한 팩트 시트 6개월에서 5세 사이의 개인에 코로나 바이러스 질병 2019(COVID-19)를 예방하기 위한 모더나 COVID-19 백신의 긴급 사용 승인 (June 17, 2022)	6 months - 5 years of age	한국어 (Korean)
FACT SHEET PARA SA MGA TATANGGAP AT MGA NAG-AALAGA EMERGENCY USE AUTHORIZATION NG BAKUNANG MODERNA COVID-19 UPANG MAIWASAN ANG CORONAVIRUS DISEASE 2019 (COVID-19) SA MGA INDIBIDWAL 6 NA BUWAN HANGGANG 5 TAONG GULANG (June 17, 2022)	6 months - 5 years of age	Tagalog (Tagalog)
PHIỀU THỰC TẾ DÀNH CHO NGƯỜI NHẬN VÀ KHÁCH HÀNG KHẨN CẮP SỬ DỤNG SỰ CHO PHÉP CỦA THUỐC THÚ Y MODERNA COVID-19 ĐỂ PHÒNG NGỬA BỆNH LỖ CHÂN LÔNG 2019 (COVID-19) Ở CÁ NHÂN 6 THÁNG QUA 5 TUỔI	6 months - 5 years of age	Tiếng Việt (Vietnamese)

Translations of the Moderna Fact Sheet for Recipients and Caregivers for 6 through 11 years of age

Fact Sheet	Vaccine Recipient Group	Language
HOJA INFORMATIVA PARA RECEPTORES Y CUIDADORES AUTORIZACIÓN DE USO DE EMERGENCIA DE LA VACUNA CONTRA EL COVID-19 DE MODERNA PARA PREVENIR LA ENFERMEDAD DEL CORONAVIRUS 2019 (COVID-19) EN NIÑOS DE 6 AÑOS A 11 AÑOS (June 17, 2022)	6 - 11 years of age	Español (Spanish)
给受种人和监护人的情况说明书针对6岁到11岁个体预防2019冠状病毒病(COVID-19)的现代COVID-19疫苗紧急使用授权(June 17, 2022)	6 - 11 years of age	中文 (Chinese, Simplified)
수혜자와 간병인을 위한 팩트 시트 6세에서 11세 사이의 개인에 코로나 바이러스 질병 2019(COVID-19)를 예방하기 위한 모더나 COVID-19 백신의 긴급 사용 승인 (June 17, 2022)	6 - 11 years of age	한국어 (Korean)
FACT SHEET PARA SA MGA TATANGGAP AT MGA NAG-AALAGA EMERGENCY USE AUTHORIZATION NG BAKUNANG MODERNA COVID-19 UPANG MAIWASAN ANG CORONAVIRUS DISEASE 2019 (COVID-19) SA MGA 6 NA TAON HANGGANG 11 TAONG GULANG (June 17, 2022)	6 - 11 years of age	Tagalog (Tagalog)
PHIỀU THỰC TẾ DÀNH CHO NGƯỜI NHẬN VÀ KHÁCH HÀNG KHẨN CẬP SỬ DỤNG SỰ CHO PHÉP CỦA THUỐC THÚ Y MODERNA COVID-19 ĐỂ PHÒNG NGỪA BỆNH LỖ CHÂN LÔNG 2019 (COVID-19) Ở CÁ NHÂN 6 TUỔI QUA 11 TUỔI	6 -11 years of age	Tiếng Việt (Vietnamese)

Translated Materials: Pfizer-BioNTech Fact Sheets

Translations of the Pfizer-BioNTech Fact Sheet for Recipients and Caregivers for 6 months through 4 years of age		the Pfizer-BioNTech Fact Sheet for Recipients and 5 through 11 years of age		f the Pfizer-BioNTech Fact Sheet for Recipients and 12 years of age and older				
Fact Sheet	Vaccine Recipient Group	Language		Vaccine Recipient Group	Language		Vaccine Recipient Group	Language
HOJA INFORMATIVA PARA RECEPTORES Y CUIDADORES SOBRE LA VACUNA CONTRA EL COVID-19 DE PFIZER-BIONTECH PARA PREVENIR LA ENFERMEDAD DEL CORONAVIRUS 2019 (COVID-19) PARA USO EN NIÑOS DE 6 MESES A 4 AÑOS (June 17, 2022)	6 months - 4 years of age	Español (Spanish)	CUNAS PARA RECEPTORES Y CUIDADORES ER-BIONTECH CONTRA EL COVID-19 PARA DEL CORONAVIRUS 2019 (COVID-19) PARA 11 AÑOS	5 - 11 years of age	Español (Spanish)	CUNAS PARA RECEPTORES Y CUIDADORES NA DE ARNM CONTRA EL COVID-19) Y LA ECH CONTRA EL COVID-19 PARA PREVENIR ONAVIRUS 2019 (COVID-19) PARA USO EN MÁS	12 years of age and older	Español (Spanish)
面向 6 个月至 4 岁的个体使用的用于预防 2019 年冠状病毒病 (COVID-19) 的辉端生物技术 COVID-19 疫苗的受种者和监护人员情况 说明书 (June 17, 2022)	6 months - 4 years	中文 (Chinese, Simplified)	关于用于预防2019新冠肺炎(COVID-19) 新冠肺炎疫苗以个人使用的信息概况说	5 - 11 years of age	中文 (Chinese, Simplified)	酸新冠肺炎疫苗)以及辉瑞·BioNTech2019新 動物炎的接受者和护理者须知	12 years of age and older	中文 (Chinese, Simplified)
6개월에서 4세 사이의 개인에 사용하기 위한 2019 코로나 바이러스 질병(COVID-19) 예방을 위한 화이자-바이오엔텍 COVID-19 백신에 대 한 수혜자 및 간병인을 위한 팩트 시트 (June 17, 2022)	6 months - 4 years	한국어 (Korean)	- 사람들에게 코로나바이러스감염증 2019 한화이저 (PFIZER)-바이오엔텍 (BIONTECH) 자와 의료진을 위한 백신 정보지		한국어 (Korean)	2019 (COVID-19)를 예방하기 위한 코멀나티 RNA)와 화이저 (PFIZER)-바이오엔텍 신에 대한 환자와 의료진을 위한 백신 정보	12 years of age and older	한국어 (Korean)
FACT SHEET PARA SA MGA TATANGGAP AT MGA NAG-AALAGA TUNGKOL SA BAKUNANG PFIZER-BIONTECH COVID-19 UPANG MAIWASAN ANG CORONAVIRUS DISEASE 2019 (COVID-19) PARA SA PAGGAMIT SA MGA INDIBIDWAL 6 NA BUWAN HANGGANG 4 NA TAONG GULANG (June 17, 2022)	6 months - 4 years	Tagalog (Tagalog)	CT SHEET PARA SA MGA TUMANGGAP AT GKOL SA PFIZER-BIONTECH COVID-19 VANG CORONAVIRUS DISEASE 2019 (COVID- MGA INDIBIDWAL 5 HANGGANG 11 TAONG	5 - 11 years of age	Tagalog (Tagalog)	SYON SA BAKUNA PARA SA MGA TANGGAP SA COMIRNATY (COVID-19 VACCINE, ZER-BIONTECH COVID-19 UPANG MAIWASAN SE 2019 (COVID-19)	12 years of age and older	Tagalog (Tagalog)
PHIỀU THỰC TẾ DÀNH CHO NGƯỜI NHẬN VÀ NGƯỜI CHĂM SÓC VỀ THUỐC CHỮA BỆNH PFIZER-BIONTECH COVID-19 ĐỂ PHÒNG NGỮA BỆNH HẠI LÃO HÓA 2019 (COVID-19) ĐỂ SỬ DỤNG CHO CÁ NHÂN 6 THÁNG QUA 4 TUỔI (June 17, 2022)	6 months - 4 years	Tiếng Việt (Vietnamese)	XIN DÀNH CHO NGƯỜI NHẬN VÀ NGƯỜI IZER-BIONTECH COVID-19 NHẬM PHÒNG S 2019 (COVID-19) ĐỂ SỬ DỤNG CHO CÁ	5 -11 years of age	Tiếng Việt (Vietnamese)	VỀ VẮC XIN DÀNH CHO NGƯỜI NHẬN VÀ MIRNATY (VẮC XIN COVID-19, MRNA) VÀ VẮC VID-19 ĐỂ PHÒNG NGỬA BỆNH D-19)	12 years of age and older	Tiếng Việt (Vietnamese)



Job Aid: Administration Errors

Links to:

- Administration Checklist
- CDC's Interim Clinical Considerations
- CAIR/RIDE information
- VAERS (Vaccine Adverse Event Reporting System)
- VERP (Vaccine Errors Reporting Program)

Responding to Administration Errors

California COVID-19 Vaccination Program



Incorporate this administration checklist into practice protocols to help ensure your patients receive sufficient protection after vaccination and to minimize revaccination efforts due to administration errors.

Instructions

Follow these instructions to respond to administration errors following CDC requirements.

Step	Description				
1.	Inform the recipient of the vaccine administration error.				
2.	Refer to CDC's Interim Clinical Considerations (Appendix C) to determine whether revaccination may be recommended. Contact the manufacturer for any questions. • Moderna: 1-866-MODERNA (1-866-663-3762) • Pfizer: Call 800-438-1985 • Janssen: 1-800-Janssen (1-800-526-7736)				
3.	Contact your local CAIR2/RIDE representative to determine how the dose should be entered into the CAIR, both as an administered dose and to account for inventory.				
4.	4. Report all COVID-19 vaccine administration errors to VAERS —even those not associated with an adverse event. • To file an electronic report, please see the <u>VAERS website</u> . • <u>Reporting to VERP</u> is not required but strongly encouraged to help prevent future errors or patient harm.				
5.	Determine how the error occurred and implement strategies (e.g., education/training) to prevent it from happening again. Tip. Use this guidance to prevent administration errors from occurring again.				

California COVID-19 Vaccination Program

IMM-1426 (7/12/22)





Pfizer COVID-19 Vaccine Updates & Trainings

Date & Time (linked)	Password			
Tuesday, July 19 - 12PM	PaHyM9KpY45			
Wednesday, July 20 - 9AM	EpBS3gMJW33			
Thursday, July 21 - 9AM	CmxXckkJ659			
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** (Starting June 7)
- FDA approvals, authorizations including recent authorizations
- Gray Cap, Comirnaty[®]
- Use of each vaccine presentation, including storage, handling, preparation, and administration



Moderna Infant/Toddler Vaccine Video Trainings



Link to Video Resources





How to Withdraw a 0.25mL dose: Infant/Toddler 6 months-5 years

How to Withdraw a 0.5mL Dose for Pediatrics 6 Years-11 Years

US-COV-2200159 06/2022



Therapeutics Update

Alan Hendrickson, CDPH



Therapeutics (Tx) Update

Equity

- CDC MMWR and CDPH analysis of Test-to-Treat sites in CA show equity gaps in high vulnerability zip codes
- Fewer courses of Paxlovid administered by providers located in Q1/Q2 areas

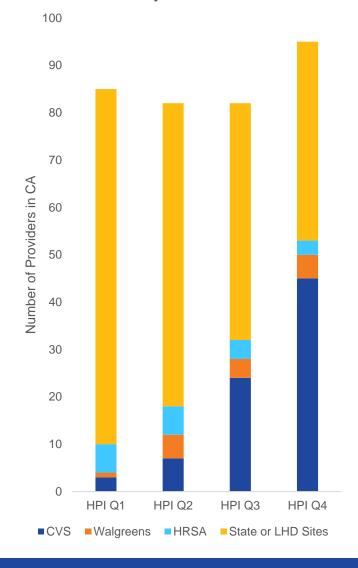
Regulatory

- FDA authorized pharmacists to prescribe Paxlovid w/ limitations
- Waiver that allows dispensing at Optum Serve sites extended to Dec 2022
- Pfizer applied for full approval of Paxlovid last week

Clinical

• FDA issued re-dosing information for Evusheld. At 6 months, patients should receive 300mg tixagevimab + 300 mg cilgavimab (i.e., 2 Evusheld prepackaged doses)

All Active Test-to-Treat Providers by HPI Q





Therapeutics (Tx) Updates

Resources

- <u>Test-to-Treat Playbook</u>
- DHCS and DMHC All Plan Letters
- Weekly Tx webinar for LHDs at 11 AM on Tuesdays, email <u>CDPHTherapeutics@cdph.ca.gov</u> to sign up
- Coming soon: Pharmacy COVID-19 therapeutics resource toolkit

Programmatic

- \$158M in FY22-23 budget for therapeutics to include:
 - Grants to safety net system to facilitate access to therapeutics, including test-to-treat
 - Public media campaign
 - State test-to-treat sites (Optum Serve)



CDPH COVID-19 Treatments: Questions and Answers



Includes resource links and answers to:

- What are COVID-19 treatments?
- What treatments are available?
- How can I get treatments?
- Do treatments replace COVID-19 vaccine?
- How much do treatments cost?

California Department of Public Health COVID-19 Treatments

What are COVID-19 treatments?

COVID-19 treatments are medications (pills, shots, or IV) that can prevent serious symptoms and the need for hospital care after COVID-19 symptoms start.

A health care provider can tell you if you are eligible to receive treatment and which type would work best for you.

You can get treatments if you:

- Test positive for COVID-19 (get tested by your health care provider, at a Test to Treat site, pharmacy, or use an at-home test), AND
- Are more likely to get very sick (older than 50, unvaccinated, or have <u>certain medical conditions</u>*).

Treatments are available for both adults and children who qualify.

The sooner the better

Act quickly: Treatment must be started within days after you first develop symptoms to be effective.

How can I get treatments?

Option A: Contact your health care provider.

- If you have COVID-19 symptoms, a health care provider can help you get tested and get a
 prescription for a treatment. You can then go to a pharmacy to receive your medication.
- If you do not have a health care provider, call 1-877-332-6585 to find out who to talk with about your symptoms and treatment.

Option B: Go to a Test to Treat location

- If you have COVID-19 symptoms, you can get tested, get a prescription, and receive medication – all in one place at a Test to Treat site.
- Find a location using the <u>Test to Treat locator</u>. You can also call 1-800-232-0233 (TTY 1-888-720-7489).

What treatments are available?

There are different types of treatments. A health care provider or a Test to Treat location will tell you which treatment will be safest and work best for you. Treatments come in several forms including pills, IV, or shots.



Scan the QR code to see interactive links on this flyer.

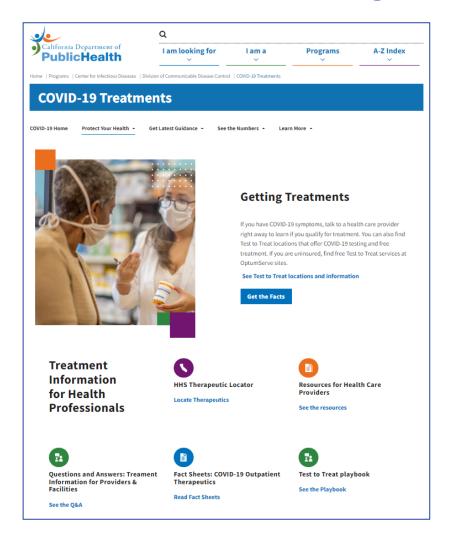


July, 2022 • © 2022, California Department of Public Healtl

July, 2022 • © 2022, California Department of Public Health

CDPH COVID-19 Treatments Updates & Webpage

- FAQs for general public and healthcare providers
- Information on allocation, distribution, and ordering
- Drug fact sheets
- Links to further resources
- Linked in the "Protect Your Health" section on the CDPH COVID-19 webpage





Clinical Update

Lily Horng, M.D., CDPH



New CDC/ACIP Influenza Vaccine Recommendation

CDC director approved influenza vaccine recommendations by ACIP* in June 22-23, 2022:

- Adults aged ≥65 years should preferentially receive one of the following influenza vaccines: quadrivalent high-dose inactivated influenza vaccine (HD-IIV4), quadrivalent recombinant influenza vaccine (RIV4), or quadrivalent adjuvanted inactivated influenza vaccine (aIIV4).
- If none of these three vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be used.

*Advisory Committee on Immunization Practices

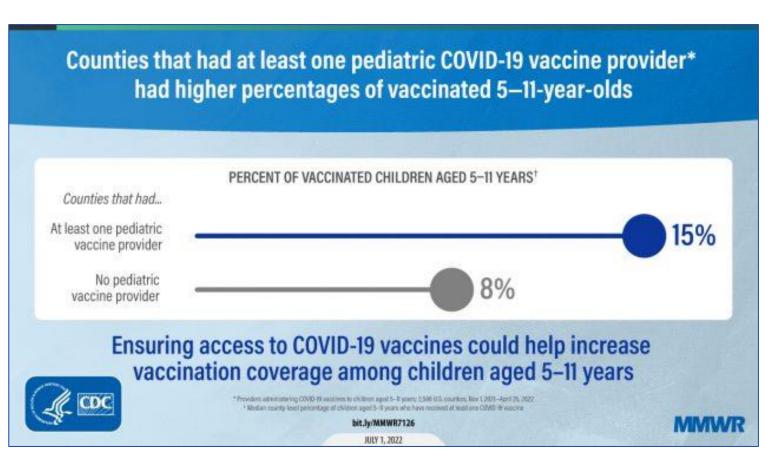
Pediatric COVID-19 Vaccine Updates

- FDA Emergency Use Authorization (EUA) given for
 - Pfizer: In children 6 months through 4 years
 - Moderna: In children 6 months through 5 years
 - Moderna: In children 6 years through 17 years
- FDA fully approved Biologics License Application (BLA) for Pfizer-BioNTech COVID-19 vaccine (Comirnaty) for 12-15-years-old.



MMWR*: COVID-19 Vaccine Provider Availability & Vaccination Coverage for Children 5 through 11 Years Old

- U.S. county-level vaccine data 11/2021-4/2022
- 87.5% of counties had at least one active vaccine provider
 - Approximately half <u>did not have</u> a pediatric clinic, family medicine clinic, or FQHC
 - Most had at least one pharmacy or public health clinic
- Vaccination for 5-11-years-old was higher in counties with at least one active vaccine provider



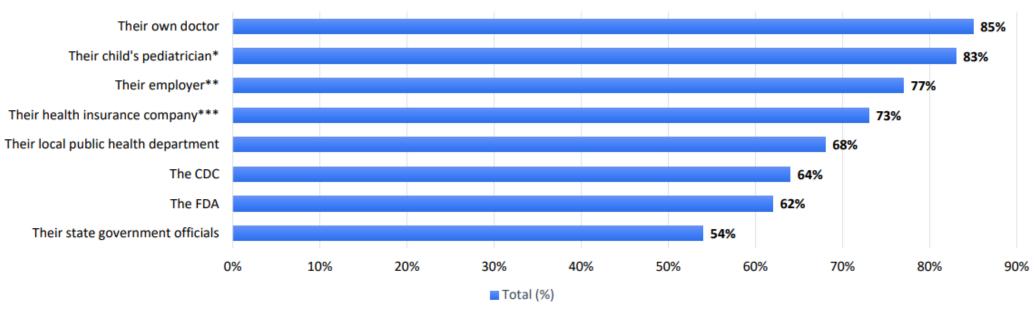
*Morbidity and Mortality Weekly Report



Personal Doctors: Most Trusted for COVID-19 Information

Percent of adults who say they have a great deal or a fair amount of trust in the following to provide reliable information about COVID-19 vaccines:





^{*}Among those who are parents or guardians of children under 18. **Among those who are employed and not self-employed. ***Among those who are insured.

The survey was conducted April 13-26, 2022, among a nationally representative random digit dial telephone sample of 1,889 adults ages 18 and older.

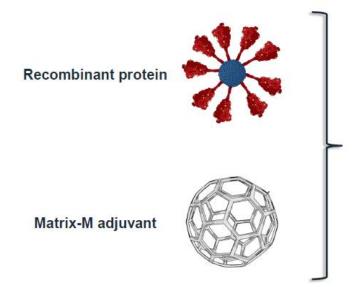
KFF COVID-19 Vaccine Monitor (April 13-26, 2022). https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-april-2022/ Accessed July 7, 2022



Novavax COVID-19 Vaccine Updates

- On 7/13/22, FDA Authorized Emergency Use of Novavax
 COVID-19 Vaccine as a 2-dose primary series in ≥18 years old.
- On 7/19/22, ACIP and CDC recommend Novavax for adults.
- On 7/19/22, Western States Scientific Safety Review Workgroup met to discuss Novavax.
- U.S. government is purchasing >3 million doses for distribution.

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, 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 <u>local</u> adverse events were tenderness and injection-site pain.
- Most common solicited <u>systemic</u> 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

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



²Lee 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.	
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



Vaccine Administration

- Adults ≥ 18 years old
- 2-dose primary series, intramuscular injection
- 3-8-week interval between doses
- At this time, Novavax is not authorized for use as booster doses.

Poll: CDPH Appreciates Your Feedback!



- 1. Is there patient or provider demand for Novavax COVID-19 vaccine?
 - ☐ Yes
 - No
 - □ N/A
- 2. Is your MCE interested in ordering Novavax?
 - ☐ Yes
 - No
 - □ N/A



For Discussion



Data question:

 What is your estimated population of Under 5-years-old in your health system catchment?

Operations questions:

- How are you integrating COVID-19 immunizations into routine primary care for pediatrics, especially Under 5-years-old?
- What are barriers to integrating COVID-19 immunizations into routine primary care for pediatrics, especially Under 5-years-old?



Storage and Handling

Kate McHugh, CDPH



Novavax Storage and Handling

- 10 dose multi-dose vials
- Refrigerated storage (2°C to 8°C) until expiration date
 - Expiration date will not be printed on vial or carton
- 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)



Single-Dose Vials

- Pfizer single-dose vials are likely coming this fall!
- Moderna may also be manufacturing single-dose vials.
- Single dose vials will be available for adults only, for the time being.
 - Due to the concentration of pediatric vaccines, it may not currently be possible for single-dose vials to be manufactured for pediatrics.
- CDPH will share more information as it is received.



Administration Errors

- Steps include:
 - Notifying patient
 - Refer to CDC's <u>revaccination information</u> 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

Maria Volk, CDPH



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.



Public

My Turn Release 29 Overview



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

- ✓ Removing flu zero out flu vaccine supplies to remove nasal spray and flu shot tags
- ✓ In-home vaccination and transportation page updates to reflect guidance for under 5 patients
- ✓ [Delivery] Update error messaging for better user experience and accessibility
- √[Continued] Failure Point Notification –
 setting up monitoring tools throughout
 system to flag (potential) issues

- ✓ [SMS/Email] Opt-out on the Walk-In flow
- ✓ [Vaccine Inventory] Entering Lot Numbers correctly
- ✓ [CAIR2] Concatenate "Cross Street 1" and "Cross Street 2"

Clinic





Monkeypox Vaccine & the My Turn Outbreaks Approach



With increased interest in expanding My Turn beyond COVID and Flu to create a solution for disease outbreaks happening across California, and especially with Monkeypox being a recent driver for this expansion, we are evaluating the development of an outbreak approach.

Stay tuned as we explore solutions for expanding My Turn for Outbreaks and we will share further information once it becomes available.

Novavax Ordering for myCAvax

- We anticipate hearing more information later this week or early next week.
- CDC may open ordering as soon as next week.
- No information on allocations yet but anticipate limited amounts of vaccine at least initially
- 100 dose minimum order



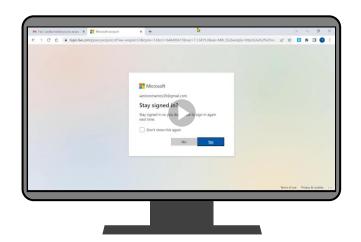
Upcoming Login Process Changes



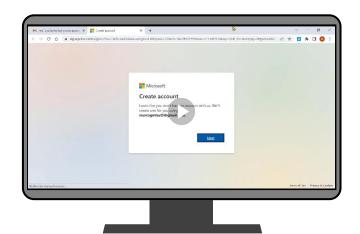


Beginning August 1, 2022, LHDs/MCEs will access the admin side of My Turn/myCAvax at: https://myapplications.microsoft.com/cdph.onmicrosoft.com. Providers will continue to access through the community portal with no changes.

This week, you will receive an email from **Invites@Microsoft.com**, inviting you to begin the process of setting up your new login account and MFA.



Setting up Multi-Factor Authentication (Microsoft Authenticator) with existing Microsoft Account



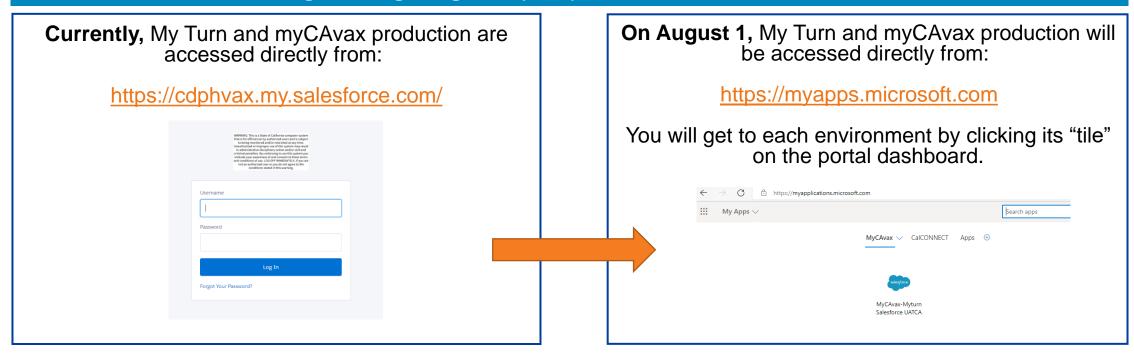
Setting up Multi-Factor Authentication
(SMS Message) without an existing
Microsoft Account



For LHDs/MCEs: Upcoming Login Process Changes



Change to Single Sign-On (SSO) Portal: New URL and Interface



Change to Sign-in Requirements: Multifactor Authentication (MFA) Needed

After inputting your username & password, the system requires identity verification via one of the following:

• Voice Call (One Time Passcode)

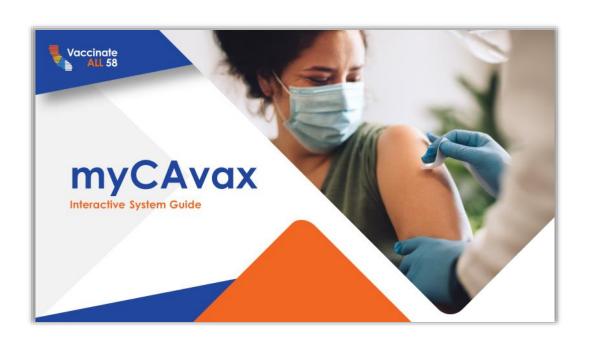
- SMS Text Message (One Time Passcode)
- Authenticator Mobile App (Passcode or Push Notification)

Upon receiving the authentication prompt, approve via mobile device or enter the passcode into the portal sign-in page.



Feedback Requested – myCAvax Interactive Guide









The myCAvax Interactive Guide is a comprehensive end-to-end resource incorporating programmatic and system knowledge.

Please email any feedback to myCAvaxInfo@cdph.ca.gov.





LHD Council Call Reminder



The next LHD Council Call is Friday, July 22nd! This call does not require registration.

Please join the meeting <u>here</u>.



APPENDIX



myCAvax – Upcoming Enhancements - *Updated 7/18*



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



✓ 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.
<u> </u>	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

RECENTLY DEPLOYED

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 Pediatrics 6-years-11years two dose series
- Moderna Adolescents12-years-17years 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 Pediatrics/Adolescents 6years-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 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

Release 28.4

July 7th (R28)

Release 29

- Moderna Pediatrics 6-years-11years two dose series
- ✓ Moderna Adolescents 12-years-17years 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

Release 29

- √ [Walk-In] Tool tips to the Homeless questions ★ ✓ [SMS/Email] Opt-out on the Walk-In.
- √ [Vaccine Inventory] Entering Lot Numbers correctly

CURRENT

July 27th (R29)

- ✓ [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 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-Ir 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 S	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 provider their COVID-19 response, specifically addressing questions about State program requirements, enrollmedistribution, 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	
\Box		 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	
	my fam omne neip besk	For technical support with My Turn Clinic for COVID-19 and flu vaccines: MyTurn.Clinic.HD@Accenture (833) 502-1245, option 4: Monday through Friday 8AM–6PM	e.com or
_		For job aids, demos, and training opportunities: flu at https://eziz.org/covid/myturn/flu/ and COVID at https://eziz.org/covid/myturn/flu/ and COVID at https://eziz.org/covid/myturn/flu/ and COVID at https://eziz.org/covid/myturn/flu/ and COVID at https://exiz.org/covid/myturn/flu/ and COVID at https://exiz.org/ and	



Public COVID-19 Call Center

- 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.







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



Thank you for joining today's webinar!

Next MCEs Updates and Discussion

Wednesday, August 3, 2022

