California Department of Public Health Respiratory Syncytial Virus (RSV) Webinar

Monday, October 16, 2023

12PM – 1PM

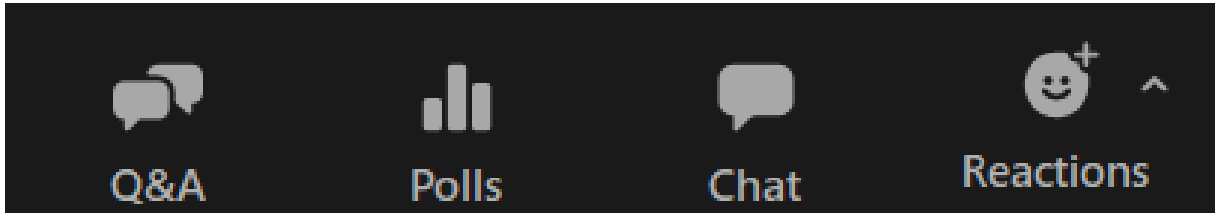
Agenda: Monday, October 16, 2023

No	Item	Speaker	Time (PM)
1	Welcome and Announcements	Leslie Amani (CDPH)	12:00 – 12:05
2	Epidemiology	Cora Hoover, MD (CDPH)	12:05 – 12:10
3	Clinical: RSV Guidance and Resources	Priyanka Saxena, DO, MPH (CDPH)	12:10 – 12:20
4	Let's Hear From You: Implementation	Cindy Blifeld, MD (Lompoc Valley Medical Center)	12:20 – 12:30
6	Vaccines for Children (VFC) and Hospitals as Critical Partners	Claudia Aguiluz (CDPH)	12:30 – 12:35
7	VFC Enrollment	Colleen Mallen and Kelley Leung, RN (CDPH)	12:35 – 12:50
8	Resources, Q&A, and Poll	Leslie Amani and CDPH Subject Matter Experts (SMEs)	12:50 – 1:00

Thank you for attending today's webinar!

Questions

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



Resource links will be dropped into, "Chat"

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:

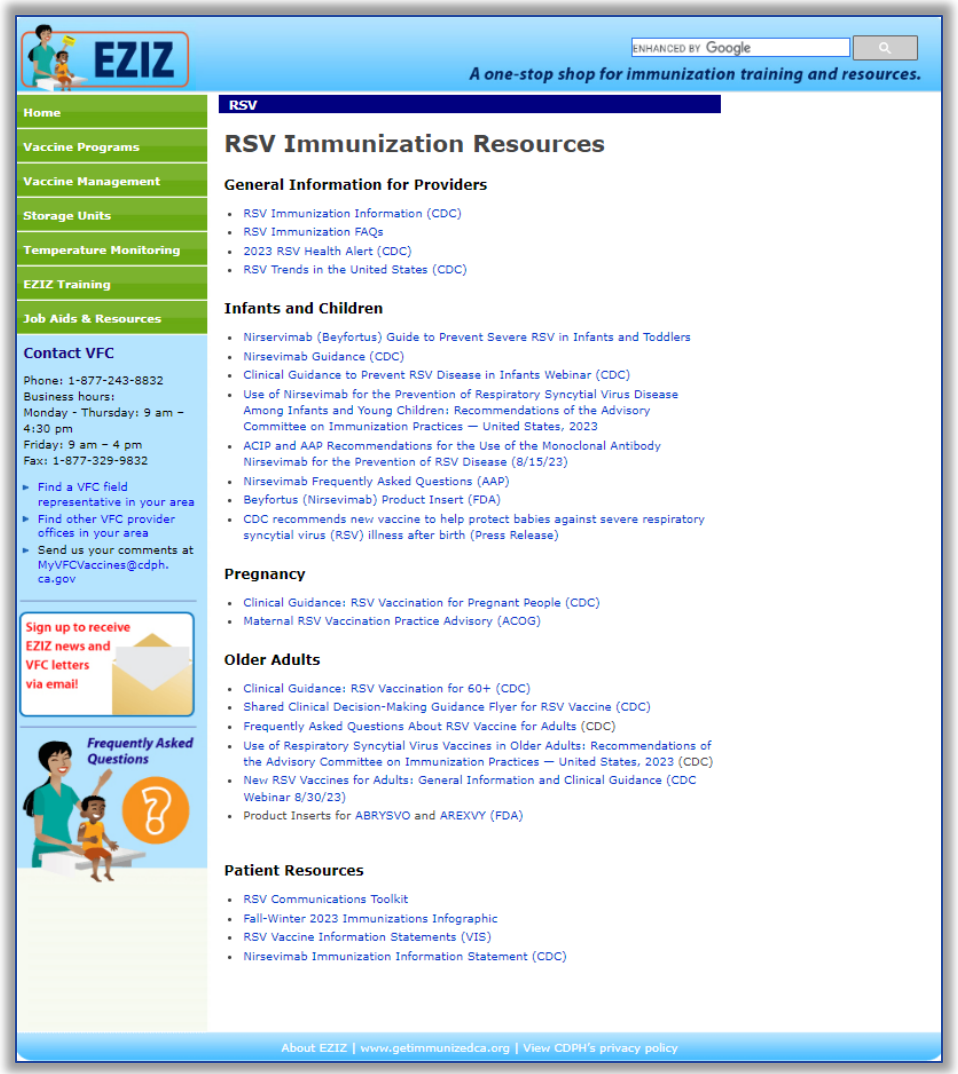
Today's session is being recorded. Access today's slides and archived presentations at: CDPH Immunization Updates for Providers on EZIZ

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

Announcements

Leslie Amani, CDPH

New RSV Resources Webpage



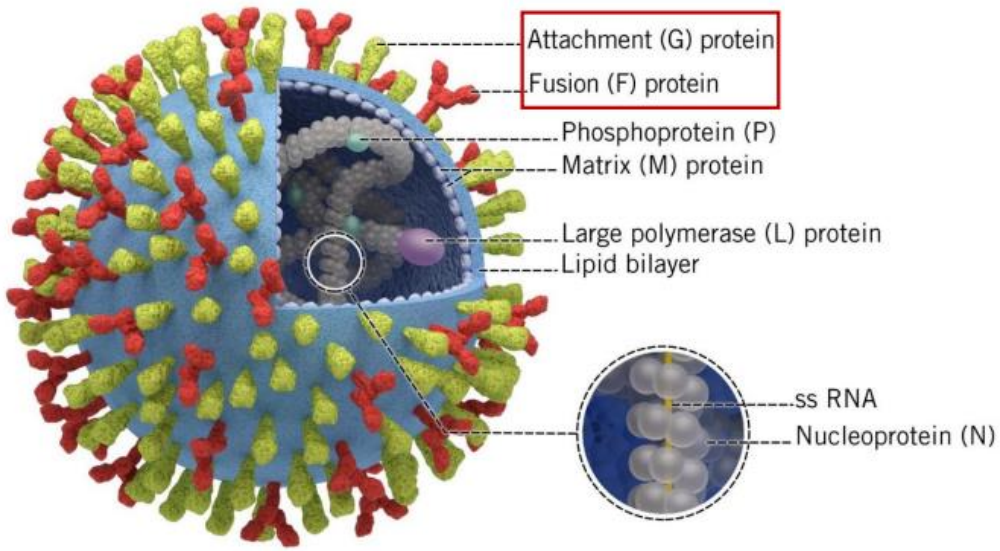
- RSV FAQs
- Nirsevimab Timing Guide
- CDC Clinical Recommendations
- Patient Resources

Epidemiology

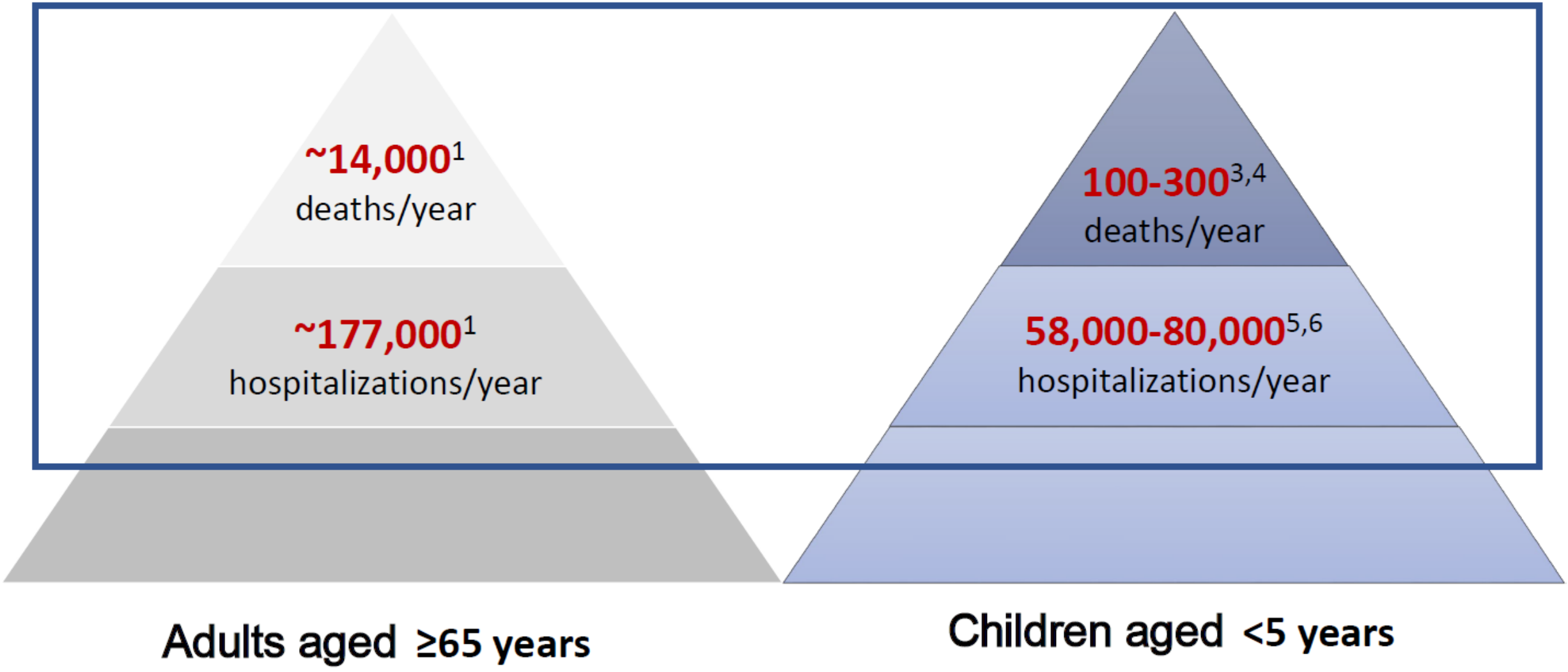
Cora Hoover, MD, CDPH

RSV Overview

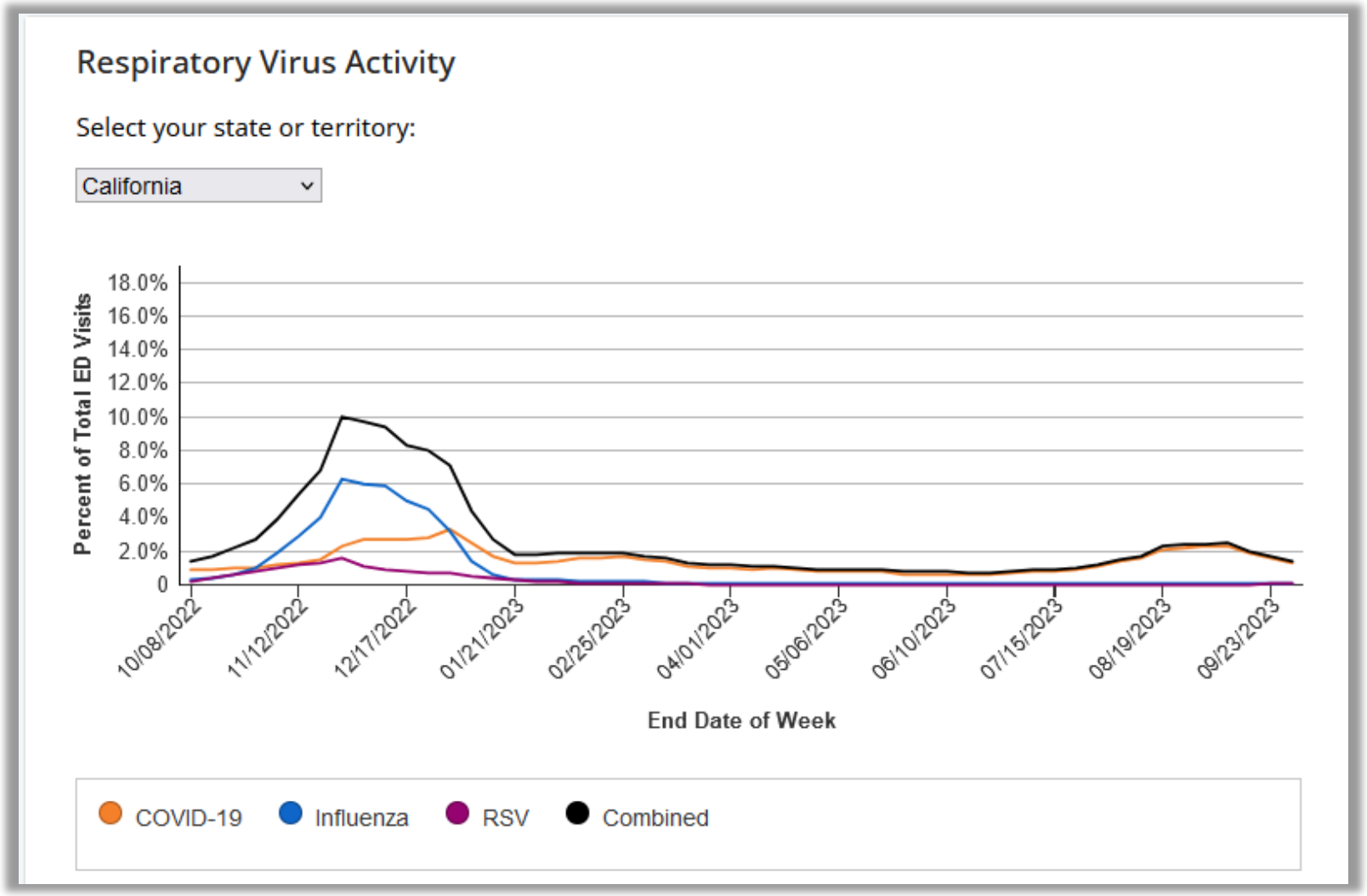
- Common respiratory virus that usually causes mild, cold-like symptoms.
- Infants and older adults are more likely to develop severe RSV and need hospitalization.
- RSV is the most common cause of hospitalization among infants
- One of the most common causes of childhood illness and frequent cause of respiratory infections in older adults
- RSV testing often not performed
- No specific recommended treatment



Burden of Hospitalization and Death Due to RSV



Overlapping Seasonality of Flu, COVID-19, RSV



Monitoring RSV Activity

National

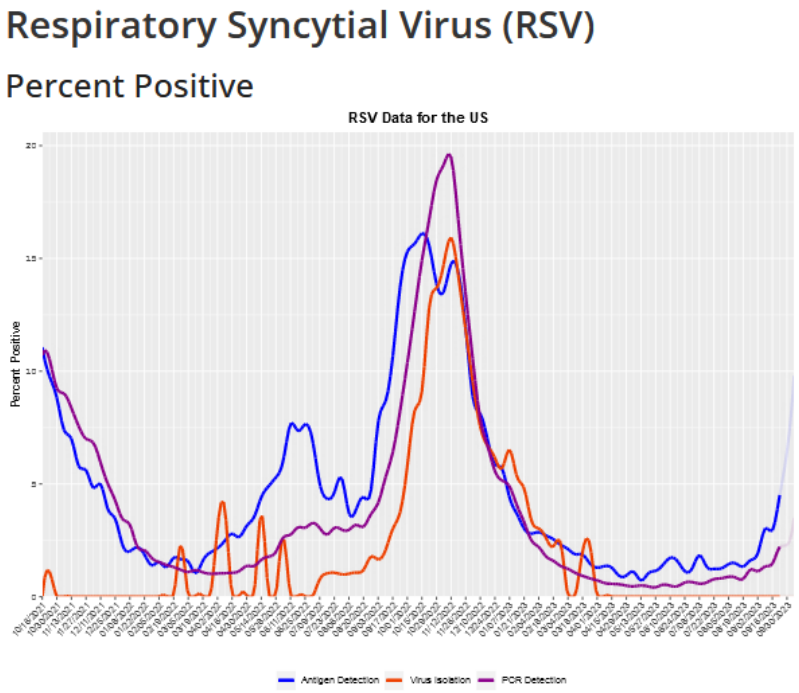
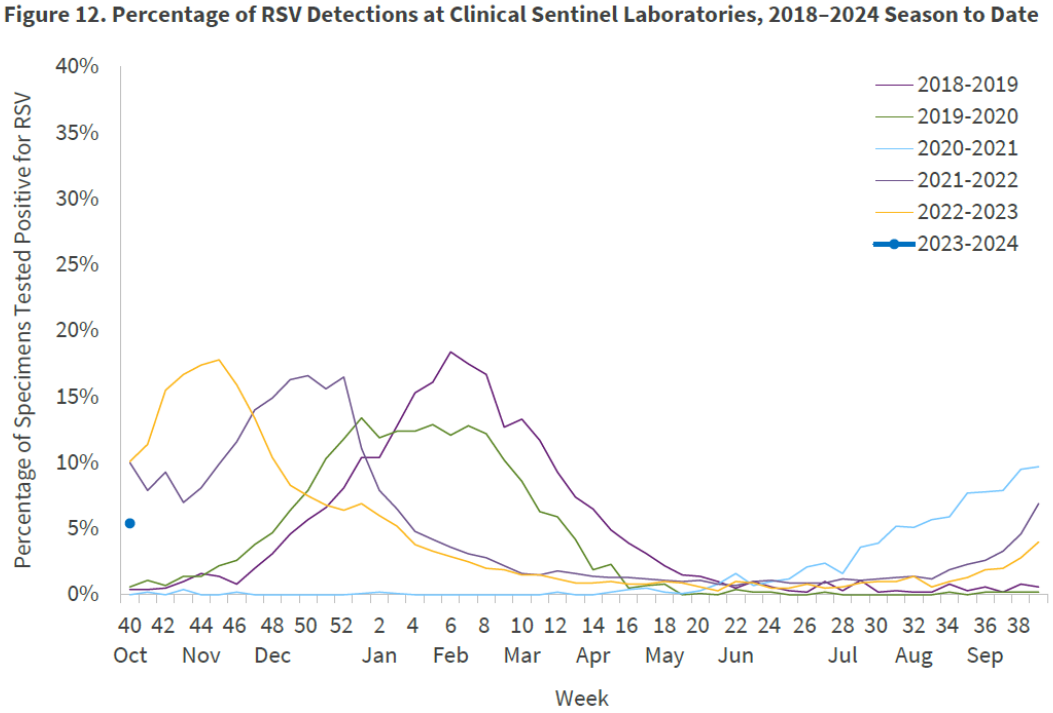


Table: Percent positive respiratory syncytial virus tests in the United States, by week

California



Note: Data have been shifted so that Week 1 aligns across seasons.

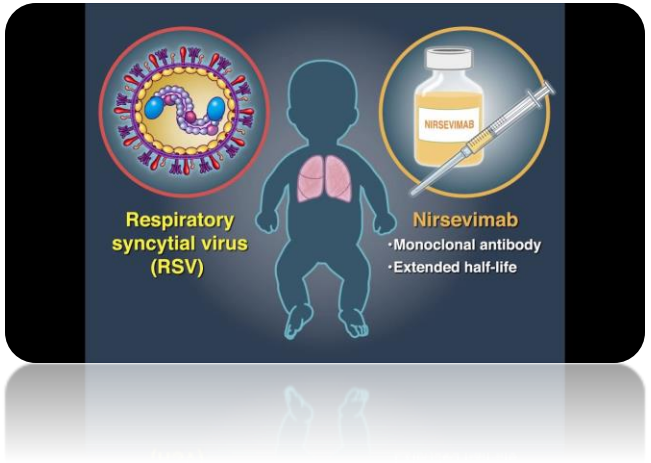
CDC: RSV National Trends
CDPH: Influenza, RSV and Other Respiratory Viruses Weekly report (linked at bottom of webpage)

Clinical: RSV Guidance and Resources

Priyanka Saxena, DO, MPH, CDPH

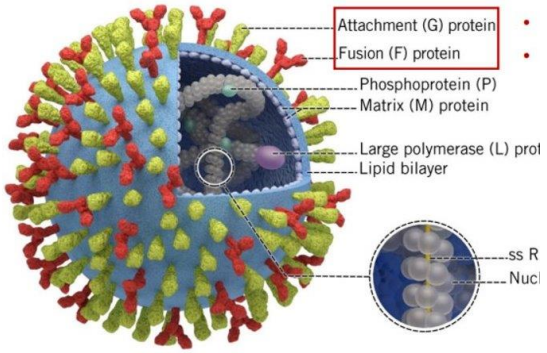
Nirsevimab Background

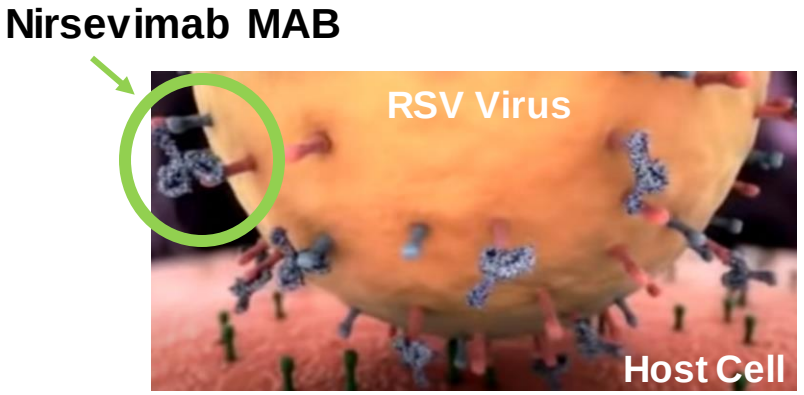
- Nirsevimab (Beyfortus™) is a monoclonal antibody that provides protection against severe RSV disease in infants and toddlers
- It is a form of passive immunization that provides RSV antibodies directly to the recipient
- Confers long-lasting protection from RSV, expected to last at least 5 months (about the length of a typical RSV season)
- Fills an unmet need: There is no other approved prophylaxis or recommended treatment for RSV for the **general infant population** and most infants have no specific protection against RSV.



How Nirsevimab Works

- Nirsevimab binds to RSV virus and inhibits fusion of RSV to the cell membrane
- This prevents viral entry, replication and severe RSV disease





Nirsevimab Inclusion in VFC Program

- CDC has determined that nirsevimab is eligible for inclusion in the childhood immunization schedule and Vaccines for Children (VFC) program
  - No statutory definition of vaccine in the statute for the Vaccines for Children (VFC) program (section 1928 of the Social Security Act)
  - No statutory definition of vaccine in the Affordable Care Act (section 2713 of PHS Act), or its implementing regulations, which has a provision that mandates coverage of vaccine recommendations included on CDC's immunization schedules

Safety & Efficacy

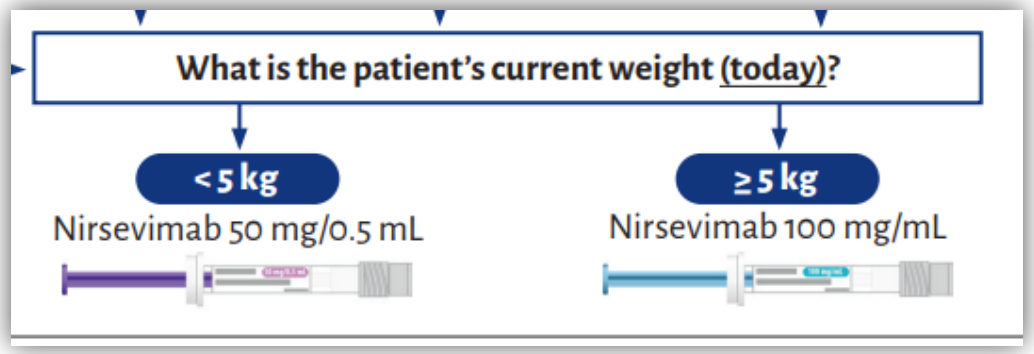
- Safety
  - Most (97%) adverse events were mild to moderate in intensity.
  - Adverse reactions that were more common among infants who received nirsevimab than placebo include:
    - Rash occurring within 14 days of injection (0.9% of nirsevimab versus 0.6% of placebo)
    - Injection site reactions occurring within 7 days of injection (0.3% of nirsevimab versus 0% of placebo).
- Efficacy: In clinical trials nirsevimab was approximately 80% effective in preventing hospitalization for RSV infection, and 90% effective against admission for intensive care.

Timing

- Typical RSV Season is from October through the end of March
  - Local RSV activity data are available at the National Respiratory and Enteric Virus Surveillance System.
  - Providers may adjust timing of administration based on guidance from public health authorities or regional medical centers.
- Optimal timing of administration is just **before** the start of the RSV season
- Nirsevimab administration should continue throughout the season

Guidance for Infants < 8 Months

- Dosing for infants younger than 8 months: 50 mg for infants <5 kg and 100 mg for infants ≥5 kg



- Infants with prolonged hospitalization (e.g., preterm infants) should be ideally be immunized shortly before or promptly after discharge.
  - If dose cannot be administered in the birth hospital, it can be given in outpatient clinic.
  - For infants born outside the RSV season, administration should be targeted shortly before the start of their first RSV season

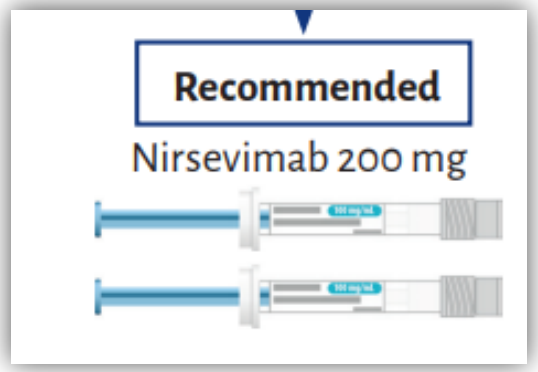
Screening for RSV Vaccine in Pregnancy

- Infants younger than 8 months of age who were born during or are entering their first RSV season should receive a single dose of nirsevimab in the first week of life if:
  - The birth parent did not receive RSV vaccine during pregnancy*
  - The birth parent's RSV vaccination status is unknown
  - The infant was born within 14 days of prenatal RSV vaccination

*RSV vaccine during pregnancy is another option available to protect young infants from severe RSV disease and is given to pregnant persons between 32-36 weeks of gestation

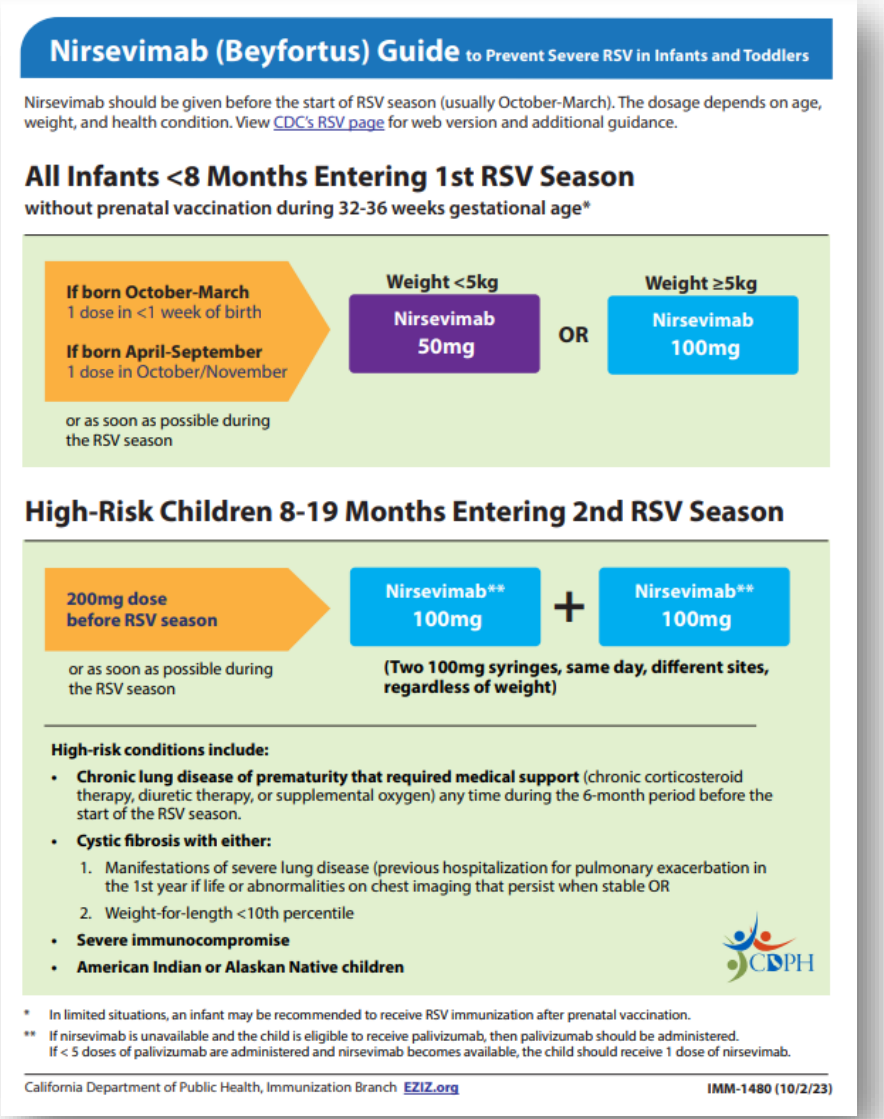
Guidance for Children 8 Months – 19 Months

- Children ages 8 months and older who are **not** at increased risk of severe RSV disease should not receive nirsevimab.
- Nirsevimab is recommended for children ages 8 months through 19 months **who are at increased risk of severe RSV disease**:
  - American Indian/Alaska Native children
  - Children with chronic lung disease of prematurity who require medical support during the six months before the start of their second RSV season
  - Children with severe immunocompromise
  - Children with severe cystic fibrosis
- Administration of a single 200 mg dose of nirsevimab for these children should be targeted shortly before the start of their second RSV season



Dosing and Timing Summary

- Dose depends on age and weight
- Infants born shortly before and during the RSV season should receive nirsevimab within the first week of life, including in hospital settings.
- Offer nirsevimab now, as soon as supplies become available.
- Protection is expected to last at least 5 months, about the length of an RSV season
- Co-administration of nirsevimab with other routine pediatric vaccines during the same visit is a recommended option.



Nirsevimab (Beyfortus) Guide to Prevent Severe RSV in Infants and Toddlers

Nirsevimab should be given before the start of RSV season (usually October-March). The dosage depends on age, weight, and health condition. View CDC's RSV page for web version and additional guidance.

All Infants <8 Months Entering 1st RSV Season

without prenatal vaccination during 32-36 weeks gestational age*

If born October-March
1 dose in <1 week of birth

If born April-September
1 dose in October/November

or as soon as possible during the RSV season

Weight <5kg		Weight ≥5kg
Nirsevimab 50mg	OR	Nirsevimab 100mg

High-Risk Children 8-19 Months Entering 2nd RSV Season

200mg dose before RSV season

or as soon as possible during the RSV season

Nirsevimab 100mg + **Nirsevimab** 100mg

(Two 100mg syringes, same day, different sites, regardless of weight)

High-risk conditions include:

- **Chronic lung disease of prematurity that required medical support** (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the RSV season.
- **Cystic fibrosis with either:**
  1. Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the 1st year if life or abnormalities on chest imaging that persist when stable OR
  2. Weight-for-length <10th percentile
- **Severe immunocompromise**
- **American Indian or Alaskan Native children**

* In limited situations, an infant may be recommended to receive RSV immunization after prenatal vaccination.

** If nirsevimab is unavailable and the child is eligible to receive palivizumab, then palivizumab should be administered. If < 5 doses of palivizumab are administered and nirsevimab becomes available, the child should receive 1 dose of nirsevimab.

California Department of Public Health, Immunization Branch EZIZ.org IMM-1480 (10/2/23)

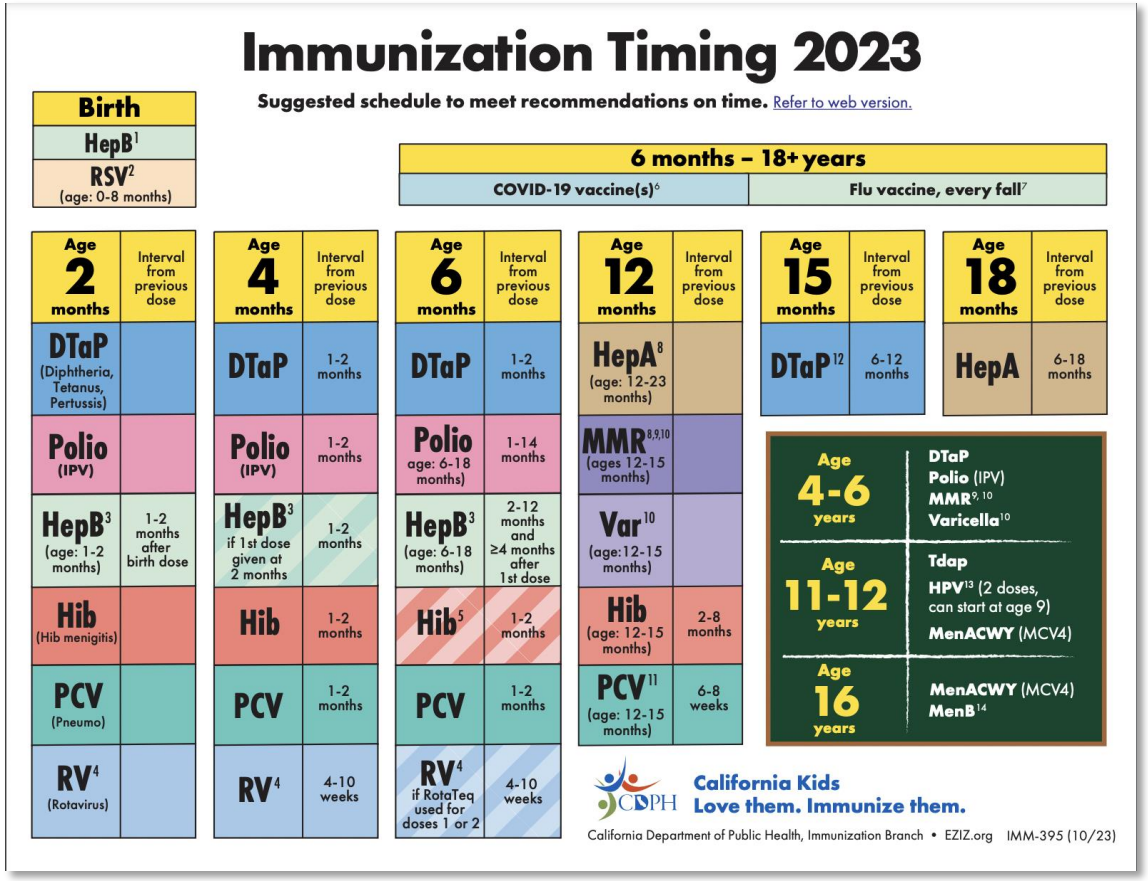
Nirsevimab (Beyfortus) Guide (CDPH)

Nirsevimab Frequently Asked Questions (aap.org)

Answers to Common Questions

- Co-administration with age-appropriate vaccines is recommended; nirsevimab can be given with birth dose of Hepatitis B vaccine
- Nirsevimab is recommended for those with a prior history of RSV infection or hospitalization
- Providers licensed to administer nirsevimab in California include physicians, physician assistants, nurses, medical assistants, pharmacists, and pharmacy interns, as long as they meet their usual conditions for immunizing.
- **If nirsevimab is not available, monthly infusions of palivizumab should be administered to high-risk children as previously recommended.** Further considerations for the use of nirsevimab or palivizumab in infants and young children at increased risk for severe RSV disease are available at ACIP and AAP Recommendations for Nirsevimab.

Updated CDPH Tools for Clinicians



Immunization Timing 2023

Suggested schedule to meet recommendations on time. Refer to web version.

Birth
- HepB[1]
- RSV[2] (age: 0-8 months)

6 months – 18+ years
- COVID-19 vaccine(s)[6]
- Flu vaccine, every fall[7]

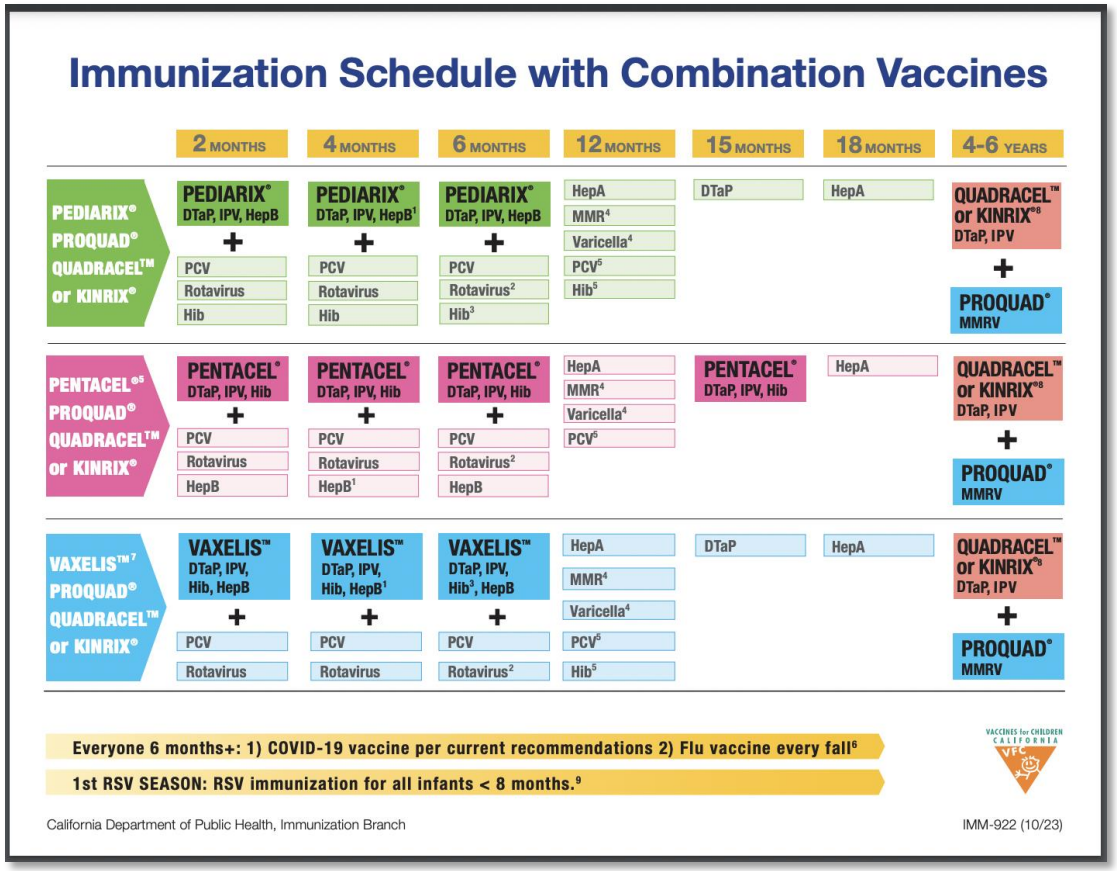
Age	Interval from previous dose
2 months	
DTaP (Diphtheria, Tetanus, Pertussis)	
Polio (IPV)	
HepB[3] (age: 1-2 months)	1-2 months after birth dose
Hib (Hib menigitis)	
PCV (Pneumo)	
RV[4] (Rotavirus)	
4 months	
DTaP	1-2 months
Polio (IPV)	1-2 months
HepB[3] if 1st dose given at 2 months	1-2 months
Hib	1-2 months
PCV	1-2 months
RV[4]	4-10 weeks
6 months	
DTaP	1-2 months
Polio age: 6-18 months)	1-14 months
HepB[3] (age: 6-18 months)	2-12 months and ≥4 months after 1st dose
Hib[5]	1-2 months
PCV	1-2 months
RV[4] if RotaTeq used for doses 1 or 2	4-10 weeks
12 months	
HepA[8] (age: 12-23 months)	
MMR[8,9,10] (ages 12-15 months)	
Var[10] (age:12-15 months)	
Hib (age: 12-15 months)	2-8 months
PCV[11] (age: 12-15 months)	6-8 weeks
15 months	
DTaP[12]	6-12 months
18 months	
HepA	6-18 months

Age 4-6 years	DTaP Polio (IPV) MMR[9, 10] Varicella[10]
Age 11-12 years	Tdap HPV[13] (2 doses, can start at age 9) MenACWY (MCV4)
Age 16 years	MenACWY (MCV4) MenB[14]

California Kids Love them. Immunize them.

California Department of Public Health, Immunization Branch • EZIZ.org IMM-395 (10/23)

Immunization Timing 2023



Immunization Schedule with Combination Vaccines

	2 months	4 months	6 months	12 months	15 months	18 months	4-6 years
PEDIARIX® PROQUAD® QUADRACEL™ or KINRIX®	PEDIARIX® DTaP, IPV, HepB + PCV, Rotavirus, Hib	PEDIARIX® DTaP, IPV, HepB[1] + PCV, Rotavirus, Hib	PEDIARIX® DTaP, IPV, HepB + PCV, Rotavirus[2], Hib[3]	HepA, MMR[4], Varicella[4], PCV[5], Hib[5]	DTaP	HepA	QUADRACEL™ or KINRIX®[8] DTaP, IPV + PROQUAD® MMRV
PENTACEL®[5] PROQUAD® QUADRACEL™ or KINRIX®	PENTACEL® DTaP, IPV, Hib + PCV, Rotavirus, HepB	PENTACEL® DTaP, IPV, Hib + PCV, Rotavirus, HepB[1]	PENTACEL® DTaP, IPV, Hib + PCV, Rotavirus[2], HepB	HepA, MMR[4], Varicella[4], PCV[5]	PENTACEL® DTaP, IPV, Hib	HepA	QUADRACEL™ or KINRIX®[8] DTaP, IPV + PROQUAD® MMRV
VAXELIS™[7] PROQUAD® QUADRACEL™ or KINRIX®	VAXELIS™ DTaP, IPV, Hib, HepB + PCV, Rotavirus	VAXELIS™ DTaP, IPV, Hib, HepB[1] + PCV, Rotavirus	VAXELIS™ DTaP, IPV, Hib[3], HepB + PCV, Rotavirus[2]	HepA, MMR[4], Varicella[4], PCV[5], Hib[5]	DTaP	HepA	QUADRACEL™ or KINRIX®[8] DTaP, IPV + PROQUAD® MMRV

Everyone 6 months+: 1) COVID-19 vaccine per current recommendations 2) Flu vaccine every fall[6]

1st RSV SEASON: RSV immunization for all infants < 8 months.[9]

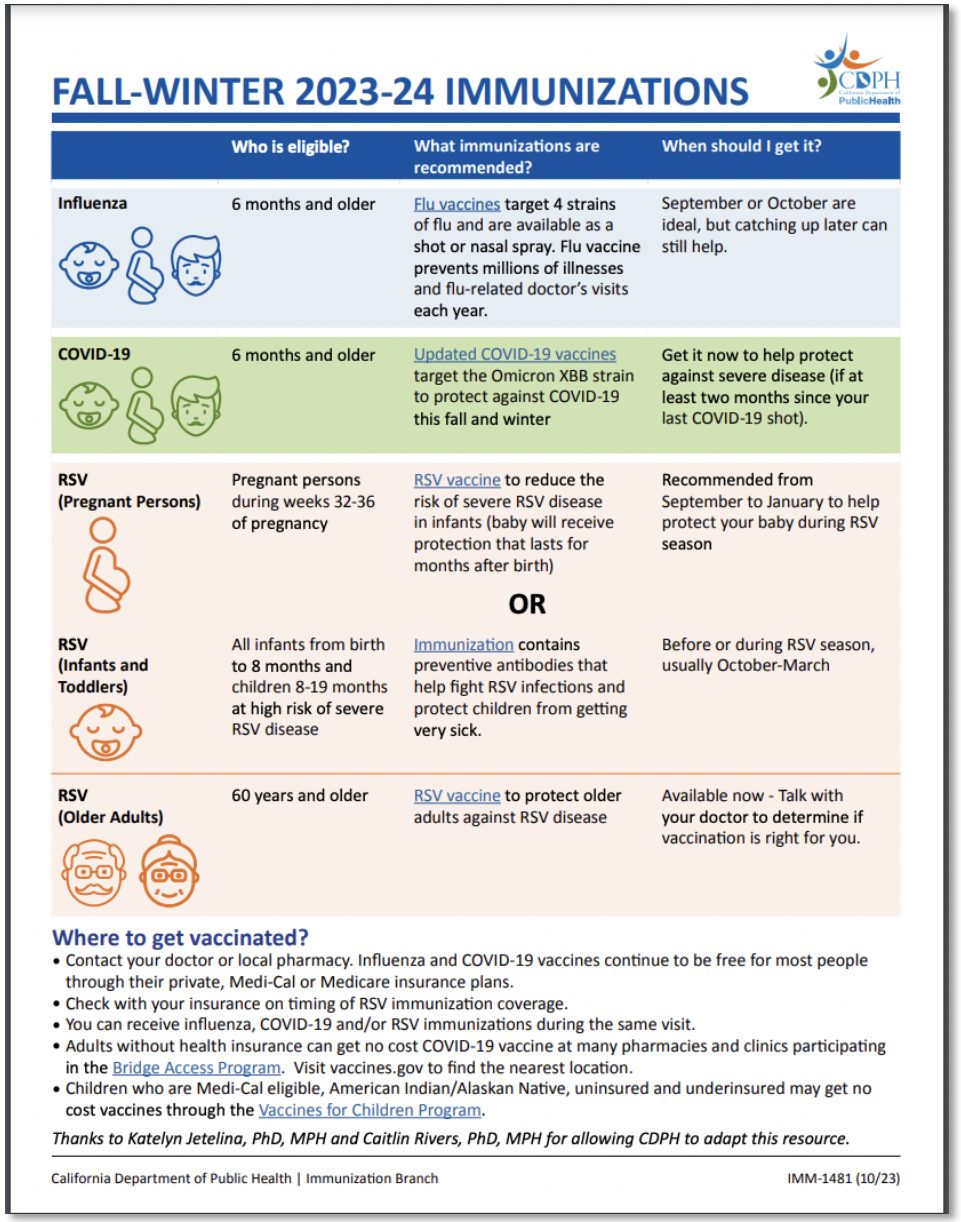
VACCINES for CHILDREN CALIFORNIA

California Department of Public Health, Immunization Branch IMM-922 (10/23)

Immunization Schedule with Combination Vaccines

EZIZ Resources & FAQs

- RSV Immunization FAQs
- RSV Resources for Providers and Patients



FALL-WINTER 2023-24 IMMUNIZATIONS

	Who is eligible?	What immunizations are recommended?	When should I get it?
Influenza	6 months and older	Flu vaccines target 4 strains of flu and are available as a shot or nasal spray. Flu vaccine prevents millions of illnesses and flu-related doctor's visits each year.	September or October are ideal, but catching up later can still help.
COVID-19	6 months and older	Updated COVID-19 vaccines target the Omicron XBB strain to protect against COVID-19 this fall and winter	Get it now to help protect against severe disease (if at least two months since your last COVID-19 shot).
RSV (Pregnant Persons)	Pregnant persons during weeks 32-36 of pregnancy	RSV vaccine to reduce the risk of severe RSV disease in infants (baby will receive protection that lasts for months after birth) **OR**	Recommended from September to January to help protect your baby during RSV season
RSV (Infants and Toddlers)	All infants from birth to 8 months and children 8-19 months at high risk of severe RSV disease	Immunization contains preventive antibodies that help fight RSV infections and protect children from getting very sick.	Before or during RSV season, usually October-March
RSV (Older Adults)	60 years and older	RSV vaccine to protect older adults against RSV disease	Available now - Talk with your doctor to determine if vaccination is right for you.

Where to get vaccinated?

- Contact your doctor or local pharmacy. Influenza and COVID-19 vaccines continue to be free for most people through their private, Medi-Cal or Medicare insurance plans.
- Check with your insurance on timing of RSV immunization coverage.
- You can receive influenza, COVID-19 and/or RSV immunizations during the same visit.
- Adults without health insurance can get no cost COVID-19 vaccine at many pharmacies and clinics participating in the Bridge Access Program. Visit vaccines.gov to find the nearest location.
- Children who are Medi-Cal eligible, American Indian/Alaskan Native, uninsured and underinsured may get no cost vaccines through the Vaccines for Children Program.

Thanks to Katelyn Jetelina, PhD, MPH and Caitlin Rivers, PhD, MPH for allowing CDPH to adapt this resource.

California Department of Public Health | Immunization Branch IMM-1481 (10/23)

FALL-WINTER 2023-24 IMMUNIZATIONS

CDC Resources

- CDC MMWR: Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023
- CDC Healthcare Providers: RSV Prevention Information
- CDC Frequently Asked Questions About RSV Immunization for Children 19 Months and Younger
- ACIP and AAP Recommendations for Nirsevimab, Red Book Online
- AAP Nirsevimab Frequently Asked Questions
- RSV ACIP Vaccine Recommendations
- Immunization Information Sheet-RSV Preventive Antibody: What You Need to Know September 25, 2023 (cdc.gov)

Let's Hear From You: Implementation

Cindy Blifeld, MD, Lompoc Valley Medical Center

Vaccines for Children (VFC) and Enrollment

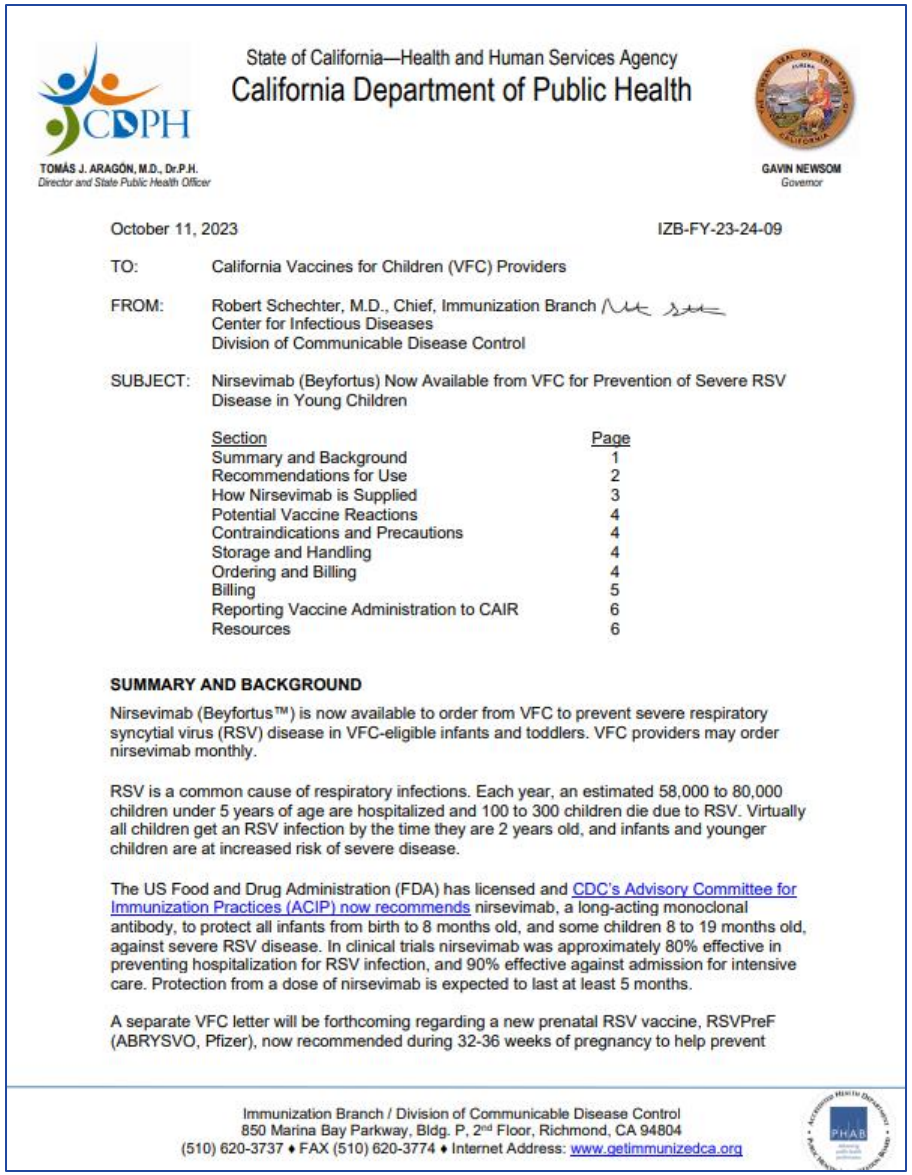
Claudia Aguiluz, CDPH

Pediatric RSV in VFC!

Beyfortus™ is became available for ordering through the Vaccines for Children (VFC) Program on October 11, 2023.

Detailed information regarding Beyfortus™ and ordering was communicated to all VFC Providers.

Note: The new prenatal RSV vaccine from Pfizer, ABRYSVO, is expected to be available through the VFC Program for pregnant adolescents. Information will be forthcoming.



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

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

GAVIN NEWSOM
Governor

October 11, 2023 IZB-FY-23-24-09

TO: California Vaccines for Children (VFC) Providers

FROM: Robert Schechter, M.D., Chief, Immunization Branch
Center for Infectious Diseases
Division of Communicable Disease Control

SUBJECT: Nirsevimab (Beyfortus) Now Available from VFC for Prevention of Severe RSV Disease in Young Children

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Summary and Background	1
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SUMMARY AND BACKGROUND

Nirsevimab (Beyfortus™) is now available to order from VFC to prevent severe respiratory syncytial virus (RSV) disease in VFC-eligible infants and toddlers. VFC providers may order nirsevimab monthly.

RSV is a common cause of respiratory infections. Each year, an estimated 58,000 to 80,000 children under 5 years of age are hospitalized and 100 to 300 children die due to RSV. Virtually all children get an RSV infection by the time they are 2 years old, and infants and younger children are at increased risk of severe disease.

The US Food and Drug Administration (FDA) has licensed and CDC's Advisory Committee for Immunization Practices (ACIP) now recommends nirsevimab, a long-acting monoclonal antibody, to protect all infants from birth to 8 months old, and some children 8 to 19 months old, against severe RSV disease. In clinical trials nirsevimab was approximately 80% effective in preventing hospitalization for RSV infection, and 90% effective against admission for intensive care. Protection from a dose of nirsevimab is expected to last at least 5 months.

A separate VFC letter will be forthcoming regarding a new prenatal RSV vaccine, RSVPreF (ABRYSVO, Pfizer), now recommended during 32-36 weeks of pregnancy to help prevent

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

Beyfortus™ Vaccine Supply Update-VFC

- On Friday October 13, 2023, CDC announced a temporary stop in Nirsevimab ordering in light of high demand and limited supply.
- VFC ordering is expected to resume this week, with vaccine allocations in place to ensure equitable availability across the US for VFC supply.
- The % of doses allocated to each state will be in accordance with VFC vaccine ordering history for vaccines used in a comparable cohort.
- Doses ordered must be used according to VFC eligibility guidelines-use in VFC-eligible patients ONLY.

Nirsevimab, Hospitals, and VFC

Cost of nirsevimab estimated at $495 per dose in the private sector

Birthing Hospital Enrollment in VFC

- This fall, birthing institutions can play a critical role in increasing equitable access to birth dose Immunizations, including RSV protection.
  - Number of Medi-Cal Hospital births 2020: 172,293

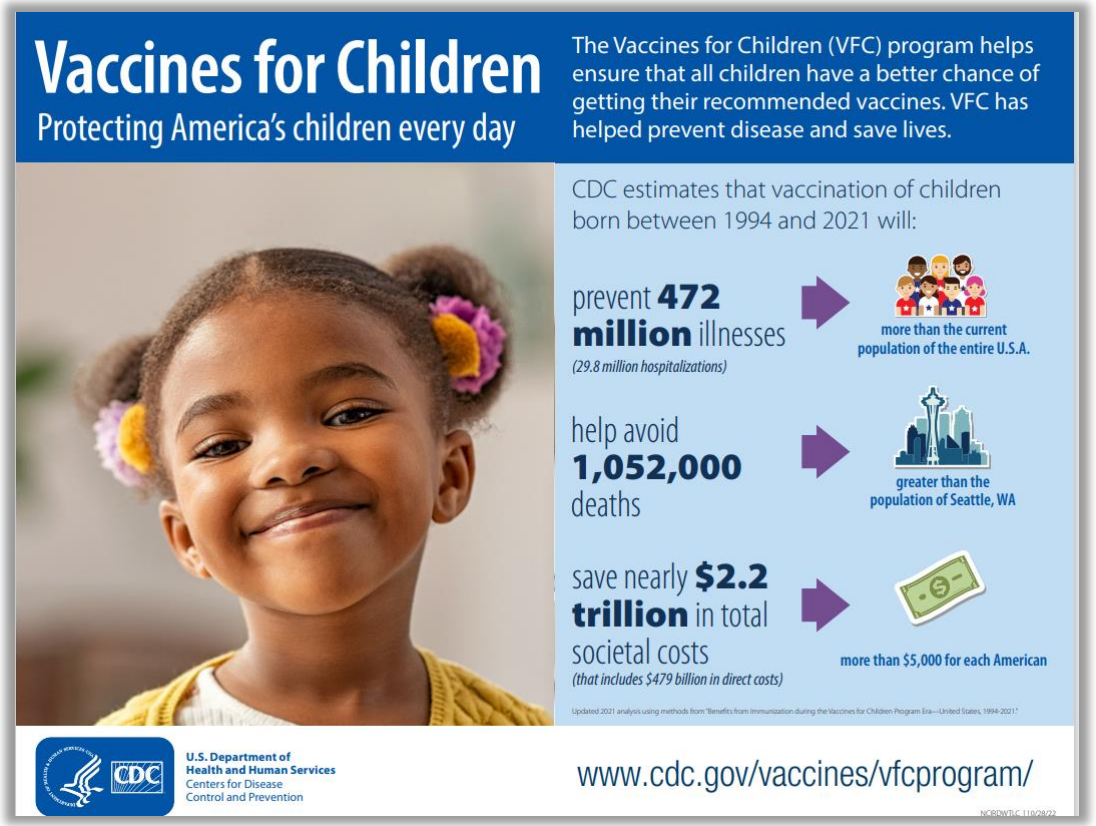
- Participation in VFC will significantly reduce supply up-front costs- VFC provides vaccines at no cost to enrolled providers for VFC-eligible children.

- It will help ensure equitable access to nirsevimab to vulnerable newborns and protect them prior to discharge.
  - Approximately 10% of all U.S. VFC provider enrollments are “birthing hospitals”.
  - For California, only 4% of provider enrollments are identified as birthing hospitals.

- Will support vaccine supply limitations during the initial rollout of nirsevimab. Beyfortus TM supply for the 50 mL formulation for babies under 5kg may not be as limited as that for babies over 5 kg.

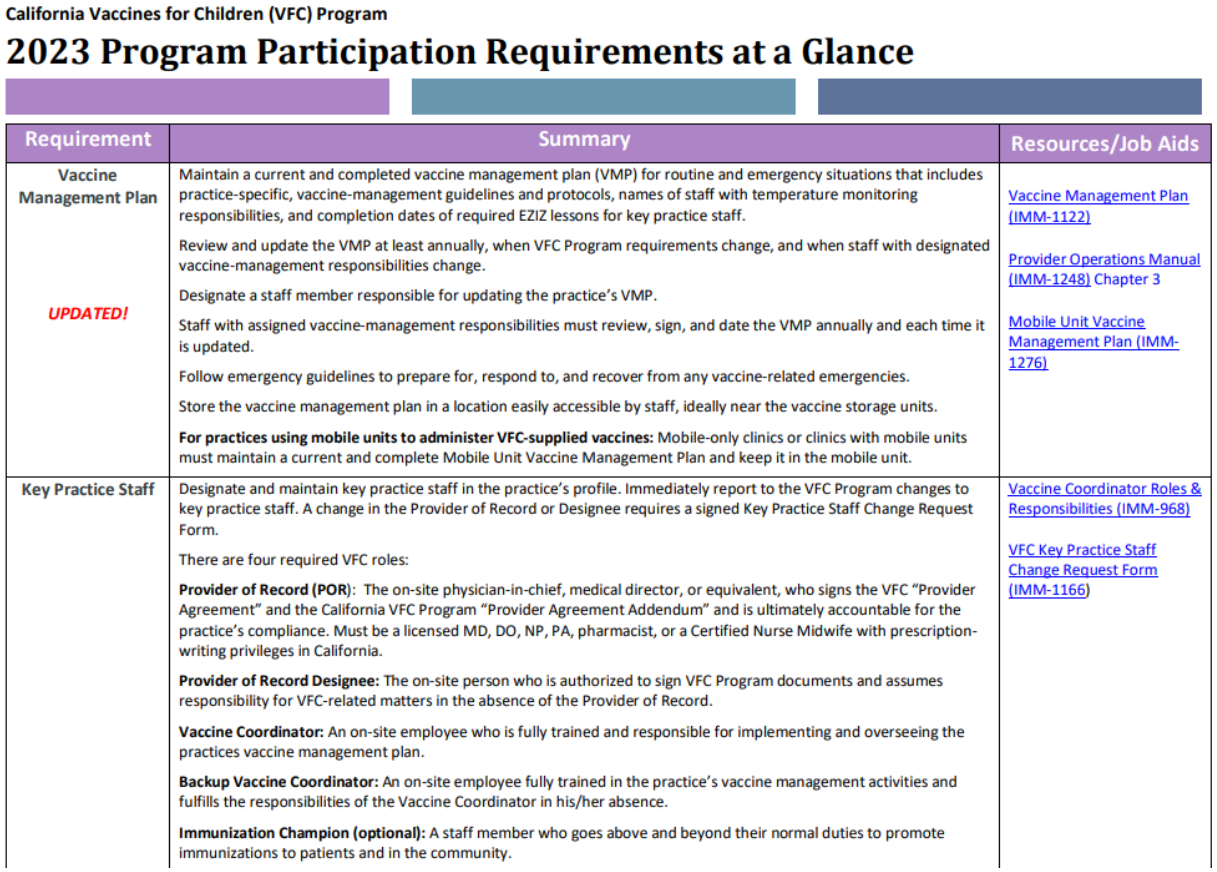
Vaccines for Children (VFC) Program

- VFC is a federally funded program which provides all routine vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) at no cost to the participating healthcare provider.
- In California, over 50% of children under 19 years of age are eligible to receive VFC supplied vaccines.
- Any healthcare provider authorized in the State of California to prescribe vaccines may enroll in the California Vaccines for Children Program and offer age-appropriate ACIP recommended vaccines.



Vaccines for Children (VFC) Program Participating Requirements

- Vaccinate VFC eligibles patients, 0 through 18 years of age who meet one or more of the following criteria:
  - Medicaid-eligible
  - Uninsured
  - American Indian or Alaska Native (AI/AN)
  - Underinsured (Underinsured children can only be vaccinated at a Federally Qualified Health Center [FQHC] or Rural Health Center [RHC]
- Hospitals may enroll in VFC to provide Hepatitis B and RSV Vaccines only
- VFC Program requirements are summarized in the Program Participation Requirements at a Glance and defined in the VFC Provider Agreement (federal agreement) and California VFC Program Provider Agreement Addendum.



California Vaccines for Children (VFC) Program

2023 Program Participation Requirements at a Glance

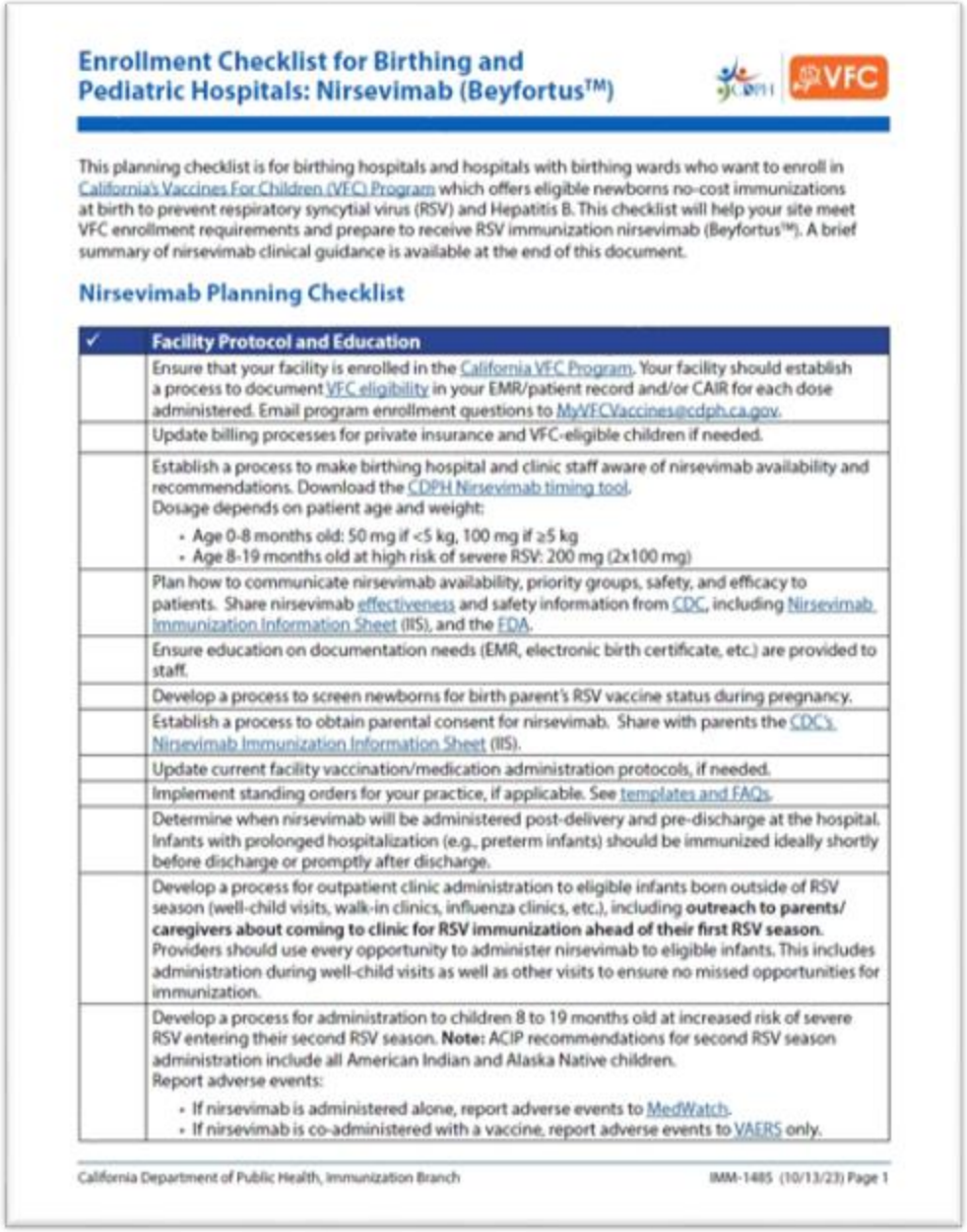
Requirement	Summary	Resources/Job Aids
Vaccine Management Plan *UPDATED!*	Maintain a current and completed vaccine management plan (VMP) for routine and emergency situations that includes practice-specific, vaccine-management guidelines and protocols, names of staff with temperature monitoring responsibilities, and completion dates of required EZIZ lessons for key practice staff. Review and update the VMP at least annually, when VFC Program requirements change, and when staff with designated vaccine-management responsibilities change. Designate a staff member responsible for updating the practice's VMP. Staff with assigned vaccine-management responsibilities must review, sign, and date the VMP annually and each time it is updated. Follow emergency guidelines to prepare for, respond to, and recover from any vaccine-related emergencies. Store the vaccine management plan in a location easily accessible by staff, ideally near the vaccine storage units. **For practices using mobile units to administer VFC-supplied vaccines:** Mobile-only clinics or clinics with mobile units must maintain a current and complete Mobile Unit Vaccine Management Plan and keep it in the mobile unit.	Vaccine Management Plan (IMM-1122) Provider Operations Manual (IMM-1248) Chapter 3 Mobile Unit Vaccine Management Plan (IMM-1276)
Key Practice Staff	Designate and maintain key practice staff in the practice's profile. Immediately report to the VFC Program changes to key practice staff. A change in the Provider of Record or Designee requires a signed Key Practice Staff Change Request Form. There are four required VFC roles: **Provider of Record (POR)**: The on-site physician-in-chief, medical director, or equivalent, who signs the VFC "Provider Agreement" and the California VFC Program "Provider Agreement Addendum" and is ultimately accountable for the practice's compliance. Must be a licensed MD, DO, NP, PA, pharmacist, or a Certified Nurse Midwife with prescription-writing privileges in California. **Provider of Record Designee:** The on-site person who is authorized to sign VFC Program documents and assumes responsibility for VFC-related matters in the absence of the Provider of Record. **Vaccine Coordinator:** An on-site employee who is fully trained and responsible for implementing and overseeing the practices vaccine management plan. **Backup Vaccine Coordinator:** An on-site employee fully trained in the practice's vaccine management activities and fulfills the responsibilities of the Vaccine Coordinator in his/her absence. **Immunization Champion (optional):** A staff member who goes above and beyond their normal duties to promote immunizations to patients and in the community.	Vaccine Coordinator Roles & Responsibilities (IMM-968) VFC Key Practice Staff Change Request Form (IMM-1166)

VFC Enrollment

Colleen Mallen and Kelley Leung, RN, CDPH

Enrollment Checklist for Birthing and Pediatric Hospitals

- CDPH has developed a checklist to assist providers in meeting VFC enrollment requirements and preparing your site to receive nirsevimab.
- Contains useful links to CDPH, VFC, CDC, and CAIR resources as well as a brief summary of nirsevimab clinical guidance.
- This document will be available through RSV – California Vaccines for Children (VFC) (eziz.org)



Enrollment Checklist for Birthing and Pediatric Hospitals: Nirsevimab (Beyfortus™)

This planning checklist is for birthing hospitals and hospitals with birthing wards who want to enroll in California's Vaccines For Children (VFC) Program which offers eligible newborns no-cost immunizations at birth to prevent respiratory syncytial virus (RSV) and Hepatitis B. This checklist will help your site meet VFC enrollment requirements and prepare to receive RSV immunization nirsevimab (Beyfortus™). A brief summary of nirsevimab clinical guidance is available at the end of this document.

Nirsevimab Planning Checklist

✓	Facility Protocol and Education
	Ensure that your facility is enrolled in the California VFC Program. Your facility should establish a process to document VFC eligibility in your EMR/patient record and/or CAIR for each dose administered. Email program enrollment questions to MyVFCVaccines@cdph.ca.gov.
	Update billing processes for private insurance and VFC-eligible children if needed.
	Establish a process to make birthing hospital and clinic staff aware of nirsevimab availability and recommendations. Download the CDPH Nirsevimab timing tool. Dosage depends on patient age and weight: • Age 0-8 months old: 50 mg if <5 kg, 100 mg if ≥5 kg • Age 8-19 months old at high risk of severe RSV: 200 mg (2x100 mg)
	Plan how to communicate nirsevimab availability, priority groups, safety, and efficacy to patients. Share nirsevimab effectiveness and safety information from CDC, including Nirsevimab Immunization Information Sheet (IIS), and the FDA.
	Ensure education on documentation needs (EMR, electronic birth certificate, etc.) are provided to staff.
	Develop a process to screen newborns for birth parent's RSV vaccine status during pregnancy.
	Establish a process to obtain parental consent for nirsevimab. Share with parents the CDC's Nirsevimab Immunization Information Sheet (IIS).
	Update current facility vaccination/medication administration protocols, if needed.
	Implement standing orders for your practice, if applicable. See templates and FAQs.
	Determine when nirsevimab will be administered post-delivery and pre-discharge at the hospital. Infants with prolonged hospitalization (e.g., preterm infants) should be immunized ideally shortly before discharge or promptly after discharge.
	Develop a process for outpatient clinic administration to eligible infants born outside of RSV season (well-child visits, walk-in clinics, influenza clinics, etc.), including **outreach to parents/caregivers about coming to clinic for RSV immunization ahead of their first RSV season.** Providers should use every opportunity to administer nirsevimab to eligible infants. This includes administration during well-child visits as well as other visits to ensure no missed opportunities for immunization.
	Develop a process for administration to children 8 to 19 months old at increased risk of severe RSV entering their second RSV season. **Note:** ACIP recommendations for second RSV season administration include all American Indian and Alaska Native children. Report adverse events: • If nirsevimab is administered alone, report adverse events to MedWatch. • If nirsevimab is co-administered with a vaccine, report adverse events to VAERS only.

California Department of Public Health, Immunization Branch IMM-1485 (10/13/23) Page 1

Enrolling in VFC: Key Practice Staff

1. 

PROVIDER OF RECORD (POR): Responsible for the clinic's overall compliance with VFC Program requirements. Must be a licensed MD, DO, NP, PA, Pharmacist or a Certified Nurse Midwife.

2. 

PROVIDER OF RECORD Designee: An on-site staff member designated by the clinic's POR to act on his/her behalf for VFC Program related matters when the POR is unavailable.

3. 

VACCINE COORDINATOR: A designated, on-site, and fully trained staff member responsible for all vaccine management activities within the practice.

4. 

BACKUP VACCINE COORDINATOR: A designated, on-site, and fully trained staff member responsible for all vaccine management activities within the practice *when the Vaccine Coordinator is unavailable.*

Enrolling in VFC: Required Training

ALL KEY STAFF MUST take the following EZIZ lessons as relevant

Tip 1: Register as a "New Enrollment" to receive the necessary user ID and completion code, then start the training.

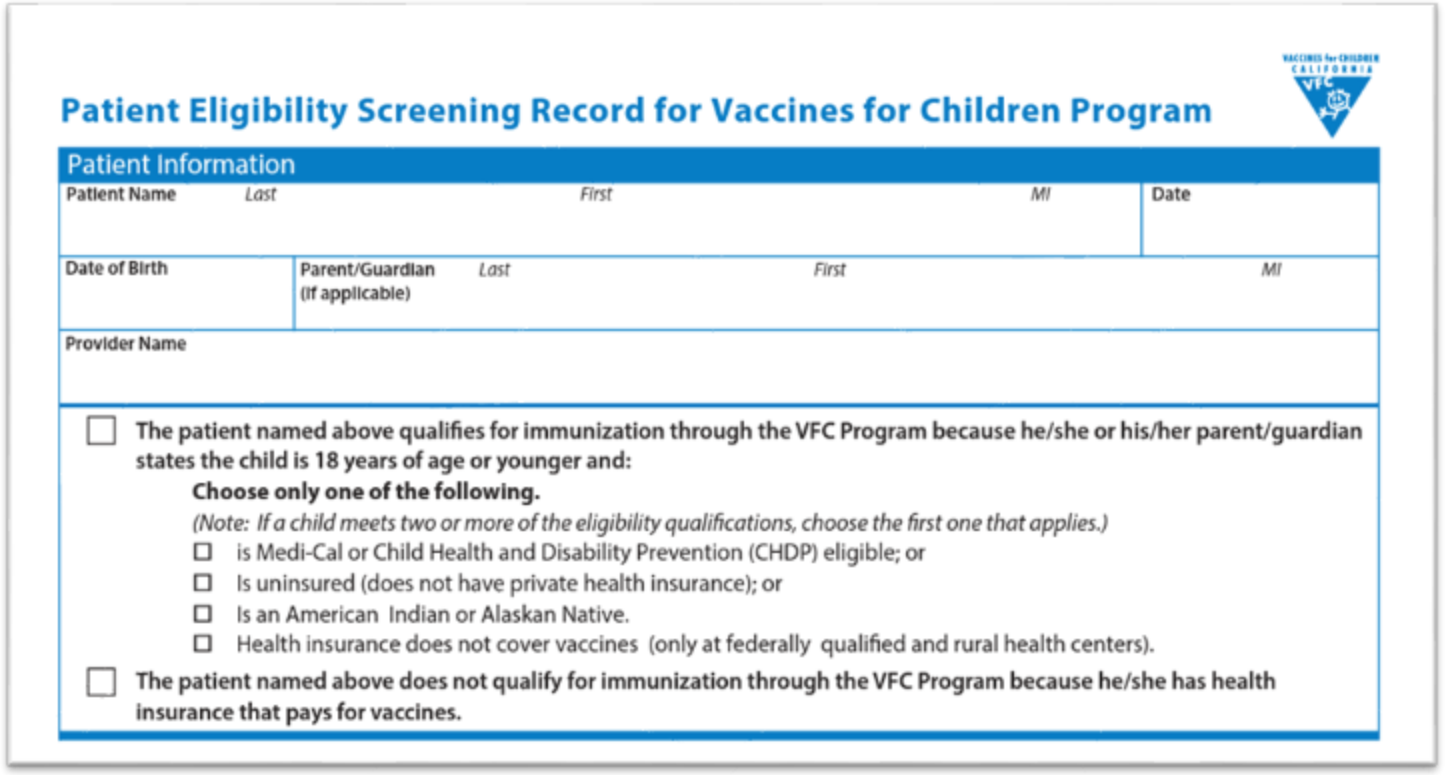
Tip 2: Complete all training modules:

- VFC Program Requirements
- Storing Vaccines
- Monitoring Storage Unit Temperatures
- Conducting a Vaccine Inventory (Not required for Provider of Record or their Designee)
- Provider Operations Manual (Review and Acknowledgement)
- Vaccine Management Plan (Review and Acknowledgement)

Tip 3: After completing all the required lessons, each registered EZIZ user from your clinic will receive a unique **User ID and Confirmation Code** that will be visible on your Learning History page.

Enrolling in VFC: Eligibility and Screening

Ensure you have a process in place to verify what type of insurance the patient has.



Patient Eligibility Screening Record for Vaccines for Children Program

Patient Information

Patient Name *Last*	*First*	*MI*	Date

Date of Birth	Parent/Guardian (If applicable) *Last*	*First*	*MI*

Provider Name

☐ **The patient named above qualifies for immunization through the VFC Program because he/she or his/her parent/guardian states the child is 18 years of age or younger and:**

Choose only one of the following.

(Note: If a child meets two or more of the eligibility qualifications, choose the first one that applies.)

- ☐ is Medi-Cal or Child Health and Disability Prevention (CHDP) eligible; or
- ☐ Is uninsured (does not have private health insurance); or
- ☐ Is an American Indian or Alaskan Native.
- ☐ Health insurance does not cover vaccines (only at federally qualified and rural health centers).

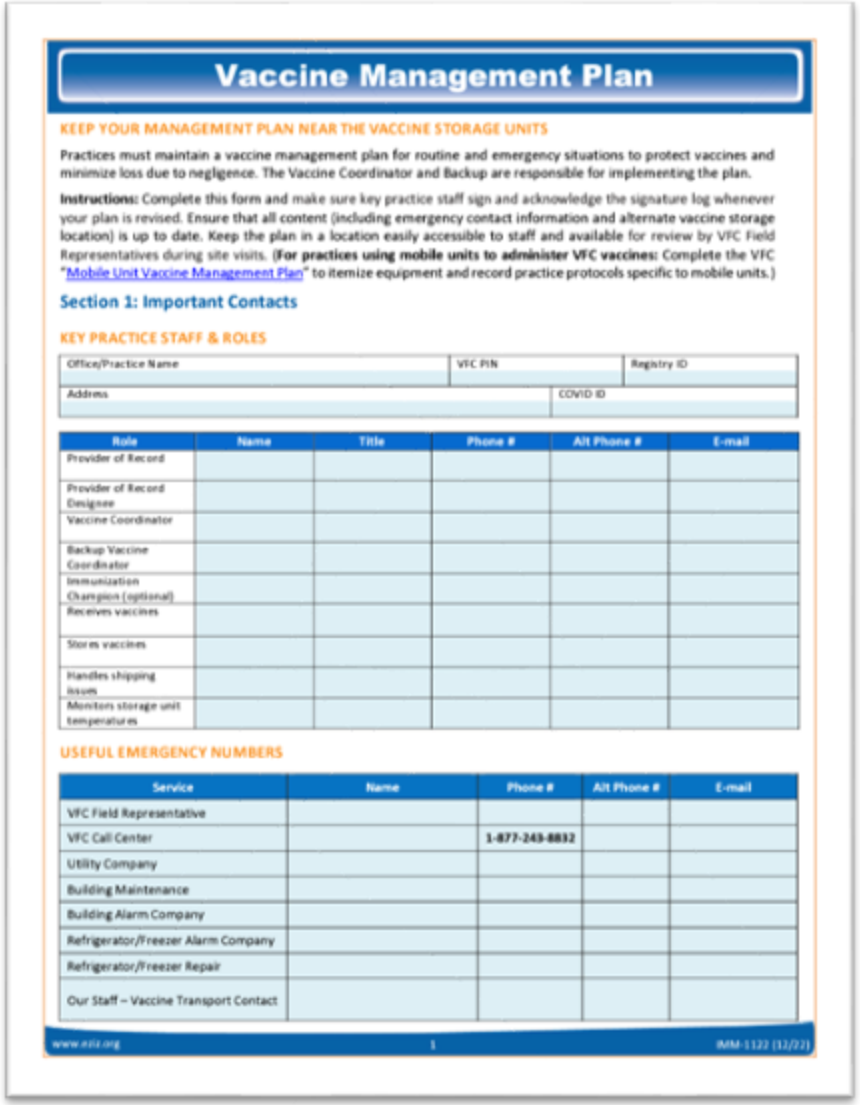
☐ **The patient named above does not qualify for immunization through the VFC Program because he/she has health insurance that pays for vaccines.**

Patient Eligibility Screening Form

Enrolling in VFC: Vaccine Management Plan

VACCINE MANAGEMENT PLAN

Complete a vaccine management plan (VMP) for routine and emergency situations that includes practice-specific, vaccine-management guidelines and protocols, names of staff with temperature monitoring responsibilities, and completion dates of required EZIZ lessons for key practice staff.



Vaccine Management Plan

KEEP YOUR MANAGEMENT PLAN NEAR THE VACCINE STORAGE UNITS

Practices must 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 (including emergency contact information and alternate vaccine storage location) is up to date. Keep the plan in a location easily accessible to staff and available for review by VFC Field Representatives during site visits. **(For practices using mobile units to administer VFC vaccines:** Complete the VFC "Mobile Unit Vaccine Management Plan" to itemize equipment and record practice protocols specific to mobile units.)

Section 1: Important Contacts

KEY PRACTICE STAFF & ROLES

Office/Practice Name	VFC PIN	Registry ID
Address		COVID ID

Role	Name	Title	Phone #	Alt Phone #	E-mail
Provider of Record					
Provider of Record Designee					
Vaccine Coordinator					
Backup Vaccine Coordinator					
Immunization Champion (optional)					
Receives vaccines					
Stores vaccines					
Handles shipping issues					
Monitors storage unit temperatures					

USEFUL EMERGENCY NUMBERS

Service	Name	Phone #	Alt Phone #	E-mail
VFC Field Representative				
VFC Call Center		1-877-243-8832		
Utility Company				
Building Maintenance				
Building Alarm Company				
Refrigerator/Freezer Alarm Company				
Refrigerator/Freezer Repair				
Our Staff – Vaccine Transport Contact				

www.eziz.org 1 IMM-1122 (12/22)

Vaccine Management Plan

California Immunization Registry(CAIR)/Healthy Futures

- The California Immunization Registry (CAIR) or Health Futures (Alpine, Amador, Calaveras, Mariposa, Merced, San Joaquin, Stanislaus, and Tuolomne counties) is a secure, confidential, statewide computerized immunization information system for California residents.
- Helps providers track patient immunization records, reduce missed opportunities, and help fully immunize residents of all ages. Reporting immunizations to the registry is required by law.
- There are two ways in which a provider can submit data to CAIR: 1) Through your EHR via data exchange or 2) via manual entry of the vaccine into the registry
- CAIR Training is available online for regular or power users and Help Desk services are available to assist with any questions

How to Enroll (ca.gov)

CAIR User FAQs

Enrolling in VFC: Handling and Storage - Refrigerator

MUST

✓Maintain temperatures 36 ºF - 46 ºF (2 - 8 ºC)

✓ Must be pharmacy or biologic grade if 11 cubic feet or smaller

✓Must have enough space to store all vaccines

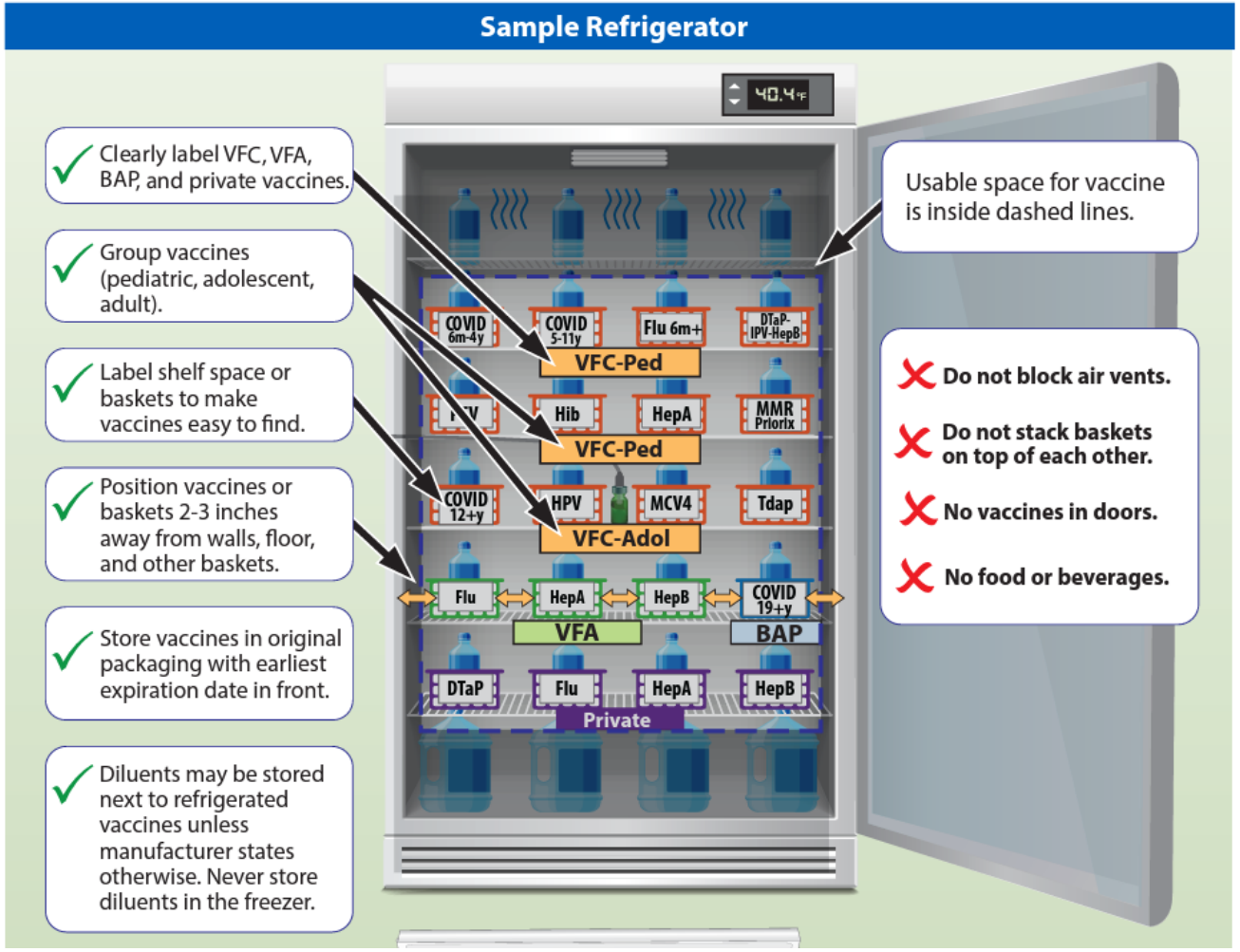
✓Use VFC supplied temperature logs

✓Post DO NOT UNPLUG stickers on electrical outlets and circuit breakers

ACCEPTABLE

✓Acceptable to store along with other refrigerated vaccines including privately supplied vaccines

✓ Only order Nirsevimab and Hepatitis B if your practice only provides care to babies



Enrolling in VFC: Storage and Handling Requirements

DIGITAL DATA LOGGERS (DDLs)

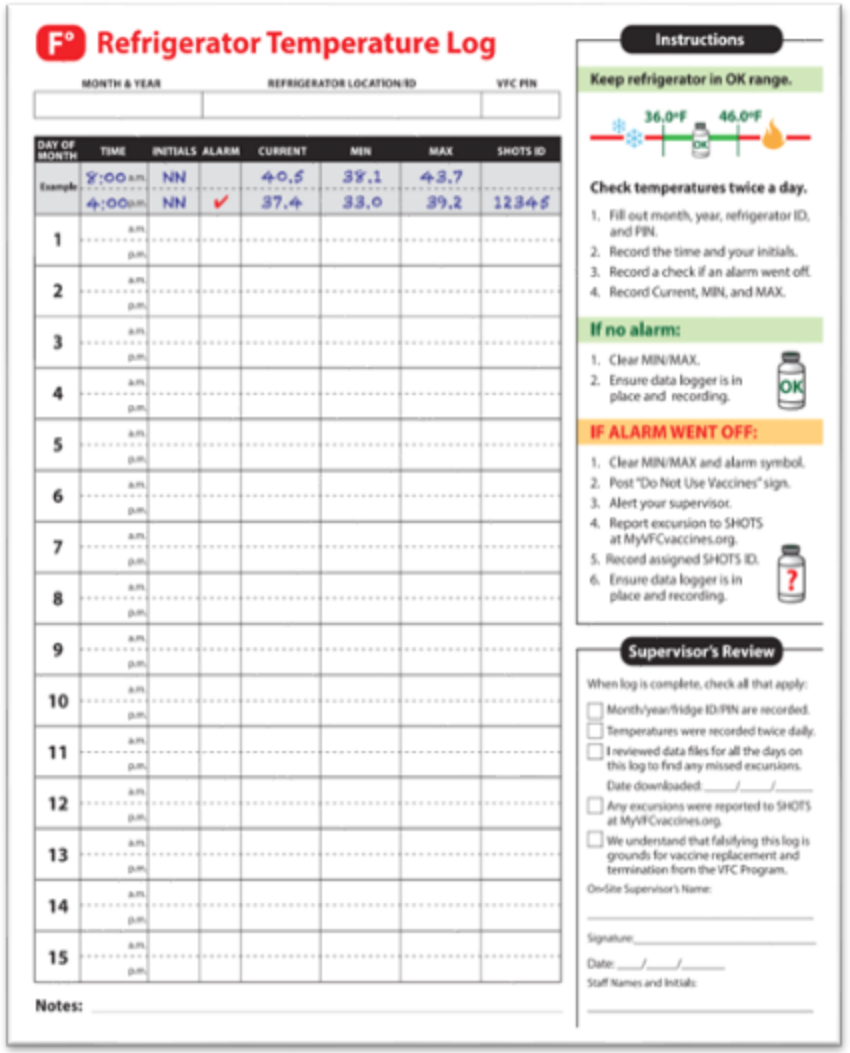
- VFC vaccine must be monitored with an acceptable digital data logger
- Digital data loggers read and record temperatures at set time intervals and store data in an internal memory
  - Clinic staff can download and save the data as an electronic file on a computer and analyze vaccine storage unit temperature trends over time
- DDLs provide alerts when temperatures are out of the recommended range
- DDLs must have acceptable certificates of calibration

Digital Data Loggers – California Vaccines for Children (VFC) (eziz.org)
DDL setup and use
DDL Certificate of Calibration Checklist

Enrolling in VFC: Storage and Handling Requirements

TEMPERATURE LOGS

- Current, minimum and maximum temperatures must be recorded twice daily on VFC supplied temperature logs.
- Action must be taken on out of range temperatures.



F° Refrigerator Temperature Log

MONTH & YEAR | REFRIGERATOR LOCATION/ID | VFC PIN

DAY OF MONTH	TIME	INITIALS	ALARM	CURRENT	MIN	MAX	SHOTS ID
Example	8:00 a.m.	NN		40.5	38.1	43.7	
	4:00 p.m.	NN	✓	37.4	33.0	39.2	12345
1	a.m. p.m.						
2	a.m. p.m.						
3	a.m. p.m.						
4	a.m. p.m.						
5	a.m. p.m.						
6	a.m. p.m.						
7	a.m. p.m.						
8	a.m. p.m.						
9	a.m. p.m.						
10	a.m. p.m.						
11	a.m. p.m.						
12	a.m. p.m.						
13	a.m. p.m.						
14	a.m. p.m.						
15	a.m. p.m.						

Notes:

Instructions

Keep refrigerator in OK range.

36.0°F 46.0°F OK

Check temperatures twice a day.

1. Fill out month, year, refrigerator ID, and PIN.
2. Record the time and your initials.
3. Record a check if an alarm went off.
4. Record Current, MIN, and MAX.

If no alarm:

1. Clear MIN/MAX.
2. Ensure data logger is in place and recording.

IF ALARM WENT OFF:

1. Clear MIN/MAX and alarm symbol.
2. Post "Do Not Use Vaccines" sign.
3. Alert your supervisor.
4. Report excursion to SHOTS at MyVFCvaccines.org.
5. Record assigned SHOTS ID.
6. Ensure data logger is in place and recording.

Supervisor's Review

When log is complete, check all that apply:

- ☐ Month/year/fridge ID/PIN are recorded.
- ☐ Temperatures were recorded twice daily.
- ☐ I reviewed data files for all the days on this log to find any missed excursions.
  Date downloaded: ____/____/____
- ☐ Any excursions were reported to SHOTS at MyVFCvaccines.org.
- ☐ We understand that falsifying this log is grounds for vaccine replacement and termination from the VFC Program.

On-Site Supervisor's Name:

Signature:

Date: ____/____/____

Staff Names and Initials:

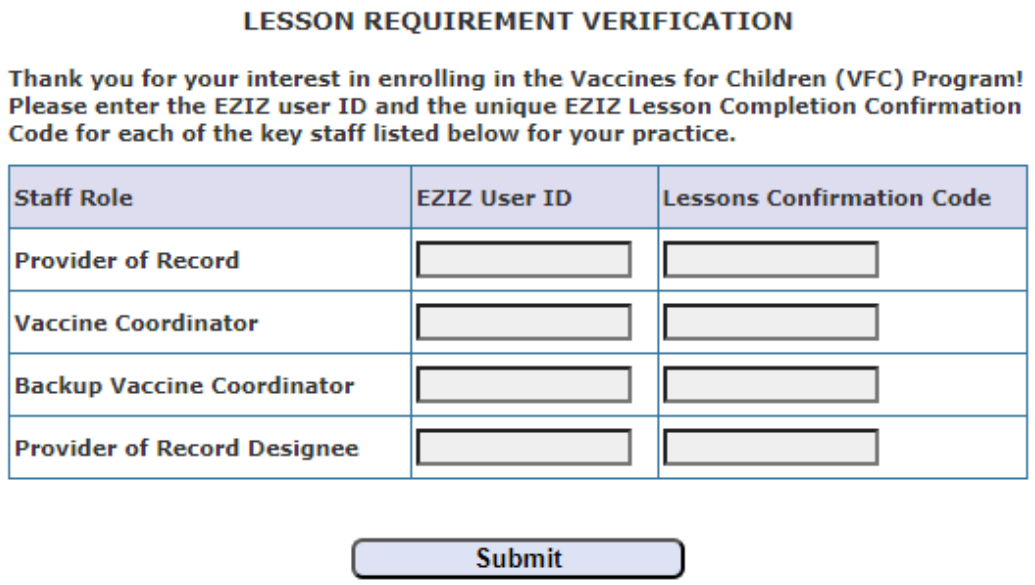
[Refrigerator Temperature Log VFC]

Enrolling in VFC: Enrollment Process

Key Practice staff identified, and training completed

Upload photos or scans of:

- ❑VFC Temperature Logs
- ❑Digital Data Logger downloads
- ❑Digital Data Logger Certificate of Calibration
- ❑Vaccine Storage Units including the interior and exterior
- ❑DO NOT UNPLUG sticker
- ❑Completed Vaccine Management Plan



LESSON REQUIREMENT VERIFICATION

Thank you for your interest in enrolling in the Vaccines for Children (VFC) Program! Please enter the EZIZ user ID and the unique EZIZ Lesson Completion Confirmation Code for each of the key staff listed below for your practice.

Staff Role	EZIZ User ID	Lessons Confirmation Code
Provider of Record		
Vaccine Coordinator		
Backup Vaccine Coordinator		
Provider of Record Designee		

Submit

Enrolling in VFC: Enrollment Process

Completing enrollment application on eziz

- Information about your site
  - ❑CAIR ID
  - ❑Type of practice
  - ❑Contact information, address, insurance accepted, patient population, hours of operation, when can you receive VFC vaccine
  - ❑License numbers of medical staff
  - ❑Information about your vaccine storage unit(s) and DDLs
  - ❑Signature of the provider of record

Enrolling in VFC: Enrollment Process

VFC application is submitted to the VFC Central Office to review application

Sent to VFC staff member who will contact within 5 business days

- Review any information missing
- Schedule Enrollment Site Visit
  - Enrollment visits will be scheduled asap. Depending on staffing some enrollment visits may have to be virtual.

Enrolling in VFC: Enrollment Visits

Storage & Handling

- Vaccine storage units
- Digital data loggers
  - Certificates of calibration
  - Downloads
- Temperature logs
- Setup of Vaccine Storage Unit

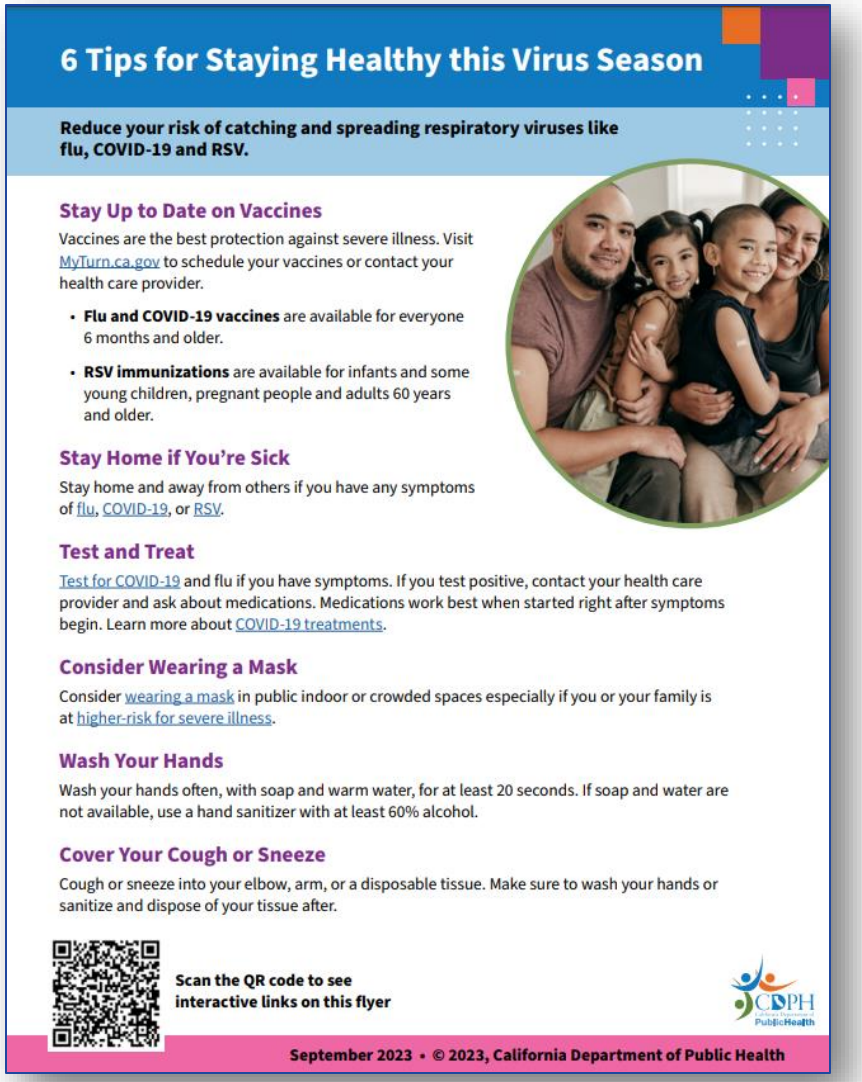
Eligibility

- Knowledge of eligible patients
- Measures in place complete eligibility screening and maintain eligibility history

Resources, Q&A, and Poll

Leslie Amani and CDPH Subject Matter Experts (SMEs)

Stay Healthy this Virus Season



6 Tips for Staying Healthy this Virus Season

Reduce your risk of catching and spreading respiratory viruses like flu, COVID-19 and RSV.

Stay Up to Date on Vaccines

Vaccines are the best protection against severe illness. Visit MyTurn.ca.gov to schedule your vaccines or contact your health care provider.

- **Flu and COVID-19 vaccines** are available for everyone 6 months and older.
- **RSV immunizations** are available for infants and some young children, pregnant people and adults 60 years and older.

Stay Home if You're Sick

Stay home and away from others if you have any symptoms of flu, COVID-19, or RSV.

Test and Treat

Test for COVID-19 and flu if you have symptoms. If you test positive, contact your health care provider and ask about medications. Medications work best when started right after symptoms begin. Learn more about COVID-19 treatments.

Consider Wearing a Mask

Consider wearing a mask in public indoor or crowded spaces especially if you or your family is at higher-risk for severe illness.

Wash Your Hands

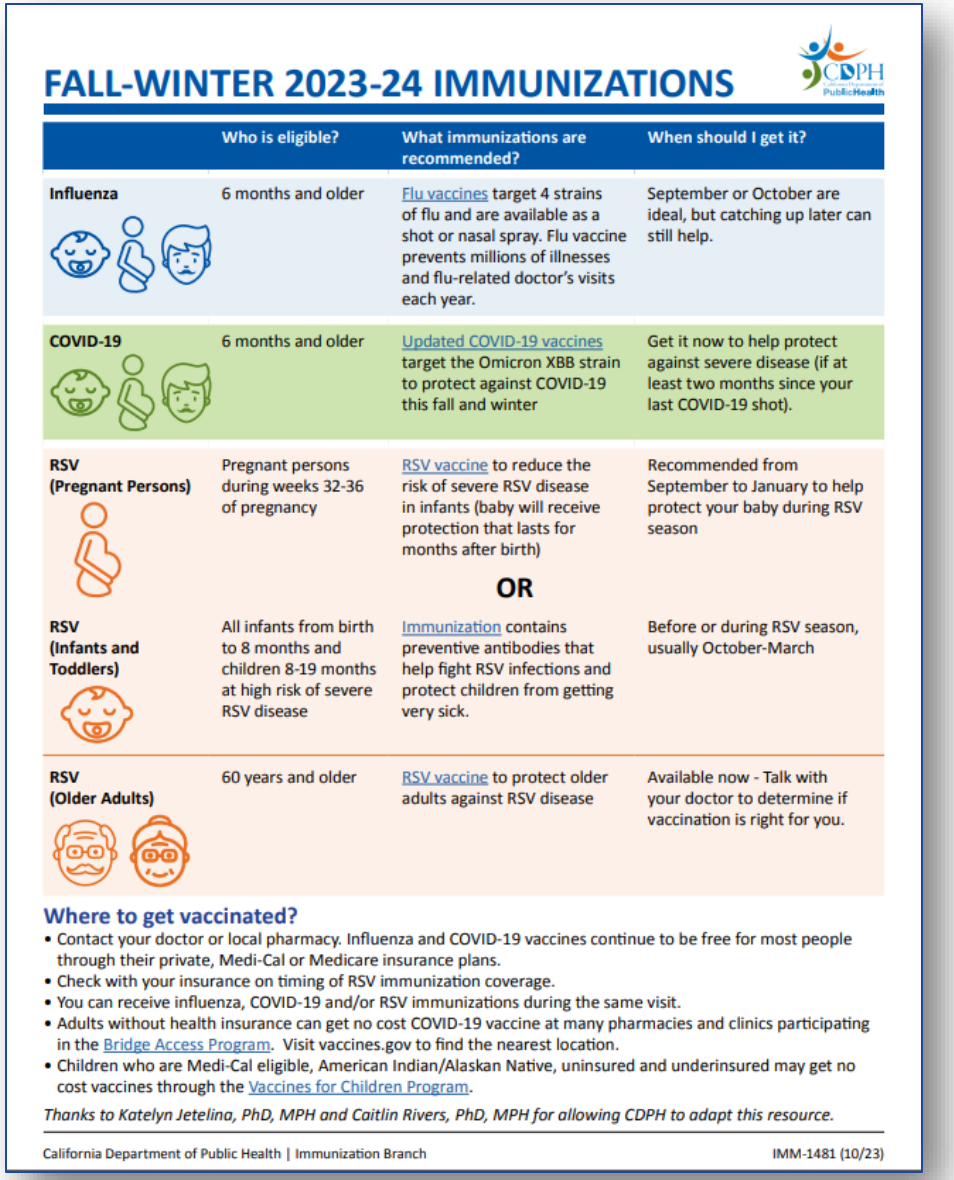
Wash your hands often, with soap and warm water, for at least 20 seconds. If soap and water are not available, use a hand sanitizer with at least 60% alcohol.

Cover Your Cough or Sneeze

Cough or sneeze into your elbow, arm, or a disposable tissue. Make sure to wash your hands or sanitize and dispose of your tissue after.

Scan the QR code to see interactive links on this flyer

[Winter Virus Tip Sheet (CDPH)]



FALL-WINTER 2023-24 IMMUNIZATIONS

	Who is eligible?	What immunizations are recommended?	When should I get it?
Influenza	6 months and older	Flu vaccines target 4 strains of flu and are available as a shot or nasal spray. Flu vaccine prevents millions of illnesses and flu-related doctor's visits each year.	September or October are ideal, but catching up later can still help.
COVID-19	6 months and older	Updated COVID-19 vaccines target the Omicron XBB strain to protect against COVID-19 this fall and winter	Get it now to help protect against severe disease (if at least two months since your last COVID-19 shot).
RSV (Pregnant Persons)	Pregnant persons during weeks 32-36 of pregnancy	RSV vaccine to reduce the risk of severe RSV disease in infants (baby will receive protection that lasts for months after birth)	Recommended from September to January to help protect your baby during RSV season
		OR	
RSV (Infants and Toddlers)	All infants from birth to 8 months and children 8-19 months at high risk of severe RSV disease	Immunization contains preventive antibodies that help fight RSV infections and protect children from getting very sick.	Before or during RSV season, usually October-March
RSV (Older Adults)	60 years and older	RSV vaccine to protect older adults against RSV disease	Available now - Talk with your doctor to determine if vaccination is right for you.

Where to get vaccinated?

- Contact your doctor or local pharmacy. Influenza and COVID-19 vaccines continue to be free for most people through their private, Medi-Cal or Medicare insurance plans.
- Check with your insurance on timing of RSV immunization coverage.
- You can receive influenza, COVID-19 and/or RSV immunizations during the same visit.
- Adults without health insurance can get no cost COVID-19 vaccine at many pharmacies and clinics participating in the Bridge Access Program. Visit vaccines.gov to find the nearest location.
- Children who are Medi-Cal eligible, American Indian/Alaskan Native, uninsured and underinsured may get no cost vaccines through the Vaccines for Children Program.

Thanks to Katelyn Jetelina, PhD, MPH and Caitlin Rivers, PhD, MPH for allowing CDPH to adapt this resource.

California Department of Public Health | Immunization Branch IMM-1481 (10/23)

[Fall-Winter 2023-24 Immunizations Infographic (CDPH)]

CDC RSV Resources

- RSV Immunizations Overview
- RSV Immunization for Infants and Young Children
- RSV Vaccine for Pregnant People

Vaccine Support

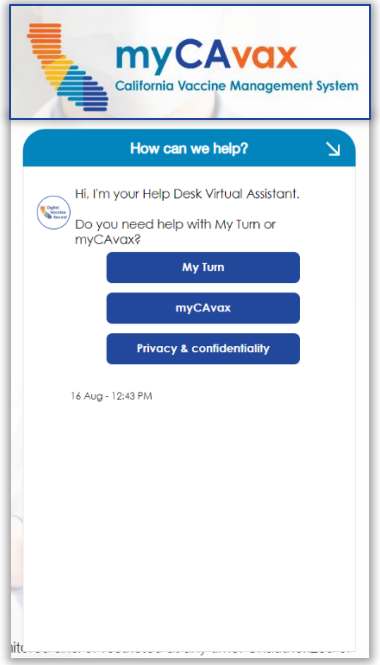
Provider Call Center

Dedicated to medical providers and Local Health Departments in California, specifically addressing questions about State program requirements, enrollment, and vaccine distribution.

- For myCAvax Help Desk inquiries: myCAvax.hd@cdph.ca.gov
- For My Turn Clinic Help Desk inquiries: MyTurn.Clinic.HD@cdph.ca.gov
- For all other inquiries: providercallcenter@cdph.ca.gov
- Phone: (833) 502-1245, Monday through Friday from 8AM–5PM

myCAvax

- Virtual Assistant resolves many questions but will direct you to the Provider Call Center queue for live assistance!
- Knowledge Center houses key job aids and videos that are updated every release. Once logged in, you can access job aids from the myCAvax homepage (or at various places throughout the system) using the links as shown below. Need help? View our jobs aids in the Knowledge Center, or contact us.



CDPH Provider Webinars and Trainings

Week of October 16, 2023

	Monday 10/16	Tuesday 10/17	Wednesday 10/18	Thursday 10/19	Friday 10/20
Live Webinars and Training	Nirsevimab Updates and Implementation Guidance and Considerations for RSV *12:00 pm – 1:00 pm*		COVID-19 Crucial Conversations Webinar: Talking with Patients about the Fall COVID-19, Flu, and RSV Season *12:00 pm – 1:00 pm*	Bi-Weekly State General Fund (SGF) Program Office Hours *11:00 am – 11:30 am*	CDPH Immunization Updates for Providers *9:00 am – 10:30 am*
View On Demand	• Intro to My Turn Onboarding *(v. 1/4/22)* • CDPH Weekly Provider Webinars Archived Recordings and Slides		• myCAvax Release Notes for LHJs and CDPH Users (*Requires myCAvax Login)* • Latest Features in myCAvax for Providers (*Requires myCAvax Login)* • COVID-19 Crucial Conversations Archived Webinars and Slides		• Moderna COVID-19 Vaccine Resources for Providers • CDC COVID-19 Vaccine Webinar Series • California Immunization Coalition COVID Conversation Series • AIM Vaccine Confidence Toolkit Webinar Series

Help	***Help Desk***	***General***	***Mpox***
	myCAvax Help Desk Email: mycavax.hd@cdph.ca.gov My Turn Help Desk Email: myturn.clinic.hd@cdph.ca.gov My Turn Onboarding Email: myturnonboarding@cdph.ca.gov	CDPH Provider Call Center: 1-833-502-1245, 8am-5pm, Mon-Fri Email: providercallcenter@cdph.ca.gov Vaccines: COVID-19 Vaccines Therapeutics: COVID-19 Therapeutics	Email: stdcb@cdph.ca.go General Website: Mpox Website Vaccines: Mpox Vaccines Website

American Academy of Pediatrics Webinar

When: Tuesday, October 17, 2023

Time: 5PM, PST

Nirsevimab implementation strategies in outpatient practices (AAP)

Please register using the Registration Link

Upcoming COVID-19 Crucial Conversations Webinar

Topic: Talking with Patients about the Fall COVID-19, Flu, and RSV Season

Description: Learn how to effectively communicate with patients about the upcoming respiratory virus season and strategies for increasing vaccine administration.

Speaker: Dr. Ilan Shapiro

When: **Wednesday, October 18, 2023**

Time: 12PM - 1PM PT

Please register **here**

Questions

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

Resource links will be dropped into, "Chat"

Poll: VFC Enrollment

1. Are you currently enrolled in the VFC Program?
   - ❑ Yes
   - ❑ No
   - ❑ N/A
2. After attending today's RSV webinar, do you feel that enrollment in VFC is feasible for your organization?
   - ❑ Yes
   - ❑ No
   - ❑ N/A
3. What resources or information would your organization need to assist you in successfully enrolling in the Vaccines for Children (VFC) program? [Short Answer]
4. What are the biggest barriers to VFC enrollment for your organization? [Short Answer]

Upcoming Webinar Opportunities

CDPH Immunization Updates for Providers

Next session: Friday, October 20, 2023

9AM – 10:30AM