

Vaccines for Children Program in Pharmacies Pilot Program Informational Webinar

September 19, 2024



COLORADO
Department of Public
Health & Environment

Agenda

- Overview of Vaccines for Children Program.
- Pharmacies and vaccines.
- Overview of VFC in pharmacies pilot program.
- VFC Program requirements – deep dive.
- Questions.



Overview of the VFC Program



Vaccines for Children Program

- The VFC Program is a federally-funded vaccine program that has been in place since 1994 and is administered by CDPHE.
- CDC provides funding to 61 state, local, and territorial immunization program awardees to implement and oversee the VFC Program.
- The VFC Program provides vaccines to children whose parents or guardians may not be able to afford them, and serves as one of the nation's most important contributors to health equity. The program helps ensure that all children have a better chance of getting their recommended vaccines on schedule and stay healthy.
- The program includes all ACIP-recommended vaccines for children from birth through 18 years old, including COVID-19, nirsevimab, and maternal RSV.



Vaccines for Children (VFC) Program

30 years of protecting children

500 million+

Vaccinations will have prevented about 508 million illnesses in children born during 1994 through 2023.

74 million

VFC distributed over 74 million pediatric vaccines in 2023 to participating healthcare providers.

90%

Almost 90% of VFC-eligible children born during 2011 through 2020 received the measles, mumps, and rubella vaccine.

Almost 90% of VFC-eligible children born during 2011 through 2020 received the MMR vaccine.



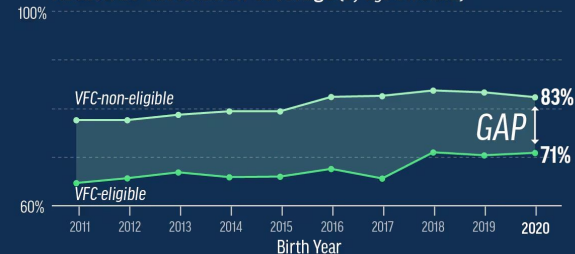
Steps healthcare providers can take to increase vaccination



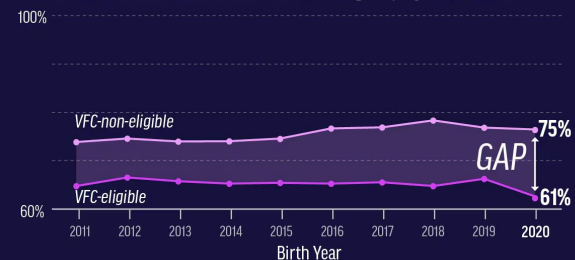
Reference:

<https://www.cdc.gov/vitalsigns/vaccines-for-children/index.html>

Rotavirus vaccination coverage (by age 8 months)



Combined 7-vaccine series coverage (by age 24 months)



Vaccines for Children Program

- A child is eligible for VFC vaccines if they are 0-18 years and:
 - Medicaid eligible or Medicaid enrolled,
 - Uninsured,
 - Underinsured (can be seen at FQHC, RHC or LPHA), and/or
 - American Indian or Alaska Native.
- There are approximately 38,000 providers enrolled in the VFC Program nationwide.
 - As of 2020, 34 states expressly allowed pharmacies to participate in the VFC Program.*
 - As of June 2022, 160 (or 0.4%) VFC providers nationwide were pharmacies.**

*Source: Immunize Colorado, [Successes and Barriers to Pharmacists' Participation in the VFC Program in the U.S., August 4, 2020](#). Accessed May 2023.

**Source: National Academy for State Health Policy, [Increasing Access to Routine Child Immunizations: State Approaches for Increasing Pharmacy Enrollment in the VFC Program](#). Accessed May 2023.



Colorado's VFC provider network, September 2024

Number of VFC provider locations	598
Number of counties with at least one VFC provider	63*
Number of counties with three or fewer VFC providers	24
Number of VFC doses distributed**	1,025,992
Value of VFC doses distributed**	\$77,687,344.42
Number of children served through VFC**	220,260

**Exceptions: Gilpin County*

***In calendar year 2023*



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Colorado's VFC-eligible population estimate, 2024

	0-1 year	1-2 years	3-6 years	7-18 years	Total
Number of children enrolled in Medicaid (percentage of total VFC-eligible population)	27,411 (75%)	59,221 (77%)	128,727 (79%)	388,355 (82%)	603,714 (80%)
Number of American Indians/Alaska Natives	3,731	7,375	13,806	31,826	56,738
Number of uninsured children	3,578	7,088	13,894	39,234	63,794
Number of underinsured children	1,751	3,521	6,800	14,483	26,555
Subtotal number of VFC-eligible children (percentage of total population)	36,471 (45%)	77,204 (48%)	163,227 (52%)	473,898 (53%)	750,801 (52%)
Number of insured children	45,122	84,450	153,652	420,919	704,142
Total population	81,593	161,654	316,879	894,817	1,454,943



CDPHE's management of the VFC Program

The Immunization Branch within the Division of Disease Control and Public Health Response manages the VFC Program for the state of Colorado.

Work activities include:

- Processing vaccine orders, distributing vaccines, and processing vaccine returns through the Colorado Immunization Information System.
- Complying with state and federal regulations.
- Recruiting, enrolling, and retaining providers in the program.
- Evaluating performance.



CDPHE's management of the VFC Program (cont.)

Work activities include:

- Providing quality assurance and improvement opportunities for providers.
- Conducting provider site visits.
- Responding to temperature excursions that could compromise the viability of VFC vaccines.
- Providing ad hoc education and technical assistance.
- Addressing instances of potential fraud and abuse.



Pharmacies and vaccines



Pharmacies as Medicaid providers

- Colorado allows pharmacists to administer vaccines to all ages under their licensure.
 - Many pharmacies set internal minimum age requirements for vaccine services.
- Until recently, pharmacies had not been allowed to enroll in Colorado's VFC Program.
- A total of 673 pharmacy locations in Colorado report data regularly to the Colorado Immunization Information System.



Pharmacies as Medicaid providers (cont.)

- Pharmacies were the **number one location** for COVID-19 vaccine administration among Medicaid members of all ages.
- Privately insured children can receive their vaccines at Colorado pharmacies today, but **VFC-eligible children cannot**. This further limits vaccine access for VFC-eligible children, exacerbating existing inequities.



COVID-19 vaccination sites, Colorado Medicaid members 6m-18y

Type of location	Percentage of Medicaid members 6 months -18 years receiving COVID-19 vaccine at location
Pharmacies	34.7%
Pediatric clinics	10.7%
Large health systems	9.3%
Smaller medical clinics	8.8%
Local public health clinics	8.1%
Federally qualified health centers	7.8%
Mobile vaccine clinics	7.3%
Family practice clinics	5.5%



Colo. Medicaid members seeking first COVID-19 dose at pharmacies, by age

	0-4 years	5-11 years	12-19 years
Number of Medicaid members who received first COVID-19 dose at a pharmacy	265	10,963	51,388
Percentage of Medicaid members within age group who received first COVID-19 dose at a pharmacy	2.49%	19.53%	40.38%



VFC in pharmacies pilot program



Pilot program overview

- The pilot program will be implemented in collaboration with HCPF and with input from a variety of partner organizations.
- The pilot will focus on enrolling pharmacies serving large numbers of Medicaid members in counties with the lowest vaccination rates and the fewest existing VFC providers.
- The pilot program is a deliberate and thoughtful effort to preserve the operational integrity of the existing VFC Program infrastructure. It also will evaluate whether pharmacy participation in VFC increases access and immunization rates while minimizing any unintended consequences.



Why is exploring this pathway important?

- Pharmacies are often known and trusted providers within their communities, with closer and more convenient locations, and evening and weekend hours to better serve working families.
 - About 90% of the U.S. population lives within five miles of a pharmacy.
- Bringing VFC to pharmacies will address longstanding equity concerns, as privately insured children are already able to receive their vaccines at pharmacies while publicly insured children cannot.
 - A VFC pharmacy program has the potential to address socioeconomic and racial/ethnic disparities in vaccination coverage that stem from inequitable access.



Why is exploring this pathway important?

- Overall immunization rates for Medicaid-eligible children and adolescents continue to lag behind those of the general population in Colorado. Pharmacies were the number one location for COVID-19 vaccination among Colorado Medicaid members of all ages.
- Bringing VFC to pharmacies will reestablish access to publicly funded COVID-19 vaccines now that commercialization has occurred, as well as expand access to publicly funded routine vaccines for Medicaid members.



Anticipated outcomes of pilot program

- This pilot program will:
 - Determine the level of demand enrolled pharmacies will place on the existing VFC Program infrastructure.
 - Identify the impacts VFC-enrolled pharmacies may have on well-child visits and the receipt of other essential health care services among children who receive VFC vaccines at enrolled pharmacy locations.
 - Allow CDPHE to evaluate whether expanding VFC to pharmacies increases access to vaccines.
 - Enable CDPHE to analyze whether the program should be expanded.



Initially targeted pilot participants

- CDPHE invited a total of 32 pharmacy locations to participate in the initial pilot.
 - 20 of the 32 locations were independently owned.
 - 12 of the 32 locations were retail pharmacies.
- CDPHE selected initial pharmacies based on one or more of the following criteria:
 - Operating within a county with kindergarten MMR rates lower than 73% and/or with medium-high to high social vulnerability.
 - Widely accessible by residents in the county.
 - Currently providing services to underserved populations.



Initially targeted pilot counties

County	2022-23 Kindergarten MMR rate	Social Vulnerability Index	# of Existing VFC Provider Locations
Adams	81.8%	High	39
Alamosa	72.9%	High	5
Baca	75.6%	Medium-High	2
Bent	67.5%	High	2
Chaffee	73.2%	Medium-High	5
Conejos	83.3%	High	5
Denver	81.4%	Medium-High	63
El Paso	69.3%	Medium-High	46
Fremont	75.1%	Medium-High	6
Kit Carson	66.3%	Medium-High	1
Lake	72.6%	Medium-High	3
Las Animas	73.8%	High	3
Lincoln	70.3%	Medium-High	4
Logan	76.5%	Medium-High	5
Mesa	72.9%	Medium-High	17
Moffat	70.2%	High	5
Montezuma	73.1%	Medium-High	4
Otero	75.8%	High	5
Prowers	88.9%	High	7
Pueblo	78.9%	High	19
Weld	79.9%	Medium-High	30



Initial pilot efforts

As part of initial recruitment efforts starting in June 2023, CDPHE:

- Held information webinars with partner organizations and target pharmacies.
- Performed direct and recurring outreach to target pharmacies.
- Developed a FAQ document to address commonly perceived barriers to VFC participation.
- Offered digital data loggers free of charge.
- Offered reimbursements up to \$3,500 for vaccine storage unit purchases.
- Held recurring meetings with interested pharmacies to address questions and concerns.



Challenges and opportunities



Common barriers

- Temperature monitoring requirements are too burdensome.
- Pharmacy is short staffed and does not have the personnel resources required to manage VFC.
- Existing vaccine storage units do not meet VFC requirements.
- Concerns about how waiving a vaccine administration fee for those who might not be able to pay will impact their bottom line.



Common barriers

- Concerns about how punitive VFC compliance visits could be.
- Inability to update billing system to only bill for vaccine administration fees (concerns about being flagged for fraud and abuse).
- Concerns with the time consuming nature of pediatric vaccine visits and their impact to the pharmacy's efficiency.



CDC vs. Colorado VFC requirements

- Following difficulties with pharmacy recruitment, we performed a deep analysis comparing CDC VFC Program requirements with Colorado-specific VFC Program requirements.
- Where Colorado imposes more burden:
 - The VFC400 or TRED30-16R are required as primary data loggers. Colorado does not accept requests for alternate thermometers or temperature monitoring systems to use as primary or backup thermometers.
 - Rationale: Ease of having all VFC providers using same data loggers to connect automatically to our cloud for faster identification of temperature excursions.
 - Colorado requires twice daily manual logging of vaccine storage unit temperatures plus daily min/max.
 - Rationale: Backup in the event temperature monitoring system goes down or loses data.



Opportunities

- Allowing pharmacies with robust temperature monitoring systems that meet CDC requirements to use those for VFC vaccine.
 - Exploring possibility of connecting other temperature monitoring systems to our cloud for automated reporting.
- Possibility of relaxing the requirement for twice daily manual logging of temperatures if the temperature monitoring system automatically logs and stores that data.
- Vaccine replacement models.
- Expansion of pilot to all Colorado pharmacies.



VFC Program requirements



VFC Program requirements

VFC Program requirements

- Enrollment, recertification, and unenrollment.
- Designated clinic-level VFC contacts and staff educational requirements.
- Vaccine storage equipment.
- Reporting storage and handling incidents (temperature excursions).
- Recording temperatures and reviewing temperature data.
- Temperature monitoring equipment.
- VFC site visits (compliance, unannounced storage and handling, and educational visits).
- VFC patient eligibility and screening requirements.
- Vaccine ordering, reconciliation, dose level accountability, borrowing, and inventory management.
- Billing and administration of VFC-supplied vaccines.



Minimum qualifications for participation in the VFC Program

- Clinic is open and seeing VFC-eligible patients.
- Clinic reports data to the Colorado Immunization Information System.
- Clinic carries all age-appropriate, ACIP-recommended vaccines for the privately insured patient population served.
- All providers at each clinic (MDs, DOs, NPs, PAs) must have a Medicaid/NPI number and medical license number and be in good standing with DORA and OIG.
- Store all refrigerated vaccines in a pharmaceutical-grade unit (unit must have a microprocessor and fan-forced air).
- Store all frozen vaccines in a stand-alone freezer or pharm-grade combo unit.
- Utilize digital data loggers that meet CDC requirements as primary and backup thermometers in all VFC vaccine storage units.



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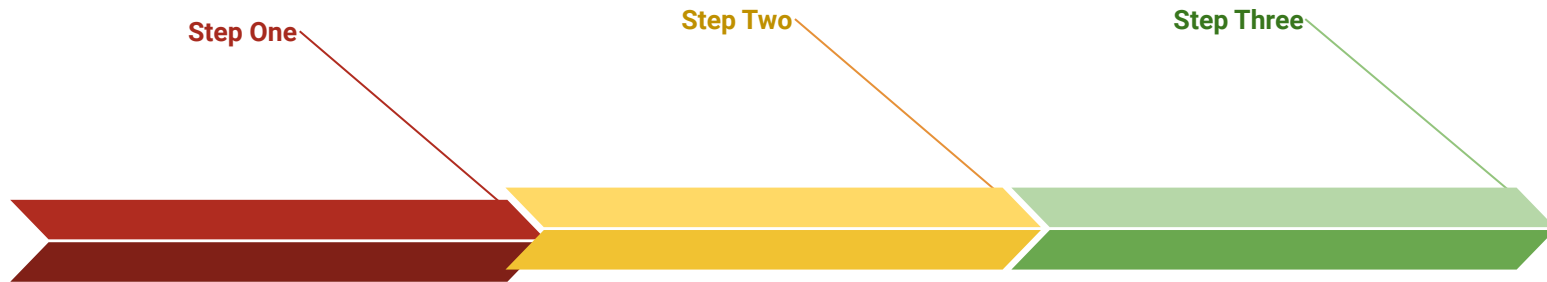
Enrolling in the VFC Program

- To enroll in the VFC Program:
 - Complete a [Vaccines for Children \(VFC\) Provider Enrollment Application](#)
 - Submit a signed CDC Provider Agreement and Colorado VFC Supplement Provider Agreement
 - Complete the Colorado VFC Annual Training Course
 - Prepare for an enrollment visit to go over the program requirements and proper storage and handling of vaccines once you have completed and returned the enrollment application and agreements.



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VFC provider enrollment process overview



Submit VFC Provider Enrollment Application

The application will be processed by the VFC Program.

Complete Enrollment Visit

This visit is conducted in-person and takes 2 hours to complete.

Complete Site Compliance Visit

This visit is conducted in-person, 3 to 6 months post-enrollment.



VFC recertification and unenrollment

- Each year, the provider of record must recertify to continue their participation in the VFC Program by updating their training, completing a new provider profile, and signing new agreements.
- Provider offices that do not complete recertification are unenrolled.
 - To re-enroll, providers must complete the enrollment process as a new VFC provider, including an enrollment visit, to participate in the program again.
- The VFC Program may unenroll a provider for failure to comply with VFC Program requirements.
- Providers may voluntarily terminate their agreement with the VFC Program at any time.



Provider staff and education requirements

- Providers must designate key program staff responsible for implementing and managing the VFC Program.
 - **Provider of record (POR):** The office's medical director or equivalent (MD, DO, NP, PA) who signs the enrollment agreements. The POR is responsible for the clinic's overall compliance with VFC Program requirements.
 - **Primary vaccine coordinator:** A designated, fully-trained staff member on site every day the clinic is open, responsible for all vaccine management activities in the clinic and the primary contact for the VFC Program.
 - **Secondary vaccine coordinator:** A designated, fully-trained staff member on site every day the clinic is open, responsible for all vaccine management activities in the clinic when the primary vaccine coordinator is unavailable.
- The primary and secondary vaccine coordinators and the provider of record are required to take the [VFC annual training course](#).



Vaccine storage units

- Approved storage units
 - Refrigerators: Stand-alone or combination pharmaceutical-grade units. Unit must be large enough to store public and private vaccines at peak season; must be at a minimum of 6 cubic feet or larger.
 - Freezers: Stand-alone household, commercial, or combination pharmaceutical-grade units.
- Dormitory-style (or bar-style) units are **prohibited** for any VFC vaccine storage at any time.



Vaccine storage and handling

- Store vaccines within recommended temperatures at all times.
 - Refrigerated vaccines between 36.0 F and 46.0 F (2.0 C and 8.0 C).
 - Frozen vaccines between -40.0 F and 5.0 F (-40.0 C and -15.0 C).
- Contact the VFC Program immediately for guidance in the event of a temperature excursion. Vaccines exposed to out-of-range temperatures must be quarantined and labeled “do not use” until the CDPHE’s VFC Program marks the excursion resolved, and notifies the clinic of the resolution.



Temperature monitoring equipment

- VFC provider locations must use a DDL with continuous temperature monitoring capability and a current and valid Certificate of Calibration Testing (also known as a Report of Calibration) in each unit storing public vaccines.
- Approved Digital Data Loggers:
 - Colorado supplies the VFC400 or TRED30-16R as primary data loggers **free of charge**. Approved back-up data loggers are the VFC400, TRED30-16R, or the TRED30-7R.
 - **The VFC Program will accept requests for alternate thermometers or temperature monitoring systems to use as primary or backup thermometers if they meet CDC requirements during the pilot.**



Recording temperatures and documentation

- Record min/max temperature and current temperature once per day on a paper log.
 - Colorado will allow recording once a day temperatures during the pilot.
 - Documenting temperatures on a paper log is required even if a data logger is used to monitor temperatures or an alarm system is installed.
- Download and review temperature data from the data logger at least once each week, and print the data logger report.
 - Download and review the temperature data from the data logger every time an alarm is triggered or the min/max reading indicates out-of-range temperatures.
- All temperature data must be kept for three years.



VFC site visits

- Enrolled VFC providers agree to receive site visits from VFC Program staff, including:
 - VFC enrollment visit prior to approval in the VFC Program.
 - Scheduled VFC compliance site visit at least every 24 months to evaluate compliance with VFC requirements and offer support and guidance to providers.
 - First compliance site visit will be three to six months after the VFC enrollment visit.
 - Unannounced storage and handling visits.
 - Any active VFC provider may be selected to receive an unannounced storage and handling visit. The VFC Program selects 5% of all providers annually.
 - Ad-hoc visits for educational and programmatic support.



Vaccine eligibility screening and documentation

- Screen and document eligibility categories for all patients 0-18 years prior to vaccine administration at **every** visit.
- Records must include the date of the visit and the child's specific eligibility category.
- Use screening results to ensure that only VFC-eligible children receive VFC vaccine.
- Eligibility status must be readily available to staff administering vaccine.
- Keep all VFC eligibility records on file for three years.



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Vaccine ordering and reconciliation

- VFC vaccine orders must be placed in CIIS.
- Providers can place an order the 1st through the 21st of every month.
- VFC processes orders Monday through Friday.
- Vaccine deliveries occur Tuesday through Thursday.
- VFC providers are required to complete inventory reconciliations within seven days prior to placing a VFC vaccine order in CIIS.
- VFC has a Vaccine Ordering Module helpdesk, job aids and instructional videos to assist providers in meeting this requirement.



Vaccine accountability, borrowing, and inventory management

- Maintain adequate inventories of vaccines to administer to both privately insured and VFC-eligible children. **Do not** use VFC vaccines to supplement privately purchased vaccine inventory.
- Ensure that borrowing between vaccine inventories is a rare, unplanned occurrence, and pay back doses as soon as possible.
- Maintain [vaccine administration records](#) in accordance with the National Childhood Vaccine Injury Act.



Vaccine accountability, borrowing, and inventory management

- Borrowing VFC vaccines must NEVER prevent a VFC-eligible child from receiving a needed vaccination because VFC vaccine was administered to a non-VFC-eligible child and VFC inventory is depleted.
- VFC vaccines cannot be intentionally administered to ineligible children. CDPHE has the responsibility to follow up with all cases of suspected fraud and abuse and to escalate to federal investigators when necessary.



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Administration fees and billing

- Providers may charge a vaccine administration fee, per dose, up to \$21.68 for non-Medicaid, VFC-eligible patients.
- For Medicaid patients, you will bill Medicaid for the administration fee.
- Patients should never be billed for the cost of the vaccine.
- The administration fee must be waived if the patient is unable to pay at the time of service. You cannot deny access to VFC vaccines due to inability to pay.
 - VFC patients may be issued only a single bill for the administration fee up to 90 days after the date of service.
 - If the admin fee is not paid after the date of service, the patient may not be sent to collections.



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Administration fees and billing

- Medicaid allows billing for administration of VFC vaccines via the medical or the pharmacy benefit.
- Medicaid will pay the administration fee, but does not reimburse for the vaccine product provided, at no cost, by VFC.
- VFC participation and use of VFC products is the only route for reimbursement when administering routine vaccines to Medicaid members under the age of 19.
- Pediatric COVID-19 vaccines, nirsevimab and maternal RSV vaccine are part of VFC. As a result, VFC participation and use of VFC products is the only route for reimbursement when vaccinating Medicaid members under the age of 19 against COVID-19 or RSV. The same is true for annual flu vaccines.



Medicaid billing resources

- Immunizations Billing Manual: instructions and information about coverage and billing
<https://hcpf.colorado.gov/immunizations-billing-manual>
- Regional Provider Support: for individualized claim or enrollment assistance
<https://hcpf.colorado.gov/regional-provider-support>
- Benefit Manager: For questions about coverage or policy
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Next steps

- Review the [VFC minimum qualifications](#) to see if your pharmacy already meets them.
- If you meet the minimum qualifications, complete the online [VFC Enrollment application](#) to move forward with VFC enrollment.
- Contact the VFC Program at cdphe_vfc@state.co.us or at 303-692-2650 if you have questions or need assistance in completing the application.



Resources

[VFC Requirements at a Glance](#)

[VFC annual training course](#)

[VFC Enrollment application](#)

[Approved vaccine storage units](#)

[VFC Pharmacy Pilot FAQ](#)



Questions?



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