UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, et al.,
Plaintiffs/Counterclaim Defendants,

v. Case No. 1:25-cv-11916 (BEM)

ROBERT F. KENNEDY, JR., et al.,
Defendants,

and

CHILDREN'S HEALTH DEFENSE, et al.,

Intervenor-Defendants/Counterclaim Plaintiffs
v.
AMERICAN ACADEMY OF PEDIATRICS, et al.,

Counterclaim Defendants

INTERVENOR-DEFENDANTS' SUPPLEMENTAL MEMORANDUM IN OPPOSITION TO PRELIMINARY INJUNCTION AS TO THE COVID-19 VACCINE CLAIMS IN COUNTS III AND IV

Intervenor-Defendants' February 18, 2026 filings—the Memorandum in Opposition, the Declaration of Richard Jaffe, and the Proposed Answer with Affirmative Defenses and Counterclaims—addressed the preliminary injunction motion primarily with respect to the safety record of the childhood immunization schedule and the balance of equities between Plaintiffs' declarants and the families Intervenors represent. The Proposed Answer denied the merits of all four counts, but neither the opposition brief nor the declaration developed the factual record for the COVID-19-specific claims. This supplemental memorandum addresses those claims—the September 19, 2025 ACIP vote on the COVID-19 vaccine (Count III) and the May 19 Directive (Count IV)—in advance of the March 4 hearing. It is supported by the accompanying Supplemental Declaration of Richard Jaffe ("Supp. Jaffe Decl."), filed herewith.

I. The Factual Predicate for Counts III and IV Has Collapsed

Plaintiffs filed this action on July 7, 2025, challenging the May 2025 Secretarial Directive removing the routine COVID-19 vaccine recommendation for healthy children and pregnant women. Plaintiffs' three individual declarants — Jane Does 1, 2, and 3 — describe alleged difficulty accessing the COVID-19 vaccine at pharmacies and physician offices in the summer of 2025. Plaintiffs attribute that difficulty to the Directive.

What Plaintiffs do not address — and what the accompanying declaration documents — is what happened *after* those difficulties occurred. In July and August 2025, three separate FDA actions, and actions by the vaccine makers validated the substance of the Directive:

On July 9, 2025, the FDA approved Moderna's supplemental BLA for Spikevax in children six months through eleven years, but *limited the approval to children with at least one underlying condition* putting them at high risk. Moderna itself had revised its application on June 19, 2025, removing the indication for healthy children. The Director of CBER, Dr. Vinayak Prasad, wrote: "FDA has a regulatory duty to only grant marketing authorization in settings where we have substantial certainty the benefits outweigh the risks. For healthy children that standard is not met." Supp. Jaffe Decl. ¶ 11.

On August 27, 2025, the FDA took similar action on Pfizer's Comirnaty: approving it for high-risk children aged five through eleven, while simultaneously *revoking* Pfizer's EUA for all children under five. As of that date, no COVID-19 vaccine from any manufacturer was approved or authorized for healthy children of any age in the United States. Supp. Jaffe Decl. ¶¶ 12–13.

Separately, effective July 1, 2025, the CDC changed VFC program policy so that providers enrolled in the Vaccines for Children program are no longer required to stock COVID-19 vaccines. Supp. Jaffe Decl. ¶ 14. The VFC enforcement mechanism that Plaintiffs ask this

Court to restore — the same mechanism that destroyed Dr. Samara Cardenas's pediatric practice when she declined to order the COVID vaccine for healthy children, Supp. Jaffe Decl. ¶¶ 3–6 — no longer exists even within the program that enforced it.

II. The Balance of Equities Favors Denial

Under *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008), a preliminary injunction requires a "clear showing" of irreparable harm and that the balance of equities tips in movant's favor. *See also Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004).

Plaintiffs present three individuals who allegedly experienced temporary difficulty accessing the COVID-19 vaccine at pharmacies and physician offices. ECF Nos. 185-49, 185-50, 185-53. On the other side of the equation, Dr. Cardenas lost her ability to order *any* vaccines through VFC, lost her Medicaid managed care contract with CalOptima, and ultimately closed a practice serving 1,900 Medicaid children — for exercising the same clinical judgment that the FDA validated three months later. Supp. Jaffe Decl. ¶¶ 3–6, 13.

AAP's own former committee chair, Dr. Jesse Hackell, told *AAP News* that the VFC policy change "reflect[s] the reality many pediatricians have not been stocking it for quite some time now, because the demand is low and the cost is high." Supp. Jaffe Decl. ¶ 16. Plaintiffs' own declarant, Jane Doe 2, was told by an urgent care clinic that "it had been a while since anyone asked for the Covid vaccine." ECF No. 185-53, at 6. The difficulty the Jane Does experienced was not caused by the Directive. It was caused by the absence of patient demand — a market reality that private-pay practices had already absorbed.

COVID-19 vaccination has never been required for school entry in Massachusetts or any other state. A restored recommendation would not return the vaccine to private-pay practices that

stopped carrying it because families were not requesting it. The only mechanism that ever translated the federal recommendation into a compulsory ordering requirement was the VFC program — and that program now permits providers to decline to stock it entirely. Supp. Jaffe Decl. ¶¶ 14–16.

III. The Requested Injunction Restores a Structural Disparity

The COVID-19 vaccine recommendation operated differently for Medicaid families than for everyone else. For private-pay or commercially-insured children, the recommendation was advisory. Pediatricians could exercise individualized clinical judgment about whether the vaccine was appropriate for a particular child, and families could choose providers who shared their assessment. For Medicaid children enrolled in VFC, the recommendation was compulsory. The VFC program required participating providers to order and administer every ACIP-recommended vaccine — or lose access to the program entirely. There was no opt-out, no exercise of clinical judgment, no consideration of medical necessity, no choice of provider. Supp. Jaffe Decl. ¶ 9.

Dr. Cardenas is the proof of what that structure meant in practice. She declined to order the COVID-19 vaccine for healthy children based on her professional medical judgment. VFC refused to process any of her vaccine orders. CalOptima terminated her Medicaid managed care contract. She closed a practice serving 1,900 Medicaid children. Supp. Jaffe Decl. ¶¶ 3–6. A private-pay pediatrician who made the identical clinical decision lost nothing.

AAP's own former committee chair recognized this problem. When the CDC relaxed VFC stocking requirements in July 2025, Dr. Jesse Hackell warned that the policy "could lead to treatments of the VFC-eligible and the non-VFC-eligible population differently in practice." Supp. Jaffe Decl. ¶ 16; see also Exhibit H (Melissa Jenco, "CDC Relaxes Rules on Stocking

Vaccines in VFC Program," *AAP News* (July 16, 2025)). Dr. Hackell was describing the consequence of *relaxing* the mandate. The injunction Plaintiffs seek would do the opposite: it would *reimpose* it.

The practical effect of the requested injunction as to Counts III and IV is to restore a compulsory ordering obligation for a vaccine that the FDA has determined does not meet the benefit-risk standard for healthy children, that the VFC program has stopped requiring, and that AAP's own members had already stopped stocking because no one was asking for it. That obligation would fall on VFC providers serving Medicaid families — and *only* on VFC providers serving Medicaid families. Private-pay and commercially-insured families would continue to access pediatricians who exercise individualized clinical judgment. Medicaid families would not. The nation's poorest children would again be the only population in the country subject to a compelled vaccination protocol for a product that the FDA has concluded does not meet the benefit-risk standard for their demographic. That is not preserving the status quo. It is restoring a disparity that the government itself has already dismantled.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' Motion for Preliminary Injunction as to Counts III and IV.

Dated: February 23, 2026

RESPECTFULLY SUBMITTED

/s/ Richard Jaffe
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CERTIFICATE OF SERVICE

I hereby certify that the foregoing Supplemental Memorandum in Opposition to Preliminary Injunction and the accompanying Supplemental Declaration of Richard Jaffe with Exhibits F, G, and H, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

February 23, 2026

/s/ Richard Jaffe

Richard Jaffe

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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SUPPLEMENTAL DECLARATION OF RICHARD JAFFE IN SUPPORT OF INTERVENORS' OPPOSITION TO PRELIMINARY INJUNCTION (COVID-19 VACCINE CLAIMS, COUNTS III AND IV)

I, Richard Jaffe, declare as follows:

1. I am counsel of record for the proposed Intervenors. I submitted a Declaration in Support of the Motion to Intervene on February 18, 2026. Intervenors' February 18 filings—the Memorandum in Opposition, my declaration, and the Proposed Answer with Affirmative Defenses and Counterclaims—addressed the preliminary injunction motion primarily with respect to the safety record of the childhood immunization schedule and the balance of equities. The Proposed Answer denied the merits of all four counts, but the opposition brief and declaration did not develop the factual record for the COVID-19-specific claims. This supplemental declaration provides that record for the claims before the Court

at the March 4 hearing: the September 19, 2025 ACIP vote on the COVID-19 vaccine (Count III) and the May 19 Directive (Count IV).

2. My original declaration referenced *Cardenas v. Monarez*, No. 8:25-cv-00867 (C.D. Cal.), at paragraph 2, but did not attach the complaint or discuss its substance. Because the second hearing addresses the COVID-19 vaccine claims directly, I now attach the Cardenas complaint as Exhibit F and explain its relevance to the pending motion.

I. THE CARDENAS COMPLAINT AND THE VFC ENFORCEMENT MECHANISM

3. On April 25, 2025, I filed *Cardenas v. Monarez* on behalf of Dr. Samara Cardenas, a pediatrician who served 1,900 Medicaid children in Anaheim, California. Dr. Cardenas refused to administer the COVID-19 vaccine to healthy children in her practice based on her professional judgment that it was neither clinically indicated, medically necessary, nor appropriate for her patients. The CDC's Vaccines for Children (VFC) program responded by refusing to process any of her vaccine orders — not just the COVID vaccine, but all vaccines — because her vaccine orders did not include the COVID shot. CalOptima, the Orange County, California Medicaid provider, then terminated her contract and reassigned all 1,900 of her patients to other providers, which resulted in Dr. Cardenas closing her practice. Cardenas Complaint ¶¶ 35–40; Exhibit A (VFC email).

4. The VFC email attached states: "We noticed you have not yet submitted a vaccine request for any presentations of COVID vaccine available. All participating providers are required to order and offer ACIP recommended vaccines to their patient population." As a result VFC refused to process her order for any vaccines. Cardenas Complaint, Exhibit A.

5. Plaintiffs' Fourth Amended Complaint asks this Court to restore the pre-May 2025 COVID-19 vaccine recommendation for children and pregnant women (Count IV) and to reverse the September 2025 ACIP vote downgrading COVID to shared clinical decision-making for those under 65 (Count III). Plaintiffs present the removal of the recommendation as causing harm. Dr. Cardenas's experience shows what the recommendation caused when it was in place: a physician who exercised clinical judgment on the COVID vaccine lost her ability to order any vaccines, lost her Medicaid contract, and lost her practice. The VFC enforcement mechanism that destroyed her practice is the same mechanism Plaintiffs ask this Court to restore.

6. I voluntarily dismissed the Cardenas complaint on August 11, 2025, after Secretary Kennedy removed the COVID-19 vaccine from the recommended schedule for children and pregnant women, which caused the VFC program to no longer require physicians to order the COVID shot, the combination of which made the Cardenas suit moot. The factual allegations in the complaint remain true and are directly relevant to this Court's consideration of whether reimposing the prior recommendation serves the public interest.

II. THE COVID-19 VACCINE FOR HEALTHY CHILDREN: WHAT THE FOURTH AMENDED COMPLAINT FAILS TO ADDRESS

7. The Fourth Amended Complaint presents the COVID-19 vaccine removal as self-evidently harmful. It does not engage in any post-pandemic risk calculus for healthy children. The Cardenas complaint does. The factual allegations of the Cardenas complaint, drawn from CDC's own publications, establish that: healthy children without underlying conditions were at exceptionally low risk of critical illness from COVID-19; by 2023, newer variants caused significantly less severe disease; no new clinical trial data

demonstrated meaningful benefit of continued COVID-19 vaccination in healthy children post-pandemic; and the COVID-19 vaccine for children remained under Emergency Use Authorization — an investigational product that had never received full FDA licensure for the pediatric population. Cardenas Complaint ¶¶ 14–18, 28–34.

8. The Cardenas complaint further alleges that the CDC failed to conduct a thorough risk-benefit analysis of COVID-19 vaccines in children, despite VAERS data recording hundreds of thousands of adverse events. Cardenas Complaint ¶¶ 19–27. This is the other side of the ledger that Plaintiffs' three Jane Does do not present. Jane Does 1 and 2 allegedly had difficulty accessing the vaccine during pregnancy. Jane Doe 3 allegedly had difficulty getting her teenage sons vaccinated at a pharmacy. Dr. Cardenas lost her medical practice because she concluded, based on her professional judgment, that the vaccine was not appropriate for her healthy pediatric patients. No party has put this perspective before the Court.

III. THE EQUAL PROTECTION DIMENSION

9. The Cardenas complaint also raises a dimension of the COVID vaccine issue that is absent from the Fourth Amended Complaint and from Defendants' filings: the disparate impact of the VFC mandate on Medicaid-enrolled children. Private-pay or commercially insured families could access pediatricians outside the VFC program who could exercise individualized clinical judgment. Medicaid families could not. The VFC structure required their pediatricians to order and administer every ACIP-recommended vaccine — including the COVID shot — or lose the ability to treat those patients entirely. Cardenas Complaint ¶¶ 65–72. If this Court restores the prior COVID recommendation, it restores this disparity. The nation's poorest children will again be subject to a compelled

vaccination protocol that wealthier families can avoid. As discussed below, AAP's own former committee chair publicly warned that the VFC policy change "could lead to treatments of the VFC-eligible and the non-VFC-eligible population differently in practice." *See* ¶¶ 15–16, *infra*.

IV. POST-CARDENAS DEVELOPMENTS CONFIRM THE FACTUAL BASIS OF THE COMPLAINT

10. At the time I filed the Cardenas complaint in April 2025, the COVID-19 vaccine for children under twelve was available only under Emergency Use Authorization. Neither Pfizer's Comirnaty nor Moderna's Spikevax had received full Biologics License Application ("BLA") approval for pediatric use in that age group. Both had BLA approval for ages twelve and older. For children six months through eleven years — Dr. Cardenas's patient population — the product remained investigational.

11. I think the Court should consider the following administrative facts when it considers the second part of Plaintiffs' preliminary injunction motion: The FDA took a series of actions that confirmed Dr. Cardenas's clinical judgment. On July 9, 2025, the FDA approved Moderna's supplemental BLA for Spikevax in children six months through eleven years — but limited the approval to children with at least one underlying condition putting them at high risk for severe COVID-19 outcomes. *See* FDA, Approval Letter, BLA STN BL 125752 (July 9, 2025), available at https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/july-9-2025-approval-letter-spikevax.pdf. Moderna itself had revised its application on June 19, 2025, removing the indication for healthy children. *See* FDA, CBER Center Director Decisional Memorandum (July 9, 2025), available at

https://www.fda.gov/media/187542/download. The Director of the FDA's Center for Biologics Evaluation and Research, Dr. Vinayak Prasad, wrote: "FDA has a regulatory duty to only grant marketing authorization in settings where we have substantial certainty the benefits outweigh the risks. For healthy children that standard is not met." *Id.at end*

12. On August 27, 2025, the FDA approved Pfizer's supplemental BLA for Comirnaty for children five through eleven years — again, only for those with at least one underlying condition putting them at high risk for severe COVID-19 outcomes. *See* FDA, Approval Letter, BLA STN BL 125742/656 (Aug. 27, 2025), available at https://www.fda.gov/media/188439/download. Simultaneously, the FDA revoked Pfizer's Emergency Use Authorization for all children under five. *See* FDA, Revocation Memorandum (Aug. 27, 2025), available at https://www.fda.gov/media/188454/download. The FDA rejected all three of Pfizer's objections to the revocation.

13. The net result: as of August 27, 2025, no COVID-19 vaccine from any manufacturer is approved or authorized for healthy children of any age in the United States. The FDA has determined that the benefit-risk standard is not met for this population. That is the same conclusion Dr. Cardenas reached when she declined to administer the shot to her healthy pediatric patients. VFC destroyed her practice for it.

14. Effective July 1, 2025, the CDC itself changed VFC program policy so that providers enrolled in the VFC program are no longer required to routinely stock COVID-19 vaccines. Providers who do not stock the vaccine need only maintain a referral arrangement with a safety-net provider such as a local health department. *See* North Carolina Division of Public Health, "Important VFC Policy Updates" (June 30, 2025),

attached hereto as Exhibit G, communicating the CDC's policy change. The VFC program that refused to process any of Dr. Cardenas's vaccine orders in late 2023 because she would not order the COVID shot now permits providers to decline to stock it altogether. The policy AAP asks this Court to restore no longer exists even within the program that enforced it.

15. AAP's own publication confirmed the VFC policy change. In an article titled "CDC Relaxes Rules on Stocking Vaccines in VFC Program," AAP News reported that VFC providers would no longer be required to stock COVID-19 vaccines for VFC-eligible children. *See* American Academy of Pediatrics, "CDC Relaxes Rules on Stocking Vaccines in VFC Program" (July 16, 2025), attached hereto as Exhibit H.

16. Jesse M. Hackell, M.D., former chair of the AAP Committee on Practice and Ambulatory Medicine, told AAP News that the new guidance "reflect[s] the reality many pediatricians have not been stocking it for quite some time now, because the demand is low and the cost is high." *Id.* Dr. Hackell further cautioned that "codifying it does open the door to politics influencing the decision of what vaccines are provided or required by VFC." *Id.* Dr. Hackell also warned that the relaxed stocking requirement "could lead to treatments of the VFC-eligible and the non-VFC-eligible population differently in practice." *Id.* In other words, AAP's own former committee chair acknowledged that pediatricians had already stopped stocking the COVID vaccine before the government changed the policy — because families were not requesting it. But that option was available only to private-pay practices. VFC providers like Dr. Cardenas could not exercise that same judgment. They were required to order and administer the COVID

vaccine or lose access to the entire VFC program — which is precisely the equal protection problem identified in the Cardenas complaint at ¶¶ 65–72.

V. CONCLUSION

17. Plaintiffs ask this Court to restore a recommendation that the agency responsible for drug safety has rejected for healthy children, that the program responsible for enforcement has ceased to enforce, and that Plaintiffs' own members had already abandoned in practice. The Cardenas complaint (Exhibit F) and the VFC policy update (Exhibit G) and the Haskell quotes (Exhibit H) provide the factual record this Court needs before ruling on Counts III and IV.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on February 23, 2026.

/s/ Richard Jaffe

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RICHARD JAFFE

TABLE OF EXHIBITS

EXHIBIT F

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, SANTA ANA DIVISION

SAMARA CARDENAS, M.D. Plaintiffs, v. SUSAN P. MONAREZ in her official capacity as the Acting Director of the Centers for Disease Control and Prevention (CDC), Defendant.	Case No: COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

I. JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this action arises under the Constitution and laws of the United States, including the Administrative Procedure Act, 5 U.S.C. § 701 et seq.

2. This Court has authority to issue declaratory and injunctive relief pursuant to

5 U.S.C. § 702, 28 U.S.C. §§ 2201 and 2202, and its inherent equitable powers.

3. Venue is proper in the United States District Court for the Central District of California pursuant to 28 U.S.C. § 1391(e)(1) because Plaintiff resides in this district and no real property is involved in the action. Venue is also proper under 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims occurred in this district.

II. INTRODUCTION

4. This case challenges the federal policy that forces physicians who treat Medicaid children to administer the investigational COVID-19 vaccine, which has never been shown to confer any clinical benefit to healthy children, years after the pandemic ended, and when the risk to children had virtually disappeared. The Centers for Disease Control and Prevention (CDC) continues to promote mass COVID-19 vaccination for all children six months and older, while negligently failing to assess and/or disclose necessary information about Covid vaccine-related injuries.

5. Dr. Samara Cardenas, a pediatrician who served disadvantaged families in Anaheim, California, refused to administer this vaccine to healthy children based on her professional judgment. For exercising that judgment, the CDC's Vaccine for Children program ("VFC") barred her from ordering any vaccines, which caused CalOptima (the Orange County Medicaid provider) to terminate her contract and remove all 1900 of her Medicaid pediatric patients, which caused her to close her medical practice.

6. The federal government's mindless insistence on perpetuating this obsolete policy, even as the pandemic ended and knowing the almost nonexistent risk to healthy children, endangers the very children it claims to protect, punishes ethical physicians, and reduces public health to an exercise in forced compliance rather than evidence-based medicine which should evolve with changes in circumstances and risk.

7. This lawsuit seeks to compel the CDC to abandon its misguided and scientifically untethered policy, and stop the unnecessary mass vaccination of the nation's poorest children.

III. THE PARTIES

8. Plaintiff Samara Cardenas, M.D. is a licensed pediatrician who, at all relevant times, maintained a pediatric practice serving CalOptima (Medicaid)-enrolled children in Anaheim, California, within the Central District of California.

9. Defendant Susan P. Monarez is the Acting Director of the Centers for Disease Control and Prevention (CDC), an agency within the United States Department of Health and Human Services (HHS). The CDC administers the Vaccines for Children (VFC) program challenged in this action. Dr. Monarez is sued in her official capacity.

IV. FACTUAL BACKGROUND

A. The Vaccines for Children (VFC) Program and Its Role in Medicaid Pediatrics

10. The Vaccines for Children (VFC) Program is a federally funded initiative

operated by the Centers for Disease Control and Prevention (CDC). It provides vaccines at no cost to Medicaid physicians for use in their pediatric practices for Medicaid-eligible, uninsured, or underinsured children or children who otherwise meet eligibility criteria.

11. Participation in the VFC program is effectively mandatory for pediatricians who serve Medicaid populations. In many states, including California, pediatricians (and family practice physicians) who treat Medicaid patients must enroll in the VFC program to be eligible to provide Medicaid-covered services.

12. Under the VFC program, pediatricians are required to administer all vaccines listed on the CDC's immunization schedule to eligible children unless a recognized medical contraindication or precaution applies. Providers may not charge patients for vaccines supplied through VFC, and purchasing vaccines privately for Medicaid patients is financially infeasible because patients' families cannot be billed.

13. As a result, termination by VFC, or a physician's inability to order vaccines from the VFC program (which is what happened to Plaintiff) effectively eliminates a physician's ability to treat Medicaid eligible children. That is because most states (like California) require participation in the program as a condition to participate in Medicaid (CalOptima in Plaintiff's case). Low-income families lose access to their trusted physicians.

B. COVID-19 Risk to Children and Lack of Demonstrated Vaccine Benefit

14. From the outset of the pandemic, it was evident that children faced substantially lower risks of serious illness, hospitalization, and death from COVID-19 compared to adults. Subsequent studies confirmed that healthy children without underlying conditions were at exceptionally low risk of critical illness.

15. Studies consistently show that the overwhelming majority of healthy children infected with COVID-19 experience mild or asymptomatic disease. Hospitalization and critical illness among healthy children are exceedingly rare events.[1]

16. According to the CDC, children with significant underlying medical conditions remain at higher risk of severe COVID-19 disease, while healthy children experience substantially milder outcomes.[2]

17. Despite the dramatically reduced risk posed to healthy children, the CDC continued to recommend COVID-19 vaccination for all children six months and older, without distinguishing the recommendation based on individual medical risk.

18. By recommending COVID-19 vaccination for all children without regard to individual medical risk, the CDC abandoned the most basic principles of risk

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[1] *See* CDC, *Protecting Infants and Children from COVID-19–Associated Hospitalization*, https://www.cdc.gov/ncird/whats-new/protecting-infants-and-children-from-covid-19-associated-hospitalization.html.

[2] *Id.*

stratification and responsible medical practice, needlessly exposing low-risk children to an investigational intervention that has not demonstrated any clinical benefit to vaccine recipients.

C. CDC's Failure to Compile and Analyze Vaccine Injury Data

19. The CDC operates the Vaccine Adverse Event Reporting System (VAERS), a passive surveillance system for monitoring vaccine safety.

20. VAERS data from 2021–2024 (when Dr. Cardenas lost VFC access and her Medicaid contract) recorded hundreds of thousands of adverse events following administration of COVID-19 vaccines, including reports of serious adverse events and deaths.

21. By mid-2023, VAERS had accumulated over 37,000 death reports and hundreds of thousands of serious adverse event reports temporally associated with COVID-19 vaccination across all age groups. (*See* VAERS Summary Data, https://vaers.hhs.gov/data.html.) Notably, thousands of children under 18 are included in these reports.

22. Despite this alarming accumulation of data, the CDC failed to conduct a thorough or public risk-benefit analysis of COVID-19 vaccines in children after the pandemic emergency ended in April 2023.

23. Evidence indicates that passive surveillance systems like VAERS substantially underreport vaccine injuries. A Harvard Pilgrim Health Care study found

that fewer than 1% of adverse vaccine events are ever reported to VAERS.[3]

24. Other researchers, including Rosenthal et al. (2021) and Shimabukuro et al. (2015), have similarly concluded that passive surveillance systems like VAERS are subject to significant underreporting biases.[4]

25. As a result, the true incidence of serious adverse effects from COVID-19 vaccination, particularly in children, remains unknown but is likely far higher than publicly acknowledged.

26. Rather than fulfilling its critical safety-monitoring role, the CDC left physicians without the necessary curated and analyzed data to make an informed, professional, and ethical risk-benefit assessment regarding COVID-19 vaccination in children.

27. In short, the CDC abandoned its duty to rigorously monitor and transparently report vaccine safety outcomes, choosing instead to demand unquestioning compliance from physicians serving vulnerable populations while potentially misleading parents about the true risk profile of COVID-19 vaccination and the true

[3] *See* Lazarus et al., *Electronic Support for Public Health—Vaccine Adverse Event Reporting System* (*ESP: VAERS*), Harvard Pilgrim Healthcare, https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf.

[4] *See* Rosenthal et al., *Serious Adverse Events Reported to the Vaccine Adverse Event Reporting System, United States, 1990–2010*, Vaccine (2021); Shimabukuro et al., *Safety monitoring in VAERS*, Vaccine (2015).

(lack of) significant threat posed by COVID-19 illness in healthy children.

D. Post-Pandemic Policy Inertia

28. On April 10, 2023, President Biden officially declared the COVID-19 pandemic emergency over.

29. By this time, newer COVID-19 variants such as Omicron and its subvariants were widely recognized to cause significantly less severe disease compared to earlier variants like Delta.

30. Scientific consensus, including statements from CDC officials, confirmed that the virus had evolved into a substantially less lethal form by 2023. (*See CDC COVID-19 Variant Reports*, https://www.cdc.gov/coronavirus/2019-ncov/variants/variant.html.)

31. Despite this viral evolution and the vanishing justification for universal administration of the COVID-19 vaccine for children, the CDC failed to reevaluate or rescind its blanket recommendation for COVID-19 vaccination of all children six months and older.

32. No new clinical trial data demonstrated any meaningful benefit of continued COVID-19 vaccination in healthy children post-pandemic.

33. By clinging to outdated pandemic-era policies, the CDC has continued a recommendation that is disconnected from the still investigational status of the vaccine for children and the pediatric risk profile.

34. In short, while the risk from the infection to the population as a whole, and children in particular, materially dissipated, the CDC's recommendation remained the same.

E. Dr. Cardenas Loses Access to VFC Vaccines and then Loses her Medical Practice

35. In late 2023, Dr. Cardenas was notified by the VFC program that her vaccine orders were being scrutinized because she was not ordering the Covid shots.

36. Upon inquiry, Dr. Cardenas' office disclosed that she was not ordering COVID-19 vaccines for her pediatric patients because, in her professional judgment, it was neither necessary nor appropriate to administer an investigational vaccine to healthy children at negligible risk from COVID-19.

37. The clinic's next vaccine order was not processed with an explanation that the order was incomplete because it did not include the Covid vaccine. (VFC Communication attached as Exhibit A.)

38. Because she lost access to VFC-provided vaccines, Dr. Cardenas was unable to provide any vaccines to her Medicaid patients, which led CalOptima to terminate her contract and reassign all 1900 of her CalOptima patients to other providers.

39. Dr. Cardenas had built her practice over several decades, serving disadvantaged children in Anaheim, California. The forced removal of her patients

ended her practice.

40. The loss of her access to VFC-supplied vaccines, and then the termination of her CalOptima contract, was solely based on her refusal to administer an investigational vaccine that has never been shown to confer a clinical benefit on her patients.

41. And yet, the CDC claims that it is all about evidence-based medicine. However, this case demonstrates a mind-numbing, obstinate adherence to dogmatic consensus, unconnected to changed circumstance and information, and suggests that much change is needed at the CDC, and particularly at its principal vaccine advisory committee.

F. Federal Funding for Pediatric COVID-19 Vaccination After the Pandemic

42. During the COVID-19 pandemic (2020–2022), pediatric COVID-19 vaccine doses were purchased by the federal government using emergency appropriations, and not through the regular VFC budget.[5]

43. In 2023, as federal emergency supplies were depleted, the CDC transitioned the procurement of pediatric COVID-19 vaccine doses into the VFC

[5] *See COVID-19 Vaccination Provider Requirements and Support* | CDC, https://www.cdc.gov/vaccines/covid-19/reporting-requirements/index.html.

program.

44. For fiscal year 2024, the CDC's budget allocation for the VFC program rose sharply to approximately $7.2 billion, an increase of more than $2 billion compared to pre-pandemic levels.[6]

45. This $2 billion increase was attributable in significant part to the need to purchase COVID-19 vaccine doses for pediatric use within the VFC program.

46. The VFC program exclusively serves children, and no other comparable program expansions occurred that would explain this sharp budget increase.

47. Thus, after the pandemic officially ended, and despite the absence of clinical evidence showing that COVID-19 vaccines benefitted healthy children, the federal government committed over $2 billion in new taxpayer funds to continue mass vaccinating low-risk Medicaid-enrolled children against COVID-19.

48. In short, at a time when it was well-understood that the virus posed little to no serious threat to healthy children, and without clear evidence of clinical benefit of the COVID-19 vaccine for children, and an under-analyzed harm determination for this (or any) patient subset, the government substantially increased spending to continue injecting children with this investigational product.

[6] *See CMS FY2022 Congressional Justification*, https://www.cms.gov/about-cms/budget/fy2022-congressional-justification.

G. ACIP Has Become a Detached Bureaucratic Monolith, Out of Step with Science, Ethics, Democracy, and Common Sense

49. At its April 2025 meeting, the Advisory Committee on Immunization Practices (ACIP) considered, for the first time in nearly two years, whether to revise its blanket recommendation that all children over six months old receive the COVID-19 vaccine. This discussion occurred not in 2022, when the pandemic waned, nor in 2023, after it ended, but in 2025 — long after COVID-19 was known to be of little risk to healthy children.

50. During that meeting, ACIP member Dr. Denise Jamieson responded to a proposal to adopt a risk-based recommendation — one that would limit the vaccine to only the high-risk pediatric population. She opposed it. Why? Because, as she explained, the "U.S. has a history of not being able to implement such variable recommendations," and the public, she implied, is simply not capable of understanding risk stratification. In short, the CDC should continue to push a vaccine that is clinically unnecessary for healthy children **not because of medical necessity, but because the American public is not intelligent enough to handle nuance.**

51. This is not merely arrogance. It is government-by-committee at its most dangerous — where unelected public health advisors retain extraordinary power to shape national policy, and yet display open disdain for the very people whose lives they affect. Rather than trust doctors or parents to weigh individualized risk, ACIP

reflexively defaults to universal recommendations which are enforced by state vaccine mandates. Rather than confront the public with honest data, it hides behind the fiction of simplicity and compliance.

52. This episode is not isolated. Other slides from the April 2025 meeting confirm this mindset. One slide read: "Although shared clinical decision-making recommendations can be difficult to implement…" — as if the difficulty of communicating nuanced medical advice justifies erasing the nuance itself. Another slide bluntly asks: "How much increased risk is needed to be included in a risk-based recommendation?" The answer, evidently, is that no amount of clinical safety or epidemiological irrelevance will loosen the Committee's grip.

53. ACIP has become an unelected ruling body, accountable to no one, with a stranglehold over public health guidance — guidance that the CDC has heretofore converted into policy with minimal scrutiny. The public deserves better. And the law requires it.

H. ACIP's Conflicts of Interest and the Use of Waivers: Undermining Trust and Objectivity

54. While the Advisory Committee on Immunization Practices (ACIP) wields extraordinary influence over national vaccine policy — including the Vaccines for Children (VFC) program — it is not composed of disinterested public servants. Many ACIP members have financial or professional ties to vaccine manufacturers or related

interests.

55. Rather than recusing these individuals or excluding them, the CDC routinely issues conflict of interest waivers, allowing otherwise conflicted members to participate in policy discussions and, in some cases, help shape official recommendations. A 2000 Congressional hearing revealed that the CDC had granted such waivers to every single member of its advisory committee — a practice that continues to this day.[7]

56. Although current policies prohibit voting by those with direct conflicts, these members may still engage in substantive deliberations, setting the terms of the scientific and ethical debate and influencing outcomes through advocacy or pressure.

57. The CDC defends these waivers as necessary to preserve "unique expertise." But that justification has become a shield for insider dominance. The waiver system has created a self-reinforcing advisory network — one that lacks diversity of viewpoint, excludes dissenting science, and rarely questions the pro-vaccine orthodoxy that sustains it.

58. The ACIP committee thus fails not only the appearance-of-impropriety test, but the functional integrity test as well. That a body riddled with waivers and

[7] *FACA: Conflicts of Interest and Vaccine Development—Preserving the Integrity of the Process: Hearing Before the H. Comm. on Gov't Reform*, 106th Cong. (2000), https://www.govinfo.gov/content/pkg/CHRG-106hhrg73042/html/CHRG-106hhrg73042.htm.

institutional entanglements continues to mandate an investigational vaccine for healthy children — a vaccine never proven to deliver clinical benefit — is a stark indictment of the current system.

FIRST CLAIM FOR RELIEF

Administrative Procedure Act (5 U.S.C. § 706)

(Agency Action That Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law)

59. Plaintiff realleges and incorporates by reference all preceding paragraphs of this Complaint.

60. Under the Administrative Procedure Act ("APA"), a court must "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

61. The CDC's endorsement and adoption of the ACIP recommendation for COVID-19 vaccination of all children six months and older constitutes final agency action within the meaning of the APA.

62. The CDC's continued recommendation of COVID-19 vaccination for healthy children, despite the absence of evidence showing clinical benefit, despite the dramatically reduced risks posed by COVID-19 post-pandemic, and despite the failure to perform adequate safety surveillance and analysis, is arbitrary, capricious, and an abuse of discretion.

63. The CDC's failure to engage in a meaningful risk-benefit analysis—particularly in light of known adverse event data and the evolving scientific understanding of COVID-19's impact on children—renders its actions unlawful under the APA.

64. Plaintiff is entitled to a declaration that the CDC's recommendation was arbitrary and capricious, and to appropriate injunctive relief setting aside or enjoining reliance upon the recommendation.

SECOND CLAIM FOR RELIEF

Fifth Amendment Equal Protection

(Discrimination Against Medicaid-Enrolled Children)

65. Plaintiff realleges and incorporates by reference all preceding paragraphs of this Complaint.

66. The Fifth Amendment to the United States Constitution prohibits the federal government from denying equal protection of the laws.

67. By continuing to recommend and require COVID-19 vaccination for all children, including those served by Medicaid programs, without regard to individual medical risk, the CDC and its associated programs have created an unjustified disparity between poor children and children whose families can afford private-pay care.

68. Medicaid-enrolled children are uniquely dependent on VFC-enrolled pediatricians for access to vaccines, and therefore uniquely subject to the CDC's rigid

vaccination mandates without meaningful individualized risk assessment.

69. Private-pay patients are able to access pediatricians outside the VFC program who are not under the same federal constraints, and who can make individualized recommendations based on clinical judgment.

70. This differential treatment imposes a greater burden on Medicaid children's ability to access conscientious medical care and infringes upon their right to receive individualized, ethical medical advice and services.

71. There is no rational basis, much less any heightened justification, for the federal government to create or perpetuate such a disparity.

72. Plaintiffs are entitled to a declaration that this unequal treatment violates the Fifth Amendment and to appropriate injunctive relief.

THIRD CLAIM FOR RELIEF

Fifth Amendment Substantive Due Process

(Violation of Physician's Right to Professional Judgment)

73. Plaintiff realleges and incorporates by reference all preceding paragraphs of this Complaint.

74. The Fifth Amendment protects a physician's right to exercise professional medical judgment free from arbitrary and irrational government interference.

75. The CDC's blanket mandate that all pediatricians participating in the VFC program offer and administer COVID-19 vaccines to all children, regardless of

individualized medical risk, impermissibly infringes on physicians' professional judgment.

76. In the case of Medicaid providers, the CDC's policy forces pediatricians to either administer an investigational product to low-risk children or lose their ability to practice medicine for an entire vulnerable patient population.

77. Plaintiff Cardenas exercised her professional judgment by determining that administering COVID-19 vaccines to her healthy pediatric patients was neither clinically indicated nor ethically justified.

78. The CDC's actions effectively punished her for exercising that professional judgment by terminating her VFC participation, leading to the loss of her CalOptima Medicaid practice.

79. The CDC's coercion of physicians serving disadvantaged populations into acting contrary to their professional and ethical obligations violates substantive due process protections under the Fifth Amendment.

80. Plaintiff is entitled to a declaration that the CDC's policy and actions violated Dr. Cardenas' substantive due process rights and to appropriate injunctive relief.

FOURTH CLAIM FOR RELIEF

Declaratory and Injunctive Relief to Require the Defendant to Remedy the Structural Failure in the CDC's Delegation of Policy-Making to ACIP

81. Plaintiff realleges and incorporates by reference all preceding paragraphs of this Complaint.

82. Plaintiff brings this claim to expose and remedy a dangerous structural defect in how vaccine policy is made in the United States — namely, the CDC's de facto delegation of decision-making power to ACIP, an advisory committee whose processes are opaque, its membership homogenous, and its integrity compromised by conflicts of interest**.**

83. ACIP's recommendations are routinely adopted by the CDC without meaningful review and are used to drive mandates under the Vaccines for Children (VFC) program. Yet the committee operates without Senate oversight, lacks broad scientific and ethical representation, and functions outside any formal administrative process subject to public comment or judicial review.

84. The CDC further undermines the credibility of this process by granting conflict of interest waivers to ACIP members with direct ties to vaccine manufacturers or federal funding streams. These waivers allow conflicted individuals to participate in deliberations and set the tone and direction of policy — a practice that violates both administrative integrity and public trust.

85. This waiver regime, combined with the CDC's near-automatic adoption of ACIP recommendations, creates an environment of regulatory capture — where insiders make rules that benefit their own networks, shielded from accountability.

86. The CDC's current structure and policy-making process are therefore arbitrary, capricious, and inconsistent with the due process and transparency requirements of the Administrative Procedure Act.

87. Plaintiff seeks a declaration that the CDC's reliance on conflicted ACIP members and its use of waivers to sustain biased deliberations violates the law and public health ethics.

88. Plaintiff seeks injunctive relief requiring that:

a. The CDC publicly disclose all conflict-of-interest waivers granted to ACIP members;

b. Members with financial ties to vaccine manufacturers or industry-sponsored trials be barred from participating in discussions, not merely voting;

c. The CDC establish an independent ethics oversight board to vet future ACIP appointments and manage waiver requests;

d. No ACIP recommendation be adopted as binding CDC policy without a formal, independent risk-benefit analysis and public comment opportunity.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

A. Declare that the CDC's continued recommendation of COVID-19 vaccination for all children, without regard to individualized risk, is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law under the Administrative Procedure Act;

B. Declare that the CDC's actions violate the Fifth Amendment's guarantee of equal protection by subjecting Medicaid-enrolled children to different treatment standards without rational basis;

C. Declare that the CDC's actions violate the Fifth Amendment's substantive due process protections by coercing pediatricians to act against their professional judgment;

D. Enjoin Defendant from relying on or enforcing the challenged CDC recommendation as to COVID-19 vaccination of children under the Vaccines for Children (VFC) program or any other program under Defendant's purview;

E. (1) Mandate that the CDC publicly disclose all conflict-of-interest waivers granted to ACIP members; Members with financial ties to vaccine manufacturers or industry-sponsored trials be barred from participating in discussions, not merely voting;

(2) Require the CDC to establish an independent ethics oversight board to vet future ACIP appointments and manage waiver requests;

(3) Mandate that no ACIP recommendation be adopted as binding CDC

policy without a formal, independent risk-benefit analysis and public comment opportunity.

F. Grant such other and further relief as the Court deems just and proper.

Dated: April 25, 2025

Respectfully submitted,

RICHARD JAFFE, ESQ.
Email: rickjaffeesquire@gmail.com
Attorney for Plaintiff
428 J Street, 4th Floor
Sacramento, California 95814
Tel: 916-492-6038
Fax: 713-626-9420

EXHIBIT A

Fwd: ACTION NEEDED: VFC Vaccine Order Needs Corrections

From: Lourdes Torres (lourdes@drspcardenas.com)

To: drsamarapcardenas@aol.com

Date: Wednesday, November 29, 2023 at 10:23 AM PST

---------- Forwarded message ---------
From: **MyVFCVaccines** <MyVFCVaccines@cdph.ca.gov>
Date: Tue, Nov 28, 2023 at 5:48 PM
Subject: ACTION NEEDED: VFC Vaccine Order Needs Corrections
To: lourdes@drspcardenas.com <lourdes@drspcardenas.com>

IMPORTANT - PLEASE DO NOT RESPOND DIRECTLY TO THIS EMAIL

Your VFC vaccine order has not been processed and requires your attention.

Thank you for your recent VFC vaccine order for **PIN 031638**.

Unfortunately it cannot be processed due to the following reason:

Other
â€œThank you for your vaccine order. We noticed you have not yet submitted a vaccine request for any presentations of COVID vaccine available. All participating providers are required to order and offer ACIP recommended vaccines to their patient populatio

Please log in to MyVFCVaccines and click on the orange 'Edit Order' button to make corrections to your order. Orders pending in the system for more than 14 days will be deleted and a new order will have to be submitted.

Sincerely,

California VFC Central Office

Phone: (877) 243-8832
Fax: (877) 329-9832
Website: www.eziz.org

EXHIBIT G

NCDHHS
Division of Public Healt

MONDAY, JUNE 30, 2025

Important VFC Policy Updates: COVID-19 Vaccine, RSV Monoclonal Antibodies, and Inventory Guidance

Share to: (/#facebook) (/#email) (/#linkedin) (/#x) (/#bluesky)

NORTH CAROLINA IMMUNIZATION PROGRAM

We are writing to inform you of several changes to the Vaccines for Children (VFC) program policies that may affect your practice, effective July 1, 2025. These updates pertain to the COVID-19 vaccine recommendations, RSV monoclonal antibody products, private stock vaccine requirements and the definition of underinsured. Please review the information below and reach out with any questions.

COVID-19 Vaccine Stock

Following the Centers for Disease Control and Prevention (CDC) release of updated Child, Adolescent (https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html), and Adult Immunization Schedules (https://www.cdc.gov/vaccines/hcp/imz-schedules/adult-medical-condition.html) with revised COVID-19 vaccine recommendations, new VFC policies will take effect **July 1, 2025**. Private providers enrolled in the VFC Program will no longer be required to routinely stock COVID-19 vaccines. However, they must be able to refer VFC-eligible children to a safety net provider, such as a Local Health Department (LHD), if needed as part of their routine vaccine management plan. LHDs should continue to maintain at least the minimum ordering quantity of state-supplied VFC COVID-19 vaccines to serve this role. While no longer required, providers are strongly encouraged to continue stocking and administering COVID-19 vaccines to protect their patients. Ensuring access in primary care settings promotes timely vaccination and prevents missed opportunities.

Providers who do not stock the COVID-19 vaccine are expected to be aware of and prepared to refer patients to locations known to stock the vaccine, similar to procedures for non-routine VFC vaccines like **mpox** and **PPSV23**. To support continuity of care, it is important to confirm that the provider receiving referrals is equipped and ready to provide the necessary additional immunizations.

Private Stock and VFC Vaccines

Starting **July 1, 2025**, CDC will no longer require VFC providers to maintain a full stock of all privately purchased ACIP-recommended vaccines for non-VFC-eligible patients if they do not plan to offer all ACIP-recommended vaccines to this population. This guidance pertains to all ACIP-recommended products, including **RSV**

monoclonal antibody products. Providers that serve and plan to vaccinate privately insured, non-VFC eligible population, must continue to maintain a separate vaccine inventory to vaccinate their non-VFC-eligible population.

If a VFC provider does not carry private stock, they are not permitted to use VFC stock on non-VFC-eligible patients. Routine borrowing and replacement of VFC vaccines and monoclonal antibody products for use among privately insured, non-VFC-eligible patients will not be permitted.

RSV Monoclonal Antibody Products

All VFC-enrolled providers that serve VFC-eligible children 19 months of age or younger are required to carry VFC-supplied RSV monoclonal antibody products at **the start of RSV season**, which typically begins **October 1**. We anticipate ordering will open prior to the start of RSV season and will provide further guidance on the ordering process soon.

Updated Definition of Underinsured

The definition of "underinsured" for VFC-eligible patients has been updated:

- A person under age 19 is now considered underinsured if:
    - Their insurance does **not cover any** ACIP-recommended vaccines,
    - Their insurance covers **only some** ACIP-recommended vaccines, or

- Their insurance does **not provide first-dollar coverage** (i.e., vaccine coverage is subject to copays, coinsurance, or deductibles).

/Note: As a reminder, underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), a Rural Health Clinic (RHC), a Local Health Department (LHD), or a private provider with an approved deputization agreement. All other providers should refer underinsured children to one of these facilities in order to receive VFC supplied vaccines.

Patients must be screened for eligibility at each immunization encounter, so before administering a vaccine, providers must verify whether the child's health insurance plan covers ACIP-recommended vaccine. For underinsured children, whose medical home is not with a FQHC, RHC, or LHD, the provider should notify the parent /guardian that the patient is VFC eligible and could receive VFC vaccines at one of these designated provider types.

If the parent/guardian chooses to receive vaccines for their child at their non-deputized medical home, the patient would receive private purchased vaccine and would be financially responsible for the cost of the purchased vaccine and the associated administration fees.

Birth dose hepatitis B policy for enrolled hospitals

To ensure we are consistent with CDC's 317 funding policy and recent clarifications from CDC, we are no longer allowing universal administration of the birth dose hepatitis B vaccine to infants using state supplied vaccines, starting **July 1, 2025**. Beginning **July 1,**

2025, birthing hospitals must screen infants to determine eligibility and use the appropriate vaccine stock (state supplied VFC, state supplied 317, or hospital privately purchased).

This policy applies **only** to birth dose hepatitis B vaccines administered prior to hospital discharge. RSV immunizations are not affected; state-supplied RSV vaccines have never been universally available and remain limited to VFC-eligible patients only. Due to this change, private providers may begin seeing more children who did not receive the hepatitis B birth dose in the hospital.

Thank you for your attention to these policy changes. Updates to the VFC coverage criteria will be forthcoming to align with recent changes. We will continue to monitor the immunization landscape and communicate any future updates to VFC policies as they become available.

How to contact us:

For assistance, please contact the NCIP Help Desk by phone at 1.877.USE.NCIR (1-877-873-6247 (tel:18778736247)) or by email (mailto:ncirhelp@dhhs.nc.gov).

Thank you for your ongoing partnership and dedication to improving immunization outcomes in North Carolina.

In Health,
NC Department of Health and Human Services

Related Topics:

- Immunization - HCPs

(/press-release-terms/immunization-hcps)

CONTACT

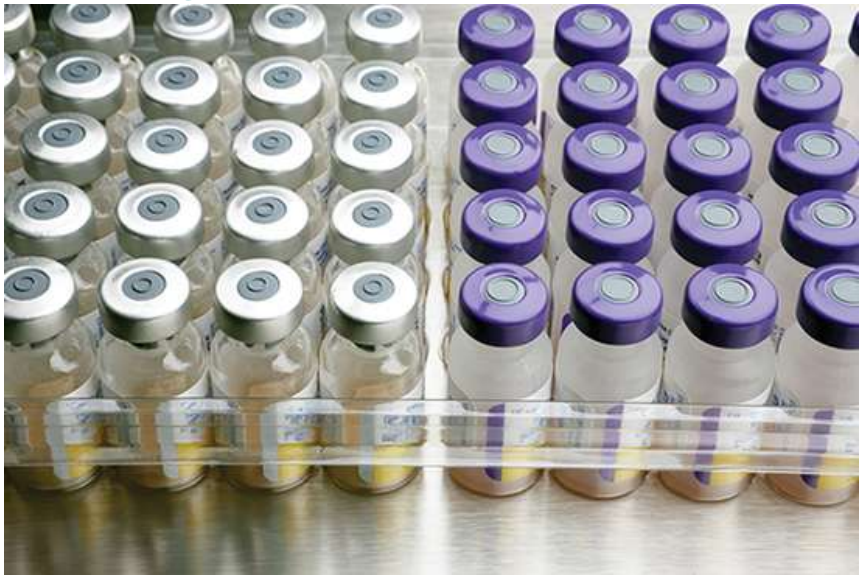
NCIP Help Desk

ncirhelp@dhhs.nc.gov (mailto:ncirhelp@dhhs.nc.gov)

(877) 873-6247 (tel:(877) 873-6247)

EXHIBIT H

AAP News™



CDC relaxes rules on stocking vaccines in VFC program

July 16, 2025

Melissa Jenco, Senior News Editor

Article type: News

Topics: COVID-19, Infectious Diseases, RSV, Vaccine/Immunization

Editor's note: *For the latest news on COVID-19, visit http://bit.ly/AAPNewsCOVID19.*

Federal health officials are relaxing some of the rules for stocking vaccines in the Vaccines for Children (VFC) program.

VFC providers no longer will have to maintain a full stock of all recommended vaccines for privately insured children if they don't plan to offer all vaccines to this population, according to a summary of changes the Centers for Disease Control and Prevention (CDC) provided to state immunization managers and the AAP. In addition, they will not have to stock COVID-19 vaccines for VFC-eligible patients.

The VFC program provides free immunizations to children who are uninsured, underinsured, Medicaid-eligible, American Indian or Alaska Native. States can choose to make their own vaccine stocking rules but typically follow CDC guidance.

Changing requirements for VFC providers around stocking vaccines for privately insured children likely will have the biggest impact on birthing hospitals, which give limited immunizations. They also have a different payment structure with bundled care that makes adding immunizations for privately insured children complicated. The CDC has been trying to enroll more of these facilities in the VFC program so they can provide respiratory syncytial virus (RSV) immunizations to newborns if their mother was not vaccinated during pregnancy. For infants born in October through March, the ideal time to immunize is during the first week of life. However, some families may face barriers to receiving vaccines early; for example, children who do not have an identified medical home may not have early access to the immunization.

Children who do not have commercial insurance are less likely to be seen by their primary care provider within a week of birth compared to children who are privately insured, according to Georgina Peacock, M.D., M.P.H., division director for the CDC's Immunization Services Division.

"Therefore, it's important to have an option in the birthing hospital," Dr. Peacock told CDC vaccine advisers in June. "Birthing hospitals play a vital role in ensuring there are no missed opportunities for RSV immunization before hospital discharge and coordination of care with pediatricians."

When RSV immunization nirsevimab became available in the fall of 2023, just 10% of birthing hospitals were enrolled in the VFC program. By the end of March 2025, that figure was up to 36%, according to Dr. Peacock's presentation.

Jesse M. Hackell, M.D., FAAP, former chair of the AAP Committee on Practice and Ambulatory Medicine, agreed it would be beneficial for more birthing hospitals to participate in VFC so that more children have access to RSV immunizations.

In addition, "it may simplify matters with a pediatrician a little bit, if we encourage more kids to have been protected by the time they get to the pediatric office for the first visit," he said.

The CDC has allowed some flexibility around private stock requirements for RSV immunizations and COVID-19 vaccines in recent years, but the new rule applies to all immunizations.

While largely beneficial, it could have unintended consequences, Dr. Hackell said.

"I don't anticipate it's going to be a huge problem, but I think it would be foolish to not at least recognize that it could lead to treatments of the VFC-eligible and the non-VFC- eligible population differently in practice," he said.

In another rule change, the CDC will no longer require VFC providers to stock COVID-19 vaccines for VFC-eligible children.

"Given the unique considerations of COVID-19 vaccination, it may not be practical for all VFC providers to stock this vaccine for VFC-eligible patients," the guidance says.

Providers should identify locations where they can refer VFC-eligible children for COVID-19 vaccination. However, combined with the rule discussed above, fewer providers may stock it for either group of children.

This change comes amid low vaccination rates and new CDC guidance that removes routine recommendations for healthy children. Children may be vaccinated after a conversation with their doctor. The AAP will be publishing its own evidence-based recommendations as it has for its entire 95-year history.

The CDC said its new guidance on stocking COVID vaccines is similar to other non-routine VFC vaccines like mpox.

Dr. Hackell said the guidance "reflect(s) the reality many pediatricians have not been stocking it for quite some time now, because the demand is low and the cost is high."

"However, codifying it does open the door to politics influencing the decision of what vaccines are provided or required by VFC," he said.

The updated guidance was slated to go into effect July 1. The CDC is expected to publish its full VFC operations guide in the coming weeks.