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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, SANTA ANA DIVISION

SAMARA CARDENAS, M.D. Plaintiff, v. Matthew Buzzelli, in his official capacity as Chief of Staff performing the duties of the Acting Director of the Centers for Disease Control and Prevention (CDC), Defendant.	Case No: 8:25-cv-00867 FLA (ADSx) FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Pursuant to Rule 15 (a) of the Federal Rules of Civil Procedure, Plaintiff alleges against the Defendant as follows:

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.

I. 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.

II. 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 Matthew Buzzelli, is being sued in his official capacity only as the Chief of Staff performing the duties of the acting Benter for Disease Control (CDC) Director, 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.

III. 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,

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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.*

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 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

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[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).

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 (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 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

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

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

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.

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

[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.

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 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: May 15, 2025

Respectfully submitted,

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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

VFC Vaccines for Children Program 1-877-243-8832 eziz.org

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