

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**CDC'S VACCINES FOR CHILDREN  
PROGRAM RECIPIENTS DID NOT  
CONDUCT SITE VISITS AT SOME  
PROVIDERS AS REQUIRED**

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**September 2023  
A-09-22-01000**

# *Office of Inspector General*

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## Report in Brief

Date: September 2023  
Report No. A-09-22-01000

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**



### Why OIG Did This Audit

The Vaccines for Children (VFC) program provides vaccines at no cost to children whose parents or guardians may not be able to afford them, which helps ensure that all children have a better chance of receiving recommended vaccinations on schedule. The Centers for Disease Control and Prevention (CDC) requires that program recipients conduct three types of provider site visits (enrollment, compliance, and storage and handling), which allow recipients to determine whether vaccines are stored, handled, and administered in accordance with the laws and policies governing the VFC program. However, multiple State auditors' reports identified overdue site visits, site visits that were not conducted, and overdue followup actions for compliance issues.

Our objective was to determine whether CDC's VFC program recipients conducted site visits at enrolled and active VFC providers according to program requirements.

### How OIG Did This Audit

We identified 39,120 providers and 2 CDC-approved depot providers that were enrolled and active at any point from July 1, 2020, through June 30, 2021. We reviewed 3 years' worth of data for all enrollment, compliance, and storage and handling site visits and reviewed the data for more than 127,000 followup actions associated with these site visits.

## CDC's Vaccines for Children Program Recipients Did Not Conduct Site Visits at Some Providers as Required

### What OIG Found

CDC's VFC program recipients conducted enrollment site visits for all newly enrolled and reenrolling VFC providers as required. However, recipients did not meet all program requirements for conducting compliance site visits and storage and handling site visits. Specifically, recipients did not: (1) conduct compliance site visits in a timely manner at 11,499 of 39,120 enrolled and active providers (29 percent), (2) conduct storage and handling site visits at either of the 2 CDC-approved depot providers, (3) conduct storage and handling site visits for at least 5 percent of their providers, and (4) verify that providers completed followup actions by the deadlines for 33,316 of 127,594 issues (26 percent) identified during compliance and storage and handling site visits.

CDC officials stated that staffing constraints and the COVID-19 pandemic were reasons that program recipients did not conduct site visits at some providers as required. CDC officials also stated that, during the COVID-19 pandemic, CDC and recipients were focused on the priority of COVID-19 vaccination program development and vaccine distribution, some providers were temporarily closed, and travel was restricted. In addition, we found that CDC did not have internal written policies and procedures for CDC's monitoring and oversight activities, including oversight of recipients' site visits at providers. Finally, CDC's Provider Education, Assessment, and Reporting online system did not have interactive reminders or alerts related to overdue site visits and followup actions. Because recipients did not conduct site visits as required or verify that providers completed followup actions to address identified compliance issues, CDC and recipients could not ensure that providers were complying with VFC program requirements.

### What OIG Recommends and CDC Comments

We recommend that CDC: (1) work with program recipients to implement a plan and timeline to conduct the required site visits that are overdue and verify the completion of followup actions that had not been completed by the deadlines and (2) develop an action plan to enforce site visit requirements by CDC's planned date of July 1, 2023. The report lists two more procedural recommendations. CDC concurred with our recommendations and described actions that it had taken or planned to take to address our recommendations, including working with recipients that have overdue site visits to develop an implementation plan and timeline for conducting those site visits and developing an action plan to provide guidance to recipients for site visits.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

The Vaccines for Children (VFC) program provides vaccines at no cost to children whose parents or guardians may not be able to afford them, which helps ensure that all children have a better chance of receiving recommended vaccinations on schedule. The Centers for Disease Control and Prevention (CDC) provides funding for the VFC program through a cooperative agreement with program recipients—i.e., State health departments and certain local and territorial public health agencies. One of CDC’s requirements is that program recipients conduct site visits at VFC providers. Site visits allow recipients to determine whether vaccines are stored, handled, and administered in accordance with the laws and policies governing the VFC program. COVID-19 vaccines were not administered as part of the VFC program but were administered as part of a separate COVID-19 vaccine program.

Multiple State auditors’ reports identified overdue site visits, site visits that were not conducted, and overdue followup actions for compliance issues discovered during site visits of VFC providers.<sup>1</sup> Therefore, we conducted this audit to determine whether program recipients nationwide complied with VFC program requirements for site visits at enrolled and active providers.<sup>2</sup>

### OBJECTIVE

Our objective was to determine whether CDC’s VFC program recipients conducted site visits at enrolled and active VFC providers according to program requirements.

### BACKGROUND

#### Vaccines for Children Program

Authorized by section 1928 of the Social Security Act, the VFC program is an entitlement program (a right granted by law) for eligible children. A child is eligible for the VFC program if the child is younger than 19 years of age and is one of the following: eligible for the Medicaid

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<sup>1</sup> The State auditors’ reports were for the States of California, Connecticut, and Illinois for fiscal year ended June 30, 2019. In addition, a prior Office of Inspector General report *Vaccines for Children Program: Vulnerabilities in Vaccine Management* ([OEI-04-10-00430](#)), issued June 5, 2012, examined the extent to which selected VFC providers and program recipients adhered to CDC’s requirements for vaccine management.

<sup>2</sup> To enroll in the VFC program, a provider must have an enrollment site visit, and to remain active in the program, the provider must order vaccines every 12 months.

program, uninsured, underinsured, or an American Indian or Alaska Native (Social Security Act § 1928(b)(2)(A)).<sup>3</sup>

The VFC program provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. This program helps ensure that all children have a better chance of getting their recommended vaccines on schedule and has helped prevent disease and save lives. The vaccines provided protect children against chickenpox, diphtheria, measles, rubella, tetanus, pertussis, and other diseases.

In fiscal years 2020 and 2021, CDC's funding for the VFC program totaled more than \$4.5 billion and \$3.8 billion, respectively, for vaccine direct assistance (purchase of vaccines) and for program operations and infrastructure (program oversight, quality improvement, and vaccine management). CDC awards funding to program recipients for VFC program operations and infrastructure through cooperative agreements. CDC also refers to program recipients as "awardees," "grantees," and "immunization programs." (In this report, we use "program recipients" or "recipients.") Cooperative agreement funding is awarded by budget periods, which run from July 1 through June 30.

### **VFC Program Management**

CDC is responsible for policy development and implementation of the VFC program. CDC administers the VFC program at the national level through its National Center for Immunization and Respiratory Diseases (NCIRD). Within NCIRD, the Immunization Services Division's Program Operations Branch provides policy guidance and oversight for the VFC program, provides technical assistance to program recipients on all program components, and monitors program recipients' performance.

CDC buys vaccines at a discount and distributes them to VFC providers at the direction of program recipients. To manage the VFC program, recipients perform many tasks, including recruiting and enrolling providers in the program, evaluating performance, providing quality assurance, completing surveys, and conducting site visits at providers.

A VFC provider is any health care provider location that is licensed or otherwise authorized by a State to administer pediatric vaccines and is enrolled in the VFC program. CDC-approved depots are considered VFC providers; however, they only store vaccines and do not administer them.

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<sup>3</sup> "Underinsured" means the child has health insurance but that insurance does not cover vaccines or does not cover certain vaccines or covers vaccines but has a fixed dollar limit or cap for vaccines. Once that fixed dollar amount is reached, a child is then eligible for the VFC program. Underinsured children are eligible to receive vaccines only at Federally Qualified Health Centers or Rural Health Clinics.

There are 61 program recipients for the 50 States, the District of Columbia, 5 territories, and 5 cities.<sup>4</sup> We identified 39,122 VFC providers that participated in the VFC program during our audit period.

### Program Recipients' Site Visits and Related Followup Actions

CDC's *Immunization Program Operations Manual* requires that: (1) recipients and providers adhere to VFC requirements and guidance for all areas as outlined in CDC's *VFC Operations Guide* (Operations Guide) and (2) recipients conduct site visits at VFC providers (Unit II, chapter C). To ensure the quality of VFC vaccines and the integrity of the VFC program, the Operations Guide requires recipients to conduct:

- an enrollment site visit for all new and reenrolling VFC providers before they receive VFC vaccines,
- compliance site visits for all enrolled and active VFC providers within 12 months of enrollment and every 24 months thereafter,<sup>5</sup>
- scheduled storage and handling site visits at CDC-approved depot providers every 12 months, and
- unannounced storage and handling site visits at a minimum of 5 percent of VFC providers during each cooperative agreement budget period.

**Enrollment site visits** educate providers on implementing VFC program requirements and assess providers' storage and handling equipment. **Compliance site visits** evaluate whether providers are complying with and understand program requirements. **Storage and handling site visits** assess providers' compliance with and knowledge of requirements for storing and handling vaccines.

Site visits allow recipients to determine provider compliance with VFC program requirements, including requirements for vaccine eligibility screening and documentation, accountability, and management. Site visits also evaluate whether vaccines are stored, handled, and administered properly.<sup>6</sup> The goal is to ensure that VFC-eligible children are receiving properly managed and viable vaccines. Recipients also use site visits to identify areas in which providers are doing well and areas needing additional followup, and to provide training for providers on program requirements.

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<sup>4</sup> The five territories are the Commonwealth of Puerto Rico, U.S. Virgin Islands, American Samoa, Guam, and the Northern Mariana Islands. The five cities are Chicago, Houston, New York City, Philadelphia, and San Antonio.

<sup>5</sup> Recipients are not required to conduct compliance site visits at CDC-approved depots.

<sup>6</sup> Proper storage and handling of vaccines ensures that they are kept at the correct temperatures. Vaccines exposed to too much heat, cold, or light may lose their potency, which can render them less effective or even useless, and unable to provide immunity for vaccinated individuals.

After a compliance or storage and handling site visit has been conducted, the recipient must discuss the outcome with the provider and agree on a plan with followup actions and deadlines for addressing identified compliance issues or opportunities for improvement. Followup actions are mandatory corrective actions that providers must implement within a given timeframe. Examples of followup actions include but are not limited to documenting screening of patient eligibility for vaccines, documenting the temperature of vaccine storage units, removing expired vaccines from storage units, and placing appropriate thermometers in storage units.

### **CDC's Provider Education, Assessment, and Reporting Online System**

The Operations Guide requires that program recipients use CDC's Provider Education, Assessment, and Reporting (PEAR) online system to document provider site visits and any compliance issues identified during those visits. PEAR contains reviewer guides that recipients must use to conduct site visits, with a series of questions that recipients must address during each visit. For each question, onsite or followup actions are specified to address identified compliance issues. Each followup action includes a due date for completion, ranging from immediate (onsite actions) to 6 months after the site visit. Followup actions may require action by either the provider or the recipient, or both. An example of a required recipient action would be conducting a followup site visit to verify completion of a followup action by the provider.

PEAR serves as an oversight management tool for both CDC and program recipients, as discussed in the following sections.

#### *CDC's Management of the VFC Program Using the PEAR Online System*

PEAR serves as an oversight management tool for CDC. According to CDC officials, as part of its oversight of the VFC program, CDC performed annual testing of PEAR to ensure data validity and system integrity, performed an annual review of PEAR dashboards (which are graphical, real-time representations of data in PEAR) and reports, and routinely analyzed PEAR data. Additionally, before the COVID-19 pandemic, as part of its oversight, CDC conducted regular technical assistance site visits at all 61 recipients annually to review each recipient's data, dashboards, and reports, and addressed overdue site visits and followup actions.

#### *Program Recipients' Management of the VFC Program Using the PEAR Online System*

PEAR also serves as an oversight management tool for recipients. PEAR collects relevant VFC data to support overall program activities and is used to document recipients' quality assurance activities, capture recipients' compliance with various policies and reporting requirements, and note provider noncompliance when applicable. CDC requires recipients to use PEAR to: (1) document followup actions for compliance issues identified during site visits and (2) monitor and evaluate program performance. PEAR enables recipients to track providers' progress on followup actions and to maintain information on other contacts (e.g., by email or phone) with

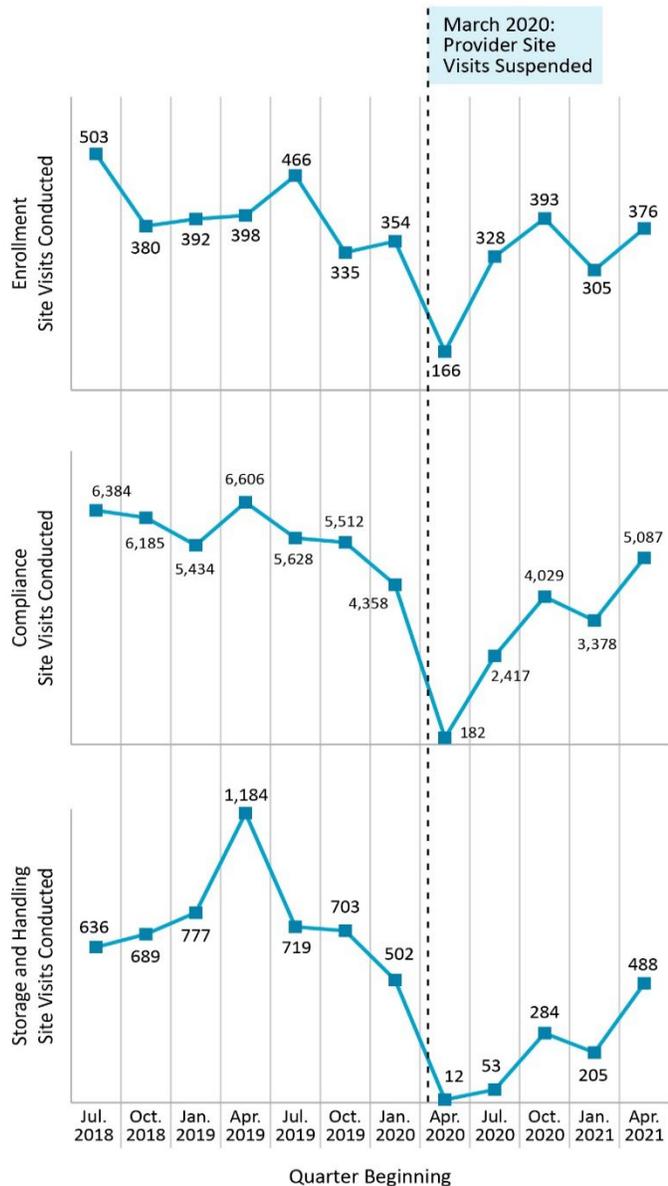
VFC providers unrelated to site visits. Recipients can use the PEAR dashboards and reports to monitor provider and program level issues and trends.

### Impact of the COVID-19 Pandemic on the VFC Program

CDC officials described to us the impact of the COVID-19 pandemic on the VFC program, especially with respect to recipients' ability to conduct site visits. Staffing constraints, travel restrictions, re-prioritizing of resources, and temporary provider closures were all reasons that CDC offered to explain why recipients delayed site visits. According to CDC officials, because of CDC's own staffing constraints, CDC delayed its work on developing internal written policies and procedures for program oversight. Key staff were deployed for multiple extended periods to support COVID-19-related activities, which required delaying or suspending routine calls with recipients and annual site visits to provide technical assistance to recipients.

CDC suspended all provider site visits by recipients in mid-March 2020 but required recipients to submit plans for ensuring providers' proper storage and handling of vaccines. In mid-May 2020, CDC allowed recipients to resume in-person site visits at their discretion. In addition, CDC authorized hybrid site visits in July 2020 and virtual site visits in August 2020.<sup>7</sup> Figure 1 shows the number of site visits of each type conducted from July 1, 2018, through June 30, 2021, by quarter. The variations in the number of site visits conducted reflected the changes in CDC's guidance.

**Figure 1: The Number of Site Visits That Program Recipients Conducted Significantly Decreased Starting in March 2020 and Gradually Increased Over the Remainder of 2020 and in 2021**



<sup>7</sup> A hybrid visit is a compliance site visit that is conducted partly in-person (onsite) and partly remotely. A virtual visit is an enrollment, compliance, or storage and handling site visit conducted entirely remotely.

## HOW WE CONDUCTED THIS AUDIT

We reviewed CDC's operations manuals and guidance related to VFC program requirements for site visits at providers. We identified 39,122 providers, consisting of 39,120 providers that administered VFC vaccines and 2 CDC-approved depot providers, that were enrolled and active at any point from July 1, 2020, through June 30, 2021 (audit period).<sup>8</sup> To determine whether the 61 program recipients conducted the required site visits at providers, we reviewed 3 years' worth of PEAR data (July 1, 2018, through June 30, 2021) for all enrollment, compliance, and storage and handling site visits conducted at the identified providers. We determined the "due date" of a provider's next required site visit and calculated the number of days of delay for an overdue site visit. To determine whether providers completed followup actions by the PEAR system-assigned deadlines, we reviewed the PEAR data for 127,594 followup actions associated with these site visits. We analyzed the status of these followup actions and identified the number of days between the assigned deadlines and the actual completion dates.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology.

## FINDINGS

CDC's VFC program recipients conducted enrollment site visits for all newly enrolled and reenrolling VFC providers as required. However, recipients did not meet all program requirements for conducting compliance site visits and storage and handling site visits. Specifically:

- Recipients did not conduct compliance site visits in a timely manner at 11,499 of 39,120 enrolled and active providers (29 percent).
- Recipients did not conduct storage and handling site visits at either of the two CDC-approved depot providers.
- Most recipients (43 of 61 recipients) did not conduct storage and handling site visits for at least 5 percent of their providers.

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<sup>8</sup> CDC indicated that there were three CDC-approved depot providers. However, we determined that one of the CDC-approved depot providers that was enrolled and active during our audit period was not included in the PEAR data because the program recipient did not accurately enroll the provider. CDC officials stated that the recipient was working to correct the enrollment error.

- Recipients did not verify that providers completed followup actions by the deadlines for 33,316 of 127,594 issues (26 percent) identified during compliance and storage and handling site visits.

CDC officials stated that staffing constraints and the COVID-19 pandemic were reasons that recipients did not conduct site visits at some providers as required. CDC officials also stated that, during the COVID-19 pandemic, CDC and recipients were focused on the priority of COVID-19 vaccination program development and vaccine distribution, some providers were temporarily closed, and travel was restricted. In addition, we found that CDC did not have internal written policies and procedures for CDC's monitoring and oversight activities, including oversight of recipients' site visits at providers. Finally, CDC's PEAR online system did not have interactive reminders or alerts related to overdue site visits and followup actions. Because recipients did not conduct site visits as required or verify that providers completed followup actions to address identified compliance issues, CDC and recipients could not ensure that providers were complying with VFC program requirements.

### **PROGRAM RECIPIENTS DID NOT CONDUCT COMPLIANCE SITE VISITS IN A TIMELY MANNER AT SOME PROVIDERS**

According to the Operations Guide, recipients must conduct compliance site visits that cover different compliance areas at each VFC provider at least every 24 months. These areas include provider information (e.g., the names of key staff and the number of VFC-eligible children served by the provider), patient eligibility, documentation (e.g., screening and eligibility, billing records, temperature logs, and vaccine-ordering records), storage and handling of vaccines, and inventory management. The first compliance site visit for newly enrolled or reenrolled providers must be completed within 12 months of enrollment.

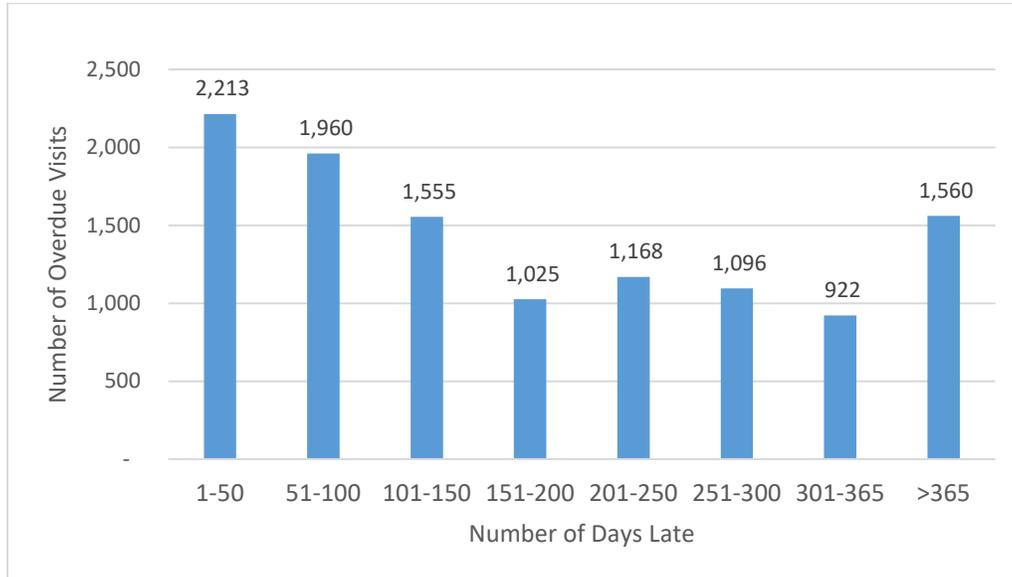
Recipients did not conduct the required compliance site visits in a timely manner at 11,499 of the 39,120 providers (29 percent) that were enrolled and active during our audit period. Specifically, recipients did not conduct the required compliance site visits at 10,365 providers within the 24-month timeframe and did not conduct the first compliance visit at 1,134 providers within 12 months of the provider's enrollment.<sup>9</sup>

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<sup>9</sup> Of the 10,365 providers, 455 should have had a compliance site visit before CDC allowed suspension of site visits (in March 2020) in response to the COVID-19 pandemic. Of the 1,134 providers, 263 should have had their first compliance site visit before CDC allowed suspension of site visits.

Figure 2 shows the number of overdue compliance site visits by the number of days the site visits were late.<sup>10</sup>

**Figure 2: The Number of Overdue Compliance Site Visits Conducted by Program Recipients**



**PROGRAM RECIPIENTS DID NOT CONDUCT STORAGE AND HANDLING SITE VISITS AT EITHER OF THE CDC-APPROVED DEPOT PROVIDERS**

According to the Operations Guide, recipients are required to perform a scheduled storage and handling site visit at each CDC-approved depot provider every 12 months to ensure compliance with storage and handling requirements.

For each of the two CDC-approved depot providers that were enrolled and active during our audit period, recipients did not conduct the required storage and handling site visits within the 12-month timeframe. Specifically, neither of these depot providers had any storage and handling site visits in the 3-year period from July 1, 2018, through June 30, 2021.

**MOST PROGRAM RECIPIENTS DID NOT CONDUCT STORAGE AND HANDLING SITE VISITS AT A MINIMUM OF 5 PERCENT OF PROVIDERS**

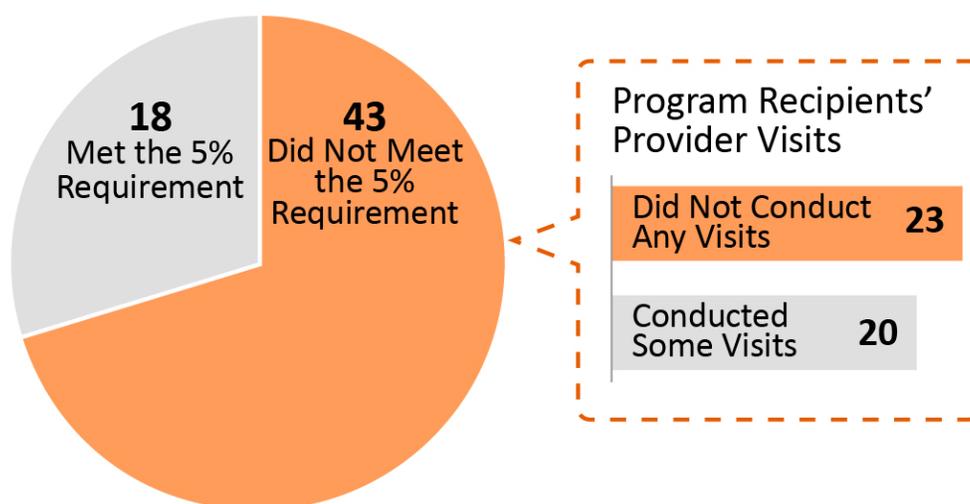
According to the Operations Guide, recipients are required to conduct unannounced storage and handling site visits at a minimum of 5 percent of VFC providers during each cooperative

<sup>10</sup> To determine the “due date” of a provider’s next required compliance site visit, we used: (1) the provider’s enrollment date and added 12 months for a newly enrolled or reenrolled provider or (2) the date of the provider’s prior compliance site visit and added 24 months. We then determined the number of days of delay for an overdue site visit by counting the number of days that had elapsed between the due date and the actual date of the first compliance site visit if one had been conducted or the provider’s unenrollment date if applicable or June 30, 2021 (the last date of site visits in the 3-year period), whichever was earlier.

agreement budget period. Because of the COVID-19 pandemic, CDC allowed recipients to conduct scheduled storage and handling site visits in lieu of unannounced visits, effective August 28, 2020.

Of the 61 recipients, 43 did not conduct storage and handling site visits at a minimum of 5 percent of their providers. To meet the requirement, these 43 recipients should have conducted storage and handling site visits at 1,268 providers. However, the recipients conducted storage and handling site visits at 277 providers. Of those 43 recipients, 23 did not conduct any storage and handling site visits during our audit period, which was the same as the cooperative agreement budget period. (See Figure 3.)

**Figure 3: Most Program Recipients Did Not Meet the 5-Percent Requirement**



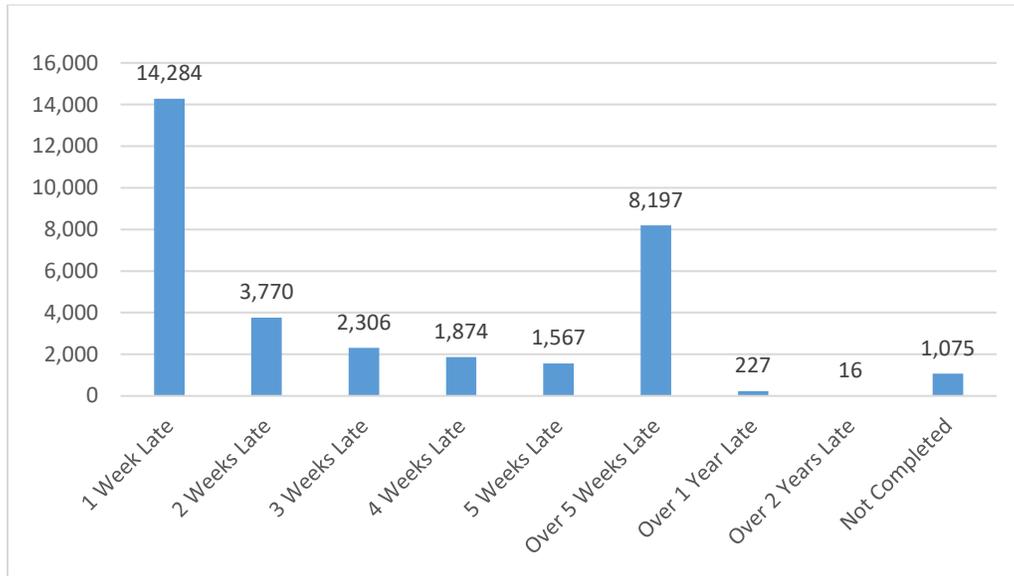
### **PROGRAM RECIPIENTS DID NOT VERIFY THAT PROVIDERS COMPLETED FOLLOWUP ACTIONS BY THE DEADLINE**

According to the Operations Guide, recipients are required to use PEAR to document recipient or provider followup actions for compliance issues identified during a site visit. Recipients should also review planned and required provider followup actions in PEAR that are overdue or have not been implemented.

Recipients did not verify that providers completed by the deadline 33,316 of the 127,594 followup actions required for issues identified during compliance and storage and handling site visits. As shown in Figure 4 on the next page, of overdue followup actions, approximately 43 percent were completed within 1 week after the deadline. However, more than 8,000 followup actions were not completed in the first 5 weeks after the deadline, and more than 200 followup actions were not completed until 1 or 2 years after the deadline.<sup>11</sup>

<sup>11</sup> In Figure 4, the 1,075 followup actions that were not completed by the deadline had not been completed as of January 28, 2022, which was the date that CDC retrieved the data.

**Figure 4: The Number of Overdue Followup Actions Completed by Providers**



**SITE VISITS WERE NOT CONDUCTED AND FOLLOWUP ACTIONS WERE NOT COMPLETED BECAUSE OF RECIPIENTS’ STAFFING CONSTRAINTS AND CDC’S LACK OF WRITTEN POLICIES**

CDC officials stated that recipients’ staffing constraints (e.g., a hiring freeze, high rate of staff turnover within immunization programs, and reassigning staff to work on COVID-19-related areas) were significant reasons that recipients did not conduct compliance site visits and storage and handling site visits, both before and during the COVID-19 pandemic. CDC officials also stated that, during the COVID-19 pandemic, CDC and recipients were focused on the priority of COVID-19 vaccination program development and vaccine distribution, some providers were temporarily closed, and travel was restricted. For 3 years since the pandemic started in March 2020, CDC has not enforced site visit requirements, even though these requirements have been in effect and CDC authorized alternatives to conducting site visits in-person (e.g., allowing recipients to make hybrid and virtual site visits and allowing recipients to schedule storage and handling visits in lieu of unannounced visits).<sup>12</sup>

In addition, CDC did not have internal written policies and procedures for CDC’s monitoring and oversight activities related to the VFC program, including oversight of recipient site visits at providers to ensure that requirements are met. CDC started developing these internal policies before the COVID-19 pandemic, but as of April 2023, these internal policies had not been issued. According to CDC officials, this work was delayed because of competing priorities of the pandemic. Furthermore, although PEAR could generate dashboards and reports that provided information on site visits and followup actions, there were no interactive reminders or alerts to inform and remind CDC and recipients about: (1) overdue site visits and recipients’ progress

<sup>12</sup> On January 11, 2023, CDC officials stated that they planned to start enforcing the site visit requirements on July 1, 2023.

toward meeting the 5-percent requirement and (2) followup actions that had not been completed by the deadlines.

## **CONCLUSION**

Program recipients' site visits evaluate whether providers are complying with and understand overall VFC program requirements. Site visits are intended to ensure the quality of VFC vaccines and the integrity of the VFC program. Proper storage and handling of vaccines is important in preventing the loss of vaccines due to exposure to temperatures outside of allowable limits and ensuring their effectiveness. Because recipients did not conduct compliance and storage and handling site visits as required or verify that providers had completed followup actions to address identified compliance issues, CDC and recipients could not ensure that providers were complying with VFC program requirements.

## **RECOMMENDATIONS**

We recommend that the Centers for Disease Control and Prevention:

- work with program recipients to implement a plan and timeline to: (1) conduct the required site visits that are overdue and (2) verify the completion of followup actions that had not been completed by the deadlines;
- develop an action plan to enforce site visit requirements by CDC's planned date of July 1, 2023;
- complete the development and implementation of internal written policies and procedures for VFC program oversight activities, including oversight of program recipients' site visits to ensure that requirements are met; and
- update its Provider Education, Assessment, and Reporting online system to include interactive reminders or alerts related to overdue site visits and followup actions.

## **CDC COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, CDC concurred with our recommendations and described actions that it had taken or planned to take to address our recommendations. CDC stated that it will: (1) work with recipients that have overdue site visits to develop an implementation plan and timeline for conducting those site visits; (2) develop an action plan to provide guidance to recipients for site visits and followup actions; (3) complete and implement internal written policies and procedures for VFC program oversight activities; and (4) make enhancements to its PEAR online system, including sending automatic email alerts to recipients and CDC staff regarding site visits and followup actions. In addition, CDC provided detailed information to emphasize the impact of the COVID-19 pandemic on the VFC program.

After reviewing the information provided by CDC, we updated our description of the impact of the COVID-19 pandemic on the VFC program on page 5 of the report.

CDC also provided technical comments on our draft report, which we addressed as appropriate. CDC's comments, excluding the technical comments, are included in their entirety as Appendix B.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

We reviewed CDC's operations manuals and guidance related to VFC program requirements for site visits at providers. We identified 39,122 providers, consisting of 39,120 providers that administered VFC vaccines and 2 CDC-approved depot providers, that were enrolled and active at any point from July 1, 2020, through June 30, 2021. To determine whether the 61 program recipients conducted the required site visits at providers, we reviewed 3 years' worth of data (July 1, 2018, through June 30, 2021) for all enrollment, compliance, and storage and handling site visits conducted at the identified providers. We determined the "due date" of a provider's next required site visit and calculated the number of days of delay for an overdue site visit. To determine whether providers completed followup actions by the deadlines, we also reviewed the data for 127,594 followup actions associated with these site visits. We analyzed the status of these followup actions and identified the number of days between the assigned deadlines and the actual completion dates.

We did not assess the overall internal control structure of CDC. Rather, we limited our review to CDC's internal controls related to its oversight activities for ensuring that recipients conducted required site visits. To determine the effectiveness of the design and implementation of these internal controls, we interviewed CDC officials, reviewed CDC's operating manuals related to program requirements and the PEAR online system, and reviewed provider and site visit data from PEAR. Our review of PEAR data allowed us to evaluate the operating effectiveness of internal controls.

We conducted our audit from January 2022 to April 2023.

### METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal regulations and guidance;
- reviewed CDC's operations manuals to identify VFC program requirements;
- reviewed CDC guidance issued in response to the COVID-19 pandemic;
- interviewed CDC officials to identify CDC's oversight activities related to recipients' conducting of provider site visits;
- obtained data from CDC's PEAR online system for: (1) VFC providers who were enrolled and active during our audit period, (2) site visits conducted at these providers, and (3) providers' followup actions related to these site visits;

- identified 39,122 providers, consisting of 39,120 providers that administered VFC vaccines and 2 CDC-approved depot providers, that were enrolled and active at any point during our audit period;
- reviewed 3 years' worth of data for all enrollment, compliance, and storage and handling site visits conducted at these identified providers;
- reviewed data for 127,594 followup actions associated with the site visits and providers being reviewed; and
- discussed our findings with CDC officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## APPENDIX B: CDC COMMENTS



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30329-4027

**TO:** Amy J. Frontz  
Deputy Inspector General for Audit Services

**FROM:** Centers for Disease Control and Prevention (CDC)

**DATE:** August 9, 2023

**SUBJECT:** Office of the Inspector General (OIG) Draft Report

Attached is the CDC response to the OIG draft report, "*CDC's Vaccines for Children Program Recipients Did Not Conduct Site Visits at Some Providers as Required (A-09-22-01000)*."

Sincerely,

A handwritten signature in cursive script that reads "Mandy K. Cohen".

Mandy K. Cohen, MD, MPH  
Director, Centers for Disease Control and  
Prevention and Administrator, Agency for Toxic  
Substances and Disease Registry

Attachments:  
Response to the report



The Centers for Disease Control and Prevention (CDC) appreciates the Office of the Inspector General's (OIG) time drafting this report; however, it does not acknowledge that during the time period analyzed, public health staff (CDC and state-level) were expected to focus on the top COVID-19 priority: vaccination program development and vaccine distribution. During the pandemic, the charge of the Vaccine for Children (VFC) program fundamentally changed. VFC program priorities shifted from routine operations to primarily supporting COVID-19 vaccine availability for children in the face of this emergency. COVID-19 vaccine distribution was the largest single vaccine distribution effort in U.S. history with the volume of the vaccines distributed within the first two years of the COVID-19 response far exceeding the annual VFC program. Developing and implementing this emergency program from the ground up involved thousands of immunization personnel, who were already limited in number prior to 2020. The same personnel who are responsible for VFC site visits were responsible for this historic vaccination program, which required activities including COVID-19 vaccination provider enrollment, vaccinator training, coordination of vaccine orders and transport, provider site visits, communications, and so forth. This report does not thoroughly describe the real-world factors that led to a temporary decrease or delay in VFC site visit numbers. During the analyzed audit period, these include:

- Almost all VFC staff were reassigned to work on COVID-19 response activities during the 2019-2021 budget period.
- Temporary provider location closures and limits on personnel allowed in provider offices, with many providers conducting business via telehealth.
- Federal and state restrictions on travel for personnel, which prevented most official travel during this time period.

During this same audit period in 2020-2021, the VFC program priorities fundamentally shifted from routine operations (routine site visits, updating SOPs/manuals, etc.) to using and expanding the VFC infrastructure to support COVID-19 vaccination. While VFC site visits were reduced during the pandemic, CDC still conducted more than 5,000 COVID-19 vaccination-specific site visits and associated follow-ups in 2020-2021. CDC and awardee staff continued to support and be flexible where possible, despite severe challenges. For example,

- Calls with individual awardees were repurposed to focus on COVID-19 vaccination activities. Only the group routine VFC calls for all awardees in aggregate were delayed or suspended.
- Technical assistance continued to be provided to awardees through ad hoc individual calls and fully functioning VFC and Provider Education, Assessment, and Reporting (PEAR) helpdesks.

Since the time period analyzed in this report, CDC has made headway in reducing overdue site visits. Currently, eight percent of providers are overdue for a site visit, which is much improved from pandemic numbers (29 percent during the audit period). CDC's plans will focus on ensuring that awardees have strategies to prevent severely overdue site visits in the future.



CDC would like to request that in the report, this fundamental shift in VFC program prioritization and data surrounding the COVID pandemic context to include in the executive summary, the call-out section on the COVID context, and the conclusions section.

OIG recommends that CDC:

- 1) Work with program recipients to implement a plan and timeline to (a) conduct the required site visits that are overdue and (b) verify the completion of follow-up actions that had not been completed by the deadlines.

**CDC Response:** CDC concurs and will work with awardees with overdue site visits to develop an implementation plan and timeline for conducting overdue visits. VFC program recipients have been able to drastically reduce the number of overdue VFC site visits and outstanding follow-up actions as the VFC program has worked closely with awardees through routine check ins and enhanced technical assistance. Since the OIG audit period, the proportion of overdue VFC compliance site visits have decreased from 11,499 providers overdue (29 percent) to 2971 providers overdue (eight percent) nationwide. In addition, as of the current budget period (which began July 1, 2023), more than half of all awardees have already met the requirement for conducting unannounced storage and handling visits with providers.

- 2) Develop an action plan to enforce site visit requirements by CDC's planned date of July 1, 2023.

**CDC Response:** CDC concurs and is developing an awardee action plan to provide guidance to awardees for site visits and follow up action catch up activities. This action plan will be shared with awardees in September 2023.

- 3) Complete the development and implementation of internal written policies and procedures for VFC program oversight activities, including oversight of program recipients' site visits to ensure that requirements are met.

**CDC Response:** CDC concurs and will complete and implement internal written policies and procedures for VFC program oversight activities. The anticipated completion date is September 2023.

- 4) Update its Provider Education, Assessment, and Reporting online system to include interactive reminders or alerts related to overdue site visits and follow-up actions.

**CDC Response:** CDC concurs and is in the process of making enhancements to PEAR that will supplement current functionality by sending automatic email alerts to immunization program awardees and CDC staff (i.e., project officers, VFC program staff) regarding site



visits and follow-up actions when a certain threshold of overdue providers per jurisdiction is reached. These enhancements will also include an interactive oversight dashboard for awardee leadership (e.g., content administrators) and site visit reviewers regarding overdue visits and follow-up actions. These updates are scheduled to go live in late August 2023.