2022-2023 VFC Site Visit Guidance
Cycle 7/1/2022 through 6/30/2023

Site visits are conducted with VFC providers to assess compliance with VFC program requirements. This includes identifying potential issues with accountability and determining if VFC vaccines are being stored, handled, and administered appropriately. Site visits are opportunities to engage provider staff and strengthen relationships. It is the LHD reviewer's responsibility to assure the practice understands VFC requirements.

The goals of these visits are to:

- Identify areas where providers are doing well and areas needing additional follow-up
- Identify educational needs of VFC providers in order to support them with meeting requirements
- Ensure that VFC-eligible children receive properly managed and viable vaccine

Training Requirements

All LHD staff conducting VFC site visits are required to attend the MDHHS Quality Improvement & VFC Site Visit Training Webinar in addition to the training held by their MDHHS Field Representative (FR). FR training can be in-person or conducted using a virtual platform. Before initiating visits this cycle, LHD staff must receive approval from their MDHHS Field Representative to start scheduling their visits. LHD staff who are new to conducting VFC & QI visits must be observed by their FR or an LHD seasoned site visitor (approved by the MDHHS Field Rep) prior to being approved for conducting site visits. MDHHS Field Representatives must also perform VFC and QI Observations as required.

Frequency

In Michigan, local health department (LHD) staff must conduct site visits to all VFC providers. Per CDC requirements, no more than 24 months may lapse from the date of their prior site visit. Most VFC or AVP providers receive the standard "Compliance Visit": See "Visit Requirements for Select Providers" for more details.

- Yearly visits are encouraged but cannot be sooner than 11 months from prior compliance visit
- The City of Detroit must visit 100% of their sites every funding cycle

Preparation & Tools for Support

A variety of tools have been created to support site reviewers/consultants as well as the provider. These include pre-visit and post-visit letters to send to the provider, as well as checklists for preparation for the reviewer and provider.

- Always use the most recent Site Visit Reviewer Guide from PEAR (questionnaire)
- **VFC Documents for Site Reviewer Support (posted online at www.Michigan.gov/SiteVisitGuidance):**
    1. General Site Visit Notice for All Providers
    2. Site Visit Confirmation Letter: QI/VFC Combined or QI only
    3. VFC Reviewer Checklist: Pre-, During, and Post-Visit
    4. VFC Frequently Used Reviewer Tools
        - Documentation Companion
        - Additional storage unit sheets when several units are assessed
    5. VFC/PEAR Specific Resources
        - PEAR Section 7: Michigan Specific Follow-up Reference Guide
    6. Post-Visit Follow-up Letter
    7. Documenting Annual Training in PEAR

Section 7: Awardee Policies & Procedures

All but one of the Michigan-specific requirements below have been added to their most relevant PEAR question. If applicable, they are found on the gold line within the question stating: "View additional requirements from your program".

- Corrective actions can be **"added"** where indicated. If selected it will then appear in the Provider Follow-up Plan.
- The ONLY required documentation that is not addressed is in question **5.5** regarding the backup data logger:
    - Please enter the model number, calibration date, and expiration date of the backup data logger in the "Reviewer Note" section of PEAR.

- If charting via paper, ensure you print and use the **"PEAR Section 7: Michigan Specific Follow-up Reference Guide".**

VFC/QI Site Visit Options

Conducting VFC Compliance/QI Visit

QI visits and VFC Compliance visits can be performed together or separately. Traditionally, VFC and QI visits have occurred at the same visit, however, the option is now available to conduct separated VFC and QI site visits. The VFC Compliance visit and QI visit can still be completed on the same day or the VFC Compliance visit and the QI visit can occur on different days.

Sites that do not receive the VFC Compliance and/or QI visit this year must receive their VFC Compliance and/or QI visit in the following year. The VFC and QI visit do not need to be performed by the same LHD staff member.

VFC Compliance Site Visit Documentation & PEAR

- CDC requires that all visits be conducted **online in PEAR during the visit** if internet access is available. Document and submit visit in PEAR **on the same day** that the visit was performed.
- If a visit must be completed on paper, enter visit into PEAR as soon as possible, but no later than 10 business days of the visit. Be sure to use the date of the actual visit. Reviewers must document a reason for performing a paper site visit.
- If, during the site visit, a provider does not meet requirements nor agree to make changes necessary to meet them, consult your MDHHS Field Representative. Every effort must be made to bring providers into compliance before removing them from the program.

QI visit documentation & REDCap*

- Generation of the CDC Standard QI report and documentation of Provider on time vaccination percentages and goals must be entered into the correct Project Year in the REDCap QI database prior to the QI visit. This information must be entered into the database no more than 10 business days prior, as well.
- All other QI documentation can occur during the QI visit or after the QI visit has been completed
    - There are paper tools to record and take notes about the QI visit (if you are not documenting into the QI database) on the www.michigan.gov/sitevisitguidance web page
- Documentation must be completed within 10 business days of the QI visit
- All QI follow ups must be recorded into the provider's site in the QI database for the current project year
    - Consultants must adhere to the follow up timelines to receive payment for a completed QI cycle at the 12-month follow up visit

Multi-Site QI Visits

- The IQIP Program now offers the option to conduct QI collectively with multiple locations within a Provider Group or Health System
- **The Consultant must get approval from their MDHHS Field Rep prior to scheduling the visit**
- The Consultant must arrange and conduct the meeting (Virtual or In-Person) with representatives from each Provider location
- The CDC Standard QI report must be generated for each provider in the multi-site visit and all QI data must be entered for each location in the current REDCap Project Year QI database according to Michigan guidelines*
- 2-month, 6-month, and 12-month follow ups can be separate or combined - with a representative from each Provider location in attendance
- All QI follow ups must be recorded into each provider's site in the QI database for the current project year
    - Consultants must adhere to the follow up timelines to receive payment for a completed QI cycle at the 12-month follow up visit

Enrollment Visit

LHDs must conduct a new enrollment visit with a new VFC or AVP provider before the practice begins immunizing with public vaccine. These visits qualify for payment and should be listed on the Fixed Fees Quarterly Summary Worksheet (FSR). A follow up compliance site visit must be conducted within 3-6 months of the enrollment visit. If this full compliance visit is not completed in this timeframe, it MUST be completed within 12 months.

- Once an enrollment is processed in MCIR and the provider is assigned a VFC PIN – the three-month count-down begins! After three months, the enrollment will expire if it is not complete.
- Enrollment checklists are available to support the provider, and the previous enrollment checklist for site reviewers has been updated. The enrollment checklist for providers will be posted on the VFC Resource Guide online (www.michigan.gov/VFC), and the checklist for site reviewers will be posted on the Site Visit Guidance website (www.michigan.gov/SiteVisitGuidance).
- Enrollment is documented in PEAR within: "Tools"➔"Provider Management", search for PIN, click "Continue" and then select Enrollment Visit. Assess all questions for "met" or "unmet". Complete documentation of the enrollment visit: click on "Open Notepad". This is an open text field to document details of the visit. When this enrollment visit section is finished and all areas "met", notify MDHHS VFC for final activation.

Visit Requirements for Select Provider Types

Standard VFC Provider

- All VFC providers receive a **full VFC Compliance Visit** within 24 months of the previous compliance visit; These providers are maintained in PEAR; therefore, you must utilize PEAR for site visit documentation, online and documented same day (following guidance above in "Site Visit Documentation & PEAR")
- All Michigan VFC Providers receive a **Quality Improvement (QI)** visit within 24 months of the previous QI visit; these providers are maintained in REDCap, defined by Project Years, therefore, you must utilize the current Project Year in REDCap for QI visit documentation.
- QI visits can be performed with all your VFC Compliance visits every year, or you can perform the QI visit with 50% of your VFC Providers in one QI Cycle and the other 50% in the next QI Cycle. A minimum of 50% of the VFC providers must receive a QI visit every year.
- All documentation for the VFC Compliance Visit and the QI visit must be recorded and submitted in their respective databases within 10 business days
- **Detroit requires that all their VFC Providers receive a VFC Compliance visit every year**

Tribal Health Centers

- Please visit tribal health centers **annually**, rather than within the 24-month expectation of CDC and performing the **full VFC Compliance Visit**. Therefore, if 11 months have elapsed since a tribal health center has been seen, they should be scheduled for a visit this cycle.

Adult-Only Providers (MI-AVP only)

- These providers receive a **full VFC Compliance Visit.** These providers are not maintained in PEAR; therefore, you must utilize the **paper** Reviewer Guide & email or fax the completed form to the VFC Coordinator upon completion. Be sure to also bring the paper Follow-up Plan to identify provider compliance/noncompliance issues for their follow-up.

Hepatitis A-Only Providers

- These providers receive an **Announced Storage & Handling Visit**. These providers are typically not maintained in PEAR if they are adult-only. Utilize the paper Reviewer Guide & email or fax to the VFC Coordinator. Also utilize the paper Follow-up Plans to share with the provider on compliancy/non-compliancy (if the visit information is not entered in PEAR, a follow-up plan is not automatically generated).

Universal Hepatitis B Vaccine Providers: Birthing Hospital Visits

- These providers receive a **full VFC Compliance Visit**; Hospitals participating in the Universal Hep B Program have unique screening requirements because all children are eligible for the birth dose of Hep B. Universal Hep B sites are not required to document each child's eligibility in the chart or immunization record. Assistance with responses to questions regarding eligibility, documentation and storage and handling is outlined below:

  - **Section 2: Eligibility**
    - Q 2.1 - Staff can clearly describe all VFC eligibility criteria. A-F mark YES.
    - Q 2.2 - Bill insurance only for the cost of vaccine administration. A-E mark YES. F mark N/A. G mark N/A.
    - Q 2.3 - Administration fee no more than $23.03
  - **Section 3: Documentation**
    - Q3.1 – A & B mark YES, C: 10, D & E mark YES, F mark NO
    - Q3.2 – Must review 10 records and answer B appropriately
    - Q3.3 – Mark YES
    - Q3.4 – Mark NO, skip to 3.6
  - **Section 6: Inventory**
    - Q6.1 – Assess that inventory proportionately reflects populations identified on the Provider Profile
    - Q6.2 - YES because Universal Hepatitis B providers are specialty providers offering selected vaccines.
    - Q6.2C – N/A, provider does not serve population eligible for non-routine vaccines
    - Q6.3A - N/A because the Provider is in a universal state and does not carry private stock

Unannounced Storage & Handling Visits

CDC requires that 5% of providers receive an unannounced S&H visit each cycle: This equates to 60 providers in Michigan. LHDs are allowed to conduct unannounced storage and handling visits and receive reimbursement of $100. To request approval, email Heather Barnes (BarnesH2@michigan.gov). These visits can only be completed if eligible according to current CDC requirements (e.g., visits cannot be performed for providers who have any visit that is either in "In progress" or "submitted" status).

VFC Site Visit Guidance:
Temporary Authorizations Related to COVID-19

These are temporary authorizations. CDC will designate when virtual/hybrid approaches are no longer permitted.

Virtual VFC Enrollment Visit Guidance

Reviewers may temporarily conduct virtual enrollment visits (i.e., via phone or webinar). CDC recommends conducting virtual enrollment visits in areas where there are limited enrolled providers or a recent increase in eligible persons which exceeds the capacity of currently enrolled providers (i.e., access challenges). Enrollment requirements remain the same; however, components normally done in-person may be assessed remotely such as:

- Electronic submission of vaccine management and emergency response plan
- Electronic submission of temperature documentation
- Pictures of storage units (inside and out)
- Pictures of digital data logger (DDL) probe placement
- Certificates of calibration
- Pictures of "Do Not Disconnect" signs
- Training: VFC training and MCIR VIM training

Visit Formats Temporarily Available - VFC options: VFC visits may occur in-person or using two new temporary alternative options: Hybrid VFC site visit or a fully Virtual VFC site visit. See below for information on Hybrid and Virtual VFC visits (compliance and storage and handling visits).

Hybrid Compliance Site Visit Guidance

To reduce the amount of time reviewers must spend physically onsite conducting a site visit, LHDs may conduct hybrid (virtual + remote) compliance visits. The remote (virtual) half of the hybrid compliance site visit must be performed prior to the in-person portion. Tele-IQIP and the virtual portion of a Hybrid VFC visit may occur on the same day.

The following portions of the visit may occur **remotely and prior to the in-person portion:**

- All of Section 1 (provider details)
- Most of Section 2 (eligibility; except 2.1)
- Billing practices, admin fee
- Most of Section 3 (documentation; except 3.1, 3.2, and 3.6)
- Record retention, borrowing documentation, VIS, VAERS
- All of Section 7 (awardee policies and procedures, unless awardee policies or procedures relate to vaccine storage and handling)
- Any required training associated with the visit

The following portions of the visit must occur **in-person**:

- Q 2.1: Eligibility categories
- Q 3.1: Intake process, records review for eligibility
- Q 3.2: Records review for dose documentation
- Q 3.6: Vaccine management plan
- All of Section 4 (storage and handling: per unit)
- All of Section 5 (storage and handling: site wide)
- All of Section 6 (inventory)
- The remote portion of the visit must occur **prior to the in-person portion**. This will allow reviewers to distribute the Provider Follow-Up Plan and collect a signed copy of the required Acknowledgment of Receipt. Reviewers should conduct any remote portions of the visit as close to the in-person portion of the visit as possible. **Both portions must be conducted and documented in PEAR within 10 business days.**

Any required training associated with the visit should occur after the in-person portion of the visit is conducted. This ensures providers answer questions based on their clinic practices instead of the training received.
NOTE: This is temporary; CDC will designate when we must resume conducting compliance visits in-person.

Documentation for Hybrid Visits
Use the following guidance to document hybrid compliance visits in PEAR:

- Document all hybrid visits as "This visit was conducted using the hybrid "method"
- **Date of visit**: Enter the date when the **in-person site visit is completed or is scheduled to be completed**

Virtual VFC Visit (Compliance Visit and/or Storage and Handling Visit)

LHDs may conduct virtual VFC compliance and storage and handling site visits as an alternative to in person or hybrid (virtual + in-person) site visits**.** CDC will notify when in-person visits must be resumed. Virtual VFC site visits must adhere to existing VFC guidance related to not sharing reviewer guide content with providers at any time. A virtual visit can occur fully remotely. The virtual visit must occur via either a web-conference platform such as Teams, Skype, Zoom, etc. or via telephone. However**, a virtual platform with screensharing functionality must be utilized for document/record review using HIPAA-compliant processes.** Below are additional requirements:

- Reviewers must utilize a virtual platform with screensharing functionality for document/record review
- Reviewers must use HIPAA-compliant processes and platforms when conducting record reviews or conduct that portion of the site visit in-person to protect personally identifiable information. If this cannot be achieved, then the provider is NOT eligible for a virtual VFC compliance visit.

Information Regarding Virtual Storage & Handling Assessment: Use of a portable device (e.g., phone, tablet, laptop) is recommended for storage unit inspections. However, you may request for providers who lack mobile devices to walk around the practice and send picture(s) of the storage unit (inside and out) beforehand for review during the visit

You may choose to request temperature monitoring documentation through pre-visit notification and communication. If a provider is unable to present their storage unit using the selected virtual platform with screensharing functionality, reviewers must collect the following electronic storage and handling documentation:

- Pictures of storage units (inside and out)
- Pictures of digital data logger (DDL) probe placement
- Certificates of calibration
- Three months of temperature documentation (i.e., temperature logs or digital data logger [DDL] reports)
- Pictures of "Do Not Disconnect" Signage Placement

Documentation of Virtual Visit

- Select the option in PEAR when starting visit "This visit was conducted virtually on" and add date
- Document and submit conducted visit online in PEAR
- Submit visit in PEAR on the same day that the visit was performed. If unable to submit on the same day - submit within 10 business days.

Site Visit Follow-up for Questions Normally Requiring an On-Site Follow-up Visit

The following guidance was provided in a document "COVID-19 Guidance for On-Site PEAR Follow-up Actions". Please use the following to complete follow-ups that would normally require a follow-up site visit.

Question 1.2 – Changes to Key Staff

- **Reviewer – Immediate Follow-up**: Provide training on all key requirements during compliance site visit. If this is not possible, schedule a follow-up educational visit. [Source: PEAR]
- **COVID-19 Guidance**: Reviewers should provide follow-up education via phone or webinar instead of scheduling a follow-up educational visit.

Question 2.3 – Vaccine Administration Fees

- **Reviewer – Six months:** Perform follow-up site visit to assess whether the provider is charging a vaccine administration fee that exceeds the state CMS fee cap. If the provider continues to bill above the CMS cap, add custom follow-up in PEAR based on immunization program protocol. [Source: PEAR]
- **COVID-19 Guidance:** Reviewers should request required documentation via email or fax. Alternatively, reviewers may assess via webinar if providers/staff are able to share their screens while reviewing electronic patient records.

Question 3.1 – Eligibility Screening and Documentation

- **Sub question A OR F – Reviewer – Six months**: Conduct a follow-up site visit to observe the screening and intake process. Review a random selection of patient records containing an immunization visit since the date of the compliance visit to determine whether eligibility is being assessed and documented properly. (Note: Number must be proportional to the provider's overall patient population but not fewer than 20.) If the provider is still not fully compliant, add follow-up based on immunization program protocols and fraud and abuse and/or restitution policies as applicable until the issue is resolved. [Source: PEAR]
- **COVID-19 Guidance:** Reviewers may assess via webinar if providers/staff are able to share their screens while reviewing electronic patient records. If not, reviewers should accept documentation of the clinic's revised protocols as compliance to complete the required follow-up and submit the completed follow-up plan for the compliance visit.

Question 6.3 – Separation of Stock

- **Reviewer – Six months:** Conduct a follow-up site visit to assess whether the provider can differentiate public stock from private stock (if applicable). [Source: PEAR]
- **COVID-19 Guidance:** Reviewer should request photos of their current storage unit setup to assess separation of stock remotely.