

# 2020-2021 VFC Site Visit Guidance Cycle 7/1/2020 through 6/30/2021

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.



**For COVID-19 Guidance Including Temporary Allowances & Alternate Visit Formats – see page 3**

## 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 training by their MDHHS Field Representative. Before initiating visits this cycle, LHD staff must attend the MDHHS VFC & QI Site Visit Training Webinar and receive approval from their MDHHS Field Representative to start 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. This includes pre-visit and post-visit letters to send 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](http://www.Michigan.gov/SiteVisitGuidance)):**
  1. General Site Visit Notice for All Providers
  2. Immunization Site Visit Confirmation Letter
  3. VFC Reviewer Checklist: Pre-, During, and Post-Visit
  - 4a. Documentation Companion
  - 4b. Only storage unit sheets, to print extras when several units are assessed
  - 5a. Section 7 Awardee-Specific Follow-up Reference Guide
  - 5b: Section 7 Paper Assessment Tool
  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.

- These appear within PEAR to "add" where indicated – They will then appear in Follow-up Plan.
- The ONLY remaining question to assess in PEAR, that is not addressed throughout, will be **7.1** below:
  - For 7.1, Select YES if the provider has saved/bookmarked the VFC Resource Guide and Provider Manual. Select NO if provider does not have the VFC Resource Guide and Provider Manual saved/bookmarked.
- If charting via paper, ensure you print the "Section 7 Paper Assessment Tool"

## 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.
- If 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 removal.

## 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 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.
- **NEW** 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](http://www.michigan.gov/VFC)), and the checklist for site reviewers will be posted on the Site Visit Guidance website ([www.michigan.gov/SiteVisitGuidance](http://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”. 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”)

### 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. These providers will also be identified in monthly PEAR reports generated by the VFC Coordinator (highlighted in green).

### 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 to VFC Coordinator upon completion. Be sure to also bring the paper Follow-up Plan to identify provider compliance/noncompliance 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 paper Reviewer Guide & email or fax to VFC Coordinator. Also utilize the paper Follow-up Plans to share with the provider on compliancy/non-compliancy (if not entered in PEAR, a follow-up plan 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. Universal Hep B sites are not required to document each child’s eligibility in the chart or immunization record. Assistance for 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.
- 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

### VFC Mass Vaccination Provider (VFC Influenza-Only Mass Vaccinator)

CDC Definition: Stores AND/OR administers vaccine only for mass vaccination clinics.

These providers must follow a typical enrollment process but sign an additional enrollment form specific to VFC flu-only vaccinators. CDC indicates that mass vaccinators receive a **full VFC Compliance Visit PLUS** see “note” below; If they have VFC/pediatric vaccine, they will be entered in PEAR and the visit can be performed online in PEAR.

- **NOTE:** Visit must assess (in the SAME DAY) both the facility that stores vaccines AND at least one mass clinic that receives vaccines from this storage facility (assuming all clinics are being conducted under the same protocols)

### MI-AVP Flu-Only Provider (Enrolling for flu-only AVP vaccine)

These are providers onboarding as part of the enhanced flu vaccination efforts for the 2020-2021 flu season. Non-traditional AVP providers may enroll and receive public flu vaccine. These providers must follow a typical enrollment process but sign an additional enrollment form specific to flu-only vaccinators (public flu vaccinator agreement). They are eligible to receive an **Announced Storage & Handling Visit (Same as providers enrolled for HepA only)**. Utilize paper Reviewer Guide & email or fax to VFC Coordinator. Also utilize the paper Follow-up Plans to share with the provider on compliancy/non-compliancy (if not entered in PEAR, a follow-up plan not automatically generated)

### Other Non-Traditional Providers – Enrolling for public COVID vaccine

To be determined. CDC has not yet provided details on enrollment and oversight of COVID vaccine providers. We anticipate these providers will receive follow a typical enrollment process but sign an additional enrollment form specific to their participation as a COVID-only vaccinator. However, further details will be shared when available.

### NEW – Unannounced Storage & Handling Visits

This year, the option is available for LHDs to conduct unannounced storage and handling visits. CDC requires that 5% of providers receive an unannounced S&H visit each cycle: This equates to 60 providers in Michigan. Traditionally, Field Representatives have performed these visits; However, this year we are offering LHD staff the opportunity to perform these visits and receive reimbursement (a specific column has been added to the FSR). LHDs may request approval to perform an unannounced visit to occur at the time of a required INE for vaccine losses > \$1500. To request approval, email Maria McGinnis & Darcy Wildt. As all visits, 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). **CDC has modified the “unannounced” aspect of these visit for this year only as follows:**

- Reviewers should conduct scheduled storage and handling visits in lieu of unannounced storage and handling visits. (Note: scheduled storage and handling visits WILL count towards awardee’s 5% unannounced storage and handling visit cooperative agreement requirements for the 2020-2021 budget period [7/1/2020-6/30/2021].)

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

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

### Safety Guidance for Performing In-Person Site Visits

For those that conduct in-person visits, staff must follow CDC’s “Awardee Safety Guidance for VFC and IQIP Visits.”

### Storage and Handling Contact (Spot Check) Guidance

Awardees should discontinue storage and handling spot checks now that virtual site visits have been authorized.

## Digital Data Logger Calibration Expiration Due Dates

It is a requirement to maintain digital data logger calibration up-to-date and not permit a lapse in expiration. However, for providers faced with challenges that impede the ability to maintain this requirement due to COVID-19, CDC will allow a one-time extension to the calibration expiration date ONLY for certificates expiring this calendar year. The due date may be extended to January 1, 2021. For example, a certificate set to expire 6/30/2020 could be extended to 1/1/2021 if it is identified that the provider is unable to recalibrate the device immediately due to COVID-19. This would likely be assessed in real-time, such as at the time of a site visit rather than promoted, because up-to-date calibration should be sought as the standard. A site reviewer reviewing calibration dates and noting an expired device can document expiration as 1/1/21 if the provider indicates that they are unable to re-calibrate the device due to COVID-19 circumstances. A note should also be added in PEAR. We want to caution that if the device begins to drift or there is concern with its accuracy and it is found to be expired, please aim to recalibrate according to the original due dates rather than applying extension. **As much as feasible, maintaining up-to-date calibration remains the expectation and ensures accurate vaccine storage temperatures.** This approach is simply an alternative meant to support providers faced with fiscal and operational challenges during this challenging time.

## 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 (outside and inside)
- Pictures of DDL probe placement
- Certificates of calibration
- Pictures of “Do Not Disconnect” signs
- Training: VFC training and MCIR VIM training

## NEW OPTIONS for VFC Site Visits

### Conducting Separate VFC compliance/QI Visit

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, with prior MDHHS approval. If your LHD conduct the QI and VFC compliance visits on different dates, every provider receiving a visit must still receive BOTH the VFC compliance and the QI visit, prior to the end of the cycle. If BOTH VFC and QI visits are not conducted in the cycle, FSR payment will be denied. While both visits must occur, the VFC and QI visit do not need to be performed by the same LHD staff member. Combined Tele-IQIP and Virtual VFC compliance visits cannot occur on the same date, however Tele-IQIP and the virtual portion of a Hybrid VFC visit may occur on the same day. When IQIP and VFC are not combined, MDHHS recommends they be separated 1-10 business days, but must be conducted prior to the end of the cycle, June 30 2021.

**NEW 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 submit requests via Survey Monkey to conduct hybrid (virtual + remote) compliance visits. Tele-IQIP and the virtual portion of a Hybrid VFC visit may occur on the same day. When IQIP and VFC visits are not combined, MDHHS recommends they be separated 1-10 business days, but must be conducted prior to the end of the cycle, June 30 2021.

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 “conducted using the hybrid visit 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.
- Combined Tele-IQIP and Virtual VFC compliance visits cannot occur on the same date. MDHHS recommends they be separated 1-10 business day but must be conducted prior to the end of the cycle, June 30, 2021.

**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 use 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 DDL probe placement
- Certificates of calibration
- Three months of temperature documentation (i.e., temperature logs or digital data logger reports)
- Pictures of “Do Not Disconnect” Signage Placement

## Documentation of Virtual Visit

- Select the option in PEAR when starting visit “This visit was performed using the virtual approach”
- Document and submit conducted visit online in PEAR during the visit. Submit visit in PEAR on the same day that the visit was performed. If unable to submit same day, submit within 10 business days.

## **Site Visit Follow-up for Q’s 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.