TEXAS
Health and Human Services

Texas Department of State Health Services

Quality Assurance and Improvement

For TVFC Responsible Entities

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DISCLAIMER

The information presented today is based on the CDC's most recent guidance and may change.

Agenda

- Quality Assurance (QA):
  - Compliance Process, Focusing on Storage and Handling
- Follow-Ups to Site Visits
- Provider Oversight Using Reports
- Quality Improvement: Immunization Quality Improvement for Providers (IQIP)

Quality Assurance

Compliance Process

Purpose of QA

The purpose of QA is to assess, support, and educate the staff regarding Texas Vaccines for Children (TVFC) policies and procedures.

Provider Education Assessment and Reporting (PEAR):

- The Quality Assurance and Improvement (QAI) team uses the PEAR software to document, review, and monitor all TVFC provider site compliance visits.
- PEAR-generated reports are used for quality assurance evaluations of providers' compliance to TVFC program policies.

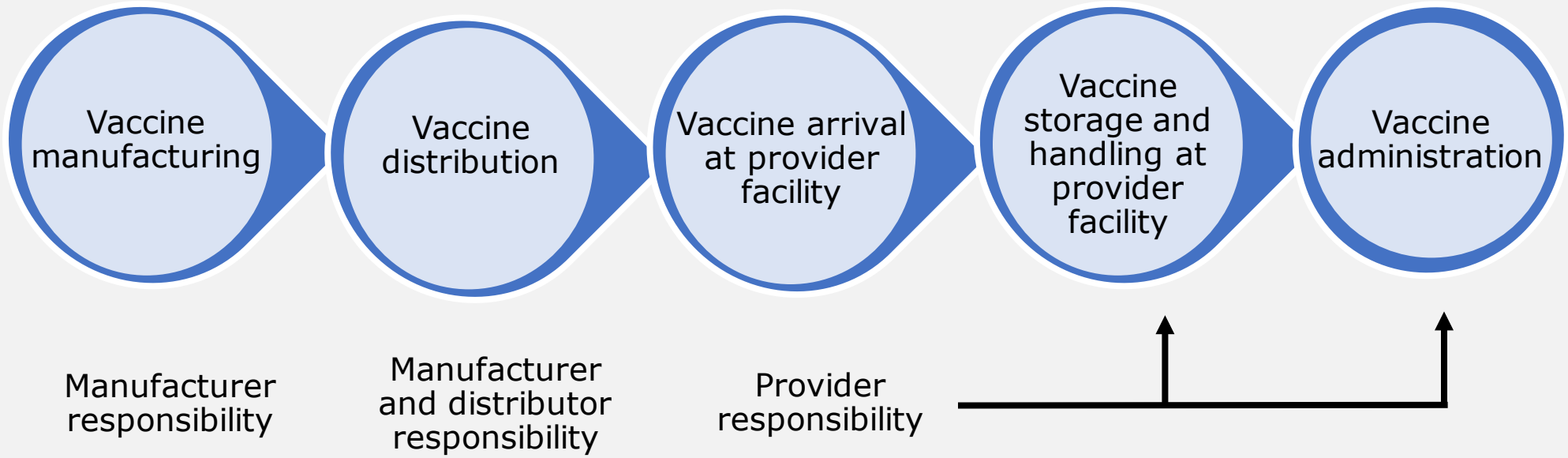
Types of QA Visits

Enrollment Visit: All new program provider enrollees receive the enrollment visit. The new program provider can order vaccines only after this enrollment visit is conducted and completed.

TVFC Compliance Visit: For the TVFC program, compliance visits occur every 12 months with no less than 11 months in between.

Unannounced Storage and Handling (USH) Visits: USH visits can occur anytime within the project year as often as a provider needs assistance. However, there must be at least three months between visit types.

Cold Chain



[CDC Vaccine Storage and Handling Toolkit]

Temperature Ranges

Refrigerators:

- Must maintain temperatures between –36.0°F and 46.0°F (2.0°C and 8.0°C).

Freezers:

- Must maintain temperatures between –58.0°F and 5.0°F (–50.0°C and –15.0°C).

Ultra-cold freezers:

- Must maintain temperatures between –130.0°F and –76.0°F (–90.0°C and –60.0°C).

Storage Unit Type

Acceptable:

- Stand-alone
  - Freezer
  - Refrigerator
- Doorless/vending style
- Ultra-cold freezer

Not Acceptable:

- Dormitory-style
- Bar-style
- Combination
  - Both sections used
  - Freezer section only
  - Refrigerator section only

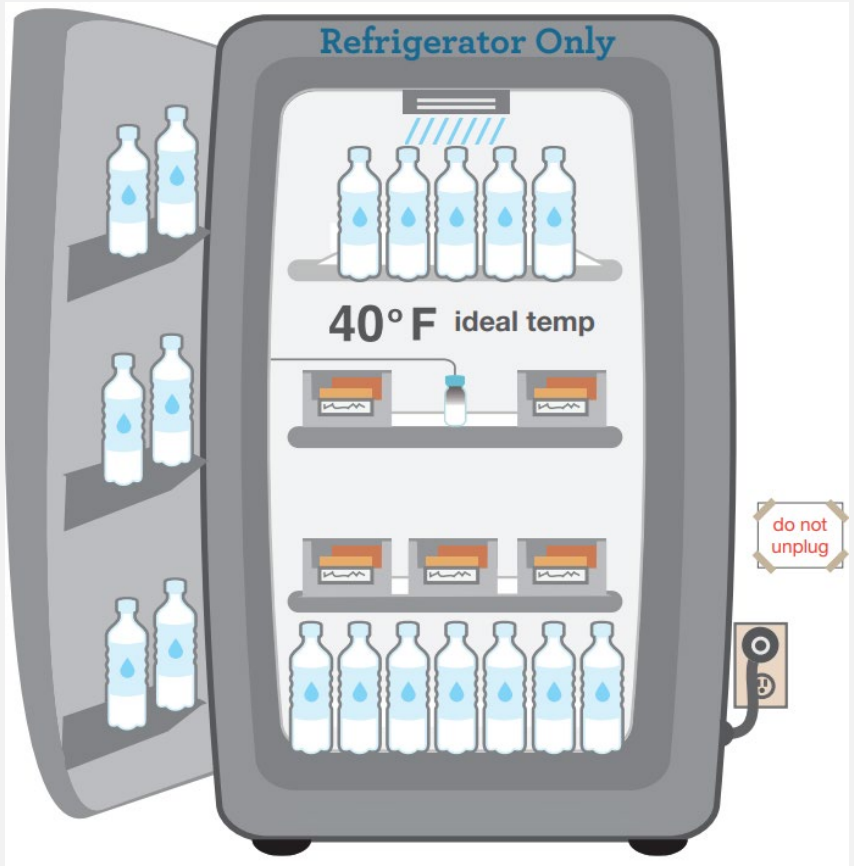
Storage Unit Grade

- Pharmaceutical
- Commercial/household
- Purpose-built

Inside The Unit

- Vaccines
- Digital data logger (DDL) probe
- Water bottles
  - Proper placement
  - Appropriate quantity
  - No gel packs

It is important to prevent overcrowding.



Outside The Unit

- Plug guards
  - "Do Not Disconnect" labels
- Current temperature visible
- Circuit breaker
  - Contact information
  - Labeled as circuit breaker for each unit
  - "Do Not Disconnect" labels
- DDL for each unit

Digital Data Loggers

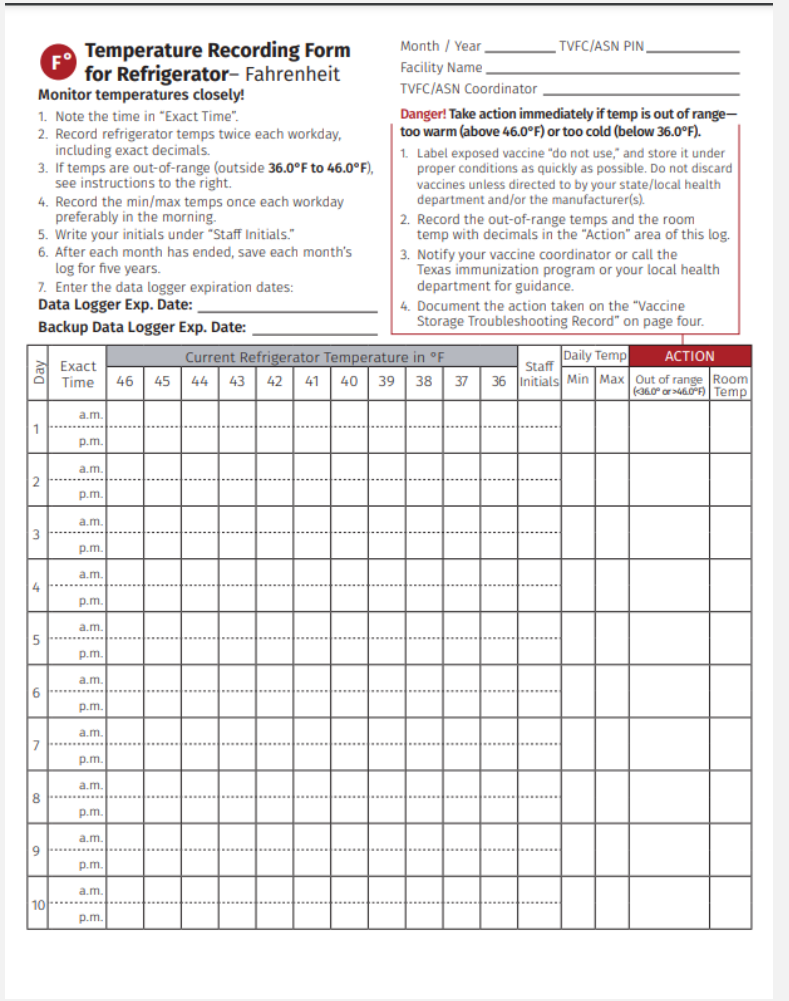
- DDL for each unit
- Backup DDL must be available
- Different expiration dates for backup DDLs (recommended)
- Current and valid certificates of calibration testing

Required Documentation

- Temperature logs
  - Minimum, maximum, and current for refrigerator and freezer
    - Current month
    - Last three months
- DDL certificates of calibration
  - Freezer
  - Refrigerator
  - Backup

Temperature Logs

- Temperature Recording Form PDF



Temperature Recording Form for Refrigerator– Fahrenheit

Monitor temperatures closely!

1. Note the time in "Exact Time".
2. Record refrigerator temps twice each workday, including exact decimals.
3. If temps are out-of-range (outside **36.0°F to 46.0°F**), see instructions to the right.
4. Record the min/max temps once each workday preferably in the morning.
5. Write your initials under "Staff Initials."
6. After each month has ended, save each month's log for five years.
7. Enter the data logger expiration dates:

Data Logger Exp. Date: _____

Backup Data Logger Exp. Date: _____

Month / Year _____ TVFC/ASN PIN _____

Facility Name _____

TVFC/ASN Coordinator _____

Danger! Take action immediately if temp is out of range—too warm (above 46.0°F) or too cold (below 36.0°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp with decimals in the "Action" area of this log.
3. Notify your vaccine coordinator or call the Texas immunization program or your local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page four.

Day	Exact Time	Current Refrigerator Temperature in °F											Staff Initials	Daily Temp		ACTION	
		46	45	44	43	42	41	40	39	38	37	36		Min	Max	Out of range (<36.0° or >46.0°F)	Room Temp
1	a.m.																
	p.m.																
2	a.m.																
	p.m.																
3	a.m.																
	p.m.																
4	a.m.																
	p.m.																
5	a.m.																
	p.m.																
6	a.m.																
	p.m.																
7	a.m.																
	p.m.																
8	a.m.																
	p.m.																
9	a.m.																
	p.m.																
10	a.m.																
	p.m.																

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Temperature Log Steps

Part 1

- Temperature monitoring and recording requirements:
  - Record to the 10th degree (e.g., 23.5°F)
  - Month and year
  - VFC PIN
  - Facility name
  - TVFC coordinator
  - Person recording temperature initials for "AM" and "PM"
  - Exact time temperature was recorded for "AM" and "PM"

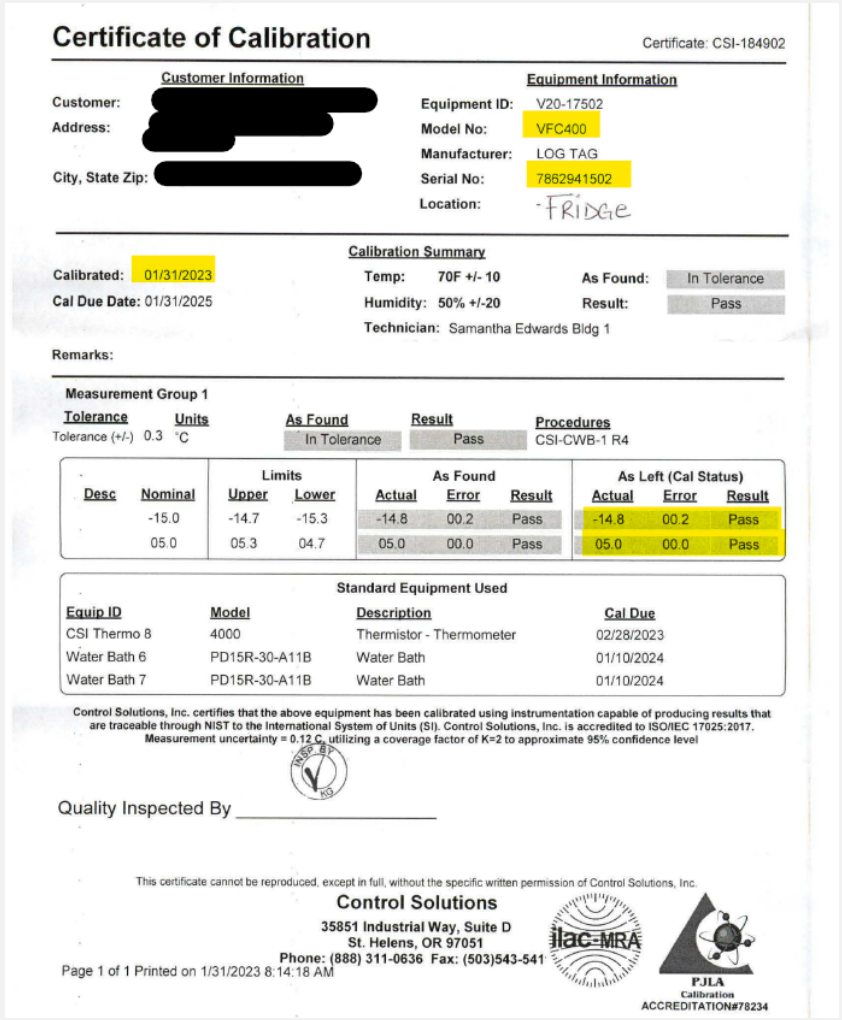
Temperature Log Steps

Part 2

- Record the minimum and maximum temperature to the tenth degree at the beginning of the clinic day.
- Record current temperature for the "AM" and "PM‟ columns to the tenth degree.
- If temperature is out of range, record the temperature in the “Action” section.
- If room thermometer is available, record room temperature in the "AM" and "PM" columns.
- Include data logger expiration date.

Note: Ensure the correct form is used (e.g., refrigerator or freezer, Celsius or Fahrenheit).

Certificates of Calibration Testing



Certificate of Calibration

Certificate: CSI-184902

Customer Information

Customer: [redacted]

Address:

City, State Zip:

Equipment Information

Equipment ID: V20-17502

Model No: VFC400

Manufacturer: LOG TAG

Serial No: 7862941502

Location: FRIDGE

Calibration Summary

Calibrated: 01/31/2023

Cal Due Date: 01/31/2025

Temp: 70F +/- 10

Humidity: 50% +/-20

Technician: Samantha Edwards Bldg 1

As Found: In Tolerance

Result: Pass

Remarks:

Measurement Group 1

Tolerance: Tolerance (+/-) 0.3 °C

Units:

As Found: In Tolerance

Result: Pass

Procedures: CSI-CWB-1 R4

Desc	Nominal	Limits Upper	Limits Lower	As Found Actual	As Found Error	As Found Result	As Left (Cal Status) Actual	As Left (Cal Status) Error	As Left (Cal Status) Result
	-15.0	-14.7	-15.3	-14.8	00.2	Pass	-14.8	00.2	Pass
	05.0	05.3	04.7	05.0	00.0	Pass	05.0	00.0	Pass

Standard Equipment Used

Equip ID	Model	Description	Cal Due
CSI Thermo 8	4000	Thermistor - Thermometer	02/28/2023
Water Bath 6	PD15R-30-A11B	Water Bath	01/10/2024
Water Bath 7	PD15R-30-A11B	Water Bath	01/10/2024

Control Solutions, Inc. certifies that the above equipment has been calibrated using instrumentation capable of producing results that are traceable through NIST to the International System of Units (SI). Control Solutions, Inc. is accredited to ISO/IEC 17025:2017. Measurement uncertainty = 0.12 C, utilizing a coverage factor of K=2 to approximate 95% confidence level

Quality Inspected By _____

This certificate cannot be reproduced, except in full, without the specific written permission of Control Solutions, Inc.

Control Solutions
35851 Industrial Way, Suite D
St. Helens, OR 97051
Phone: (888) 311-0636 Fax: (503)543-541

Page 1 of 1 Printed on 1/31/2023 8:14:18 AM

ilac-MRA

PJLA Calibration ACCREDITATION#78234

- Certificates must contain:
  - Model number
  - Serial number
  - Date of calibration
  - Measurement results indicating that the unit passed testing

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Certificates of Calibration Testing
Continued

- It is important to document that uncertainty is within suitable limits (recommended uncertainty is plus or minus one degree Fahrenheit or 0.5 degree Celsius) and the name of the device.
- It is also important to label certificates with the unit they are for.

Emergency Transport

Emergency Transport

- Emergency transport overview
- Alternative storage facility
- Emergency transport steps
- Acceptable containers
- Pack for transport
- Emergency transport: frozen vaccines

Emergency Transport

Overview

Facilities should:

- Transport for a maximum of 8 hours
- Transport diluents with their corresponding vaccines
- Have a sufficient supply of materials
- Record the temperature throughout all stages of transport

Alternative Storage Facility

Providers must have a working agreement with at least one alternative storage facility. Examples of locations include:

- Hospitals
- Long-term care facilities
- State depots
- The Red Cross
- Fire stations

Alternative storage must have:

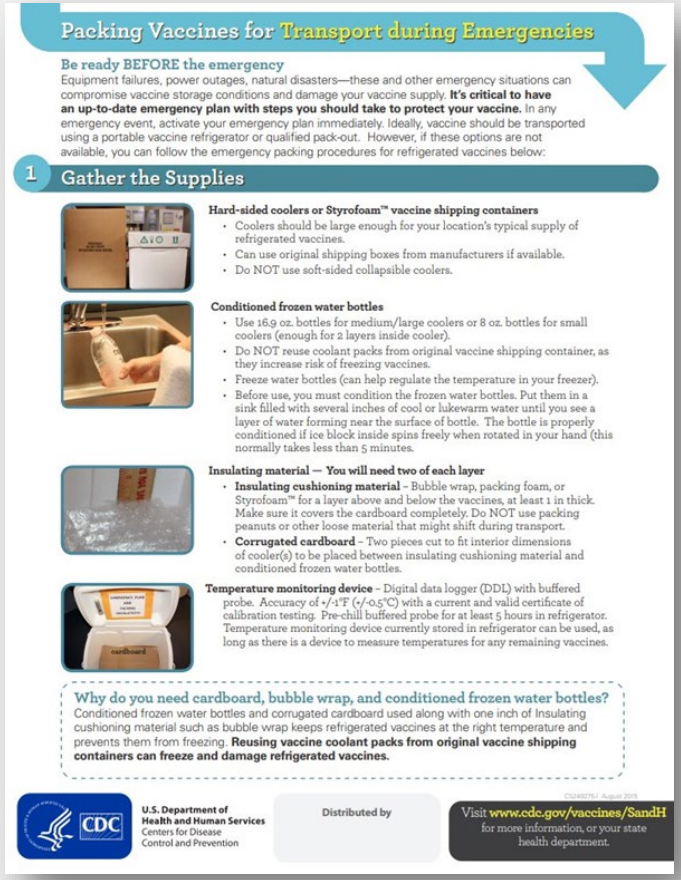
- 24-hour access
- Dedicated unit or shared space that can maintain the required vaccine temperature range between 2 – 8°C

Emergency Transport Steps

1. Gather the supplies
2. Pack for transport
3. Arrive at the destination

Emergency Transport Unit Process

Review the [CDC Emergency Transport Guide.]



Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately. Ideally, vaccine should be transported using a portable vaccine refrigerator or qualified pack-out. However, if these options are not available, you can follow the emergency packing procedures for refrigerated vaccines below:

1 Gather the Supplies

Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.

Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand (this normally takes less than 5 minutes.

Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.

Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of +/-1°F (+/-0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of Insulating cushioning material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Distributed by

Visit www.cdc.gov/vaccines/SandH for more information, or your state health department.

Packing Vaccines for Transport during Emergencies

2 Pack for Transport

Conditioning frozen water bottles (this normally takes less than 5 minutes)

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice "sticks," put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.

8. Temperature Monitoring Device Display (on lid)
7. Conditioned Water Bottles
6. Cardboard Sheet
5. Bubble wrap, packing foam, or Styrofoam™
4. Vaccines, Diluents, and Temperature Monitoring Device Probe
3. Bubble wrap, packing foam, or Styrofoam™
2. Cardboard Sheet
1. Conditioned Water Bottles

Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.

Insulating cushioning material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.
Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.
Vaccines – Stack boxes of vaccines and diluents on top of insulating material.

Insulating cushioning material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

NOTE:
This pack-out can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.
Storage – Transfer boxes of vaccines quickly to storage refrigerator.
Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines "Do Not Use" and store at appropriate temperatures until a determination can be made.

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Gather the Supplies

- Hard-sided coolers or Styrofoam vaccine shipping containers
- Conditioned frozen water bottles
- DDL with buffered probe
- Insulating material in two layers each:
  - Cushioning material like bubble wrap, packing foam, or Styrofoam
  - Corrugated cardboard as two pieces cut to fit inside cooler between cushioning material and conditioned frozen water bottles

Acceptable Containers

Container	Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator or Freezer	Yes
Qualified Container and Packout	Yes
Conditioned Water Bottle Transport System/Packing Vaccines for Transport During Emergencies tool	Yes
Manufacturer's Original Shipping Container	Yes (last resort only)
Food and Beverage Coolers	No

Conditioning Frozen Water Bottles

Part 1

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until a layer of water forms inside the bottle.
- The bottle is properly conditioned if the ice block inside spins freely when rotated in your hand.
- If ice sticks, put the bottle back in the water for another minute.

Conditioning Frozen Water Bottles

Part 2

- Dry each bottle.
- Line the bottom and top of the cooler with a single layer of conditioned water bottles.
- Do not reuse coolant packs from original vaccine shipping container.

Pack for Transport

Part 1

1. Conditioned frozen water bottles: Line bottom of the cooler with a single layer of conditioned water bottles.
2. Insulating material: Place one sheet of corrugated cardboard over water bottles to cover them completely.
3. Insulating material: Place a layer of bubble wrap, packing foam, or Styrofoam on top. The layer must be at least one inch thick and cover cardboard completely.

Pack for Transport

Part 2

4. Vaccines:
   - Stack boxes of vaccines and diluents on top of insulating material.
   - Temperature monitoring device: When the cooler is halfway full, place the DDL buffered probe in the center of vaccines, but keep the DDL display outside cooler until finished loading.
   - Add remaining vaccines and diluents to cooler, covering the DDL probe.

Pack for Transport

Part 3

5. Insulating material: Cover vaccines with another inch layer of bubble wrap, packing foam, or Styrofoam.
6. Insulating material: Another sheet of cardboard may be needed to support top layer of water bottles.
7. Conditioned frozen water bottles: Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.
8. Closing: Close the lid and attach DDL display and temperature log to the top of the lid.

Note: This packout can maintain appropriate temperatures for up to eight hours, but the container should not be opened and closed repeatedly.

Arrive at Destination

- Before opening the cooler: Record date, time, and temperature and initial
- Storage: Transfer vaccines to storage refrigerator
- Troubleshooting temperature excursions:
  - Contact vaccine manufacturer and the Responsible Entity (RE) or Local Health Department (LHD)
  - Label "Do Not Use"
  - Store at appropriate temperature

Temperature Monitoring

- DDL in each container
- Record temperature:
  - Prior to transport
  - During transport (if applicable)
  - Upon arrival
  - While at alternative storage facility

Emergency Transport:
Frozen Vaccines

If it is necessary to transport frozen vaccines, use a portable vaccine freezer unit or qualified container and packout that maintains temperatures between –58.0°F and 5.0°F (–50.0°C and –15.0°C).

Steps for transporting frozen vaccines:

- Place a DDL (preferably with a buffered probe) in the container as close as possible to the vaccines.
- Immediately upon arrival at the destination, unpack the vaccines and place them in a freezer at a temperature range between –58.0°F and 5.0°F (–50.0°C and –15.0°C). Any stand-alone freezer that maintains these temperatures is acceptable.

Temperature Excursion

Definition

- Any temperature reading that is outside the recommended range for vaccine storage as defined in the manufacturer's package insert. Providers should contact the vaccine manufacturer for vaccines involved in a temperature excursion. The CDC lists general temperature ranges for vaccine storage units:
  - Refrigerators: 36.0°F to 46.0°F (2.0°C to 8.0°C)
  - Freezers: –58.0°F to 5.0°F (–50.0°C to –15.0°C)
  - Ultra-cold freezers: –130°F to –76°F (–90°C to –60°C)

Temperature Excursion Steps

1. Notify the RE, the primary vaccine coordinator (PVC), or backup vaccine coordinator (BVC) of the excursion. Notify staff to not use vaccines and isolate the vaccines with a sign that says, "Do not use."
2. Document details of the excursion on page 4 of temperature logs.
3. Contact the manufacturers of the vaccines involved and get direction on the vaccines' viability.
4. Make sure units are in range before adding vaccines back.

TVFC Temperature Recording Form

Resources and General Guidelines

Storage and handling practices and procedures:

- Food and beverages should never be stored in the unit with vaccines.
- Do not store any vaccines in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.
- Never leave a vaccine shipping container unpacked and unattended.

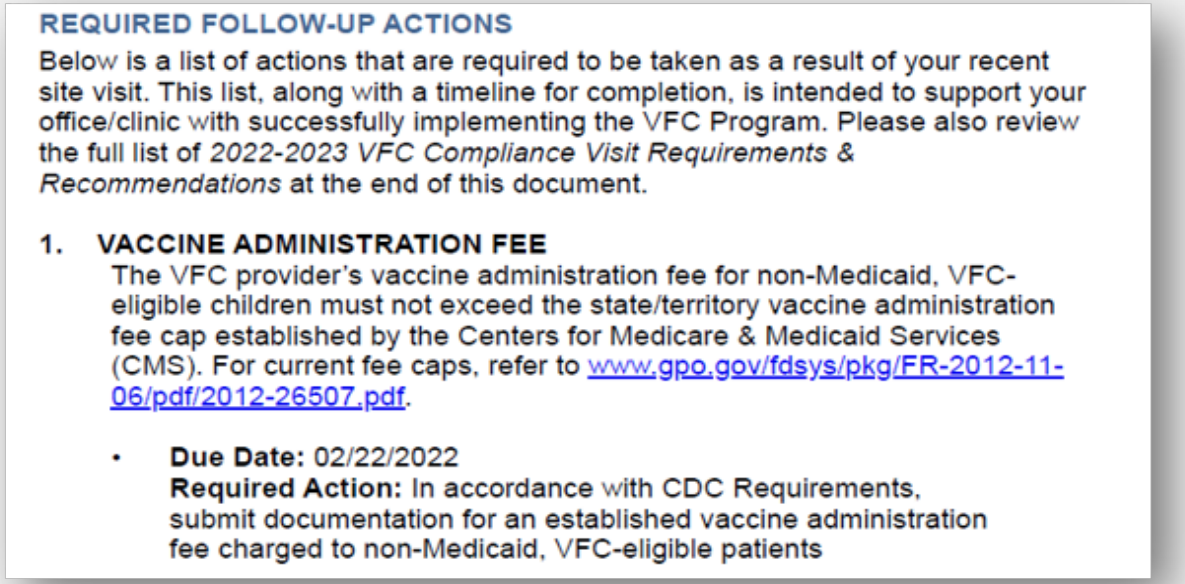
CDC vaccine storage and handling resources:

- Visit CDC Healthcare Providers: Vaccine Storage and Handling.
- Review the CDC Vaccine Storage and Handling Toolkit - March 2024.

PEAR Follow-Up Action Items

Follow-Up Actions

- At the end of every compliance site visit or storage and handling visit, the reviewer will discuss any follow-up actions items with the PVC, BVC, and the signing clinician (SC). Providers must resolve follow-up action items to avoid suspension.
- Follow-up action items example:



REQUIRED FOLLOW-UP ACTIONS

Below is a list of actions that are required to be taken as a result of your recent site visit. This list, along with a timeline for completion, is intended to support your office/clinic with successfully implementing the VFC Program. Please also review the full list of *2022-2023 VFC Compliance Visit Requirements & Recommendations* at the end of this document.

1. **VACCINE ADMINISTRATION FEE**

   The VFC provider's vaccine administration fee for non-Medicaid, VFC-eligible children must not exceed the state/territory vaccine administration fee cap established by the Centers for Medicare & Medicaid Services (CMS). For current fee caps, refer to www.gpo.gov/fdsys/pkg/FR-2012-11-06/pdf/2012-26507.pdf.

   - **Due Date:** 02/22/2022
     Required Action: In accordance with CDC Requirements, submit documentation for an established vaccine administration fee charged to non-Medicaid, VFC-eligible patients

Follow-Up Action List Table

Due Date: Date the noncompliant action item from site visit is due. Follow-up action items are overdue if the site has not resolved the issue by the due date.

Content Area: Displays the section of the PEAR Reviewers Guide where questions and direction are found.

FOLLOW-UP ACTION LIST TABLE SAVE

Due Date	Content Area	Follow-up Type	Action Details	Source	Provider Action Completed on:	Reviewer Action Completed on:	Add or Edit Follow-up	Add or View Attachment
09/13/2023	VACCINE MANAGEMENT PLAN	Immediate Action	Provide a copy of the immunization program Vaccine Management Plan and/or Vaccine Emergency Plan templates.	CDC	N/A	9/13/2023	Add follow-up	Add Attachment
10/13/2023	VACCINE MANAGEMENT PLAN	Document Review	Provider - One month: *Submit updated and complete Vaccine Management Plan.* Add Additional Instruction	CDC	10/6/2023	10/6/2023	Add follow-up	Add Attachment

Follow-Up Type: Immediate Actions are noncompliant actions that site reviewers must correct with the provider at the time of visit.

Follow-Up Type: Document Reviews are for noncompliant actions that the RE must correct with the provider before the due date.

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Follow-Up Action List Table

Continued

Action Details: Displays the noncompliant item and the direction to correct the program infraction.

Provider Action Completed On: Date provider sent supportive documents to resolve noncompliant item.

FOLLOW-UP ACTION LIST TABLE SAVE

Due Date	Content Area	Follow-up Type	Action Details	Source	Provider Action Completed on:	Reviewer Action Completed on:	Add or Edit Follow-up	Add or View Attachment
09/13/2023	VACCINE MANAGEMENT PLAN	Immediate Action	Provide a copy of the immunization program Vaccine Management Plan and/or Vaccine Emergency Plan templates.	CDC	N/A	9/13/2023	Add follow-up	Add Attachment
10/13/2023	VACCINE MANAGEMENT PLAN	Document Review	Provider - One month: *Submit updated and complete Vaccine Management Plan.* Add Additional Instruction	CDC	10/6/2023	10/6/2023	Add follow-up	Add Attachment

Reviewer Action Completed On: Date entered by site reviewer for an immediate action item or by the RE if the due date is at later time.

Add or View Attachment: Area for RE to add attachment to show proof of resolved noncompliant item.

PEAR: Follow-Up Types

Immediate Action:

- Reviewer must complete immediate action items during a site visit.
- Immediate actions can only be prescribed by CDC or the awardee, not reviewers.

Document Review:

- Document review will appear on the "Provider Follow-up Plan." For many instances of noncompliance, the provider must not only remedy the issue but also to submit documents proving completion of the required actions.
- The reviewer must review this documentation to verify completion.

PEAR: Follow-Up Types
Continued

Site Visit:

- Program-specific follow-up site visits to the provider to resolve noncompliance issues found during a compliance or storage and handling visit.
- Reviewer must revisit the provider site at a future date to verify that the site has resolved the issue.

Other Contact:

- Any follow-up needed to resolve noncompliance identified during a visit that is not an on-site visit or a document review.
- Contact can occur using phone or emails to resolve noncompliance issues.

PEAR: Follow-Up Content Areas

Part 1

Reviewer Guide Question	Reviewer Guide Question Content Area	Question Description
1.1	Provider Demographic Information	Please check to confirm that all provider information is current. If there are any changes, please note them in the space.
1.2	Changes to Key Staff	Ask the provider about changes to key staff to answer the questions.
2.1	VFC Eligibility Categories	Was the individual responsible for determining patient VFC eligibility able to explain all the factors (including age) that make a child eligible to receive VFC vaccines?

PEAR: Follow-Up Content Areas

Part 2

Reviewer Guide Question	Reviewer Guide Question Content Area	Question Description
2.2	Billing Practices	Is the individual or department responsible for billing able to clearly explain how they bill for both the cost of vaccine AND the vaccine administration fee for each of the eligibility categories?
2.3	Vaccine Administration Fee	Document the actual vaccine administration fee charged to non-Medicaid, VFC-eligible patients (confirm with billing department).

PEAR: Follow-Up Content Areas

Part 3

Reviewer Guide Question	Reviewer Guide Question Content Area	Question Description
3.1	Eligibility Screening and Documentation	To answer the questions, the provider must clearly demonstrate the patient intake process and review a sample of patient records that contain an immunization visit within the last 6–12 months.
3.2	Vaccine Dose Documentation	Review a MINIMUM of 10 patient immunization records from the last six months (or 12 months if necessary) to assess compliance with documentation requirements set forth by Statute 42 US Code 300aa-25.

PEAR: Follow-Up Content Areas

Part 4

Reviewer Guide Question	Reviewer Guide Question Content Area	Question Description
3.3	Record Retention	Is the provider able to demonstrate (preferred) or clearly describe how they maintain historical VFC eligibility documentation for three years?
3.4	Borrowing Documentation	Review borrowing documentation and discuss borrowing practices with the provider to answer the questions.

PEAR: Follow-Up

Part 5

Reviewer Guide Question	Reviewer Guide Question Content Area	Question Description
3.5	Borrowing Reasons	Based on your discussion with the provider and a review of borrowing reports, document the number of doses borrowed for each reason and answer the questions.
3.6	Vaccine Management Plan	Physically review the provider's Vaccine Management Plan and standard operating procedures (SOPs) to answer the questions.
3.7	VIS and VAERS	Review the providers Vaccine Information Statements (VIS) and discuss providers VAERS process to answer the questions.

PEAR: Follow-Up Content Areas

Part 6

Reviewer Guide Question	Reviewer Guide Question Content Area	Question Description
4.1	Storage Unit Build and Use	Select the build and use of the vaccine storage unit you are assessing.
4.2	Storage Unit Type	Document the grade of the vaccine storage unit you are assessing.
4.3	Thermometer in the Unit	Determine whether there is a thermometer in this section of the storage unit and answer the questions.

PEAR: Follow-Up Content Areas

Part 7

Reviewer Guide Question	Reviewer Guide Question Content Area	Question Description
4.4	Thermometer Type	Assess the thermometer in this section of the storage unit to answer the questions.
4.5	Certificate of Calibration Testing	Review the certificate of calibration testing for the thermometer in this section of the storage unit and answer the questions.
4.6	Thermometer Placement	Is the thermometer properly placed in this section of the storage unit?

Pear: Follow-Up Content Areas

Part 8

Reviewer Guide Question	Reviewer Guide Question Content Area	Question Description
4.7	Temperature Documentation	Review the temperature documentation for this section of the storage unit to determine whether the provider has a process in place for properly documenting temperatures once per day.
4.8	Temperature Excursions	In the event that a temperature excursion(s) occurred in this unit within the last three months, request and review documentation of actions taken to determine whether the provider has a process for properly addressing excursions. Answer the questions.

PEAR: Follow-Up Content Areas

Part 9

Reviewer Guide Question	Reviewer Guide Question Content Area	Question Description
4.9	Vaccine Placement	Look inside the unit to answer the questions.
4.10	Disconnection from Power Source	Ask the provider to demonstrate what measures are taken to ensure that vaccine storage units are not accidentally physically disconnected from the power supply. Which of the following describes the measure(s) taken on this unit?

PEAR: Follow-Up Content Areas

Part 10

Reviewer Guide Question	Reviewer Guide Question Content Area	Question Description
5.1	Cost and Quantity of Vaccines	Have a discussion with the provider about the cost and quantity of VFC vaccines they are responsible for annually. Address the points listed in the Note to Reviewer.
5.2	Dorm-style units	Determine whether the provider has any dorm-style units on site and answer the questions.
5.3	Storage Unit Space Availability	Does the provider have sufficient room across storage units to store current stock as well as any additional stock acquired during peak season without overcrowding?

PEAR: Follow-Up Content Areas

Part 11

Reviewer Guide Question	Reviewer Guide Question Content Area	Question Description
5.4	Expired Vaccines	Look in each unit: Are there expired vaccines in ANY of the vaccine storage units at this site?
5.5	Back-up Thermometer	Does the provider have a readily available back-up thermometer with a current and valid certificate of calibration testing?
5.6	Preparation of Vaccine	When does this provider prepare vaccine for administration to the patient?

PEAR: Follow-Up Content Areas

Part 12

Reviewer Guide Question	Reviewer Guide Question Content Area	Question Description
6.1	Inventory Comparison	Visually inspect storage units to determine if existing supply of vaccines proportionately mirrors populations served as defined by the provider Profile. Choose the most accurate statement.
6.2	ACIP-Recommended Vaccines	Review provider's current inventory to answer the questions

PEAR: Follow-Up Content Areas

Part 13

Reviewer Guide Question	Reviewer Guide Question Content Area	Question Description
6.3	Separation of Stock	Observe how the provider differentiates stock within their practice to answer the questions.
7	Optional Questions	Optional Questions.

PEAR Action Items

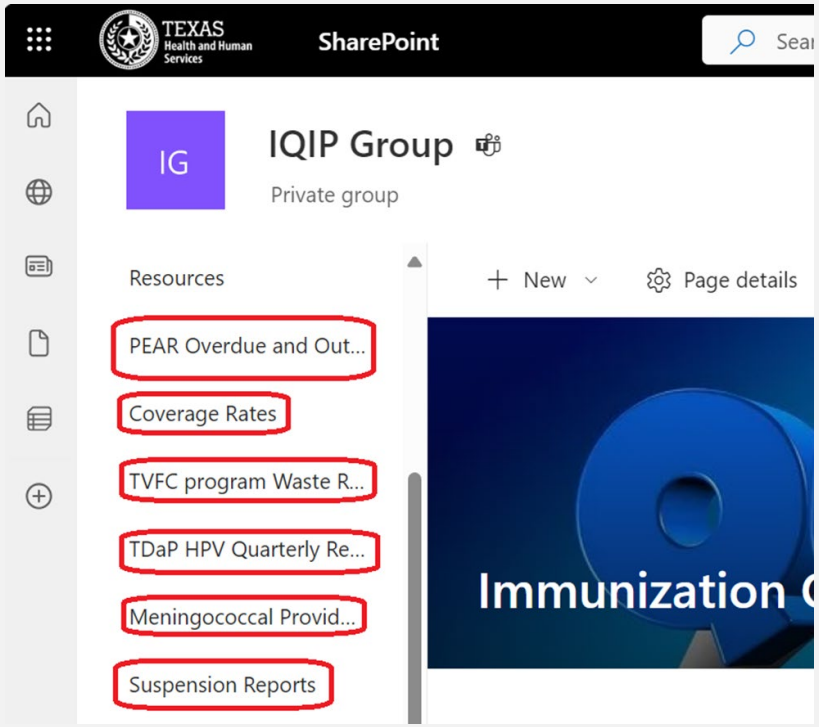
- REs are responsible for the documentation of completed action items and site visit in PEAR. If the assigned LHD or RE cannot complete this, the PHR manager will be responsible.
- It is important to complete all follow-up action items by the due date to avoid suspension.
- A suspended provider will be unable to order vaccines.
- Please use various reports that you can generate from PEAR, or use the reports sent from QAI team and TMF for oversight of follow-up action items.

Provider Oversight

Using Reports

Accessing QAI Reports

- PEAR Overdue and Outstanding
- Coverage Rates
- TVFC Program Waste Report
- Tdap HPV Quarterly Report
- Meningococcal Provider Report
- Suspension Report

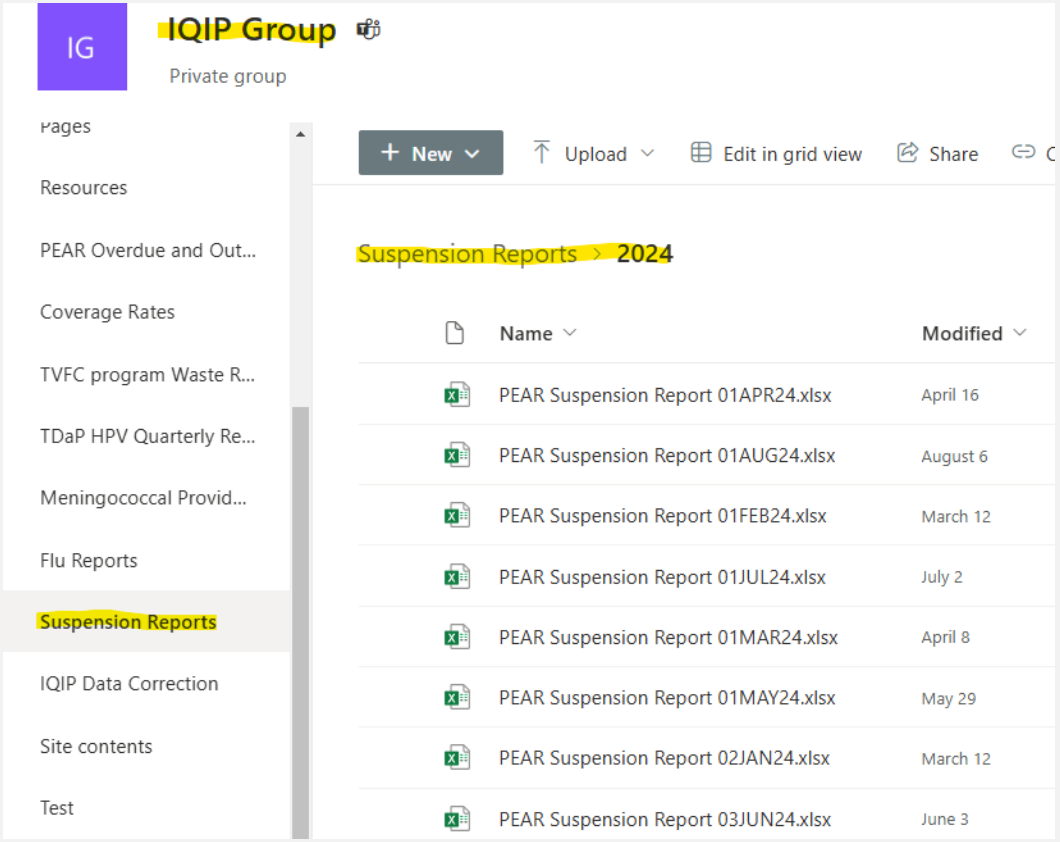


https://txhhs.sharepoint.com/sites/IQIPGroup

Suspension Report

The PEAR Suspension Report Spreadsheet includes:

- A list of newly suspended providers
- A list of currently suspended providers
- A list of providers who will be overdue and face suspension after the next 30 days if action items are not completed



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QAI PEAR Reports

Weekly Reports

The following four reports are sent out to all REs every Monday.

1. Overdue Report: This report has providers listed by region that have not resolved pending action items by the due date post site visit. The provider will get suspended if these are not resolved by the end of the month. REs must prioritize reaching out to these providers.
2. Outstanding Report: This report lists providers that have pending action items, irrespective of the due date.

QAI PEAR Reports

3. Follow-Up Action Item Report: This report shows providers with both overdue and outstanding action items. The reports provides the follow-up due date, follow-up type, content area, and follow-up description of all the action items that are due.

4. Submitted-No Overdue Outstanding Report: This report lists providers who have completed all action items given to them at the site visit. The RE will only need to change the submitted status to completed.

Coverage Rate Report

- This report encompasses the immunizations rates and patient population for a year.
- Providers can see the percentage change over the course of a year for each respective vaccine (e.g., Tdap, polio).
- Providers can use this monthly report to determine their baseline.

Childhood Vaccines

	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
Patients Assessed	101	107	120	122	155	192	207	214	217	226	228	233
DTaP	29%	29%	32%	33%	50%	63%	62%	61%	64%	66%	70%	72%
Polio	47%	45%	48%	48%	59%	70%	70%	68%	70%	72%	75%	77%
MMR	56%	54%	54%	52%	60%	72%	74%	76%	79%	82%	84%	85%
Hib	46%	49%	50%	57%	74%	81%	81%	83%	85%	86%	90%	92%
HepB	47%	46%	47%	48%	61%	73%	72%	71%	73%	74%	78%	79%
Varicella	50%	49%	48%	45%	56%	70%	72%	74%	77%	80%	83%	85%
PCV13	45%	44%	44%	43%	50%	68%	69%	68%	71%	73%	77%	79%
Series	22%	21%	20%	21%	35%	55%	56%	56%	58%	61%	65%	67%
Flu, UTD	53%	52%	53%	52%	58%	67%	66%	67%	70%	70%	71%	71%
Series w/ Flu	17%	16%	16%	16%	26%	46%	46%	47%	49%	53%	57%	58%

Adolescent Vaccines

	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
Patients Assessed	27	31	35	37	52	62	64	69	73	74	71	75
Tdap	81%	84%	80%	81%	71%	74%	77%	74%	75%	76%	75%	76%
MCV4	81%	87%	83%	84%	73%	77%	78%	77%	78%	78%	77%	79%
HPV	37%	48%	49%	51%	48%	47%	50%	51%	48%	46%	46%	45%
HPV, 1 dose	78%	74%	74%	73%	75%	71%	72%	70%	73%	72%	72%	71%

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Texas Department of State Health Services

Vaccine Waste Report

Vaccine Waste Report: IQIP uploads the report to the IQIP group SharePoint page and emails it to TMF (DSHS Contractors) and REs:

- Compliance visits include discussions of vaccine waste data.
- REs can use the data in this report to reach out to providers to prevent future loss.

The Vaccines Waste Report spreadsheet includes:

- A list of providers with corresponding vaccine waste details
- Vaccine waste data from the previous 12 months

Reviewing TMF Reports

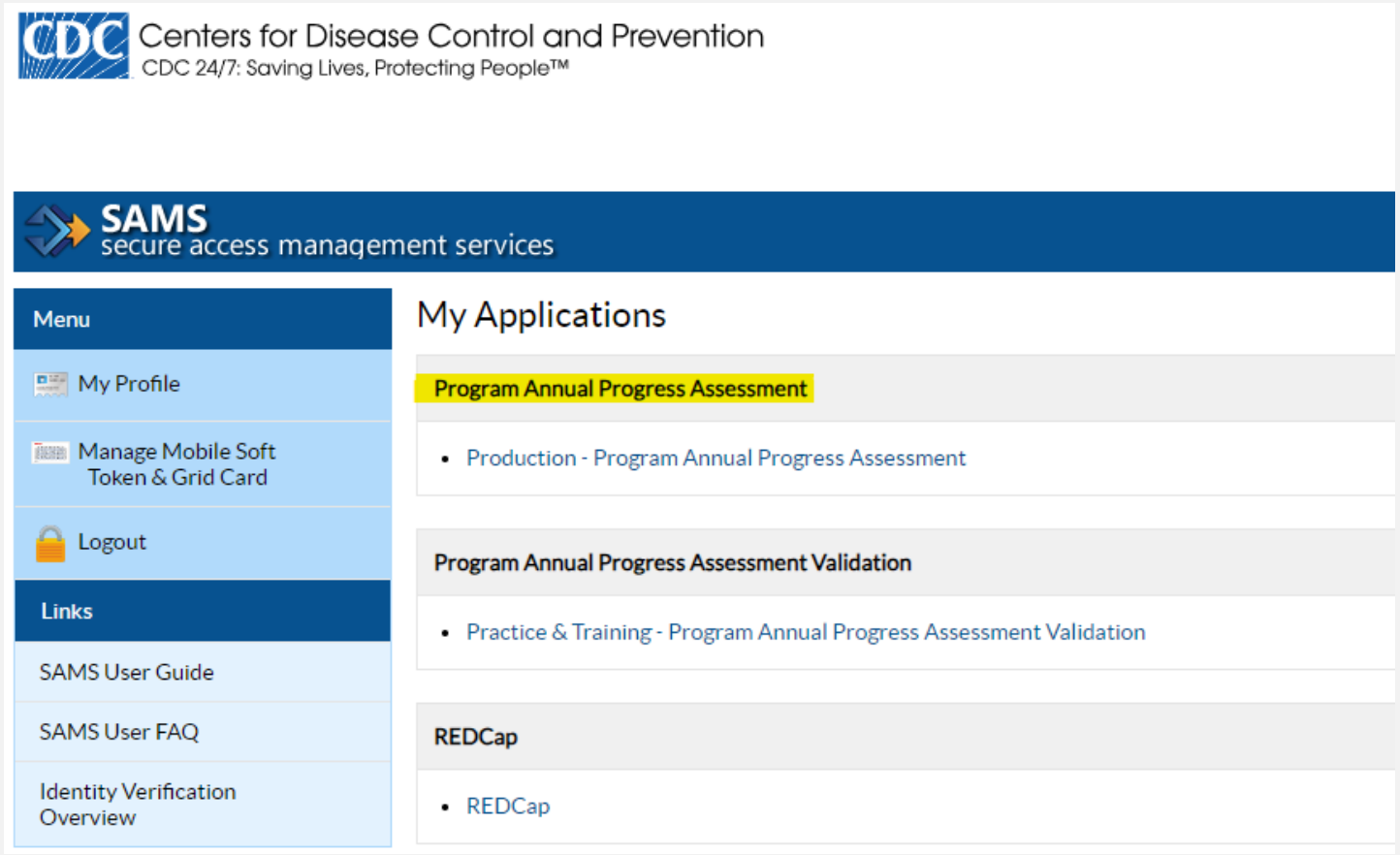
REs receive these mandatory reports on a weekly basis. The report includes:

- Temperature excursions
- Out-of-range temperature excursions
- Vaccines that are expired vaccines or expiring within 90 days
- Overcrowding
- Borrowing
- Nonfunctional data logger
- Dorm-style unit with vaccines on site
- Thermometer probe on the unit wall (permanent)
- Missing emergency supplies

TMF All Regions Site Visit List

- TMF emails the All-Regions Site Visit List report on a weekly basis.
- The All-Regions Site Visit List shows completed and scheduled site visits.
- The report is used by regions to determine which provider needs their site visit reviewed and completed in PEAR system.
- The All-Regions Site Visit List helps regions determine future workload for REs.
- The All-Regions Site Visit List is an oversight tool for timely completion of compliance visits for private providers.

Accessing PEAR Reports



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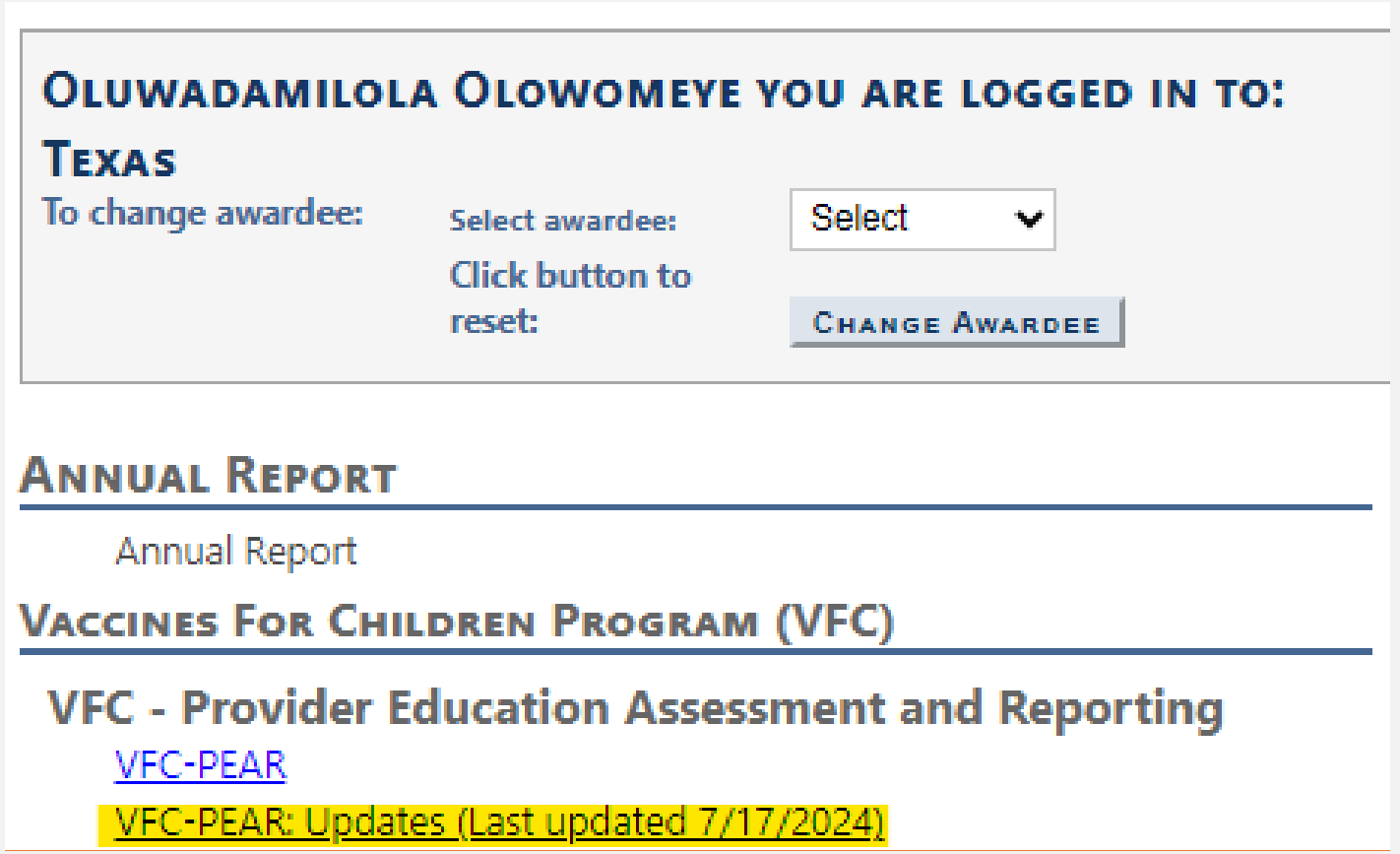
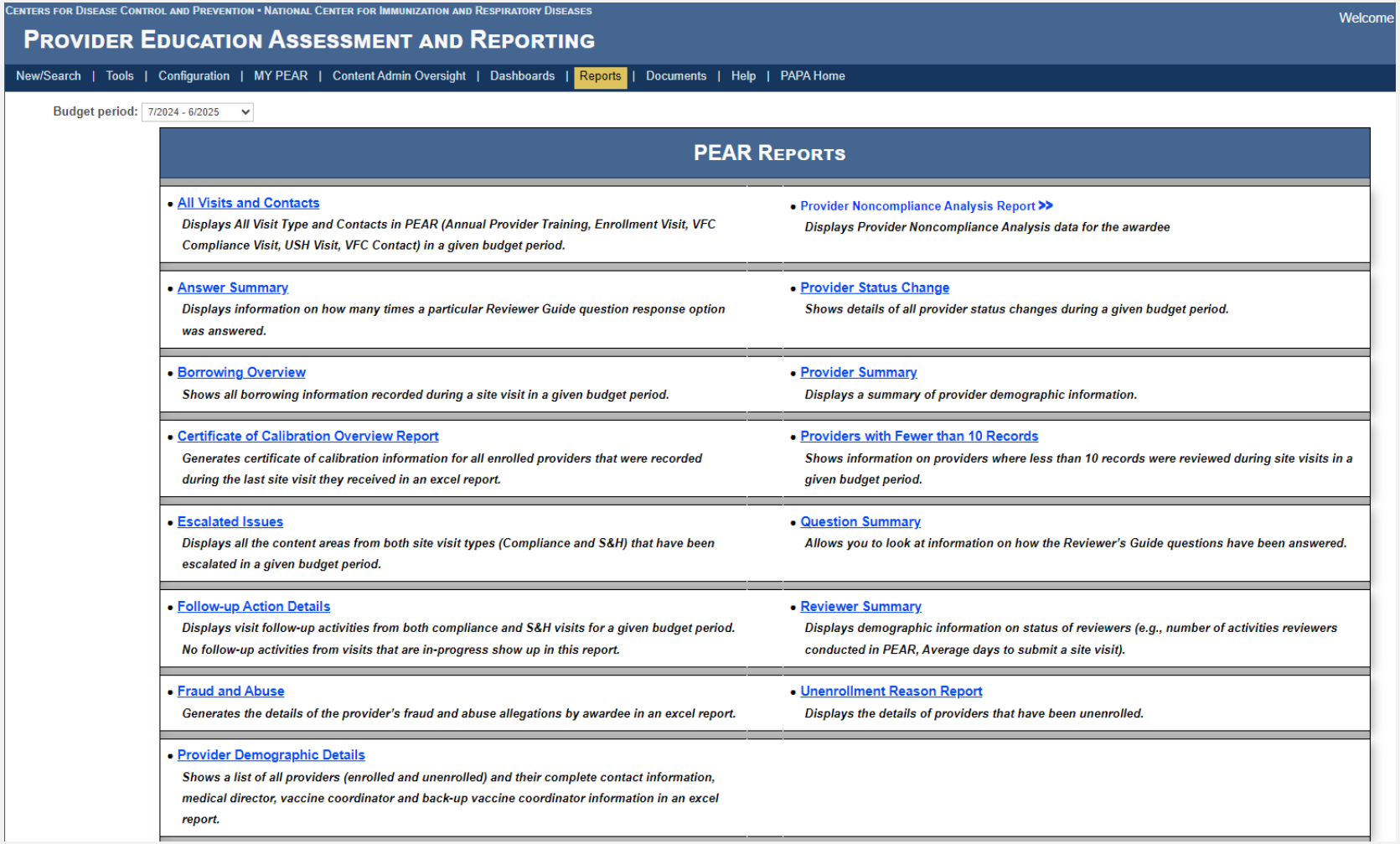
Accessing PEAR Reports



Accessing PEAR Reports
Continued



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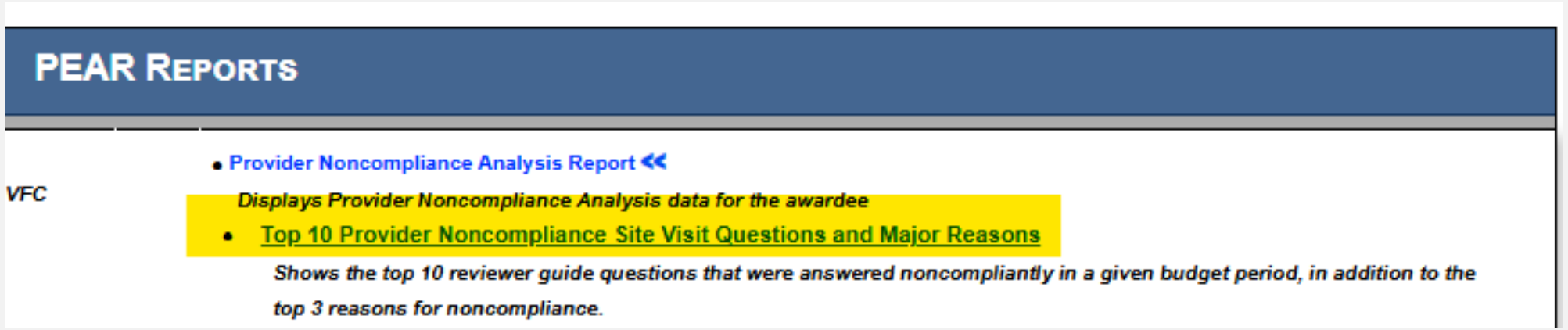
Principal PEAR Reports

- All Visits and Contacts Report: Displays all visit type (Annual Provider Training, Enrollment Visit, VFC Compliance Visit, USH Visit, VFC Contact) and contacts in PEAR in a given budget period.
- Providers With Fewer Than 10 Records Report: Shows information on providers who have less than 10 records reviewed during site visits in a given budget period.
- Follow-up Action Details Report: Displays visit follow-up activities from both compliance and storage and handling visits for a given budget period. No in-progress follow-up activities from visits show up in this report.

Principal PEAR Reports
Continued

- Top 10 Noncompliance Issues Report: Shows the top 10 reviewer guide questions with noncompliant answers along with the top three reasons for noncompliance in a given budget period.



Quality Improvement

Immunization Quality Improvement for Providers

Purpose

- IQIP increases on-time vaccination among child and adolescent patients following the ACIP-routine immunization schedule.
- IQIP gives providers technical assistance and four strategies proven to increase vaccine uptake.
- IQIP ensures providers receive personalized:
  - Improvement plans
  - Assessments
  - Training
  - Resources

IQIP Cycle

1

Site Visit:

- Observation of provider's vaccination workflow
- Review of initial coverage
- Strategy selection
- Selection of action items for strategy implementation plan

2

Two- and Six-Month Check-Ins:

- Review of progress toward strategy implementation
- Updated strategy implementation plan

3

12-Month Follow-Up:

- Review of progress toward strategy implementation
- Review of year-over-year coverage

IQIP consultant provides technical assistance throughout the process.

Increasing Vaccine Uptake

IQIP Strategies

IQIP involves four immunization strategies:

1. Facilitate return for vaccination
2. Leverage Immunization Information System (IIS/ImmTrac2) functionality to improve immunization practices
3. Strengthen vaccine communication
4. Give a strong vaccine recommendation (including the HPV vaccine)

IQIP Coverage Assessment Rates

IQIP sends individual provider coverage assessment rates via a monthly report which will:

- Show the patient population for each provider as well as how much of that population is vaccinated for each respected vaccine.
- Include a year's worth of rates.
- Show rates for childhood vaccines and adolescent vaccines.

Coverage and Goals:

Childhood Vaccination

Initial Coverage:

- 0–80%
- 80–85%
- 85–90%
- 90–95%
- 95% and greater

Suggested 12-Month Coverage Goal:

- Increase by 10 percentage points
- Increase to 90%
- Increase by five percentage points
- Increase to 95%
- Maintain initial percentage

Coverage and Goals:

Adolescent Vaccination

Initial Coverage:

- 0–70%
- 70–75%
- 75–90%
- 90–95%
- 95% and greater

Suggested 12-Month Coverage Goal:

- Increase by 10 percentage points
- Increase to 80%
- Increase by five percentage points
- Increase to 95%
- Maintain initial percentage

Comparing Action Items

Compliance:

- Determined during announced site visits and USH visits
- Needed to complete by due date to avoid suspension
- Marked as “completed” in PEAR

IQIP:

- Determined during the initial IQIP visit along with ways to boost immunization rates
- Strongly recommended strategies to boost immunization rates (non-punitive)
- Checked verbally during the check-ins and kept track of in Redcap notes

Looking Forward

2025 QAI Program Goals

PEAR:

- Increase quality assurance score average to 97%.
- Decrease over-dues to single digits, aiming for zero.

IQIP:

- Decrease lost to follow-up (LTFU) and skipped visits.
- Increase check-in data entry accuracy and on-time completion.

2025 Training

- Annual training for TVFC providers
- Annual TMF reviewers training
- Annual RE training
- Quarterly RE meeting
- Monthly RE training

QAI Contact Information

If there are any questions, please contact the DSHS QAI team: IQIP@dshs.texas.gov

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7, 9/10	Minh Tri Dinh MinhTri.Dinh@dshs.Texas.gov
8, 11, and SAMHD	Danielle Sicard Danielle.Sicard@dshs.Texas.gov

Thank you!