Hello and welcome.

This training is intended to introduce providers to the NYS Vaccines for Children or NYS VFC program. This training will cover participation requirements for providers who are enrolled in the VFC program.
New York State Immunization Information System (NYSIIS)

- Online immunization registry used by thousands of NYS healthcare providers
- NYS Immunization Registry Law, effective 2008:
  - All healthcare providers are required to report all immunizations administered to persons less than 19 years of age, along with the person's immunization histories, to the New York State Department of Health using the New York State Immunization Information System (NYSIIS).

The New York State Immunization Information System or NYSIIS is an online immunization registry used by thousands of healthcare providers in New York State to report immunizations.

New York State legislature passed the Immunization Registry Law which, as of January 1, 2008, requires health care providers to report all immunizations administered to persons less than 19 years of age, along with the person's immunization histories, to the New York State Department of Health using NYSIIS.

Many required VFC activities are conducted in NYSIIS.
### Reporting Doses Administered
- Doses administered and patient VFC eligibility status must be entered within 14 days
- Upload information to NYSIIS via your Electronic Medical Record (EMR) or enter manually
- Doses administered must be up to date and reflect eligibility status prior to the approval of vaccine orders

### Vaccine Inventory Maintenance
- Order sufficient vaccine supply for patient population
- Submit timely returns/wastage transactions
- Accept shipments in NYSIIS to populate inventory
- Inventory must be complete and current in NYSIIS prior to the approval of vaccine orders

### Temperature Logging
- Record twice daily storage unit temperature logs in NYSIIS minimum of every 2 weeks
- Current temperature recordings in NYSIIS are required prior to the approval of vaccine orders

As mentioned on the previous slide, New York State Public Health Law (PHL 2168) requires that all doses of vaccine administered to children 18 years of age and younger be reported in NYSIIS within 14 days of administration. Patient VFC eligibility status information should be recorded in NYSIIS with each dose that is administered. Information can either be manually entered into NYSIIS, or uploaded from an electronic medical record (EMR). Vaccine orders will not be approved unless doses administered data and eligibility information are up to date in NYSIIS.

VFC providers place orders for publicly-funded vaccine and manage their public vaccine inventory through NYSIIS. The NYSIIS inventory module can help providers order sufficient vaccine supply for their patient population. The module can also be used to report and/or return expired, spoiled and wasted vaccine. Doses administered, expired, spoiled or wasted vaccine that are correctly reported in NYSIIS will automatically decrement from the provider’s inventory. Recently received shipments of vaccine lots should also be recorded in NYSIIS to maintain accurate inventory counts by using the Accept Transfer function to populate inventory. Public vaccine inventory must be complete and up-to-date in NYSIIS before provider orders will be approved.

Additionally, VFC providers are required to conduct twice daily temperature checks and regularly record the temperatures in NYSIIS. Although VFC providers are only required to submit their twice daily temperatures into NYSIIS every two weeks, it’s considered a best practice for them to document their twice daily temperatures each day. In order for a provider to place an order for vaccine, they must be regularly recording temperatures into the temperature log module in NYSIIS. Links to related trainings, forms and resources are located at
the end of this training.
How do I gain access to NYSIIS?

1) Request a NYSDOH Health Commerce System (HCS) Account
   - Commerce Account Management Unit (CAMU) Help Desk: 1-866-529-1890 or email: camu@its.ny.gov

2) Register with the New York State Immunization Information System (NYSIIS)
   - NYSIIS Help Desk: 1-866-389-0371 or email: NYSIISHelpDesk@hpe.com

For more information on enrollment requirements see:
Training #1 – VFC Program Background and Enrollment

To gain access to NYSIIS, you’ll first need a NYSDOH Health Commerce Account (HCS).

Once you have an HCS account, you can request access to the NYSIIS application via the contact information located on this slide.

For more information on enrollment requirements refer to Training # 1.
Eligibility screening and documentation are required at each immunization encounter:

- Documentation can be on paper or electronic
- Eligibility status must also be entered into NYSIIS for each dose administered
  - For additional information refer to last slide of the training

VFC providers are required to screen patients and document eligibility status for patients eligible for publicly-funded vaccine at each immunization encounter.

Providers may use their practice’s paper or electronic system to document eligibility, but they must enter eligibility status for each dose administered into NYSIIS.

Additional guidance and tools for assessing patient eligibility for publicly-funded vaccine and trainings on the use of NYSIIS are available via the links provided at the end of this training.
NYS VFC Providers must maintain all records related to the VFC program for a minimum of three years.

Examples of VFC records include:

patient screening and eligibility verification records;
temperature logs that are not recorded in NYSIIS;
dOWN-loaded temperature data from a digital data logger;
vaccine ordering records not recorded in NYSIIS;
VFC training records;
vaccine management plans; annual provider renewal forms and medical records that verify receipt of vaccine.

Medical records showing receipt of vaccine must contain all of the following elements:

The name of the vaccine that was administered, including the vaccine manufacturer and Lot #
The date the vaccine was administered
The date the Vaccine Information Statement (or VIS) was given
The VIS number and the publication date
the name and title of the person who administered the vaccine; and the address of the clinic where the vaccine was administered.

These records should be made available upon request.
Equipment Requirements: Storage Units

- Must be large enough to store vaccines and water bottles without overcrowding
- New units purchased by current VFC providers must be standalone units
- Newly enrolled VFC providers must have stand-alone storage units
- No dormitory style units permitted
- Need help? Contact NYS VFC Program 1-800-543-7468 or nyvfc@health.ny.gov

Temperature Range Requirements

Refrigerated vaccine:
- 36 to 46 degrees Fahrenheit OR 2 to 8 degrees Celsius
- -58 to -5 degrees Fahrenheit OR -50 to -15 degrees Celsius

In terms of equipment requirements, the VFC program requires that storage units are large enough to store vaccines and water bottles without overcrowding. All new unit purchases must be standalone storage units, or units that are a separate refrigerator or freezer only. Newly enrolling providers must have standalone storage units upon enrollment. Dormitory style units (small single-door combination refrigerator/freezer units) are not allowed.

The temperature ranges of vaccine storage units are included in this slide as reference. Follow the link in this slide to access an additional guidance document on purchasing storage units. If you have questions about equipment you are considering purchasing, contact the VFC program at 1-800-543-7468.
VFC Provider Equipment Requirements: Temperature Monitoring

- Use calibrated, continuous temperature monitoring devices (with calibration certificates) in storage units
- Record current temperatures twice per day and minimum and maximum temperatures once per day
- Maintain at least one back-up calibrated, continuous temperature monitoring device

VFC providers must have calibrated, continuous temperature monitoring devices in all storage units that hold publicly-funded vaccine.

VFC providers are required to document current temperatures inside all vaccine storage units housing publicly-funded vaccine twice per day, once when the office first opens and once before closing for the day. Beginning in 2018, VFC Providers will also be required to document minimum and maximum temperatures at least once per day, preferably whenever the office opens for the day.

Providers are also required to have at least one back-up calibrated, continuous temperature monitoring device in case of equipment failure or for use during recalibration of their primary temperature monitoring devices.

Additional information on temperature monitoring equipment and calibration is located in trainings 8 and 9 of this series. Click on the link in this slide to access a guidance document on temperature monitoring devices.
Report and Return Non-viable Vaccine via NYSIIS

1) Report all publicly-funded non-viable vaccine in NYSIIS monthly
   - Includes vaccine for VFC, CHIP and underinsured patients

2) Return nonviable vaccine product in its original vial or prefilled syringe to McKesson Specialty
   - Vaccine vials or syringes that have been damaged or opened should be reported in NYSIIS but are not eligible to be returned.
   - See Training #15, Vaccine Disposal and Returns for more information

The NYS VFC program requires that providers report all non-viable publicly-funded vaccine in NYSIIS on a monthly basis.

In addition to reporting non-viable vaccine, the NYS VFC program also requires that VFC providers return spoiled or expired product that is in its original vial or prefilled syringe to the CDC’s centralized distributor, McKesson Specialty.

Vaccine vials or syringes that have been damaged or opened should be reported in NYSIIS but are not eligible to be returned.

Additional information on this requirement can be found in Training #15.
Temperature Excursions

- The exposure of vaccine to out-of-range temperatures is considered a temperature excursion.
- Excursions must be reported to the NYS VFC program (1-800-543-7468) within **1 business day**
  - Enter into NYSIIS Temperature Log
- Contact manufacturer to determine viability
- Unusable products should be reported and returned via NYSIIS Returns/Wastage
- Excursions that occurred due to negligence and/or unreported excursions may require financial restitution

A temperature excursion is an event in which vaccine is exposed to out-of-range temperatures. Examples of events that can cause temperature excursions include power outages, equipment failures and human error.

The NYS VFC program requires that VFC providers report all vaccine temperature excursions to the NYS VFC program within one business day by calling the number on this slide. All temperatures should also be entered in the NYSIIS temperature log.

Providers who experience temperature excursions will be directed to contact the vaccine manufacturers to determine viability. If vaccine is deemed unusable, products should be returned to the distributor by utilizing the returns/wastage module in NYSIIS.

Excursions that occur due to staff negligence and/or excursions that have gone unreported, may result in provider responsibility for restitution of nonviable vaccine.
Here is a brief review of the VFC staff training requirements that were covered in detail in Training #2. Completion of all 17 of the VFC Training Series you are currently viewing is a requirement for all newly enrolling VFC provider staff including the VFC Provider of Record, Vaccine Coordinator and the Coordinator Backup. The trainings must be completed within 60 days of enrollment.

Whenever a change in key VFC staff occurs, such as a new VFC Provider of Record, a new Vaccine Coordinator or a new back-up, the new staff should complete the shaded trainings indicated in the second column of the table. Staff in practices already enrolled and renewing their membership in VFC program should complete the shaded trainings in the third column.

Staff who are not labeled as primary or back-up coordinators but who regularly handle or administer vaccine or who may assist the coordinators with specific tasks (such as unpacking of large deliveries, etc.) should complete trainings that are pertinent to their job duties.

Refer to Training # 2 for additional information on how to maintain documentation of trainings completed and how to submit attestation of training completion to the NYS VFC program using survey monkey.

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<th>REQUIRED VFC TRAININGS</th>
<th>VFC PROVIDER PRACTICE STATUS</th>
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<td>2. VFC Personnel and Training</td>
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<td>5. The Vaccine Cold Chain</td>
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<td>6. Selecting Vaccine Storage Units</td>
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<td>7. Setting up Vaccine Storage Units</td>
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<td>8. Selecting Temperature Monitoring Equipment</td>
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<td>9. Temperature Monitoring Device Calibration</td>
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<td>10. Monitoring Vaccine Storage Unit Temperatures</td>
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<td>16. Vaccine Preparation</td>
<td>X</td>
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<tr>
<td>17. Vaccine Transport</td>
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</tbody>
</table>
The NYS VFC program has implemented a vaccine restitution policy.

Currently, each NYS VFC provider is given a vaccine wastage allowance of 2%. Vaccine wastage is calculated for a 12-month period as: the number of vaccine doses wasted, expired or spoiled, divided by the number of vaccine doses ordered.

Providers who lose vaccine due to uncontrollable circumstances such as power outage or unforeseen equipment failure, will not have those losses counted against their wastage allowance. Additionally, providers who have an excess of vaccine and who notify NYSDOH at least 60 days in advance of expiration dates, with a reasonable explanation of why they have vaccine that will go unused, will not have those doses counted against their wastage allowance. The NYS VFC program has set up a surveymonkey link for providers to report doses that will expire before being used: https://www.surveymonkey.com/s/FBTH26G

Refer to Training #12 in this series for best practices for decreasing vaccine wastage.
Vaccine Management Plans

- Routine Vaccine Storage and Handling Plan
  - Includes routine tasks and standard operating procedures (SOPs)
  - Reviewed and updated annually
- Emergency Vaccine Storage and Handling Plan
  - Includes information and instructions in the event of an emergency
    - e.g. equipment failures, power outages or natural disasters
  - Reviewed and updated annually
  - Refer to training #4 – Vaccine Management Plans

Each VFC provider is required to have a routine vaccine storage and handling plan and an emergency vaccine storage and handling plan. The routine plan should cover routine tasks associated with the storage and handling of vaccine.

The Emergency Vaccine Storage and Handling Plan should include information and instructions in the event of an emergency. These plans should be reviewed and updated annually. Additional information on developing routine and emergency plans is available in Training #4.
Vaccine Information Statements (VIS)

- Give to all patients (or patient caregivers) prior to the administration of each dose of vaccine
  - Other languages http://www.immunize.org/vis/
- Document the following in the patient’s medical record:
  - specific VIS given (e.g., MMR)
  - VIS publication date
  - the date the VIS was given to the patient

All healthcare providers are required by federal law to give patients or their legal guardians the most current Vaccine Information Statement (VIS) just prior to the administration of each dose of vaccine. The most current VIS can be found on the Centers for Disease Control and Prevention (CDC) website at the link on this slide. The CDC website also has an area where you can sign up for email updates anytime there is a change or update to a VIS. VIS are available in 41 additional languages.

The Immunization Action Coalition also has a printable listing of the most current VIS dates. Check the dates on the VIS handout against this list and update as needed.

VFC Providers must document the following VIS information in the patient’s medical record:
The specific VIS given,
the VIS publication date, and the date the VIS was given to the patient.
VFC providers must immunize children eligible for publicly-funded vaccine at no charge to the patient for the cost of the vaccine.

VFC providers may be able to receive an office visit fee and a vaccine administration fee, depending on the eligibility category through which children qualify for the program. The categories and related vaccine administration fees are displayed in a table on this slide.

VFC providers must not deny administration of publicly-funded vaccines to any eligible child due to the inability of the child's parent or guardian to pay the vaccine administration fee. If the parent or guardian cannot pay the administration fee for a publicly-purchased vaccine, the provider must waive the administration fee.

Health care providers must not refer Medicaid and Child Health Plus (or CHP) members to other sites, such as public health clinics, for their vaccines. Health care providers who inappropriately refer patients or attempt to force collection of administration fees from patients will be prohibited from participating in the Medicaid and CHIP programs.
Vaccine Borrowing

- Allowed only when there is a lack of vaccine due to unexpected circumstances such as a delayed vaccine shipment or the vaccine spoiled in-transit to the provider.
- Borrowing vaccine must not prevent a VFC, CHP or underinsured child from receiving needed vaccination.
- Must request prior approval from the NYS VFC Program to borrow any vaccine.
  - 1-800-543-7468
- A Vaccine Borrowing Report must be completed.

VFC providers are expected to maintain adequate inventories of vaccine to administer to all privately-insured patients and patients receiving publicly-funded vaccine. Borrowing can occur only when there is a lack of vaccine due to unexpected circumstances such as a delayed vaccine shipment or the vaccine was spoiled in-transit to the provider. Publicly-funded vaccine cannot be used as a replacement system for a provider’s privately purchased inventory.

Borrowing vaccine must not prevent a VFC, CHP or underinsured child from receiving needed vaccination because the publicly-funded vaccine was administered to a non-eligible child.

VFC providers must request prior approval from the NYS VFC Program to borrow any vaccine, in the rare event that the need to borrow arises. To request approval, VFC providers should contact the VFC program to discuss the specific circumstances of each request.

All instances of borrowing must be properly documented, reported and replaced. A Vaccine Borrowing Report, pictured here, must be completed when privately-purchased vaccine is administered to a child eligible for publicly-funded vaccine.
VFC Site Visits

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<tr>
<th>TYPE</th>
<th>FREQUENCY</th>
<th>PURPOSE</th>
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</thead>
<tbody>
<tr>
<td>Initial Enrollment</td>
<td>once</td>
<td>ensure capacity to store and administer vaccine</td>
</tr>
<tr>
<td>Compliance</td>
<td>every 2 years</td>
<td>ensure ongoing compliance</td>
</tr>
<tr>
<td>Unannounced Storage &amp; Handling</td>
<td>as needed</td>
<td>follow up on previously identified issues</td>
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</table>

VFC providers must participate in site visits conducted by NYS VFC Program staff. Site visits are conducted to assess provider compliance with the laws, policies and recommendations of the NYS VFC Program and the Advisory Committee on Immunization Practices (ACIP).

The enrollment site visit is a one-time site visit following VFC program enrollment to certify that the provider has the capacity to adequately store and administer vaccine to eligible children.

A VFC Compliance visit is conducted to assure that VFC providers maintain compliance with program requirements such as screening, maintaining records for eligibility, and adhering to storage and handling requirements. These are conducted at least once every two years.

VFC Unannounced Storage and Handling Site Visits are conducted, as needed, to follow-up on storage, handling or accountability issues noted during a previous visit or based on other concerns related to the provider’s ability to meet program requirements. Providers are not notified about these visits before the visits are conducted.
Follow-up Plans and Post-Compliance Visits

Follow-up plans

- Identify unmet requirements
- Document recommendations, follow-up actions, and deadlines

Acknowledgement of receipt

- Visit occurred
- Provider was given results
- Site visit reviewer and provider understand any problems andremedying actions

Post compliance visits

- May be scheduled to ensure timely corrective actions are taken

Following a compliance visit, providers may be asked to complete a series of follow up actions. These actions will be outlined in a meeting following the visit and will include a formal follow-up plan with a timeline to address any issues of non-compliance as well as opportunities for improvement. The follow-up plan is a summary document that includes VFC requirements and recommendations that were addressed, an indication of whether the requirements were met, and any follow up actions (and corresponding deadlines) that need to be addressed by the provider.

VFC Providers will also be asked to sign an acknowledgement of receipt attesting that a visit was completed, that they received the results of the visit (via a Follow-up plan), and that both the NYS VFC site visit reviewer and the provider understand the issues identified and the actions needed to address them.

A post-compliance visit may be scheduled to ensure that corrective actions have been taken within a specified time frame.
The NYS VFC Program has policies in place to prevent, identify and investigate suspected cases of fraud and abuse of publicly-funded vaccine.

Some examples of potential fraud and abuse are:

- Denying VFC-eligible children VFC-funded vaccine because of parents' inability to pay for the administration fee
- Billing a patient or third party for VFC-funded vaccine
- Failing to implement provider enrollment requirements of the VFC program
- Providing VFC vaccine to non VFC-eligible children, and
- Wasting publicly funded vaccine.

As covered on a previous slide, the vaccine restitution policy holds VFC providers responsible for replacing any vaccine purchased with federal funds (VFC, 317) that are deemed non-viable because provider negligence, on a dose-for-dose basis.

To report suspected cases of fraud or abuse, complete the NYS VFC Fraud and Abuse Referral Sheet (PDF). To access the sheet, click on the form image in this slide or visit the resources section at the end of this training.
## Resources

### NYS Vaccines for Children (VFC) Program
- Borrowing Form  
- Fraud and Abuse Form  
- Order Review Process  

### New York State Immunization Information System (NYSIIS) Training Page

### Vaccine Information Statements (VIS)
- Immunization Action Coalition (IAC)  
  [http://www.immunize.org/vis](http://www.immunize.org/vis)
- Centers for Disease Control and Prevention (CDC)  
  [http://www.cdc.gov/vaccines/hcp/vis/index.html](http://www.cdc.gov/vaccines/hcp/vis/index.html)

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Here is a listing of available resources.
There are a number of additional trainings available.

The next training in this series is #4, Vaccine Management Plans.