VFC Replacement Model

Presenter: Michelle Allman

New Enrollment Consultant for the VFC Program



Agenda

- What is the Replacement Model
- Application and Program Requirements
- Financial Capacity
- Reporting Requirements
- Documentation and Submission Report
- Inventory Requirements
- Yearly Assessment
- Uninterrupted Access
- Unavailable Brands or Products
- Replacement Order
- Returns
- Wrap up and questions

What is the Replacement Model

- The replacement model is intended to allow birthing hospitals to use their private funds to establish an initial vaccine stock for use in providing vaccination services to all patients they serve.
- Birthing Hospitals will have the opportunity to administer their private stock of RSV or Hep B to VFC patients, with the ability to order VFC stock to reimburse these doses.

Application and Requirements for the Program

- ✓ Provider must be currently enrolled and in good standing in the VFC Program.
- √ The Primary and Back-up coordinators must be current with the recommended VFC training.
- ✓ All vaccine doses (private and state-supplied) must comply with CDC's VFC requirements:
 - Storage and handling
 - Inventory management
 - Eligibility screening and documentation
- ✓ Must meet CDC financial requirements.
- ✓ Submit monthly documentation of patient eligibility (via EHR or NCIR).
- ✓ Designate a responsible person to ensure compliance with all requirements upon proposal. submission.



VFC PROGRAM REQUIREMENTS

VFC Program Requirements

- Because private and public doses are stored together, all of the provider's doses are subject to CDC's VFC program requirements (i.e., eligibility screening, documentation, inventory management, and storage and handling). Although doses in inventory before the replacement process started were ordered and originally paid for by the provider, participation in the VFC Program and agreement with the provisions of the Vaccine Replacement Policy mean that any dose at that provider's site may be administered to a VFCeligible child at any time. Therefore, the provider must follow VFC Program requirements to ensure the appropriate use and safety of the vaccine.
- The provider must submit VFC re-enrollment and provider profile forms as required by NCIP for provider participation. If the provider profile data changes at any time, the provider will notify NCIP and submit an updated provider profile.
- Providers are required to designate a person at the provider site to implement the replacement model. This person is responsible for ensuring the provider site meets all of the replacement model requirements.
 - The designated person may also be the primary coordinator if appropriate.
 - The designated person must complete all required VFC trainings.
 - 2025 North Carolina Immunization Program Virtual Training; or
 - You Call the Shots Module 10 and Module 16
 - The VFC key staff (Medical Director, Primary Coordinator, and Backup Coordinator) are also responsible for knowing and meeting the replacement model requirements.



I understand and agree to the requirements.

must provide value

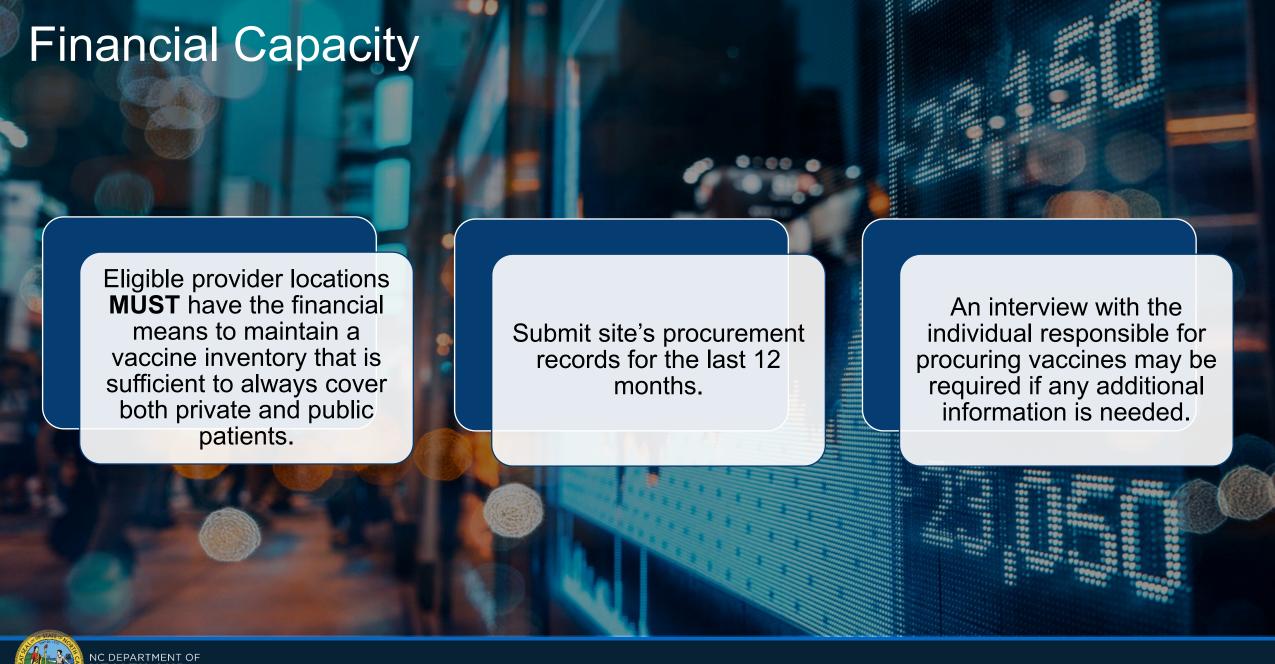


Designated Responsible Person

This person is responsible for administration and oversight of the replacement model at your facility.

First Name	Michelle	Enter the first name of the person responsible for the administration of the replacement model program
Last Name	Allman	Enter the last name of the person responsible for the administration of the replacement model program
Email	michelle.allman@dhhs.nc.gov	Enter the email of the person responsible for the administration of the replacement model program
Phone	(919) 609-3498	Enter the phone number for the person responsible for the administration of the replacement model program
VFC Training Type	 □ 2025 North Carolina Immunization Program Virtual Training ☑ CDC's You Call the Shots Module 10 (Storage and Handling) and Module 16 (Vaccines for Children) □ Haven't completed either of the above trainings 	Which of the following trainings has the provider representative completed?
VFC Training Date	07-18-2025 Today M-D-Y	Please provide the date in which the training was completed







FINANCIAL CAPACITY

Financial Capacity

 Eligible provider locations must have the financial means to always maintain a vaccine inventory that is sufficient to cover both their private and public patients at all times. Providers must demonstrate the financial capacity to maintain a vaccine inventory that adequately covers both private and VFC patients.



✓ I understand and agree to the requirements.

Financial Capacity Details

information is needed.

Enter the name of the individual who procures vaccines for the site. This individual may be contacted and should therefore be equipped to answer detailed questions related to the financial capbility of the site upon request.

First Name	Michelle
Last Name	Allman
Title	MD
Email	michelle.allman@dhhs.nc.gov
Phone	
Describe the mechanism used to procure vaccines for the site (contract, direct order, etc.).	N/A
Have purchases ever been deferred due to an inability to pay?	Yes ■ No reset
Describe how the organization makes funds available for purchase.	N/A Expand
You must be able to show procurement records (orders/invoices/payment records) for a 12-month period upon request. Are you able and willing to show these records upon request?	● Yes ○ No reset
Please upload procruement recrods from the last 12 months. An interview may be required if additional	⊥ <u>Upload file</u>



^{*} must provide value

Documentation

 All documentation must be submitted within 30 days of administration using NCIR or EHR data and submitted electronically via REDCap.

 Providers must be able to show they have a process for recording dose-level patient eligibility by category.



Reporting Requirements

Must submit monthly administration data from your site's EHR or NCIR.

NCIR not recommended if patient data is incomplete or legal name is unknown.

Hospitals must continue to report through Vital Records in addition to submitting monthly reports.



Include in Your Documentation

- Doses administered
- Date of service
- Patient eligibility
- Actual doses being replaced, including total number of doses by vaccine/brand/presentation and eligibility by category
- Patient-level data must validate that only doses used are for VFC-eligible children





DOCUMENTATION AND MONTHLY REPORT SUBMISSION

Documentation and Monthly Report Submission

- · All doses administered and the dose-level eligibility of the child on the date of service must be documented within 30 days of administration using NCIR or electronic submission of EHR reports via REDCap.
 - Data to submit:
 - Actual doses to be replaced, including total number of doses by vaccine type/brand/ presentation and eligibility by category.
 - · Patient-level data validating that only doses used for VFC-eligible children are being replaced.
 - Patient-level data must be submitted but can be de-identified.
- . You must continue to submit administrations through vital records in addition to monthly report submissions to NCIP. Vital records data does NOT include VFC-eligibility data and cannot be used to meet the monthly reporting requirement.

I understand and agree to the requirements.

* must provide value

Select what system you will use to document VFC eligibility by category and administration details.

* must provide value





reset

Upload a sample of the data report that will be submitted/ reviewed monthly to demonstrate you can fulfill the requirement.



Upload file

^{*} must provide value



Close survey queue

i≡ Survey Queue

Get link to my survey queue



This is the inventory survey queue page for DUKE CHILDRENS HEALTH CENTER NCA320004.

Monthly inventory reports must be submitted by the 15th day of the following month.

Status	Survey Title
Completed	Starting inventory
✓ Completed	Monthly Report - #1: 09-15-2025
✓ Completed	Monthly Report - #2: 09-15-2025
Completed	+ Click here to submit another report



Month	ly Re	port
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≅ Survey Queue

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HANOVER PEDIATRICS NCA650040

Instructions

Reports must be submitted by the 15th day of the following month of administration. You must submit EHR reports or IIS reports must contain patient-level data that includes:

- 1. Vaccine type/brand/presentation
- 2. Patient eligibility category (i.e., Medicaid, Uninsured, American Indian/Alaskan Native)

Patient-level data must be submitted but can be de-identified.

Submit Report Below for for HANOVER PEDIATRICS NCA650040

Upload a copy of the monthly report

* must provide value

Upload file

Enter the number of birth doses administered last month to VFC-eligible newborns that you are requesting replacements doses for in the table below.

Trade Name	NDC	Doses Administered
	RSV Monoclonal Antibody Produc	cts
Beyfortus® 50mg	49281-0575-15	
Beyfortus® 100mg	49281-0574-15	
ENFLONSIA™ 1-pack	00006-5073-01	
ENFLONSIA™ 10-pack	00006-5073-02	
	Hepatitis B Vaccines	
Engerix-B	58160-0820-52	
Recombivax® HB	00006-4093-02	



Inventory Count Trade Name Doses On-Hand NDC **RSV Monoclonal Antibody Products** Beyfortus® 50mg 49281-0575-15 45 Beyfortus® 100mg 49281-0574-15 5 ENFLONSIA™ 1-pack 00006-5073-01 65 ENFLONSIA™ 10-pack 00006-5073-02 84 Hepatitis B Vaccines **Engerix-B** 58160-0820-52 456 Recombivax® HB 54 00006-4093-02 Today's date 09-24-2025 Submit



4	А	В	С	D	E	F	G	Н	I	J
	ntact i cison. Iviina	•	011100 330	032 7301						
VF	C-eligible Hep B vac	ccines	administe	red: 238						
2 Patie	ent Initials	DOB	Imm. Date	Immunization	NDC Code	Lot #	Expiration Date	Primary	Secondary	
3			7/1/2025	Нер В	58160-820-43	AZ4TN	1/25/2027	Commercial		
4			7/1/2025	Нер В	58160-820-43	AZ4TN	1/25/2027	Commercial		
5			7/1/2025	Нер В	58160-820-43	3N2ND	1/16/2027	Medicaid Advantage		
6			7/1/2025	Нер В	58160-820-43	3N2ND	1/16/2027	Medicaid Pending		
7			7/1/2025	Нер В	58160-820-43	AZ4ATN	1/25/2027	Self-Pay		
8			7/2/2025	Prevnar 20	0005-2000-01	MF0415	3/15/2026	Medicaid Advantage	Medicaid Advantage	
9			7/2/2025	HIB (PRP-OMP)	0006-4897-01	Y007178	11/7/2026	Medicaid Advantage	Medicaid Advantage	
10			7/2/2025	DTAP / HEP B / IPV	58160-811-43	B532G	4/11/2027	Medicaid Advantage	Medicaid Advantage	
11			7/2/2025	Нер В	58160-820-43	3N2ND	1/16/2027	Medicaid Advantage		
12			7/2/2025	Нер В	58160-820-43	7NX57	12/12/2026	Medicaid Pending		
13			7/2/2025	Нер В	58160-820-43	AZ4TN	1/25/2027	Commercial		
14			7/2/2025	Нер В	58160-820-43	3N2ND	1/16/2027	Medicaid Advantage		
15			7/2/2025	Нер В	58160-820-43	3N2ND	1/16/2027	Medicaid Advantage		
16			7/2/2025	Нер В	58160-820-43	AZ4TN	1/25/2027	Self-Pay		
17			7/2/2025	Нер В	58160-820-43	AZ4TN	1/25/2027	Self-Pay		
18			7/2/2025	Нер В	58160-820-43	7NX57	12/12/2026	Medicaid Advantage	Medicaid Advantage	
19			7/2/2025	Нер В	58160-820-43	AZ4TN	1/25/2027	Self-Pay		
20			7/2/2025	Hen R	58160-820-43	A74TN	1/25/2027	Commercial		



Inventory

- Provider locations do not have to maintain a separate stock of state and private vaccines, but it is recommended.
- Once approved, your site will need to submit a starting inventory count through RedCap.
- This count must include **privately** purchased doses and NCIP supplied **VFC** doses.





Jearen	ng inventory			:= Survey Queue
	ing introduction y			AAA
				+ -
Please co	omplete the survey below			
Thank you	u!			
		Initial Inv	entory	
			•	
Enter a	current inventory count	of all VFC/state-supplied products and hepatitis E	and privately purchased RSV vaccine on-hand.	monoclonal antibody
1)	Start date		31 Today	/ M-D-Y
	* must provide value			
	Trade Name	NDC	VFC (State) Doses	Private Doses
	Trade Name		VFC (State) Doses Antibody Products	Private Doses
	Trade Name Beyfortus® 50mg			Private Doses
		RSV Monoclona		Private Doses
	Beyfortus® 50mg	RSV Monoclonal 49281-0575-15		Private Doses
	Beyfortus® 50mg Beyfortus® 100mg	RSV Monoclonal 49281-0575-15 49281-0574-15		Private Doses
	Beyfortus® 50mg Beyfortus® 100mg ENFLONSIA™ 1-pack	RSV Monoclonal 49281-0575-15 49281-0574-15 00006-5073-01 00006-5073-02		Private Doses
	Beyfortus® 50mg Beyfortus® 100mg ENFLONSIA™ 1-pack	RSV Monoclonal 49281-0575-15 49281-0574-15 00006-5073-01 00006-5073-02	Antibody Products	Private Doses
	Beyfortus® 50mg Beyfortus® 100mg ENFLONSIA™ 1-pack ENFLONSIA™ 10-pack	RSV Monoclonal 49281-0575-15 49281-0574-15 00006-5073-01 00006-5073-02 Hepatiti	Antibody Products	Private Doses



Uninterrupted Access

1

Each provider MUST have a policy and process in place that ensures all VFC-eligible children have uninterrupted access to hepatitis B and RSV monoclonal antibody product birth doses.

2

We request that you provide a copy of the policy and process that is in place at your site that ensures uninterrupted access.



UNINTERRUPTED ACCESS

Uninterrupted Access

- Each provider must have a policy and process in place that ensure VFC-eligible children have uninterrupted access to hepatitis B and RSV monoclonal antibody product birth doses.
 - When allowing a single inventory and "virtually" identifying public stock, it is essential that VFC-eligible children are not left vulnerable and unable to obtain vaccines being supplied by the VFC Program. Each provider must have a policy and process in place that ensure VFC-eligble children have uninterrupted access to all ACIP-recommended vaccines for their patient population.



I understand and agree to the requirements.

Please upload a copy of the policy and process in place that ensure VFC-eligible children have uninterrupted access to all ACIP-recommended vaccines for your patient population. Please ensure the points above are addressed in the policy.



Upload file



^{*} must provide value

^{*} must provide value

Replacement Order

- The monthly submission reports will be reviewed and assessed to validate that only doses used for VFC-eligible children are being replaced.
- The current inventory count will be reviewed and documented in REDCap, along with the number and type of doses that need to be replaced.
- A replacement order will be placed by the Help Desk team and shipped directly to the provider each month.
- Providers will receive their monthly replacement dose orders once their monthly submission has been reviewed and approved.
- Redistribution is **NOT** Allowed.





Vaccine Returns

Public vaccine returns must be submitted to represent the public portion of the total vaccine returns.

Vaccine returns, including spoiled/expired/wasted, must be submitted to represent the public portion of the total vaccine return.

In the event there is vaccine loss, and the provider is required to pay back VFC vaccines under the NCIP restitution policy, the percentage of "virtual" public vaccine from the lost stock must be identified and those doses replaced dose for dose.

• The NCIP Help Desk will assist with facilitating any returns in NCIR.



Unavailable Brands or Products Guidelines

- NCIP will notify providers if a specific brand and presentation used previously for VFC children is unavailable and if an alternate brand may be used.
- Providers must agree to accept an alternate brand or delay replacement until available.
- Providers must notify the NCIP, in advance, if they intend to switch brands to a different product.
- Doses may need to be placed in multiple orders if the replacement amount is significant.
- Please report any vaccine shortages or delays to the Helpdesk by emailing <u>Ncirhelp@dhhs.nc.gov</u> or call 877-873-6247.



Yearly Assessment

- Participation and suitability will be assessed annually.
- Failure to re-enroll in the VFC Program and /or failure to submit Annual Provider Profile numbers may be grounds for removal from the program.
- Failure to meet monthly reporting requirements may be grounds for removal from the program.
- Failure to meet VFC Program and site visit requirements may be grounds for removal from the program.
- The provider may terminate their participation in the program with notice to NCIP.





Questions

Please reach out to:

Michelle Allman- <u>michelle.allman@dhhs.nc.gov</u> or Nikki Barbour – <u>Nikki.Barbour@dhhs.nc.gov</u> with any questions or concerns regarding the application process for Replacement Model.