

# VACCINES FOR CHILDREN BIRTHING HOSPITALS

June 25, 2024

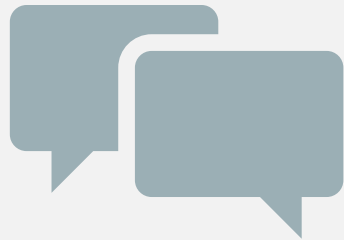
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# HOUSEKEEPING

- Please ensure you are muted throughout the presentation unless you are speaking.
- **Reminder for QA Team:**
- Please monitor the chat for questions you may be able to answer.
- **Reminder to Attendees:**
- Today's session is being recorded. Slides and webinar recordings will be uploaded to: <https://health.hawaii.gov/docd/for-healthcare-providers/vaccination-resources/vaccines-for-children-program-vfc/>
- To be added to the Hawaii VFC Program email list, please email your request to HawaiiVFC@doh.Hawaii.gov. In the subject line of the email, please write **EMAIL LIST**.

# QUESTIONS?



During today's webinar, please use the chat to ask your questions so the Hawaii VFC Program subject matter experts can respond directly.



We will be answering your questions at the end of the presentation

# OBJECTIVES

By the end of the presentation, attendees will be able to

- Understand Vaccines for Children (VFC) program requirements
- Describe VFC eligibility requirements
- Identify storage unit requirements

# VFC PROGRAM REQUIREMENTS

Submit to Hawaii VFC Program annually

- Provider agreement
- Vaccine Management Plan
- Certificates for You Call the Shots modules 10 and 16
- Annual re-enrollment must be completed by January 31<sup>st</sup> of each year
  - After January 31<sup>st</sup>, vaccine ordering will be suspended until re-enrollment is complete

Communicate all changes to key staff (Primary and backup coordinators, CMO, etc.) to HDOH VFC Program

All key staff must undergo annual training (You Call the Shots modules)


Possess working knowledge of VFC eligibility criteria

Understand that VFC vaccine is provided at no cost to the provider and eligible children

**Vaccine administration fee for non-Medicaid, VFC eligible children must not exceed state cap of \$23.11**

Document eligibility status at each immunization visit

Email all documents to [HawaiiVFC@doh.hawaii.gov](mailto:HawaiiVFC@doh.hawaii.gov). Include location name, PIN#, and name of document in subject line of email



WHO IS  
ELIGIBLE TO  
RECEIVE  
VFC  
VACCINES?

To be eligible, the child must be:

- Less than 19 years of age

AND ONE OF THE FOLLOWING:

- Medicaid eligible (QUEST)
- Uninsured
- American Indian or Alaskan Native
- Underinsured
  - A child who has private health insurance, but the coverage does not include vaccines
  - A child whose insurance covers only selected vaccines.
  - Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Center (RHC)

**No other factor can be considered  
when screening for eligibility**

# NEWBORN ELIGIBILITY

Newborns are classified as insured based on parent's insurance at time of birth

\*For mothers on Medicaid

- In most circumstances, if Medicaid pays for the birth, the newborn must be enrolled for a year.
- For more info: <https://www.medicaid.gov/sites/default/files/2023-09/sho23004.pdf>

## NIRSEVIMAB ELIGIBILITY

### VFC Criteria

- Uninsured
- Medicaid/MedQuest enrolled or reasonably anticipated to be Medicaid/MedQuest eligible based on parent's Medicaid/MedQuest insurance
- American Indian/Alaskan Native (regardless of insurance status)

**NOT purchased with 317 funds**



# HEPATITIS B VACCINE ELIGIBILITY

- Purchased and supplied using two Federal funding sources (VFC and 317) which have different patient eligibility criteria
- VFC Criteria
  - Uninsured
  - Medicaid/MedQuest enrolled or reasonably anticipated to be Medicaid/MedQuest eligible based on parent's Medicaid/MedQuest insurance
  - American Indian/Alaskan Native (regardless of insurance status)
- 317 Criteria
  - Privately insured or reasonably anticipated to be privately insured based on parent's insurance

## HEPATITIS B IMMUNE GLOBULIN

- Hepatitis B Immune Globulin (HBIG) is NOT purchased with VFC funds
- May be administered to infants born to HBsAg positive/unknown mothers, regardless of the infant's VFC or 317 eligibility status.



## DOCUMENTATION

- Records must contain ALL of the following:
  - Patient
    - Name
    - Date of birth
    - Eligibility Status
  - Name of vaccine administered
  - Date vaccine was administered
  - Date VIS was given
  - Publication date of VIS
  - Name of vaccine manufacturer
  - Vaccine lot number
  - Name and title of person who administered the vaccine
  - Address of clinic where vaccine was administered

## Nirsevimab

Nirsevimab eligibility and administration may be reported via

-Hawaii Immunization Registry

AND

-VFC Vaccine Administration Visit Records (VAVR) (record in “Other” field)

\*Nirsevimab-alip (Beyfortus™) is not included in the Hawaii Immunization Branch Universal Pediatric Hepatitis B/HBIG Program so administration cannot be recorded on the Newborn Hepatitis B Vaccine Record form.

## Hepatitis B / HBIG

Hepatitis B vaccine/HBIG eligibility and administration reported via

-Completion of the HDOH-supplied Hepatitis B Vaccine Record form

AND

-Electronic submission to the Hawaii Immunization Registry (HIR).

DOCUMENTATION

# VFC PROGRAM REQUIREMENTS

## Maintain

- Immunization records in accordance of federal law (minimum 3 years)

## Develop, maintain and implement

- Vaccine Management Plan

## Provide

- All ACIP recommended vaccines unless qualified as a specialty

## Provide

- Current (most recent publication date) Vaccine Information Statements (VIS) to patients prior to each vaccination

## Report

- Vaccination adverse events to Vaccine Adverse Event Reporting System (VAERS) <https://vaers.hhs.org>

# VFC PROGRAM REQUIREMENTS

Review downloaded digital data logger routinely

- Every 2 weeks

Submit temperature logs monthly

- Submit even during months when no order is placed

Report temperature excursions once they have occurred


Submit vaccine loss reports weekly

Vaccine borrowing

- Must be a rare and unplanned occurrence
- Bidirectional
  - Exception: Flu vaccines and Nirsevimab
- Submit borrowing logs once complete

## PRIMARY AND BACKUP COORDINATORS

If the vaccines will be stored in the hospital pharmacy  
as well as the birthing unit



Each location must have a primary and backup coordinator

# VFC SITE VISITS

## Compliance visits

- Conducted anywhere from 13 to 24 months

## Unannounced storage and handling visits

- Can occur at any time

## Site visit follow up requirements must be completed by due date

- If follow up requirements are not met, vaccine ordering will be suspended until requirements are completed



# STORAGE UNIT REQUIREMENTS

- Acceptable storage units
  - Pharmaceutical grade stand alone or combination units
  - Household/commercial stand alone units
  - If you provide frozen vaccine, a separate freezer unit is necessary
  - Dorm and bar style units are prohibited
  - Have sufficient storage space to accommodate vaccine stock at busiest time of year without overcrowding
  - Water bottles (refrigerators) and frozen water bottles (freezer) should be placed in units to stabilize temperatures and avoid placing vaccine in areas such as doors, near or against walls, close to vents or on the floor of the unit
    - For pharmaceutical grade units, check with manufacturer regarding water bottle placement
  - Label storage unit outlets and circuit breaker with DO NOT DISCONNECT labels
  - Have emergency transport supplies (i.e. Styrofoam cooler) and necessary supplies (conditioned water bottle system, bubble wrap, cardboard) readily available for emergency transport of vaccine

# VACCINE TRANSPORT

- For routine transport of vaccines, a qualified portable storage unit or qualified packout is required.
- Emergency transport supplies DO NOT qualify for use during routine transport of vaccines.

# PROPER TEMPERATURES AND MONITORING



**Must have a continuous monitoring and recording device (digital data logger) with:**

- Detachable probe in a buffered material
- Temperature can be read outside of device
- Current and valid certificate of calibration



**DDL probe should be placed in central area of unit directly with vaccines**

- Should not be placed in the doors, near or against walls, close to vents, or on the floor of the unit



**Temperature documentation must contain**

- At least two temperature readings per day
- Time/date of each reading
- Initials of person who assessed and recorded readings
- DDL min and max temps once per work day



**Review downloaded DDL data regularly**



For refrigerated vaccines,  
temperatures must be  
between 2°C and 8°C



Anything outside of this  
range is considered a  
temperature excursion

PROPER  
TEMPERATURES



## TEMPERATURE EXCURSIONS

- Document all excursion
- Quarantine and label exposed vaccines, “DO NOT USE – AWAITING GUIDANCE”
- Place affected vaccines in a unit with proper storage conditions
- Contact VFC program as soon as excursion occurs to report excursion
- Contact vaccine manufacturer to obtain documentation of vaccine viability
  - DO NOT USE STABILITY CALCULATOR
- Complete and submit troubleshooting log, downloaded DDL data, and manufacturer correspondence to Hawaii VFC Program

# VACCINE ACCOUNTABILITY

The VFC program has the primary responsibility for developing and maintaining vaccine accountability systems which:

- Ensure that vaccine loss and wastage is minimized

- Protect against fraud and abuse

- Ensure that vaccines purchased with VFC funds are administered only to VFC-eligible children

- Ensure the proper apportionment of vaccine purchases based on the VFC-eligibility data for population





PROVIDER  
ACCOUNTABILITY

- It is important that VFC providers account for and store VFC vaccine appropriately to avoid loss of vaccine due to expiration, storage and handling issues, and administration errors.

# PROVIDER ACCOUNTABILITY

Reasons of negligence include but are not limited to the following:

- ◆ *Not being available to accept/receive a vaccine delivery during stated vaccine delivery hours*
- ◆ *Failure to store vaccine promptly upon arrival*
- ◆ *Storing vaccine in a refrigerator or freezer unit that cannot consistently maintain the required temperature range*
- ◆ *Freezing vaccine intended to be refrigerated and/or refrigerating vaccine intended to be frozen*
- ◆ *Failure to check and document vaccine storage temperatures twice per workday*
- ◆ *Failure to download and review DDL data for any out-of-range temperature*
- ◆ *Failure to follow vaccine storage alarm response protocol for power outage or unit failure*
- ◆ *Failure to rotate vaccine stock, resulting in preventable expired vaccine*
- ◆ *Any other preventable incidents made by providers*



## NIRSEVIMAB ORDERING

Not included in the Hawaii Immunization Branch Universal Pediatric Hepatitis B/HBIG Program.

May order \*50mg or 100mg doses

\*Due to limited supply, VFC ordering for the 50mg presentation remains restricted to Birthing Hospitals only

Must be placed via the VFC Nirsevimab Monoclonal Antibody Order Form

- Complete Birthing Hospital Vaccine Order Form
  - Submit order form for pediatric Hepatitis B vaccine and Hepatitis B Immune Globulin (HBIG) by:
    - Email ([HawaiiVFC@doh.hawaii.gov](mailto:HawaiiVFC@doh.hawaii.gov))
    - Fax (808-586-8302)
- Hepatitis B vaccine orders for VFC-eligible (VFC) and non-VFC eligible (317) patients must be indicated as separate line items.
- “Doses administered” and “Doses on hand” information specific to VFC and 317 inventories must be reported when vaccine/HBIG orders are placed.
- The total number of HBIG should not be more than 10 doses per order.
- All orders received from Birthing Hospitals will be given priority over standard VFC provider orders, however delivery may take up to 2-3 weeks. Please plan accordingly.



HEPATITIS B  
VACCINE /  
HBIG  
ORDERING

# FRAUD AND ABUSE

## FRAUD

- Intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person
- Any act that constitutes fraud under applicable federal or state laws

## ABUSE

- Provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program (and/or include actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient), or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care
- Also includes recipient practices that result in unnecessary cost to the Medicaid program

## EXAMPLES OF FRAUD & ABUSE

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Providing VFC vaccine to non-VFC-eligible children

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Selling or otherwise misdirecting VFC vaccine

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Billing a patient or third party for VFC-funded vaccine

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Charging more than the established maximum regional charge of \$23.11 for Hawaii for administration of a VFC-funded vaccine to a VFC-eligible child

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Denying VFC-eligible children VFC-funded vaccine because of parents' inability to pay for the administration fee

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Failing to implement provider enrollment requirements of the VFC program;

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Failing to screen patients for VFC eligibility at every visit

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Failing to maintain VFC records and comply with other requirements of the VFC Program

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Failing to fully account for VFC-funded vaccine

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Failing to properly store and handle VFC vaccine

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Ordering VFC vaccine in quantities or patterns that do not match the provider's profile or otherwise over-ordering of VFC doses of vaccine

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Waste of VFC vaccine

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# HAWAII IMMUNIZATION REGISTRY

- Facility agreement must be completed annually.
  - Available online
- Each HIR user must complete the Confidentiality and Security Statement
- If either of the above are not completed by the annual due date of January 31 of each year, access will be disabled until completed
- For any HIR related questions, please contact HIR by
  - Email at [registryhelp@doh.hawaii.gov](mailto:registryhelp@doh.hawaii.gov)
  - Phone: 808-586-4665 (or toll-free at 1-888-447-1023 for neighbor islands).

# RESOURCES

## Hawaii VFC Program website:

- <https://health.hawaii.gov/docd/for-healthcare-providers/vaccination-resources/vaccines-for-children-program-vfc/>
- Online VFC Provider Reference Toolkit:  
<https://health.hawaii.gov/docd/files/2024/05/VFC-Toolkit-List.pdf>
- Toolkit is in the process of being updated

## Department of Health VFC YouTube Channel:

- [https://www.youtube.com/playlist?list=PLQ\\_ZpnRO72liSS9vG6rTS26GLfal](https://www.youtube.com/playlist?list=PLQ_ZpnRO72liSS9vG6rTS26GLfal)

## Hawaii Immunization Registry website:

- <https://health.hawaii.gov/docd/about-us/programs/hawaii-immunization-registry-hir/>

## Hawaii Department of Health YouTube Channel:

- <https://www.youtube.com/@HawaiiDOH>

## CDC VFC Operations Guide

- [operations-guide-508.pdf \(cdc.gov\)](https://www.cdc.gov/vaccines/programs/vfc/downloads/Operations-Guide-addendum-COVID-19-Nirsevimab.pdf)
- <https://www.cdc.gov/vaccines/programs/vfc/downloads/Operations-Guide-addendum-COVID-19-Nirsevimab.pdf>

# CONTACT INFO

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# POST WEBINAR SATISFACTION SURVEY

- Please use the following link to complete the satisfaction survey
  - <https://forms.office.com/pages/responsepage.aspx?id=xt5HOLJj-UOm0FikCqoaEFUigXCKFMdJlkpj-RIBWUBUQIcxTkxjWlhLVFFIN0dTUdCVFVTWFBDSi4u>





QUESTIONS