



Let's Catch Up. Recent Changes to Schedules, Policies and Products

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**Overview**

- VFC Policy Changes
  - Private Inventory
  - 317 Use Updates
- COVID Updates
- Niresvimab Allocations
- New Products and Licensure
- Newer NDIIS Processes

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**Funding Structure**

- Vaccines for Children (VFC)
  - \$16 Million annually
- Vaccines for Adults (VFA)
  - 317 vaccine budget - \$335,000 annually
  - Discretionary, up to states to determine usage while following federal policy
  - Has remained level funding for a few years even though more immunizations have been added and costs continues to increase

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## Private Inventory Policy Change (7/1/25)

- The federal VFC program will no longer require enrolled providers to stock private vaccine inventory to match their VFC vaccine inventory.
- If a facility plans to vaccinate an insured patient, they should plan to stock that particular private vaccine.
- VFC enrolled facilities will still be required to carry all ACIP recommended vaccines for the eligible populations they serve.
  - VFC eligible children are 0 through age 18 who are Medicaid eligible, American Indian/Alaskan Native, Un/underinsured.
- The only exception to this rule is for the upcoming respiratory season enrolled providers will not be required to carry COVID-19 vaccine for VFC eligible patients. Facilities will still need to make sure it is available for VFC eligible patients, whether that be through another provider offering vaccination or a follow up appointment.



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## Important Considerations

- Borrowing of public stock is NOT ALLOWED for vaccines where both a public and private inventory are maintained.
  - If doses are borrowed facilities will need to purchase a private dose to repay. This may mean purchasing an entire package quantity to pay back a single dose.
- Equitable access to vaccines is very important. If a facility decides to not carry a particular private vaccine they should be referring those patients to a facility in their community that will vaccinate the insured patient.
  - Patients should not be burdened with long distances or other issues associated with obtaining access to immunizations, regardless of their insurance status.



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## Additional Important Considerations

- Screening for insurance coverage must be done at EVERY immunization encounter. Publicly supplied vaccine should only be administered to those who are eligible.
- Enrolled facilities cannot bill for the cost of publicly supplied vaccines.
  - Administration fees may be billed but must not exceed \$20.99 and cannot be turned over to collections if the patient cannot afford to pay.



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## Find An Immunization

- <https://www.hhs.nd.gov/immunization-locator>
- Filter by immunization type (including brand), provider type, city and county

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## Find a VFC/VFA Enrolled Facility

- <https://www.hhs.nd.gov/immunizations/immunization-resources-public>
- Filter by county, city, zip, facility type and enrollment in VFC or VFA.

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## Discontinuation of the Universal Hep B Birth Dose (7/1/25)

- No longer universal for the hepatitis B birth dose at birthing facilities.
- All VFC enrolled birthing facilities need to purchase private vaccine to administer to insured infants.
- Publicly-supplied vaccines should only be administered to VFC eligible infants.
- Enrolled facilities have already been maintaining private inventories of Nirsevimab for insured infants. Hepatitis B will now follow the same protocols.

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## Data Entry Elements for Birthing Facilities

- Doses should be entered into EMR and electronic birth certificate as:
  - Public to VFC eligible category (Medicaid, AI, Un/Underinsured) OR
  - Private to Not Eligible
  - Other State Eligible should no longer be used in this situation

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## Underinsured and Newborns

- VFC enrolled facilities seeing a newborn or very young infant who may not yet have insurance coverage should infer insurance status from any of the following:
  - Parent/legal guardian report of insurance status
  - Vaccine Administration Records (VARs) where guardians have completed VFC status
  - How the visit/birth will be billed
    - If clinics are not charging out of pocket for the cost of the visit because you know they will eventually be insured, baby should not be considered uninsured.

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## Immunization Coverage Table

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Immunization Coverage Table  
As of 6/30/2025

Insurance Category	Age Group	Immunization Status
Medicaid	0-18 months	Not Eligible
Medicaid	19 months - 2 years	Not Eligible
Medicaid	2 years - 5 years	Not Eligible
Medicaid	5 years - 18 years	Not Eligible

- The immunization coverage table has been updated to reflect the new policy changes.
- <https://www.hhs.nd.gov/sites/www/files/documents/immunizationCoverageTable.pdf>

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### Rationale for Policy Changes

- The federal VFC program is prioritizing 317 vaccine funding for un/underinsured adults.
  - VFC funding is much more stable and should be used for children whenever possible.
  - Private, commercial insurance should be utilized whenever possible

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### Newer Vaccine Products and Updated Recommendations

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### Infant RSV Antibody Recommendations

- Administer RSV Antibody to infants October 1st – March 31<sup>st</sup>.
  - There may be special circumstances where the doses should be administered outside of this timeframe based on positivity rate of RSV in a specific region or state. Those extended recommendations would be communicated by the Immunization Unit.
- Doses should be given to all infants less than 8 months during their first RSV season. Preferably before they are discharged from birthing hospital.
- Children 8 – 19 months of age who have certain high-risk conditions. This includes American Indian Children.

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## Infant RSV Monoclonal Antibody Products

- Nirsevimab (Beyfortus®)
  - Manufactured by Sanofi Pasteur
  - Two different dosages depending on current weight.
    - 0.5 mL and 1.0 mL
  - Licensed for 0 – 24 months
- Clesrovimab (Enflonsia®)
  - Manufactured by Merck
  - One dosage regardless of age or weight, 105 mg/0.7 mL
  - Not approved for use in older age group during their second RSV season
  - Will be available through the VFC program

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## RSV Antibody Roll Out

- RSV Antibody doses will again be allocated by the CDC
- Allocations will begin in mid-August
- In the next week or so the Immunization Unit will send out a "prebooking" survey to begin allocating RSV doses to enrolled facilities.
  - Both RSV products will be included in the prebooking survey
  - Orders for those doses will be placed on behalf of facilities
- Private supply of RSV antibodies must be used for insured children.

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## Updated Flublok® Licensure

- For the 2025 – 2026 influenza season Flublok® is now licensed for use in individuals aged **nine** years of age and older.

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## ACIP 25-26 Influenza Vaccine Recommendations

- Recommendations for the influenza vaccination for the 2025-26 season: **ACIP reaffirms the recommendation for routine annual influenza vaccination or all persons aged ≥6 months who do not have contraindications.** (Vote: 6 yes, 0 no)
- Thimerosal Containing Influenza Vaccines:
  - **ACIP recommends children 18 years and younger receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative.** (Vote: 5 yes, 1 no, 1 abstain)
  - **ACIP recommends pregnant women receive season influenza vaccines only in single dose formulations that are free of thimerosal as a preservative.** (Vote: 5 yes, 1 no, 1 abstain)
  - **ACIP recommends all adults receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative.** (Vote: 5 yes, 1 no, 1 abstain)

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## Prebooked Influenza Vaccine Multi-Dose Vials

- The Immunization Unit has compiled a list of providers who prebooked influenza multi-dose vials. Will potentially replace those prebooks, if necessary.
  - Small percentage of doses are prebooked as multi-dose vials (3% of total)
  - Will wait for more information when CDC reviews the ACIP recommendation.  
Update will be send out in an immunization unit update.

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## Influenza Documents

- The Immunization Unit will update its annual documents including a memo with influenza vaccine recommendations, current vaccination algorithm and the dosage chart, including NDCs and CPT codes once that information has been released.
  - Hopefully in the upcoming weeks.

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## COVID-19 Vaccine Recommendations

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### CDC COVID-19 Pediatric Vaccine Recommendations

- On May 19, 2025, the HHS director issued a "Secretarial Directive" saying COVID-19 vaccines would no longer be recommended for children.
- The CDC childhood and adolescent immunization schedule was updated to recommend shared clinical decision making for COVID-19 vaccine for all children under 18 years.
- If the parent and provider choose to vaccinate a child the previous schedule should be used.

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### AAP COVID-19 Pediatric Vaccine Recommendations

- The AAP's Committee on Infectious Diseases is currently examining the evidence to make its own recommendations about COVID-19 vaccination.

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CDC COVID-19 Pregnant Women Recommendations

- On May 19, 2025, the HHS director issued a "Secretarial Directive" saying COVID-19 vaccines would no longer be recommended for pregnant women.
- The updated CDC Adult Immunization Schedule shows that there is no recommendation (for or against) COVID-19 vaccine in pregnant women.
- ACIP did vote on any COVID-19 vaccine recommendations at their recent meeting.

Vaccine	Pregnancy
COVID-19	

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ACOG COVID-19 Pregnant Women Vaccine Recommendations

- The [American College of Obstetricians & Gynecologists \(ACOG\)](#) strongly recommends that all eligible persons greater than 5 years of age, including pregnant and lactating women, receive a COVID-19 vaccine.
- This includes those who are pregnant, trying to become pregnant, recently pregnant, and who may become pregnant in the future.
- The ND HHS Immunization Unit will be following ACOG's recommendation. An updated COVID-19 & Pregnancy FAQ will be posted soon.

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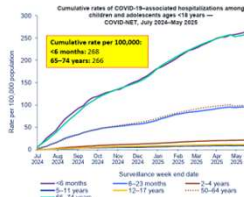
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Data from ACIP meeting

COVID-19 causes severe disease in infants ages <6 months.

- Highest rate of COVID-19-associated hospitalization among all pediatric age groups
  - Rates comparable to adults ages 65-74 years



Data reported from July 2024-May 2025. Excludes newborns who were admitted during the same hospitalization as their birth. Note that rates are not adjusted for testing. Rates are not limited to admissions where the respiratory infection is the likely primary reason for admission.

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## Data from ACIP meeting

**Infants <6 months experience high rates of severe COVID-19 disease.**

- Among infants <6 months hospitalized recently for COVID-19:
  - 22% were admitted to the ICU
  - 71% had no underlying medical conditions
  - 3.5% had any record of maternal COVID-19 vaccination during pregnancy
- No COVID-19 vaccine products are approved for infants ages <6 months.
- Any protection must come from transfer of maternal antibodies, either from vaccination during pregnancy or prior infection

Data reported from April 2024-March 2025. Hospitalizations are limited to those with COVID-19 as the likely reason for admission. Excludes newborns who were admitted during the same hospitalizations as their birth.

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## COVID-19 Vaccine Prebooks

- The Immunization Unit submitted the COVID-19 prebook to CDC.
- As additional recommendations are made the Immunization Unit will work with providers to modify any provider orders.

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## New Moderna COVID-19 Vaccine Product

- Moderna announced that the U.S. FDA approved mNEXSPIKE® (mRNA-1283) for use in all adults ages 65 and older and individuals 12-64 with at least one or more underlying risk factors as defined by the CDC. This is a next generation mRNA vaccine that showed safety and non-inferiority in phase III clinical trials compared to Moderna's previous vaccine, Spikevax.
- mNEXSPIKE® is a vaccine to protect against COVID-19. mNEXSPIKE is for people who have received a COVID-19 vaccine before

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## Other Immunization Updates

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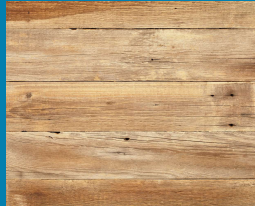
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## Measles Outbreak Update

- 34 cases in North Dakota in 2025
- No new cases of measles reported since the end of May.
- Friday, July 11<sup>th</sup> will end the measles outbreak in North Dakota (two incubation periods since last case).



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## Exemptions for MMR Vaccine - NDIIS

- History of disease should be thought about as evidence of immunity for MMR vaccine.
- Acceptable presumptive evidence of immunity against measles includes at least one of the following: ([immunize.org](https://www.immunize.org))
  - written documentation of adequate vaccination:
    - one or more doses of a measles-containing vaccine administered on or after the first birthday for preschool-age children and adults not at high risk
    - two doses of measles-containing vaccine for school-age children, adolescents, and adults at high risk, including college students, healthcare personnel, and international travelers
- laboratory evidence of immunity
- laboratory confirmation of measles (verbal history of measles does not count)
- birth before 1957

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### Exemptions for MMR Vaccine - NDIIS

- Must have documented history of disease exemption to measles, mumps and rubella in order for the NDIIS forecast to not recommend MMR vaccine.
- Medical exemption: The physical condition of the above-named person is such that immunization would endanger life or health or is medically contraindicated due to other medical conditions.
- All other reasons for an exemption would be considered personal belief exemptions (moral, philosophical and religious)



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### Measles Single Antigen Vaccine Availability

- The single antigen measles vaccine was discontinued in 2009.
- No scientific evidence exists to support that delaying vaccinations or separating them into individual antigens is beneficial for children. Rather, this practice prolongs susceptibility to disease, which could result in a greater likelihood of the child becoming sick with a serious or life-threatening disease. There could also be added expense (e.g., multiple office visits), additional time off from work for parents, and increased likelihood that the child will fail to get all necessary vaccinations. (immunize.org)



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### NDIIS Vaccine Reconciliation

- Within seven days of placing a vaccine order facilities must reconcile their vaccine inventory within the NDIIS.
- These numbers should reflect accurate inventory counts of what is currently on hand for public vaccine. Inventory counts are taken into account when approving vaccine orders.
- Inventory should be reconciled in the reconciliation portion of the NDIIS not in the vaccine order comment section.
- Only public vaccine must be reconciled however providers have the capability to reconcile their private inventory.



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## Change to NDIIS Ordering, Returns and Wastages

- The NDIIS team recently worked with the CDC to update how vaccine orders, returns and wastages are uploaded to the CDC.
- This process is now almost real-time once:
  - The vaccine order is approved
  - The vaccine return or wastage is submitted by the provider.
- This allows for much faster vaccine order approval and providers should expect to get vaccine packing slips and return labels the same day vaccine returns are submitted.



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## Post-Test

- Successfully complete the five-question post-test to receive your certificate for nursing credit using the link below:  
[https://ndhealth.co1.qualtrics.com/jfe/form/SV\\_eEfaOd6vQUPw5rU](https://ndhealth.co1.qualtrics.com/jfe/form/SV_eEfaOd6vQUPw5rU)
- Credit for this session will be available until August 12, 2025.
- This presentation will be posted to our website at:  
[www.hhs.nd.gov/immunizations](http://www.hhs.nd.gov/immunizations)



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## Immunization Unit Staff Members

For general immunization questions: [vaccine@nd.gov](mailto:vaccine@nd.gov)

For NDIIS-specific questions: [NDIIS@nd.gov](mailto:NDIIS@nd.gov)

### Immunization Unit

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