**North Carolina Department of Health and Human Services - North Carolina Immunization Program**
**2016 PRIVATE PROVIDER VACCINE AGREEMENT - NCIR**

The purpose of this agreement is to authorize _____ to receive vaccines from the North Carolina Department of Health and Human Services through the Vaccines for Children (VFC) Program. The conditions of the agreement listed below are effective for a period of 12 month.

A. The lead physician signing this agreement shall:

1. Administer vaccines provided through the North Carolina Immunization Program (NCIP), following all Advisory Committee on Immunization Practices (ACIP) guidelines, charging no third-party for the cost of vaccine. Vaccines received under this agreement must be directly administered to eligible patients and may not be given to non-NCIP health care providers or sold to any other health care provider or to any other person. Incidents of fraud and abuse can result in federal charges and must be reported to the Immunization Branch for investigation per the Fraud and Abuse Policy of the NCIP.
2. Third party billing for administration fees are permitted in accordance with the individual's insurance plan.
3. Impose no inappropriate condition or cost, such as a well-child visit, as a prerequisite to receiving vaccines. Charge no office fee in addition to the administration fee for an immunization–only or walk-in visit.
4. Record the following for each dose of vaccine administered in the NCIR: (a) the manufacturer, (b) lot number, (c) date of administration, (d) administration site and route, (e) date the relevant current VIS was given, (f) date printed on the VIS, and (g) name, address, and title of the provider who administered the vaccine.
5. Provide a signed immunization record, at no charge, to the parent, guardian, or patient each time an immunization is given as specified in G.S. 130A-154 and when needed for schools, childcare facilities, colleges/universities, or wherever immunization records are required. Keep immunization records, either electronically or in paper form, according to the retention of medical records position statement of the North Carolina Medical Board.
6. Share immunization data upon request as specified in G.S. 130A-153 and 15A NCAC 19A .0406.
7. Assume responsibility for the staff who order, store, administer and report vaccine usage. Ensure all current and new staff are fully trained in vaccine ordering, storing, handling, administration, use of the NCIR, reporting guidelines, and transportation of vaccine in an emergency situation annually, or more often as needed. Provide documentation (i.e. log sheet) of training participants and dates upon request of NCIP.
8. Assume accountability for all state supplied vaccines received by your practice/agency:
    a. Complete a physical inventory of all state-supplied vaccine at least weekly and properly reconcile with the NCIR at least monthly, with the recommendation of bi-weekly;
    b. Electronically record all vaccines into the NCIR at the time of administration or by the close of business the day the immunization is given;
9. Store vaccine on hand according to the most recent *NCIP Minimum Required Vaccine Ordering, Handling and Storage Procedures*.
10. The provider may be subject to the most current Financial Restitution Policy if vaccines are found to be wasted through the provider's failure to properly store, handle, or rotate the vaccine.
11. Notify the Immunization Branch thirty days prior to a change in the lead physician who signed this agreement.
12. Notify the Immunization Branch immediately when there are changes to the vaccine coordinator or back-up vaccine coordinator or a change in the facility shipping and mailing address.
13. Report all suspected or confirmed cases of vaccine preventable diseases to the local health department within 24 hours as specified in GS 130A-135 and 10A NCAC 41A .0101.

B. With respect to the North Carolina Immunization Registry (NCIR), the Lead Physician signing this agreement shall:

1. Designate a minimum of two NCIR Administrators, with active, up-to-date internet email addresses, to ensure that the access level for each user does not exceed that individual's role in the agency and that access is only within the user's scope of work. Deactivate all users immediately should they leave your practice.
2. Require all users accessing NCIR under your authority to sign a *User Confidentiality Agreement*, if they do not currently have one on file at your facility. The agreement must be made available to the Immunization Branch upon request.
3. As much as possible, assure that all patient names entered into the NCIR reflect the patient's true, legally-documented, complete name (e.g. birth certificate).
4. Ensure your facility has a contingency plan in place for use during periods of internal Internet disruption and/or NCIR outages.
5. Acknowledge and agree that the software does not make medical decisions and is not a substitute for competent, properly trained, and knowledgeable staff who bring professional judgment and analysis to the information presented by the software.

The Immunization Branch or provider may terminate this agreement at any time for personal reasons or failure to comply with conditions A.1 through B.5. The provider is required to comply with any additional VFC requirements as the CDC or NCIP may from time to time impose. Upon termination, the provider must properly store, handle, and return all viable, unused NCIP vaccine. All suspensions of eligibility shall be in accordance with G.S. 130A. Individuals and facilities on the "List of Excluded Individuals and Entities" published by the Department of Health and Human Services Office of the Inspector General are prohibited from participating in federally-funded health care programs including the VFC Program.

I understand the terms of this agreement and agree to comply with this agreement and the rules promulgated by the State of North Carolina.

| _____ | _____ | _____ | _____ | _____ |
|---|---|---|---|---|
| Physician's Signature (DO NOT USE A STAMP) | Physician's Name (PRINT OR STAMP) | Federal Tax ID | Physician's Medical License # | Date |

## INSTRUCTIONS

**PURPOSE:**

This document constitutes a legal agreement under which the North Carolina Immunization Branch may provide vaccines to a private provider to immunize patients and access to the North Carolina Immunization Registry.

**PREPARATION:**

1. Prepare an original and a copy.
2. Print or type the practice's name.
3. The signature must be of a Medical Doctor or Doctor of Osteopathy licensed to practice medicine in North Carolina.
4. The physician's signature must be an original; a stamp is not acceptable.
5. The agreement shall be available for review by Immunization Branch personnel.

**DISTRIBUTION:**

1. Mail, fax, or email agreement to:

   **Immunization Branch**
   **1917 Mail Service Center**
   **Raleigh, North Carolina 27699-1917**

   **Fax: 1-800-544-3058**

   **Email: ncirhelp@dhhs.nc.gov**

2. Retain a copy for your records.

**DISPOSITION:**

Completed (signed and dated) form must be retained until participation in the state-supplied vaccine program ends and for ten years following the end of the calendar year in which the agreement is terminated or for ten years following the year any vaccine recipient was immunized during the final year of the agreement. If a notice of a claim or lawsuit has been made, this agreement(s) should be retained until after final disposition of the claim or litigation (including appeals).

**SUPPORTING DOCUMENTS:**

Supporting documents, additional forms, and Branch policies may be obtained at http://www.immunize.nc.gov/ or by calling 1-877-873-6247.

# 2016 VACCINES FOR CHILDREN (VFC) PROGRAM PROVIDER AGREEMENT

| FACILITY INFORMATION | | | |
|---|---|---|---|
| Facility Name: | | | VFC Pin#: |
| Facility Address: | | | |
| City: | County: | State: | Zip: |
| Telephone: | | Fax: | |
| Shipping Address (*if different than facility address):* | | | |
| City: | County: | State: | Zip: |
| Mailing Address: | | | |
| City (Mailing): | County (Mailing): | State (Mailing): | Zip (Mailing): |

| MEDICAL DIRECTOR OR EQUIVALENT | | |
|---|---|---|
| **Instructions:** *The official VFC registered health care provider signing the agreement must be a practitioner authorized to administer pediatric vaccines under state law who will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the provider enrollment agreement. The individual listed here must sign the provider agreement.* | | |
| Last Name, First, MI: | Title: | Specialty: |
| License No.: | Medicaid or NPI No.: | Employer Identification No. *(optional):* |

| VFC VACCINE COORDINATOR | |
|---|---|
| **Primary Vaccine Coordinator Name:** | |
| Telephone: | Email: |
| Completed annual training:<br>○ Yes ○ No | Type of training received: |
| **Back-Up Vaccine Coordinator Name:** | |
| Telephone: | Email: |
| Completed annual training:<br>○ Yes ○ No | Type of training received: |

**PROVIDERS PRACTICING AT THIS FACILITY** *(additional spaces for providers at end of form)*

**Instructions:** *List below all licensed health care providers (MD, DO, NP, PA, pharmacist) at your facility who have prescribing authority.*

| Provider Name | Title | License No. | Medicaid or NPI No. | EIN *(Optional)* |
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## PROVIDER AGREEMENT

***To receive publicly funded vaccines at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with the health care facility of which I am the medical director or equivalent:***

| | |
|---|---|
| **1.** | I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if 1) the number of children served changes or 2) the status of the facility changes during the calendar year. |
| **2.** | I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories:<br><br>A. Federally Vaccine-eligible Children (VFC eligible)<br>1. Are an American Indian or Alaska Native;<br>2. Are enrolled in Medicaid;<br>3. Have no health insurance;<br>4. Are underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.<br><br>B. State Vaccine-eligible Children<br>1. In addition, to the extent that my state designates additional categories of children as "state vaccine-eligible", I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses (including 317 funded doses) to such children.<br><br>Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible), are **not** eligible to receive VFC-purchased vaccine. |
| **3.** | For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless:<br>a) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child;<br>b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions. |
| **4.** | I will maintain all records related to the VFC program for a minimum of three years and upon request make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records. |
| **5.** | I will immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine. |
| **6.** | I will not charge a vaccine administration fee to non-Medicaid federal vaccine eligible children that exceeds the administration fee cap of $20.45 per vaccine dose. For Medicaid children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans. |
| **7.** | I will not deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee. |
| **8.** | I will distribute the current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS). |

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| **9.** | I will comply with the requirements for vaccine management including:<br>a) Ordering vaccine and maintaining appropriate vaccine inventories;<br>b) Not storing vaccine in dormitory-style units at any time;<br>c) Storing vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet North Carolina Immunization Program storage and handling requirements;<br>d) Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration |
| **10.** | I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of the VFC Program:<br><br>**Fraud:** is an 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. It includes any act that constitutes fraud under applicable federal or state law.<br><br>**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 including 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. It also includes recipient practices that result in unnecessary cost to the Medicaid program. |
| **11.** | I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements. |
| **12.** | For providers with a signed deputization Memorandum of Understanding between a FQHC or RHC and the North Carolina Immunization Program to serve underinsured VFC-eligible children, I agree to:<br>a) Include "underinsured" as a VFC eligibility category during the screening for VFC eligibility at every visit;<br>b) Vaccinate "walk-in" VFC-eligible underinsured children; and<br>c) Report required usage data<br>Note: *"Walk-in" in this context refers to any underinsured child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve underinsured patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations then the policy would apply to underinsured patients as well.* |
| **13.** | I agree to replace vaccine purchased with federal funds (VFC, 317) that are deemed non-viable due to provider negligence on a dose-for-dose basis. |
| **14.** | I understand this facility or the North Carolina Immunization Program may terminate this agreement at any time. If I choose to terminate this agreement, I will properly return any unused federal vaccine as directed by the North Carolina Immunization Program. |

| | |
|---|---|
| ***By signing this form, I certify on behalf of myself and all immunization providers in this facility, I have read and agree to the Vaccines for Children enrollment requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.*** | |
| Medical Director or Equivalent Name (print): | |
| Signature: | Date: |

## ADDITIONAL PROVIDERS

| **PROVIDERS PRACTICING AT THIS FACILITY** *(attach additional pages as necessary)* | | | | |
|---|---|---|---|---|
| **Instructions:** *List below all licensed health care providers (MD, DO, NP, PA, pharmacist) at your facility who have prescribing authority.* | | | | |
| **Provider Name** | **Title** | **License No.** | **Medicaid or NPI No.** | **EIN *(Optional)*** |
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North Carolina Immunization Branch

# North Carolina Immunization Program (NCIP) Requirements

## Enrollment Requirements

The North Carolina Immunization Program works in conjunction with the federal vaccine supply program, called the Vaccines for Children (VFC) program, to provide vaccines free of cost to health care providers across the state. Participating health care providers must administer these vaccines according to NCIP guidelines. Providers may not charge patients for the cost of the vaccines, but they can charge an administration fee for each state-supplied vaccine given in an encounter. The administration fee may not exceed the rate established by the state's Medicaid program.

Over ninety percent of pediatricians who administer childhood immunizations in North Carolina are NCIP participants.

## Provider Responsibilities

NCIP participants must submit to the requirements of our program. These requirements include but are not limited to:

- Signing a legally-binding program agreement annually (only physicians licensed to practice medicine in North Carolina may sign an NCIP Provider Agreement),
- Allowing N.C. Immunization Branch staff to perform periodic site visits,
- Administering vaccines according to required guidelines,
- Maintaining correct storage and handling procedures for vaccines, and
- Accounting for every dose of state-supplied vaccine received.

NCIP participants are not required to enroll in the North Carolina Immunization Registry, although its use is strongly encouraged.

Access the following resources to learn more about program and policy information on the NCIP:

- Eligibility Errors and Replacement of Vaccine
- Administering NCIP Vaccine Offsite
- Charging for Vaccines Distributed by the North Carolina Immunization Program
- Fraud and Abuse Policy
- Medical Exemption from Immunization
- NCIP Policy on Multi-Dose Vaccine Vials
- Provider Vaccine Choice from the Immunization Program
- Recording of NCIP Immunization Doses
- Requirement for Providers to Carry Recommended Vaccines Policy
- VFC Eligibility Policy
- **Responsibilities of Provider Office**
- **Disaster Recovery Plan**
- **Financial Restitution**
- **Borrowing Policy Memo** **and** **Borrowing Policy Form**
- NCIP Vaccine Enrollment FAQs
- Re-Enrollment Statement
- Withdrawing from NCIP

## Enrollment, Annual Recertification & Withdrawing

**How do I enroll in the NCIP Program?**
Enrollment in North Carolina's VFC Program is easy. Contact the Immunization Branch at (919)707-5550 to request an enrollment packet. When e-mailing, be sure to include the practice name, mailing address, phone number, and e-mail address of the person to whom the packet should be sent. For more details see our enrollment requirements.

**I am enrolling in the NCIP Program. Do I need to mail the original enrollment forms to NCIP, or may I fax them?**
We are able to accept all enrollment forms via mail, fax, or e-mail. Originals are not necessary, but please keep a copy of the forms for your records.

**I have multiple sites. Do I need to enroll/register each individual site?**
Each site that actively administers vaccine must have a signed Provider Agreement on file with our Branch and be enrolled in our program. Vaccine is shipped directly to the provider to ensure the cold chain is maintained. This protects the cold chain, improves inventory functions in NCIR, and eases the provider burden during federally mandated site visits.

**Why should I join the North Carolina Vaccines for Children (NCIP) Program?**
Participation in our program will enhance your ability to protect your most vulnerable patients with all recommended vaccines without sending them to other locations for vaccination.

**When do I need to recertify in the NCIP program and what documentation do I need?**
All providers are required to recertify their enrollment annually. It ensures that your clinic will continue to receive publically purchased vaccines during the upcoming year. NCIP initiates the process by sending you a recertification packet. You do not need to do anything about recertification until you receive the packet.

**We are changing ownership. What do I need to do?**
Please contact the NCIP immediately to notify us of the change in ownership. Your practice will need to complete a new Provider Profile to update any practice information and if your lead physician or practice name has changed, you will need to submit a new Provider Agreement. For additional assistance, contact your NCIP Customer Service Representative at ncirhelp@dhhs.nc.gov.

**Who is my NCIP Field Representative?**
Each geographic area has designated Regional Nurse Consultant and Regional Immunization Consultant. Please contact the Branch at ImmInfo@dhhs.nc.gov to receive contact information for your consultants.

**What documentation should I retain for my records?**
Patient immunization records should never be destroyed. All VFC documentation must be retained for at least 36 months This includes:

☐ Vaccine temperature logs

☐ NC Borrowing and Replacement Forms

☐ Manual Vaccines Administered Logs (VALs)

☐ Copies of all vaccine packing slips

☐ Thermometer certificate of calibration

**How do I request temperature logs, vaccine posters, etc.?**
Resources for providers can be accessed on-line here, and printed as needed. A limited number of resources are available for order from our Materials Warehouse and can be ordered using this order form.

**How do I withdraw from NCIP?**
Should you wish to withdraw from our program, you will need to request a Withdrawal packet from the Immunization Branch by calling 1-877-873-6247 or e-mailing ncirhelp@dhhs.nc.gov. The packet includes a brief statement from the physician about why your practice is leaving, instructions for continued NCIR access, and instructions for the transfer of all remaining state-supplied vaccine.

## Withdrawal from the NCIP

A provider may terminate the NCIP Provider Agreement at any time because of lack of eligible patients, closure of a practice, or other personal reasons. Likewise, the Immunization Branch may terminate the agreement due to failure to comply with any of the conditions therein, appearance of practice staff on the Federal Office of the Inspector General's Excluded Individuals list, or failure to recertify enrollment by submission of a Provider Agreement and Provider Profile on an annual basis.

Upon termination, regardless of the reason, the provider maintains responsibility to properly store, handle, and relocate all viable, unused NCIP vaccine. In most cases this vaccine can be taken on by the county health department, but the Immunization Branch can provide assistance in finding an active provider that may be able to use excess vaccine.

Providers wishing to withdraw from the program should submit an NCIP Provider Withdrawal Statement including an inventory of all publically purchased vaccines in your facility. If your office is a user of the North Carolina Immunization Registry, you can maintain access by completing a NCIR-Only Provider Agreement within 30 days of withdrawal.

Withdrawal from the program is considered permanent. However, a provider who withdraws may be allowed to re-enroll if they demonstrate full compliance with federal and state laws and all program policies and complete the enrollment process, including completion of all certification paperwork, verification of storage facilities, and an enrollment site visit.

Annual Recertification

Each year, typically in the fall, for the continued use of state-supplied vaccines all North Carolina Immunization Program (NCIP) providers must recertify their enrollment in the program by submitting an updated Vaccine Provider Agreement and Provider Profile to the North Carolina Immunization Branch. The Branch will initiate the process by sending all providers a pre-printed recertification packet including the documents listed below. This process is mandated by the federal Vaccines For Children (VFC) Program for the continued receipt of federally-purchased vaccines. No vaccine can be sent to a provider without a current contract on file. Failure to return the signed agreements and updated profiles by the stated deadline will result in vaccine shipment delays and may result in the provider being removed from the program.

- Provider Agreement – This document lists the federal statutory requirements of the VFC Program as defined in the federal Social Security Act, Title XIX, Section 1928, 42 U.S.C. 1396s - Vaccines for Children Program (VFC) and state statutory requirements as defined by NC GS § 130A-152. This document must be signed by the lead physician of your facility (or health director for county health departments). Agreements must be signed by a Medical Doctor (MD) or Doctor of Osteopathy (DO). Contracts signed by nurse practitioners, physician assistants, and/or pharmacists will not be accepted. By signing this document, your facility agrees to abide by all requirements of the NCIP.
- Provider Profile – This document provides contact information for your facility, including a shipping address for vaccines (no P.O. boxes), days and times when vaccines can be received, and a list of all personnel (with a medical license) authorized to write prescriptions. This information is entered into our vaccine ordering system. The document also includes an estimate of your patient population listed by age group and eligibility status. This information is vital as it is used to forecast our federal vaccine budget and determine appropriate order amounts and frequency for your facility.

Though recertification packets are sent to all providers in the fall, you should notify the NC Immunization Help Desk (1-877-873-6247) at any time if:

- Your lead physician or medical director changes

- Your practice name, contact information, or vaccine shipping instructions change
- Your practice merges with another or opens a sub-clinic that will be immunizing patients
- Any changes that occur that may affect your ability to receive and/or administer vaccine as previously estimated

Instructions for the completion and return of the packet are listed on the documents themselves. Questions about completion or return of the packet may be directed to Branch staff at 1-877-873-6247.

**Subject:** **NCIP Financial Restitution Policy**

**Revised:** **December 2007**
**Updated:** **December 2012, May 2013**

**Policy:**

Session Law 1998-212, Section 12.52 (d) states that "the Division shall notify all immunization program providers that providers shall be required to pay the cost of vaccine provided to replace vaccine wasted due to provider negligence in the storage, handling, or rotation of inventory."

**Per the Immunization Program Operations Manual published by the Centers for Disease Control and Prevention (CDC), the following terms are defined below:**
**Vaccine loss:** Vaccine that has expired, spoiled, or has been wasted.
**Spoiled or expired vaccine:** Non-viable vaccine in its original container (vial or syringe) that is able to be returned for excise tax credit. This includes expired vaccine or vaccine that has been spoiled as a result of temperature excursions.
**Wasted vaccine:** Non-viable vaccine that is not able to be returned for excise tax credit. This includes broken vials or syringes, unused vaccine drawn into a syringe, or remaining doses in a multi-dose vial.

**Examples of Situations Requiring Financial Restitution**
The following situations are considered to be examples of provider negligence that will require financial restitution. This list is not exhaustive. Situations that occur which are not listed here will be considered on an individual basis by the Vaccine Distribution Manager, with final determination at the discretion of the Branch Head.

- Failure to rotate vaccine that results in expired vaccine
- Drawing up vaccine prior to patient screening (and not using the vaccine)
- Vaccine left out of the refrigeration unit and declared non-viable by Immunization Branch Staff
- Freezing of vaccine licensed to be refrigerated only
- Refrigerating vaccine licensed to be frozen only
- Refrigerator left unplugged or electrical breaker switched off
- Refrigerator door left open or ajar by provider staff, contractors, or guests
- Refrigeration unit failure with no documentation of equipment repair or replacement
- Vaccine stored in a dorm-style refrigerator
- Failure to submit correct shipping information when placing a vaccine order

**Examples of Situations Not Requiring Financial Restitution**
The following examples are situations considered to be out of the providers' control, and generally do not require financial restitution. This list is not exhaustive. Providers should always contact the Immunization Branch for a determination regarding the viability of suspect

vaccine. Documentation from third-parties (such as in the case of power outages or refrigerator repair) must be submitted within 30 days of the temperature excursion.

- Package is not delivered to the provider in a timely manner or is otherwise damaged or stored improperly during transit
- An incident or excursion in which a third-party alarm company does not notify the provider (documentation required)
- Partially used multi-dose vials
- A vial that is accidentally dropped or broken by provider
- Vaccine that is drawn after screening for contraindications and parental education, but not administered, due to parental refusal or a change in the physician orders
- Equipment failure where proof of equipment repair or replacement is provided to the Immunization Branch
- Extraordinary situations not listed above which are deemed by the Immunization Branch to be beyond the provider's control (when reporting wastage of any kind, providers should provide documentation that demonstrates staff's use of the clinic Disaster Recovery Plan)

**Procedures for Financial Restitution**

This updated policy applies to any vaccine received as wasted by the Immunization Branch on or after **April 1, 2000.**

- The provider will receive an invoice for vaccine reported as wasted to the Immunization Branch from the Department of Health and Human Services (DHHS), Controller's Office.
- The invoice will reflect the current Centers for Disease Control and Prevention (CDC) cost of the vaccine, minus the excise tax. In accordance with DHHS Cash Management Plan, reimbursement for the cost of vaccine wasted shall be due **30 days** from the date of the invoice.
- General Statute 147-86.23 requires interest be charged at the rate established pursuant to General Statute 105-241.1 on past due accounts. A late penalty of 10 percent may be charged on past due accounts.

**Procedures for Returning Vaccine to the Immunization Branch**

- The provider should call the Immunization Branch Help Desk (1-877-873-6247)as soon as it is suspected vaccine may be spoiled and prior to returning **ANY** vaccine that has not yet reached its expiration date.
- The provider should return all unopened vials and manufacturer's pre-filled syringes of spoiled or expired vaccine with a completed Wasted/Expired Form to the Immunization Branch, regardless of any financial restitution status applied to the vaccine. Needles or open vials should never be returned to the Immunization Branch.

**Procedure for Appeal Process**

The Financial Restitution Policy allows for an appeal process. If an office/agency experiences a wastage situation which is defined as provider negligence, and believe there are circumstances which prove it is not negligence, the provider may appeal ***after*** they have received the invoice. A format for appeal is attached.

This appeal must be in writing and can be submitted by mail or fax on the provider's letterhead or on a Financial Restitution Appeal Form. If the provider chooses not to use the Financial Restitution Appeal Form, the same information must be included that is contained on the form. All information that the provider would like considered in their appeal (e.g., repair invoices, indicating that the product had a service call and was repaired) must be included with the appeal form.

Fax to: (919) 870-4824
Attention: Vaccine Distribution Manager

Mail to: DHHS/DPH/Immunization Branch
Attention: Vaccine Distribution Manager
1917 Mail Service Center
Raleigh, NC 27699-1917

- Each appeal will be considered on a case by case basis.
- The provider office will receive written notification regarding the outcome of the appeal within 10 days of receipt.
- The appeal must be signed by the provider office's lead physician or, in the case of local health departments, the health director.

Approved by: _____ Date: 5/30/13

Updated: 12/12, 5/13
Filename: NCIP financial restitution policy updated 5-13

# FINANCIAL RESTITUTION APPEAL

Fax to: Vaccine Distribution Manager
(919) 870-4824

or

Mail to:
DHHS/DPH/Immunization Branch
Vaccine Distribution Manager
1917 Mail Service Center
Raleigh, NC 27699-1917

Facility Name: _____
Contact: _____
Federal Id: _____
Address: _____
_____
Phone: _____

Invoice number: _____
Invoice date: _____

We believe we should not be held financially responsible for the vaccine and request reconsideration for the following reason(s). Below is a detailed explanation of the circumstances surrounding the event(s).

Provide any necessary attachments (including maintenance records, invoices, etc.).

_____
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_____

_____
(Physician or Health Director signature and date)

For Program Use Only:

Decision rendered on: _____ By: _____

Responsible: _____ Not Responsible _____ Date Notified: _____

Part 2. Immunization.

**§ 130A-152. Immunization required.**

(a) Every child present in this State shall be immunized against diphtheria, tetanus, whooping cough, poliomyelitis, red measles (rubeola) and rubella. In addition, every child present in this State shall be immunized against any other disease upon a determination by the Commission that the immunization is in the interest of the public health. Every parent, guardian, person in loco parentis and person or agency, whether governmental or private, with legal custody of a child shall have the responsibility to ensure that the child has received the required immunization at the age required by the Commission. If a child has not received the required immunizations by the specified age, the responsible person shall obtain the required immunization for the child as soon as possible after the lack of the required immunization is determined.

(b) Repealed by Session Laws 2002-179, s. 10, effective October 1, 2002.

(c) The Commission shall adopt and the Department shall enforce rules concerning the implementation of the immunization program. The rules shall provide for:

(1) The child's age at administration of each vaccine;

(2) The number of doses of each vaccine;

(3) Exemptions from the immunization requirements where medical practice suggests that immunization would not be in the best health interests of a specific category of children;

(4) The procedures and practices for administering the vaccine; and

(5) Redistribution of vaccines provided to local health departments.

(c1) The Commission for Public Health shall, pursuant to G.S. 130A-152 and G.S. 130A-433, adopt rules establishing reasonable fees for the administration of vaccines and rules limiting the requirements that can be placed on children, their parents, guardians, or custodians as a condition for receiving vaccines provided by the State. These rules shall become effective January 1, 1994.

(d) Only vaccine preparations which meet the standards of the United States Food and Drug Administration or its successor in licensing vaccines and are approved for use by the Commission may be used.

(e) When the Commission requires immunization against a disease not listed in paragraph (a) of this section, or requires an additional dose of a vaccine, the Commission is authorized to exempt from the new requirement children who are or who have been enrolled in school (K-12) on or before the effective date of the new requirement. (1957, c. 1357, s. 1; 1971, c. 191; 1973, c. 476, s. 128; c. 632, s. 1; 1975, c. 84; 1977, c. 160; 1979, c. 56, s. 1; 1983, c. 891, s. 2; 1985, c. 158; 1993, c. 321, s. 281(a); 2002-179, s. 10; 2007-182, s. 2.)

**§ 130A-153. Obtaining immunization; reporting by local health departments; access to immunization information in patient records; immunization of minors.**

(a) The required immunization may be obtained from a physician licensed to practice medicine, from a local health department, or in the case of a person at least 18 years of age, from an immunizing pharmacist. Local health departments shall administer required and State-supplied immunizations at no cost to uninsured or underinsured patients with family incomes below two hundred percent (200%) of the federal poverty level. A local health department may redistribute these vaccines only in accordance with the rules of the Commission.

(b) Local health departments shall file monthly immunization reports with the Department. The report shall be filed on forms prepared by the Department and shall state, at a minimum, each patient's age and the number of doses of each type of vaccine administered.

(c) Immunization certificates and information concerning immunizations contained in medical or other records shall, upon request, be shared with the Department, local health departments, an immunizing pharmacist, and the patient's attending physician. In addition, an insurance institution, agent, or insurance support organization, as those terms are defined in G.S. 58-39-15, may share immunization information with the Department. The Commission may, for the purpose of assisting the Department in enforcing this Part, provide by rule that other persons may have access to immunization information, in whole or in part.

(d) A physician or local health department may immunize a minor with the consent of a parent, guardian, or person standing in loco parentis to the minor. A physician or local health department may also immunize a minor who is presented for immunization by an adult who signs a statement that he or she is authorized by a parent, guardian, or person standing in loco parentis to the minor to obtain the immunization for the minor. (1957, c. 1357, s. 1; 1959, c. 177; 1965, c. 652; 1971, c. 191; 1973, c. 476, s. 128; 1979, c. 56, s. 1; 1983, c. 891, s. 2; 1985, c. 743, ss. 1, 2; 1993, c. 134, s. 1; 1999-110, s. 2; 2009-451, s. 10.29A(a); 2010-31, s. 10.13(b); 2013-246, s. 5.)

**§ 130A-154. Certificate of immunization.**

(a) A physician or local health department administering a required vaccine shall give a certificate of immunization to the person who presented the child for immunization. The certificate shall state the name of the child, the name of the child's parent, guardian, or person responsible for the child obtaining the required immunization, the address of the child and the parent, guardian or responsible person, the date of birth of the child, the sex of the child, the number of doses of the vaccine given, the date the doses were given, the name and address of the physician or local health department administering the required immunization and other relevant information required by the Commission.

(b) Except as otherwise provided in this subsection, a person who received immunizations in a state other than North Carolina shall present an official certificate or record of immunization to the child care facility, school (K-12), or college or university. This certificate or record shall state the person's name, address, date of birth, and sex; the type and number of doses of administered vaccine; the dates of the first MMR and the last DTP and polio; the name and address of the physician or local health department administering the required immunization; and other relevant information required by the Commission. (1957, c. 1357, s. 1; 1959, c. 177; 1965, c. 652; 1971, c. 191; 1979, c. 56, s. 1; 1983, c. 891, s. 2; 1999-110, s. 3.)

**§ 130A-155. Submission of certificate to child care facility, preschool and school authorities; record maintenance; reporting.**

(a) No child shall attend a school (pre K-12), whether public, private or religious, a child care facility as defined in G.S. 110-86(3), unless a certificate of immunization indicating that the child has received the immunizations required by G.S. 130A-152 is presented to the school or facility. The parent, guardian, or responsible person must present a certificate of immunization on the child's first day of attendance to the principal of the school or operator of the facility, as defined in G.S. 110-86(7). If a certificate of immunization is not presented on the first day, the principal or operator shall present a notice of deficiency to the parent, guardian or responsible person. The parent, guardian or responsible person shall have 30 calendar days from the first day of attendance to obtain the required immunization for the child. If the administration of vaccine in a series of doses given at medically approved intervals requires a period in excess of 30 calendar days, additional days upon certification by a physician may be allowed to obtain the required immunization. Upon termination of 30 calendar days or the extended period, the principal or operator shall not permit the child to attend the school or facility unless the required immunization has been obtained.

(b) The school or child care facility shall maintain on file immunization records for all children attending the school or facility which contain the information required for a certificate of immunization as specified in G.S. 130A-154. These certificates shall be open to inspection by the Department and the local health department during normal business hours. When a child transfers to another school or facility, the school or facility which the child previously attended shall, upon request, send a copy of the child's immunization record at no charge to the school or facility to which the child has transferred.

(c) The school shall file an annual immunization report with the Department by November 1. The child care facility shall file an immunization report annually with the Department. The report shall be filed on forms prepared by the Department and shall state the number of children attending the school or facility, the number of children who had not obtained the required immunization within 30 days of their first attendance, the number of children who received a medical exemption and the number of children who received a religious exemption.

(d) Any adult who attends school (pre K-12), whether public, private or religious, shall obtain the immunizations required in G.S. 130A-152 and shall present to the school a certificate in accordance with this section. The physician or local health department administering a required vaccine to the adult shall give a certificate of immunization to the person. The certificate shall state the person's name, address, date of birth and sex; the number of doses of the vaccine given; the date the doses were given; the name and addresses of the physician or local health department administering the required immunization; and other relevant information required by the Commission. (1957, c. 1357, s. 1; 1959, c. 177; 1965, c. 652; 1971, c. 191; 1973, c. 632, s. 2; 1979, c. 56, s. 1; 1981, c. 44; 1983, c. 891, s. 2; 1997-506, s. 47; 1999-110, s. 4; 2007-187, s. 2.)

**§ 130A-155.1. Submission of certificate to college or universities.**

(a) Except as otherwise provided in this section, no person shall attend a college or university, whether public, private, or religious, unless a certificate of immunization or a record of immunization from a high school located in North Carolina indicating that the person has received immunizations required by G.S. 130A-152 is presented to the college or university. The person shall present a certificate or record of immunization on or before the date the person first registers for a quarter or semester during which the student will reside on the campus or first registers for more than four traditional day credit hours to the registrar of the college or university. If a certificate or record of immunization is not in the possession of the college or university on the date of first registration, the college or university shall present a notice of deficiency to the student. The student shall have 30 calendar days from the date of the student's first registration to obtain the required immunization. If immunization requires a series of doses and the period necessary to give the vaccine at standard intervals extends beyond the date of the first registration, the student shall be allowed to attend the college or university upon written certification by a physician that the standard series is in progress. The physician shall state the time period needed to complete the series. Upon termination of this time period, the college or university shall not permit the student to continue in attendance unless the required immunization has been obtained.

(b) The college or university shall maintain on file immunization records for all students attending the school which contain the information required for a certificate of immunization as specified in G.S. 130A-154. These certificates shall be open to inspection by the Department and the local health department during normal business hours. When a student transfers to another college or university, the college or university which the student previously attended shall, upon request, send a copy of the student's immunization record at no charge to the college or university to which the student has transferred.

(c) Within 60 calendar days after the commencement of a new school year, the college or university shall file an immunization report with the Department. The report shall be filed on forms prepared by the Department and shall state the number of students attending the school or facility, the number of students who had not obtained the required immunization within 30 days of their first attendance, the number of students who received a medical exemption and the number of students who received a religious exemption.

(d) Repealed by Session Laws 1999-110, s. 5.

(e) The provisions of this section shall not apply to:

(1) Educational institutions established under Chapter 115D of the General Statutes.

(2) Students residing off-campus and registering for any combination of:

a. Off-campus courses.

b. Evening courses.

c. Weekend courses.

d. No more than four traditional day credit hours in on-campus courses. (1985, c. 692, s. 1; 1987, c. 782, s. 17; 1991, c. 381, s. 1; 1999-110, s. 5; 2007-99, s. 1.)

**§ 130A-156. Medical exemption.**

The Commission for Public Health shall adopt by rule medical contraindications to immunizations required by G.S. 130A-152. If a physician licensed to practice medicine in this State certifies that a required immunization is or may be detrimental to a person's health due to the presence of one of the contraindications adopted by the Commission, the person is not required to receive the specified immunization as long as the contraindication persists. The State Health Director may, upon request by a physician licensed to practice medicine in this State, grant a medical exemption to a required immunization for a contraindication not on the list adopted by the Commission. (1957, c. 1357, s. 1; 1959, c. 177; 1965, c. 652; 1971, c. 191; 1979, c. 56, s. 1; 1983, c. 891, s. 2; 1987, c. 782, s. 18; 1989, c. 122; 1999-110, s. 6; 2007-182, s. 2.)

**§ 130A-157. Religious exemption.**

If the bona fide religious beliefs of an adult or the parent, guardian or person in loco parentis of a child are contrary to the immunization requirements contained in this Chapter, the adult or the child shall be exempt from the requirements. Upon submission of a written statement of the bona fide religious beliefs and opposition to the immunization requirements, the person may attend the college, university, school or facility without presenting a certificate of immunization. (1957, c. 1357, s. 1; 1959, c. 177; 1965, c. 652; 1971, c. 191; 1979, c. 56, s. 1; 1983, c. 891, s. 2; 1985, c. 692, s. 2; 2002-179, s. 17.)

**§ 130A-158. Restitution required when vaccine spoiled due to provider negligence.**

Immunization program providers shall be liable for restitution to the State for the cost of replacement vaccine when vaccine in the provider's inventory has become spoiled or unstable due to the provider's negligence and unreasonable failure to properly handle or store the vaccine. (2001-424, s. 21.86(a).)

Article 17.
Childhood Vaccine-Related Injury Compensation Program.

**§ 130A-422. Definitions.**

The following definitions apply throughout this Article, unless the context clearly implies otherwise:

(1) "Claimant" means any person who files a claim for compensation for a vaccine-related injury pursuant to G.S. 130A-425(b). In the case of a minor or incompetent, a claim may be filed by a guardian ad litem, parent, guardian, or other legal representative; and, in the case of a decedent, the claim may be filed by an administrator, executor, or other legal representative.

In the event that more than one person claims to have suffered compensable injuries as the result of the administration of a covered vaccine to a single individual, all these persons shall be treated for purposes of this Article as if they were a single claimant. A single joint claim shall be filed on behalf of all these persons, and the limitations on awards set forth in G.S. 130A-427(b) apply to that joint claim or subsequent joint action as if it were a claim filed on behalf of a single individual.

(2) "Commission" means the North Carolina Industrial Commission.

(3) "Covered vaccine" means a vaccine administered pursuant to the requirements of G.S. 130A-152.

(4) "Respondent" means the person or entity the claimant identifies in the claim as the agent of causality of the vaccine-related injury.

(5) "Vaccine-related injury", with respect to persons engaged in the manufacture, distribution, or sale, or administration of a covered vaccine, means any injury, disability, illness, death, or condition caused by the vaccine. "Vaccine-related injury" shall not mean any injury, disability, illness, death, or condition caused by the method of injection of the vaccine into the body. (1985 (Reg. Sess., 1986), c. 1008, s. 1; 1987, c. 215, s. 8.)

**§ 130A-423. North Carolina Childhood Vaccine-Related Injury Compensation Program; exclusive remedy; relationship to federal law; subrogation.**

(a) There is established the North Carolina Childhood Vaccine-Related Injury Compensation Program.

(b) The rights and remedies granted the claimant, the claimant's parent, guardian ad litem, guardian, or personal representative shall exclude all other rights and remedies of the claimant, his parent, guardian ad litem, guardian, or personal representative against any respondent at common law or otherwise on account of injury, illness, disability, death, or condition. If an action is filed, it shall be dismissed, with prejudice, on the motion of any party under law.

(b1) A claimant may file a petition pursuant to this Article only after the claimant has filed an election pursuant to Section 2121 of the Public Health Service Act, P.L. 99-660, permitting the claimant to file a civil action for damages for a vaccine-related injury or death or if the claimant is otherwise permitted by federal law to file an action against a vaccine manufacturer.

(c) Nothing in this Article prohibits any individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if the action is not barred by federal law under subtitle 2 of Title XXI of the Public Health Service Act.

(d) If any action is brought against a vaccine manufacturer as permitted by subtitle 2 of Title XXI of the Public Health Service Act and subsection (c) of this section, the plaintiff in the action may recover damages only to the extent permitted by subdivisions (1) through (3) of

subsection (a) of G.S. 130A-427. The aggregate amount awarded in any action may not exceed the limitation established by subsection (b) of G.S. 130A-427. Regardless of whether an action is brought against a vaccine manufacturer, a claimant who has filed an election pursuant to Section 2121 of the Public Health Service Act, as enacted into federal law by Public Law 99-660, permitting a claimant to file a civil action for damages for a vaccine-related injury or death, or who is otherwise permitted by federal law to file an action against a vaccine manufacturer, may file a petition pursuant to G.S. 130A-425 to obtain services from the Department pursuant to subdivision (5) of subsection (a) of G.S. 130A-427 and, if no action has been brought against a vaccine manufacturer, to obtain other relief available pursuant to G.S. 130A-427.

(e) In order to prevent recovery of duplicate damages, or the imposition of duplicate liability, in the event that an individual seeks an award pursuant to G.S. 130A-427 and also files suit against the manufacturer as permitted by subtitle 2 of Title XXI of the Public Health Service Act and subsection (c) of this section, the following provisions shall apply:

(1) If, at the time an award is made pursuant to G.S. 130A-427, an individual has already recovered damages from a manufacturer pursuant to a judgment or settlement, the award shall consist only of a commitment to provide services pursuant to subdivision (5) of subsection (a) of G.S. 130A-427.

(2) If, at any time after an award is made to a claimant pursuant to G.S. 130A-427, an individual recovers damages for the same vaccine-related injury from a manufacturer pursuant to a judgment or settlement, the individual who recovers the damages shall reimburse the State for all amounts previously recovered from the State in the prior proceeding. Before a defendant in any action for a vaccine-related injury pays any amount to a plaintiff to discharge a judgment or settlement, he shall request from the Secretary a statement itemizing any reimbursement owed by the plaintiff pursuant to this subdivision, and, if any reimbursement is owed by the plaintiff to the Department, the defendant shall pay the reimbursable amounts, as determined by the Secretary, directly to the Department. This payment shall discharge the plaintiff's obligations to the State under this subdivision and any obligation the defendant may have to the plaintiff with respect to these amounts.

(3) If:

a. An award has been made to a claimant for an element of damages pursuant to G.S. 130A-427; and

b. An individual has recovered for the same element of damages pursuant to a judgment in, or settlement of, an action for the same vaccine-related injury brought against a manufacturer, and that amount has not been remitted to the State pursuant to subdivision (2) of this subsection; and

c. The State seeks to recover the amounts it paid in an action it brings against the manufacturer pursuant to G.S. 130A-430;

any judgment obtained by the State under G.S. 130A-430 shall be reduced by the amount necessary to prevent the double recovery of any element of damages from the manufacturer. Nothing in this subdivision limits the State's right to obtain reimbursement from a claimant under subdivision (2) of this subsection with respect to any double payment that might be received by the claimant.

(f) Subrogation claims pursued under the National Childhood Vaccine Injury Act of 1986 shall be filed with the appropriate court, not with the Industrial Commission. (1985 (Reg. Sess., 1986), c. 1008, s. 1; 1987, c. 215, ss. 1, 2; 1989, c. 727, ss. 148, 149; 1991, c. 410, s. 1; 1997-443, s. 11A.85.)

**§ 130A-424. Industrial Commission authorized to hear and determine claims; damages.**

The North Carolina Industrial Commission is authorized to hear and pass upon all claims filed pursuant to this Article. The members of the Commission, or a deputy thereof, have power to issue subpoenas, administer oaths, conduct hearings, take evidence, enter orders, opinions, settlements, and awards, and punish for contempt. The Commission may appoint deputies and clerical assistants to carry out the purpose and intent of this Article, and this deputy or deputies are vested with the same power and authority to hear and determine claims filed pursuant to this Article as is by this Article vested in the members of the Commission. (1985 (Reg. Sess., 1986), c. 1008, s. 1.)

**§ 130A-425. Filing of claims.**

(a) Notwithstanding any other provision of State law, no action for compensation for a vaccine-related injury may be filed against any person unless that person was named as a respondent in a claim filed pursuant to this section and unless the claim was filed within the applicable time period set forth in G.S. 130A-429.

(b) In all claims filed pursuant to this Article, the claimant or the person in whose behalf the claim is made shall file with the Commission a verified petition in duplicate, setting forth the following information:

(1) The name and address of the claimant;

(2) The name and address of each respondent;

(3) The amount of compensation in money and services sought to be recovered;

(4) The time and place where the injury occurred;

(5) A brief statement of the facts and circumstances surrounding the injury and giving rise to the claim; and

(6) Supporting documentation and a statement of the claim that the claimant or the person in whose behalf the claim is made suffered a vaccine-related injury and has not previously collected an award or settlement of a civil action for damages for this injury. This supporting documentation shall include all available medical records pertaining to the alleged injury, including autopsy reports, if any, and if the injured person was under two years of age at the time of injury, all prenatal, obstetrical, and pediatric records of care preceding the injury, and an identification of any unavailable records known to the claimant or the person in whose behalf the claim is made.

(7) Documentation to show that the claimant has filed an election pursuant to Section 2121 of the Public Health Service Act, P.L. 99-660, permitting such claimant to file a civil action for damages for a vaccine-related injury or death or documentation to show that such claimant is otherwise permitted by federal law to file an action against a vaccine manufacturer.

(c) Upon receipt of this verified petition in duplicate, the Commission shall enter the case upon its hearing docket and shall determine the matter in the county where the injury occurred unless the parties agree or the Commission directs that the case may be heard in some other county. All parties shall be given reasonable notice of the date when and the place where the claim will be heard. Immediately upon receipt of the claim, the Commission shall serve a copy of the verified petition on each respondent by registered or certified mail. The Commission shall also send a copy of the verified petition to the Secretary, who shall be a party to all proceedings involving the claim, and to the Attorney General who shall represent the State's interest in all the proceedings involving the claim.

(d) The Commission shall adopt rules necessary to govern the proceedings required by this Article. The Rules of Civil Procedure as contained in G.S. 1A-1 **et seq.** and the General

Rules of Practice for the Superior and District Courts as authorized by G.S. 7A-34 apply to claims filed with the Industrial Commission under this Article. The Commission shall keep a record of all proceedings conducted under this Article, and has the right to subpoena any persons and records it considers necessary in making its determinations. The Commission may require all persons called as witnesses to testify under oath or affirmation, and any member of the Commission may administer oaths. If any persons refuse to comply with any subpoena issued pursuant to this Article or to testify with respect to any matter relevant to proceedings conducted under this Article, the Superior Court of Wake County, on application of the Commission, may issue an order requiring the person to comply with the subpoena and to testify. Any failure to obey any such order may be punished by the court as for contempt. (1985 (Reg. Sess., 1986), c. 1008, s. 1; 1987, c. 215, s. 3; 1989, c. 727, s. 150; 1991, c. 410, s. 2.)

**§ 130A-426. Determination of claims.**

(a) The Commission shall determine, on the basis of the evidence presented to it, the following issues:

(1) Whether any injuries alleged in the claim are vaccine-related injuries; and

(2) How much compensation, if any, is awardable pursuant to G.S. 130A-427.

(b) If the Commission determines pursuant to subsection (a) of this section that the injuries alleged in the claim are not vaccine-related injuries, it shall render a decision denying any compensation. If the Commission decides that any of the injuries are vaccine-related injuries it shall make an award pursuant to guidelines it establishes specifically adopted to relate to vaccine-related injuries. (1985 (Reg. Sess., 1986), c. 1008, s. 1.)

**§ 130A-427. Commission awards for vaccine-related injuries; duties of Secretary.**

(a) Upon determining that a claimant has sustained a vaccine-related injury, the Commission shall make an award providing compensation or services for any or all of the following:

(1) Actual and projected reasonable expenses of medical care, developmental evaluation, special education, vocational training, physical, emotional or behavioral therapy, and residential and custodial care and service expenses, that cannot be provided by the Department pursuant to subdivision (5) of this subsection;

(2) Loss of earnings and projected earnings, determined in accordance with generally accepted actuarial principles;

(3) Noneconomic, general damages arising from pain, suffering, and emotional distress;

(4) Reasonable attorneys' fees;

(5) Needs that the Secretary determines on a case-by-case basis shall be met by medical, health, developmental evaluation, special education, vocational training, physical, emotional, or behavioral therapy, residential and custodial care, and other essential and necessary services, to be provided the injured party by the programs and services administered by the Department. The Secretary shall develop an itemized list of the service needs of the injured party upon review and evaluation of the injured party's medical record and shall present it to the Commission prior to the Commission's determination. In the event that the Commission's award includes the provision of any of these services, the Secretary shall develop a comprehensive, coordinated plan for the delivery of these services to the injured party. Notwithstanding any other provision of State law, the Secretary shall waive all eligibility criteria in determining eligibility for services provided by the Department

under the plan of care developed pursuant to this subdivision. If the award includes any such services, these services shall be provided by the Department free of any cost to the injured party.

(b) The money compensation component of the award may not be made pursuant to this section in excess of an aggregate amount of the present day value amount of three hundred thousand dollars ($300,000) with respect to all injuries claimed to have resulted from the administration of a covered vaccine to a single individual. The value of all services to be provided by the Department, as part of this award is in addition to the total amount of money compensation, and is not included in the limitation prescribed by this subsection on the amount of money compensation that may be awarded. No damages may be awarded pursuant to subdivision (a)(3) on behalf of any person to whom the covered vaccine was not administered. (1985 (Reg. Sess., 1986), c. 1008, s. 1; 1989, c. 727, s. 151; 1997-443, s. 11A.86.)

**§ 130A-428. Notice of determination of claim; appeal to full commission.**

(a) Decisions of the Commission pursuant to G.S. 130A-427 shall be final and binding on the claimant and each respondent.

(b) Notwithstanding subsection (a), upon determination of the claim, the Commission shall notify all parties concerned in writing of its decision and any party shall have 15 days after receipt of such notice within which to file notice of appeal with the Commission. This appeal, when so taken, shall be heard by the Commission, sitting as a full commission, on the basis of the record in the matter and upon oral argument of the parties, and the full commission may amend, set aside, or strike out the decision of the hearing commissioner and may issue its own findings of fact and conclusions of law. Upon determination of the claim by the Commission, sitting as a full commission, the Commission shall notify all parties concerned in writing of its decision.

(c) The decision of the Commission, if not reviewed in due time, or an award of the Commission, shall be conclusive and binding as to all questions of fact; but any party to the proceedings may, within 30 days from the date of the decision or award, or within 30 days after receipt of notice to be sent by registered mail or certified mail of the award, but not thereafter, appeal from the decision or award of the Commission to the Court of Appeals for errors of law under the same terms and conditions as govern appeals from the Superior Court to the Court of Appeals in ordinary civil actions. The procedure for the appeal shall be provided by the Rules of Appellate Procedure. (1985 (Reg. Sess., 1986), c. 1008, s. 1.)

**§ 130A-429. Limitation on claims.**

(a) Except as provided in subsection (b) of this section, any claim under this Article that is filed more than six years after the administration of a vaccine alleged to have caused a vaccine-related injury is barred. Claims on behalf of minors or incompetent persons shall be filed by their parents, guardians ad litem, or guardians within the applicable limitations period established by this section.

(b) Claims that are filed in accordance with the procedures set forth in G.S. 130A-425(b) within six years after the date of the enactment of this Article shall not be barred unless, on the date the claim was filed, the claimant was barred by the applicable statute of limitations from filing an action for damages with respect to the subject matter of the claim.

(c) The period of limitation set forth in this section shall be stayed beginning on the date the claimant files a petition under Section 2111 of the Public Health Service Act, P.L. 99-660, and ending 120 days after the date final judgment is entered on the petition. (1985 (Reg. Sess., 1986), c. 1008, s. 1; 1991, c. 410, s. 3.)

**§ 130A-430. Right of State to bring action against health care provider and manufacturer.**

(a) If the Industrial Commission makes an award for a claimant who it determines has sustained a vaccine-related injury, the State may, within two years of the date the Commission renders its decision, bring an action against the health care provider who administered the vaccine on the ground that the health care provider was negligent in administering the vaccine. Damages in an action brought under this section are limited to the amount of the award made by the Commission plus the estimated present value of all the services to be provided to the claimant by the Department under G.S. 130A-427.

(b) Manufacturer. – If the Industrial Commission makes an award for a claimant who it determines has sustained a vaccine-related injury, the State may, within two years of the date the Commission renders its decision, bring an action against the manufacturer who made the vaccine on the ground that the vaccine was a defective product. Damages in an action brought under this section are limited to the amount of the award made by the Commission plus the estimated present value of all the services to be provided to the claimant by the Department under G.S. 130A-427, the reasonable costs of prosecuting the action, including, but not limited to, attorneys' fees, fees charged by witnesses, and costs of exhibits. For purposes of this subsection, a defective product is a covered vaccine that was manufactured, transported, or stored in a negligent manner, or was distributed after its expiration date, or that otherwise violated the applicable requirements of any license, approval, or permit, or any applicable standards or requirements issued under Section 351 of the Public Health Service Act, as amended, or the federal Food, Drug, and Cosmetic Act, as these standards or requirements were interpreted or applied by the federal agency charged with their enforcement. The negligence or other action in violation of applicable federal standards or requirements shall be demonstrated by the State, by a preponderance of the evidence, to be the proximate cause of the injury for which an award was rendered pursuant to G.S. 130A-427, in order to allow recovery by the State against the manufacturer pursuant to this subsection. (1985 (Reg. Sess., 1986), c. 1008, s. 1; 1987, c. 215, s. 4; 1989, c. 727, s. 152; 1997-443, s. 11A.87.)

**§ 130A-431. Certain vaccine diversions made felony.**

Any person who (i) receives a vaccine designated by the manufacturer for use in the State, (ii) directly or indirectly diverts the vaccine to a location outside the State, and (iii) directly or indirectly profits as a result of this diversion, is guilty of a Class I felony. The fine shall be twenty-five dollars ($25.00) per dose of the diverted vaccine or one hundred thousand dollars ($100,000), whichever is less. A health care professional convicted of a Class I felony pursuant to this section who is found by the court to have diverted more than 300 doses of covered vaccine shall have his license suspended for one year. (1985 (Reg. Sess., 1986), c. 1008, s. 1; 1987, c. 215, s. 5; 1993, c. 539, s. 1306; 1994, Ex. Sess., c. 24, s. 14(c).)

**§ 130A-432. Scope.**

This Article applies to all claims for vaccine-related injuries occurring on and after October 1, 1986 and, at the option of the claimant, to claims for vaccine-related injuries that occurred before October 1, 1986 if such claim has not been resolved by final judgment or by settlement agreement or is not barred by a statute of limitations.

This Article applies to all claims for vaccine-related injuries alleged to have been caused by covered vaccines administered within the State, regardless of where an action relating to the injuries is brought and regardless of where the injuries are alleged to have occurred. (1985 (Reg. Sess., 1986), c. 1008, s. 1; 1987, c. 215, s. 6.)

**§ 130A-433. Contracts for purchase of vaccines; distribution; fee; rules.**

(a) Notwithstanding any law to the contrary, the Secretary may enter into contracts with the manufacturers and suppliers of covered vaccines and with other public entities either within or without the State for the purchase of covered vaccines and may provide for the distribution

or sale of the covered vaccines to health care providers. Local health departments shall distribute the covered vaccines at the request of the Department. The Secretary shall adopt rules to implement this Article except for subsection (b) of this section.

(b) Except as otherwise provided in G.S. 130A-153(a), a health care provider who receives vaccine from the State may charge no more than a reasonable fee established by the Commission for Public Health for the administration of the vaccine. (1985 (Reg. Sess., 1986), c. 1008, s. 2; 1987, c. 215, s. 7; 1989, c. 727, s. 153; 1993, c. 321, s. 281(b); 2007-182, s. 2; 2009-451, s. 10.29A(b).)

**§ 130A-434. Child Vaccine Injury Compensation Fund established; payments from Fund; transfer of appropriations and receipts.**

(a) There is established the Child Vaccine Injury Compensation Fund within the Department to finance the North Carolina Childhood Vaccine-Related Injury Compensation Program created by this article. The money compensation components of all awards made pursuant to Article 17 of Chapter 130A of the General Statutes shall be paid by the Department from the Fund.

(b) Should the Department find that the sum of appropriations and receipts is insufficient to meet financial obligations incurred in the administration of this article, appropriations and receipts in the Department which would otherwise revert to the General Fund may be transferred to the Child Vaccine Injury Compensation Fund in order to meet such obligations. The Department may also budget anticipated receipts as needed to implement this Article. (1985 (Reg. Sess., 1986), c. 1008, s. 3(a), 3(b); 1989, c. 727, s. 154; 1997-443, s. 11A.88.)

**§§ 130A-435 through 130A-439. Reserved for future codification purposes.**

(B) An individual born before 1957 is not required to receive the mumps vaccine.

(C) The requirements for the mumps vaccine do not apply to individuals who entered the first grade for the first time before July 1, 1987 or college or university before July 1, 1994.

(D) An individual entering school, college or university before July 1, 2008 is not required to receive a second dose of mumps vaccine.

(6) *Haemophilus influenzae, b* conjugate vaccine - three doses of HbOC or PRP-T or two doses of PRP-OMP before age 7 months and a booster dose of any type on or after age 12 months and by age 16 months. However:

(A) Individuals who receive the first dose of *Haemophilus influenzae, b* vaccine on or after 7 months of age and before 12 months of age are required to have two doses of HbOC, PRP-T or PRP-OMP and a booster dose on or after 12 months of age and by age 16 months.

(B) Individuals who receive the first dose of *Haemophilus influenzae, b* vaccine on or after 12 months of age and before 15 months of age are required to have only 2 doses of HbOC, PRP-T or PRP-OMP and a booster dose two months later.

(C) Individuals who receive the first dose of *Haemophilus influenzae, b* vaccine on or after 15 months of age are required to have only one dose of any of the *Haemophilus influenzae b* conjugate vaccines.

(D) No individual who has passed his or her fifth birthday is required to be vaccinated against *Haemophilus influenzae, b.*

(7) Hepatitis B vaccine – three doses: the first dose by age 3 months, a second dose before age 5 months and a third dose by age 19 months. However:

(A) The last dose of the hepatitis B vaccine series shall not be administered before 24 weeks of age.

(B) Individuals born before July 1, 1994 are not required to be vaccinated against hepatitis B.

(8) Varicella vaccine – two doses administered at least 28 days apart; one dose on or after age 12 months of age and before age 19 months; and a second dose before entering school for the first time. However:

(A) An individual who has laboratory confirmation of varicella disease immunity or has been documented by serological testing to have a protective antibody titer against varicella is not required to varicella vaccine.

(B) An individual who has documentation from a physician, nurse practitioner, or physician's assistant verifying history of varicella disease is not required to receive varicella vaccine. The documentation shall include the name of the individual with a history of varicella disease, the approximate date or age of infection, and a healthcare provider signature.

(C) An individual born before April 1, 2001 is not required to receive varicella vaccine.

(D) The requirement for the second dose of varicella vaccine shall not apply to individuals who enter Kindergarten or first grade for the first time before July 1, 2015.

(9) Pneumococcal conjugate vaccine – Four doses; 3 doses by age 7 months and a booster dose at 12 through 15 months of age. However:

(A) Individuals who receive the first dose of pneumococcal conjugate vaccine on or after 7 months of age and before 12 months of age are required to have 2 doses at least 4 weeks apart; and a booster dose at 12 through 15 months of age.

(B) Individuals who receive the first dose of pneumococcal conjugate vaccine on or after 12 months of age and before 24 months of age are required to have 2 doses at least 8 weeks apart to complete the series.

(C) Individuals who receive the first dose of pneumococcal conjugate vaccine on or after 24 months of age and before 5 years are required to have 1 dose to complete the series.

(D) No individual who has passed his or her fifth birthday shall be required to be vaccinated against pneumococcal disease.

(E) An individual born before July 1, 2015 shall not be required to receive pneumococcal conjugate vaccine.

(10) Meningococcal conjugate vaccine – two doses: one dose is required for individuals entering the seventh grade or by 12 years of age, whichever comes first, on or after July 1, 2015. A booster dose is required by 17 years of age or by entering the 12th grade. However:

(A) The first dose does not apply to individuals who entered seventh grade before July 1, 2015.

(B) The booster dose does not apply to individuals who entered the 12th grade before August 1, 2020.

(C) If the first dose is administered on or after the 16th birthday, a booster dose is not required.

(D) An individual born before January 1, 2003 shall not be required to receive a meningococcal conjugate vaccine.

(b) The healthcare provider shall administer immunizations in accordance with this Rule. However, if a healthcare provider administers vaccine up to and including the fourth day prior to the required minimum age, the individual dose is not required to be repeated. Doses administered more than four days prior to the requirements are considered invalid doses and shall be repeated.

(c) The State Health Director may suspend temporarily any portion of the requirements of this Rule due to emergency conditions, such as the unavailability of vaccine. The Department shall give notice in writing to all local health departments and other providers currently receiving vaccine from the Department when the suspension takes effect and when the suspension is lifted. When any vaccine series is disrupted by such a suspension, the next dose shall be administered within 90 days of the lifting of the suspension and the series resumed in accordance with intervals determined by the most recent recommendations of the Advisory Committee on Immunization Practices. These recommendations may be accessed free of charge at http://www.cdc.gov/vaccines/acip/.

*History Note:* *Authority G.S. 130A-152(c); 130A-155.1;*
*Eff. February 1, 1976;*
*Amended Eff. July 1, 1977;*
*Readopted Eff. December 5, 1977;*
*Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
*Amended Eff. October 1, 1995; October 1, 1994; January 1, 1994; January 4, 1993;*
*Temporary Amendment Eff. February 23, 2000; August 20, 1999; May 21, 1999;*
*Amended Eff. August 1, 2000;*
*Temporary Amendment Eff. May 17, 2002; April 1, 2002; February 18, 2002; August 1, 2001;*
*Amended Eff. July 1, 2015; January 1, 2008; November 1, 2005; January 1, 2005; April 1, 2003.*

## SECTION .0400 - IMMUNIZATION

### 10A NCAC 41A .0401 DOSAGE AND AGE REQUIREMENTS FOR IMMUNIZATION

(a) Every individual in North Carolina required to be immunized pursuant to G.S. 130A-152 through 130A-157 shall be immunized against the following diseases and have documentation of age-appropriate vaccination in accordance with the Advisory Committee on Immunization Practices (ACIP).

(1) Diphtheria, tetanus, and pertussis (whooping cough) - five doses: three doses by age seven months; and 2 booster doses, the first by age 19 months and the second on or after the fourth birthday and before entering school for the first time. However:

(A) Individuals who receive the first booster dose of diphtheria/tetanus/pertussis vaccine on or after the fourth birthday are not required to have a second booster.

(B) Individuals entering college or university for the first time on or after July 1, 2008 must have had three doses of tetanus/diphtheria toxoid; one of which must be tetanus/diphtheria/pertussis.

(C) A booster dose of tetanus/diphtheria/pertussis vaccine is required for individuals who have not previously received it and are entering the seventh grade or by 12 years of age, whichever comes first.

(2) Poliomyelitis vaccine - four doses: two doses of trivalent type by age five months; a third dose trivalent type before age 19 months; and a booster dose of trivalent type on or after his or her fourth birthday and before entering school for the first time. However:

(A) An individual attending school who has attained his or her 18th birthday is not required to receive a polio vaccine.

(B) The requirements for the booster dose on or after the fourth birthday do not apply to individuals who began school before July 1, 2015.

(C) Individuals who receive the third dose of poliomyelitis vaccine on or after the fourth birthday are not required to receive a fourth dose if the third dose is given at least six months after the second dose.

(3) Measles (rubeola) vaccine - two doses of live, attenuated vaccine administered at least 28 days apart: the first dose on or after age 12 months and before age 16 months; and a second dose before entering school for the first time. However:

(A) An individual who has been documented by serological testing to have a protective antibody titer against measles is not required to receive measles vaccine.

(B) An individual who has been diagnosed before January 1, 1994, by a physician (or designee such as a nurse practitioner or physician's assistant) as having measles (rubeola) disease is not required to receive measles vaccine.

(C) An individual born before 1957 is not required to receive measles vaccine except in measles outbreak situations.

(D) The requirement for a second dose of measles vaccine does not apply to individuals who enter school or in college or university for the first time before July 1, 1994.

(4) Rubella vaccine - one dose of live, attenuated vaccine on or after age 12 months and before age 16 months. However:

(A) An individual who has laboratory confirmation of rubella disease or who has been documented by serological testing to have a protective antibody titer against rubella is not required to receive rubella vaccine.

(B) An individual who has attained his or her fiftieth birthday is not required to receive rubella vaccine except in outbreak situations.

(C) An individual who entered a college or university after his or her thirtieth birthday and before February 1, 1989 is not required to meet the requirement for rubella vaccine except in outbreak situations.

(5) Mumps vaccine – two doses: the first dose of live, attenuated vaccine administered on or after age 12 months and before age 16 months; and a second dose before entering school, college or university for the first time. However:

(A) An individual who has laboratory confirmation of disease, or has been documented by serological testing to have a protective antibody titer against mumps is not required to receive the mumps vaccine.

(B) An individual born before 1957 is not required to receive the mumps vaccine.

(C) The requirements for the mumps vaccine do not apply to individuals who entered the first grade for the first time before July 1, 1987 or college or university before July 1, 1994.

(D) An individual entering school, college or university before July 1, 2008 is not required to receive a second dose of mumps vaccine.

(6) *Haemophilus influenzae, b* conjugate vaccine - three doses of HbOC or PRP-T or two doses of PRP-OMP before age 7 months and a booster dose of any type on or after age 12 months and by age 16 months. However:

(A) Individuals who receive the first dose of *Haemophilus influenzae, b* vaccine on or after 7 months of age and before 12 months of age are required to have two doses of HbOC, PRP-T or PRP-OMP and a booster dose on or after 12 months of age and by age 16 months.

(B) Individuals who receive the first dose of *Haemophilus influenzae, b* vaccine on or after 12 months of age and before 15 months of age are required to have only 2 doses of HbOC, PRP-T or PRP-OMP and a booster dose two months later.

(C) Individuals who receive the first dose of *Haemophilus influenzae, b* vaccine on or after 15 months of age are required to have only one dose of any of the *Haemophilus influenzae b* conjugate vaccines.

(D) No individual who has passed his or her fifth birthday is required to be vaccinated against *Haemophilus influenzae, b.*

(7) Hepatitis B vaccine – three doses: the first dose by age 3 months, a second dose before age 5 months and a third dose by age 19 months. However:

(A) The last dose of the hepatitis B vaccine series shall not be administered before 24 weeks of age.

(B) Individuals born before July 1, 1994 are not required to be vaccinated against hepatitis B.

(8) Varicella vaccine – two doses administered at least 28 days apart; one dose on or after age 12 months of age and before age 19 months; and a second dose before entering school for the first time. However:

(A) An individual who has laboratory confirmation of varicella disease immunity or has been documented by serological testing to have a protective antibody titer against varicella is not required to varicella vaccine.

(B) An individual who has documentation from a physician, nurse practitioner, or physician's assistant verifying history of varicella disease is not required to receive varicella vaccine. The documentation shall include the name of the individual with a history of varicella disease, the approximate date or age of infection, and a healthcare provider signature.

(C) An individual born before April 1, 2001 is not required to receive varicella vaccine.

(D) The requirement for the second dose of varicella vaccine shall not apply to individuals who enter Kindergarten or first grade for the first time before July 1, 2015.

(9) Pneumococcal conjugate vaccine – Four doses; 3 doses by age 7 months and a booster dose at 12 through 15 months of age. However:

(A) Individuals who receive the first dose of pneumococcal conjugate vaccine on or after 7 months of age and before 12 months of age are required to have 2 doses at least 4 weeks apart; and a booster dose at 12 through 15 months of age.

(B) Individuals who receive the first dose of pneumococcal conjugate vaccine on or after 12 months of age and before 24 months of age are required to have 2 doses at least 8 weeks apart to complete the series.

(C) Individuals who receive the first dose of pneumococcal conjugate vaccine on or after 24 months of age and before 5 years are required to have 1 dose to complete the series.

(D) No individual who has passed his or her fifth birthday shall be required to be vaccinated against pneumococcal disease.

(E) An individual born before July 1, 2015 shall not be required to receive pneumococcal conjugate vaccine.

(10) Meningococcal conjugate vaccine – two doses: one dose is required for individuals entering the seventh grade or by 12 years of age, whichever comes first, on or after July 1, 2015. A booster dose is required by 17 years of age or by entering the 12th grade. However:

(A) The first dose does not apply to individuals who entered seventh grade before July 1, 2015.

(B) The booster dose does not apply to individuals who entered the 12th grade before August 1, 2020.

(C) If the first dose is administered on or after the 16th birthday, a booster dose is not required.

(D) An individual born before January 1, 2003 shall not be required to receive a meningococcal conjugate vaccine.

(b) The healthcare provider shall administer immunizations in accordance with this Rule. However, if a healthcare provider administers vaccine up to and including the fourth day prior to the required minimum age, the individual dose is not required to be repeated. Doses administered more than four days prior to the requirements are considered invalid doses and shall be repeated.

(c) The State Health Director may suspend temporarily any portion of the requirements of this Rule due to emergency conditions, such as the unavailability of vaccine. The Department shall give notice in writing to all local health departments and other providers currently receiving vaccine from the Department when the suspension takes effect and when the suspension is lifted. When any vaccine series is disrupted by such a suspension, the next dose shall be administered within 90 days of the lifting of the suspension and the series resumed in accordance with intervals determined by the most recent recommendations of the Advisory Committee on Immunization Practices. These recommendations may be accessed free of charge at http://www.cdc.gov/vaccines/acip/.

*History Note:* *Authority G.S. 130A-152(c); 130A-155.1;*
*Eff. February 1, 1976;*
*Amended Eff. July 1, 1977;*
*Readopted Eff. December 5, 1977;*
*Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
*Amended Eff. October 1, 1995; October 1, 1994; January 1, 1994; January 4, 1993;*
*Temporary Amendment Eff. February 23, 2000; August 20, 1999; May 21, 1999;*
*Amended Eff. August 1, 2000;*
*Temporary Amendment Eff. May 17, 2002; April 1, 2002; February 18, 2002; August 1, 2001;*
*Amended Eff. July 1, 2015; January 1, 2008; November 1, 2005; January 1, 2005; April 1, 2003.*

**10A NCAC 41A .0402 APPROVED VACCINE PREPARATIONS**

All vaccine preparations licensed for interstate use by the Bureau of Biologic Standards of the U.S. Food and Drug Administration are approved for use in fulfilling the requirements of 10 NCAC 07A .0401.

*History Note:* *Authority G.S. 130A-152(c);*
*Eff. February 1, 1976;*
*Readopted Eff. December 5, 1977.*

**10A NCAC 41A .0403 NON-RELIGIOUS PERSONAL BELIEF NO EXEMPTION**

Except as provided in G.S. 130A-156 and G.S. 130A-157, and 10A NCAC 41A .0404 and .0405, no child shall be exempt from the requirements of 10A NCAC 41 .0401; there is no exception to these requirements for the case of a personal belief or philosophy of a parent or guardian not founded upon a religious belief.

*History Note:* *Authority G.S. 130A-152(c);*
*Eff. February 1, 1976;*
*Readopted Eff. December 5, 1977;*
*Amended Eff. October 1, 1984; July 1, 1979.*

**10A NCAC 41A .0404 MEDICAL EXEMPTIONS FROM IMMUNIZATION**

(a) Certification of a medical exemption by a physician pursuant to G.S. 130A-156 shall be in writing and shall state the basis of the exemption, the specific vaccine or vaccines the individual should not receive, and the length of time the exemption will apply for the individual.

(b) Medical contraindications for which medical exemptions may be certified by a physician for immunizations are included in the most recent General Recommendations of the Advisory Committee on Immunization Practices, Public Health Services, U.S. Department of Health and Human Services, published in the Centers for Disease Control and Prevention publication, the Morbidity and Mortality Weekly Report, which is adopted by reference including subsequent amendments and additions. A copy is available for inspection in the Immunization Section at 1330 St. Mary's Street, Raleigh, North Carolina. Internet access is available by searching www.cdc.gov/nip.

*History Note:* *Filed as a Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
*Authority G.S. 130A-152(c); 130A-156;*
*Eff. July 1, 1979;*
*Amended Eff. August 1, 2000; January 4, 1993; February 1, 1990; March 1, 1988.*

**10A NCAC 41A .0405 EXEMPTION FOR CLINICAL STUDIES**

An individual enrolled in a clinical trial of the efficacy of a new vaccine preparation or dosage schedule shall be exempted from those requirements of 10A NCAC 41A .0401 and .0402 which conflict with the trial protocol. This exemption shall only apply to individuals who:

(1) participate in a clinical trial whose protocol is approved by the State Health Director, and

(2) fully participate in and complete the clinical trial.

*History Note:* *Filed as a Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
*Authority G.S. 130A-152(c);*
*Eff. October 1, 1983;*
*Amended Eff. March 1, 1988.*

**10A NCAC 41A .0406 ACCESS TO IMMUNIZATION INFORMATION**

(a) Physicians, local health departments and the Department shall, upon request and without consent release the immunization information specified in Paragraph (b) of this Rule to the following organizations:

(1) schools K-12, whether public, private or religious;
(2) licensed and registered childcare facilities as defined in G.S. 110-86(3) and G.S. 110-101;
(3) Head Start;
(4) colleges and universities, whether public, private or religious;
(5) Health Maintenance Organizations; and
(6) Other state and local health departments outside of North Carolina.

(b) The following is the immunization information to be released to the organizations specified in Paragraph (a) of this Rule:

(1) name and address;
(2) name of the parent, guardian, or person standing *in loco parentis;*
(3) date of birth;
(4) gender;
(5) race and ethnicity;
(6) vaccine type, date and dose number administered;
(7) the name and address of the physician or local health department that administered each dose; and
(8) the existence of a medical or religious exemption determined by the Immunization Section to meet the requirements of G.S. 130A-156 and 10A NCAC 41A .0404 or G.S. 130A-157. If such a determination has not been made by the Division of Public Health, the person shall have access to the certification of medical and religious exemptions required by G.S. 130A-156 or G.S. 130A-157 and 10A NCAC 41A .0404.

*History Note:* *Authority G.S. 130A-153;*
*Temporary Adoption Eff. August 9, 1993, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;*
*Eff. January 4, 1994;*
*Amended Eff. April 1, 2001; August 1, 2000; October 1, 1995.*

## SECTION .0500 - PURCHASE AND DISTRIBUTION OF VACCINE

**10A NCAC 41A .0501 PURCHASE OF VACCINE**

The Division of Public Health may enter into contracts for the purchase of vaccines. Any purchase of such vaccines shall be in accordance with Article 3 of G.S. 143 and 01 NCAC 05A.

*History Note: Temporary Rule Eff. October 5, 1986 for a period of 120 days to expire on February 1, 1987;*
*Authority S.L. 1986, c. 1008, s. 2;*
*Eff. February 1, 1987;*
*Amended Eff. September 1, 1991.*

**10A NCAC 41A .0502 VACCINE FOR PROVIDERS OTHER THAN LOCAL HEALTH DEPARTMENTS**

*History Note:* *Authority G.S. 130A-433;*
*Temporary Rule Eff. October 5, 1986 for a period of 120 days to expire on February 1, 1987;*
*Temporary Rule Eff. February 1, 1987 for a period of 120 days to expire on May 31, 1987;*
*Eff. March 1, 1987;*
*Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
*Temporary Amendment Eff. August 26, 1992, for a period 180 days or until the permanent rule becomes effective, whichever is sooner;*
*Temporary Amendment Eff. October 1, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;*
*Amended Eff. October 1, 1995; January 1, 1995; January 4, 1994; January 4, 1993;*
*Temporary Amendment Eff. December 1, 1998;*
*Amended Eff. August 1, 2000;*
*Temporary Amendment Eff. December 1, 2007;*
*Amended Eff. November 1, 2008;*
*Repealed Eff. July 1, 2014.*

**North Carolina Department of Health and Human Services**
**Division of Public Health**

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Penelope Slade-Sawyer
Division Director

February 4, 2015

**MEMORANDUM**

**TO:** North Carolina Immunization Program (NCIP) Providers

**FROM:** Wendy Holmes, RN, Head WH
Immunization Branch

**SUBJECT:** Policy on Borrowing and Replacing Vaccine

The purpose of this memo is to reiterate the vaccine borrowing/replacement policy, and to notify providers of reporting form changes based on new Centers for Disease Control and Prevention (CDC) and NCIP requirements. A copy of the updated form is included. It has always been a requirement that borrowing of vaccine supplies is to be a rare occurrence and that details of the situation are reported on a Vaccine Borrowing Report.

CDC and NCIP require that NCIP providers maintain an adequate inventory of vaccine for VFC-eligible and non-VFC-eligible patients. It is the responsibility of the provider to appropriately schedule and place vaccine orders. Providers must also rotate stock to ensure timely use of short-dated vaccines. Borrowing of vaccine between private and public inventories must be a rare, unplanned occurrence. VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory. All instances of borrowing must be properly documented, reported, and replaced.

Reasons for Borrowing/Replacement of a VFC Dose:

- Private vaccine shipment delay (order placed on time, but delay in shipping/receipt)
- Private vaccine not useable on arrival (vials broken, temperature monitor out of range)
- Short-dated private dose was exchanged with VFC stock
- Accidental use of VFC dose for a private patient (human error)
- Replacement of private dose with VFC when insurance plan did not cover vaccine

Reasons for Borrowing/Replacement of a Private Dose:

- VFC vaccine shipment delay (order placed on time, but delay in shipping/receipt)
- VFC vaccine not useable on arrival (vials broken, temperature monitor out of range)
- Short-dated VFC vaccine dose was exchanged with private dose
- Accidental use of a private dose for a VFC-eligible patient (human error)

Borrowing and replacement of seasonal influenza remains the same. Providers may use private-stock seasonal influenza vaccine to vaccinate VFC-eligible children if the VFC seasonal influenza stock is not yet available.

Those private stock doses used on VFC-eligible children can later be replaced when VFC stock becomes available. This one-directional borrowing exception is unique to seasonal influenza vaccine.

To be considered "fully documented," the report must contain all of the following elements for every instance of borrowing, either VFC or private vaccine:

- Vaccine type borrowed
- Stock used (VFC or Private)
- Patient name
- Patient date of birth
- Date the dose was administered
- Reason appropriate vaccine stock was not used
- Date dose was returned to appropriate stock

Note: The provider must keep the NCIP Vaccine Borrowing report on site for three years and allow NCIP staff to review it upon request.

Providers using the North Carolina Immunization Registry (NCIR) must contact the NCIP Help Desk at 1-877-873-6247 to correct their VFC vaccine inventory in the NCIR. Private vaccine inventory corrections can be made by the provider's NCIR Administrator or Inventory Control staff.

If providers have questions or concerns, they should contact their Regional Immunization Nurse Consultant, Regional Immunization Consultant, or the NCIP Help Desk at 1-877-873-6247.

Attachment

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cc: | SMT | CO Staff | Regional Staff | Vaccine Manufacturers | Elizabeth Hudgins | Peter Graber | Jason Swartz |
| | Frank Skwara | | Desiree Elekwa-Izuakor | Terri Pennington | Taryn Edwards | Gregg Griggs | Danny Staley |

**North Carolina Immunization Program (NCIP) VACCINE BORROWING REPORT**

Facility Name:_____

NCIP providers are expected to manage and maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. **Planned borrowing of VFC vaccine including the use of VFC vaccine as a replacement system for a provider's privately purchased vaccine inventory is not permissible.**

NCIP providers must ensure borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination.

**COMPLETE THIS FORM WHEN:**

- A dose of VFC vaccine is administered to a non VFC-eligible child
- A dose of privately-purchased vaccine is administered to a VFC-eligible child

**HOW TO COMPLETE THIS FORM:**

- Enter information on each dose of vaccine borrowed in a separate row in the Vaccine Borrowing Report Table.
- All columns **must be completed** for each dose borrowed
- The provider must sign and date at the bottom of this report
- Enter the corresponding reason code in column F of the Borrowing Report Table on page 2.
- Enter details of reason in Column F if an Other code (7Other or 13Other) is entered in the Vaccine Borrowing Report Table.

## Reason for Vaccine Borrowing and Replacement Coding Legend

| Reason for Borrowing VFC Dose | Code | | Reason for Borrowing Private Dose | Code |
|---|---|---|---|---|
| Private vaccine shipment delay (vaccine order placed on time/delay in shipping) | 1 | | VFC vaccine shipment delay (order placed on time/delay in shipping) | 8 |
| Private vaccine not useable on arrival (vials broken, temperature monitor out of range) | 2 | | VFC vaccine not useable on arrival (vials broken, temperature monitor out of range) | 9 |
| Ran out of private vaccine between orders (not due to shipping delays) | 3 | | Ran out of VFC vaccine between orders (not due to shipping delays) | 10 |
| Short-dated private dose was exchanged with VFC dose | 4 | | Short-dated VFC dose was exchanged with private dose | 11 |
| Accidental use of VFC dose for private patient | 5 | | Accidental use of a Private dose for a VFC eligible patient | 12 |
| Replacement of Private dose with VFC when insurance plan did not cover vaccine | 6 | | Other – Describe: | 13Other |
| Other – Describe: | 7Other | | | |

**WHAT TO DO WITH THIS FORM:**

- **Completed forms must be retained as a NCIP record for three years and made available to the NCIP staff upon request.**
- **Timely replacement of vaccine to appropriate stock (within 90 days) is required.**

## North Carolina Immunization Program (NCIP) VACCINE BORROWING REPORT

**Date Range of Vaccine Reporting** (date of first dose borrowed to date of last dose borrowed): ____/____/_____ **to** ____/____/_____

**VACCINE BORROWING REPORT TABLE**

| **A**<br>**Vaccine Type Borrowed** | **B**<br>**Stock Used**<br>(VFC or Private) | **C**<br>**Patient Name** | **D**<br>**Patient DOB**<br>(XX/XX/XXXX) | **E**<br>**Date Dose Administered**<br>(XX/XX/XXXX) | **F**<br>**Reason Appropriate Vaccine Stock was not Used**<br>(Use legend code on page 1 to mark one reason for each dose borrowed) | **G**<br>**Date Dose Returned to Appropriate Stock**<br>(XX/XX/XXXX) |
|---|---|---|---|---|---|---|
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**I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form.**

| **Provider Name:** | **Provider Signature:** | **Date:** |
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