

**North Carolina Immunization Law
General Statutes of North Carolina**

**Chapter 130A, Article 6
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(b) Repealed by Session Laws 2002-179, s. 10, effective October 1, 2002.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 or from a local health department. Local health departments shall administer required and State-supplied immunizations at no cost to patients who are uninsured or underinsured and have 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, 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).)

§ 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).)

§ 130A-159. Reserved for future codification purposes.

Chapter 130A, 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.

**NORTH CAROLINA ADMINISTRATIVE CODE
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 by receiving the specified minimum doses of vaccines by the specified ages:

- (1) Diphtheria, tetanus, and whooping cough vaccine -- five doses: three doses by age seven months and two booster doses, one by age 19 months and the second on or after the fourth birthday and before enrolling in school for the first time. However:
 - (A) Individuals who receive the first booster dose of diphtheria, tetanus, and whooping cough vaccine on or after the fourth birthday are not required to have a second booster dose;
 - (B) Individuals attending colleges and universities are required to have three doses of tetanus/diphtheria toxoid, one of which must have been within the last 10 years. Those individuals enrolling in college or university for the first time on or after July 1, 2008 must have had three doses of tetanus/diphtheria toxoid and a booster dose of tetanus/diphtheria/pertussis vaccine if a tetanus/diphtheria toxoid or tetanus/diphtheria/pertussis vaccine has not been administered within the past 10 years. A dose of tetanus/diphtheria/pertussis vaccine is not required for any student over the age of 64 years;
 - (C) A booster dose of tetanus/diphtheria/pertussis vaccine is required for individuals attending public school who are entering the sixth grade on or after August 1, 2008, if five years or more have passed since the last dose of tetanus/diphtheria toxoid. A booster dose of tetanus/diphtheria/pertussis vaccine is required for individuals not attending public schools who are 12 years of age on or after August 1, 2008, if five years or more have passed since the last dose of tetanus/diphtheria toxoid. However, pertussis (whooping cough) vaccine is not required for individuals between 7 years of age through the fifth grade for those attending public schools and 7 through 12 years of age for those not attending public schools.
- (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 before enrolling in school for the first time. However:
 - (A) An individual attending school who has attained his or her 18th birthday is not required to receive polio vaccine;
 - (B) Individuals who receive the third dose of poliomyelitis vaccine on or after the fourth birthday are not required to receive a fourth dose;
 - (C) The requirements for booster doses of poliomyelitis vaccine do not apply to individuals who enrolled for the first time in the first grade before July 1, 1987.
- (3) Measles (rubeola) vaccine--two doses of live, attenuated vaccine administered at least 28 days apart: one dose on or after age 12 months and before age 16 months and a second dose before enrolling in 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 prior to January 1, 1994, by a physician licensed to practice medicine as having measles (rubeola) disease is not required to receive measles vaccine;
 - (C) An individual born prior to 1957 is not required to receive measles vaccine;
 - (D) The requirement for a second dose of measles vaccine does not apply to individuals who enroll in 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 been documented by serologic 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--one dose of live, attenuated vaccine administered on or after age 12 months and before age 16 months and a second dose before enrolling in school, college or university for the first time. However:
- (A) An individual born prior to 1957 is not required to receive mumps vaccine;
 - (B) The requirements for mumps vaccine do not apply to individuals who enrolled for the first time in the first grade before July 1, 1987 or in college or university before July 1, 1994;
 - (C) An individual who has been documented by serological testing to have a protective antibody titer against mumps is not required to receive mumps vaccine;
 - (D) An individual entering school, college or university prior to 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 seven months and a booster dose of any type on or after age 12 months and by age 16 months. However:
- (A) Individuals born before October 1, 1988 are not required to be vaccinated against *Haemophilus influenzae, b*;
 - (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 two doses of HbOC, PRP-T or PRP-OMP;
 - (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* conjugate vaccines, including PRP-D;
 - (D) No individual who has passed their fifth birthday is required to be vaccinated against *Haemophilus influenzae, b*.
- (7) Hepatitis B vaccine--three doses: one dose by age three months, a second dose before age five months and a third dose by age 19 months. However:
- (A) The last dose of the hepatitis B vaccine series shall not be administered prior to 24 weeks of age;
 - (B) Individuals born before July 1, 1994 are not required to be vaccinated against hepatitis B.
- (8) Varicella vaccine--1 dose administered on or after age 12 months and before age 19 months. However:
- (A) An individual with a laboratory test indicating immunity or with a history of varicella disease, documented by a health care provider, parent, guardian or person in loco parentis is not required to receive varicella vaccine. Serologic proof of immunity or documentation of previous illness must be presented whenever a certificate of immunization is required by North Carolina General Statute. The documentation shall include the name of the individual with a history of varicella disease and the approximate date or age of infection. Previous illness shall be documented by:
 - (i) a written statement from a health care provider documented on or attached to the lifetime immunization card or certificate of immunization; or
 - (ii) a written statement from the individual's parent, guardian or person in loco parentis attached to the lifetime immunization card or certificate of immunization.

(B) An individual born prior to April 1, 2001 is not required to receive varicella 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 4 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.

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. 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

(a) The Division of Public Health shall provide vaccines required by law free of charge to the following providers for administration to individuals who need vaccines to meet the requirement of G.S. 130A-152, 130-155.1 and 10A NCAC 41A .0401:

- (1) Community, migrant, and rural health centers;
- (2) Colleges and universities for students; and
- (3) Physicians and other health care providers.

(b) Upon request of the Division, required vaccines may be distributed by local health departments operating as agents of the State to providers listed in Subparagraphs (a)(1), (2) and (3) of this Rule.

(c) Providers authorized in Paragraph (a) of this Rule shall be eligible to receive free vaccines from the Division only if they sign an agreement with the Division. This agreement will be prepared by the Division of Public Health and will require the provider to:

- (1) Charge vaccine administration fees at no more than the rates established by the State's Medicaid program. The State's Medicaid rates may be inspected at the Division of Public Health. Copies may also be obtained from the Division of Public Health at no charge;
- (2) Provide all vaccines needed during a visit unless a specific contraindication exists to one or more of the vaccine;
- (3) Charge no office fee in addition to an administration fee for an immunization-only visit;
- (4) Agree not to charge an administration fee to an individual who states that they are unable to pay;
- (5) Impose no condition as a prerequisite to receiving vaccine;
- (6) The providers shall submit a monthly doses administered report by the tenth of each month electronically through the North Carolina Immunization Registry or on a form provided by the Immunization Section.
- (7) Report adverse vaccine reactions through the Vaccine Adverse Event Reporting System (VAERS);
- (8) Provide the latest edition of the applicable Important Information Statement (IIS), or Vaccine Information Statement (VIS) to the parent, guardian, or person standing in loco parentis for each dose of vaccine administered; document this action within the patient's permanent medical record; retain the documentation for a period of 10 years following the end of the calendar year in which the vaccine dose was administered, or for 10 years following the recipient's age of majority, whichever is longer; upon request, furnish copies of the documentation to the local health department or the Division. Keep a record of the vaccine manufacturer, lot number, and date of administration for each dose of vaccine administered;
- (9) Allow periodic inspection of their vaccine supplies and records by the Division of Public Health and
- (10) Comply with the rules of this Section.

(d) A provider who fails to submit timely and accurate reports as required each month shall have vaccine shipments withheld until that month's report is received by the Immunization Section.

History Note: Authority G.S. 130A-152; 130A-155.1; 130A-433; S.L. 1986, c. 1008, s. 2; S.L. 1987, c. 215, s. 7;

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.