

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2009

H

D

HOUSE DRH70522-LNfz-186A\* (03/23)

Short Title: Universal Childhood Vaccine Program.

(Public)

Sponsors: Representative England.

Referred to:

1 A BILL TO BE ENTITLED  
2 AN ACT PERTAINING TO THE UNIVERSAL CHILDHOOD IMMUNIZATION  
3 PROGRAM; TO ESTABLISH THE NORTH CAROLINA CHILDHOOD VACCINE  
4 ASSOCIATION; TO PROVIDE FOR ASSESSMENT OF HEALTH INSURERS FOR  
5 THE PURCHASE, STORAGE, DISTRIBUTION, AND QUALITY ASSURANCE OF  
6 CERTAIN VACCINES; AND TO ESTABLISH THE CHILDHOOD IMMUNIZATION  
7 ACCOUNT, AS RECOMMENDED BY THE PUBLIC HEALTH STUDY  
8 COMMISSION.

9 The General Assembly of North Carolina enacts:

10 **SECTION 1.** Article 6 of Chapter 130A of the General Statutes is amended by  
11 adding the following new Part to read:

12 "Part 2A. Universal Childhood Immunization Program.

13 **"§ 130A-159. Title and purpose.**

14 This Part may be referred to the Universal Childhood Immunization Act. The purpose of  
15 this Part is to provide for the purchase, storage, distribution, and quality assurance of certain  
16 vaccines in this State.

17 **"§ 130A-159.1. Definitions.**

18 As used in this Part, the term:

- 19 (1) 'Association.' – The North Carolina Childhood Vaccine Association.  
20 (2) 'CDC.' – The Centers for Disease Control and Prevention.  
21 (3) 'Covered life.' – A person who is covered under a medical benefits plan that  
22 is insured or administered by a health insurer.  
23 (4) 'Covered life months.' – The number of months a covered life has coverage  
24 as a covered life during a calendar year.  
25 (5) 'Estimated vaccine cost.' – The estimated cost to the State over the course of  
26 a State fiscal year for the purchase and distribution of vaccines purchased at  
27 the federal discount rate by the Department.  
28 (6) 'Health benefit plan.' – As defined in G.S. 58-3-167.  
29 (7) 'Health insurer.' – An entity that provides medical care benefits, including  
30 excess or stop-loss insurance that covers medical care or administers medical  
31 care on an individual in this State and operating under the authority of  
32 Chapter 58 of the General Statutes, for the benefits prescribed in  
33 G.S. 58-68-25(a)(5) and excluding the benefits excepted in  
34 G.S. 58-68-25(b).  
35 (8) 'Insurer.' – Includes the following:



\* D R H 7 0 5 2 2 - L N F Z - 1 8 6 A \*

- a. An insurance company;
- b. A hospital or medical service corporation;
- c. A health maintenance organization;
- d. A multiple employer welfare arrangement;
- e. A third-party administrator or claims processor;
- f. The State Health Plan for Teachers and State Employees;
- g. The North Carolina Children's Health Insurance Program; and
- h. Any other nongovernmental entity providing a health benefit plan subject to State insurance regulation.

(9) 'Medical care.' – All of the following:

- a. The diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the human body;
- b. Transportation primarily for and essential to medical care as defined in sub-paragraph a. of this subdivision.
- c. Insurance covering medical care as defined in sub-paragraph a. of this subdivision.

(10) 'Program.' – The Universal Childhood Immunization Program in G.S. 130A-159.5.

(11) 'State-supplied vaccine.' – Vaccine purchased by the State for covered lives for whom the State is purchasing vaccine using State funds raised via assessments on health insurers.

(12) 'Total nonfederal program cost.' – The estimated childhood vaccine program cost less the amount of Federal Vaccine for Children ('FVC') funds available to the State for the purchase and distribution of vaccines.

(13) 'Vaccine.' – A preparation of killed or attenuated living microorganisms, or fraction thereof, that upon administration stimulates immunity that protects against disease and is approved by the Federal Food and Drug Administration as safe and effective and recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention for administration to children under the age of 19 years.

**"§ 130A-159.2. North Carolina Childhood Vaccine Association established; board of directors appointments; terms; powers and duties.**

(a) There is established the North Carolina Childhood Vaccine Association as a nonprofit corporation registered and regulated pursuant to Chapter 55A of the General Statutes. The Association is formed for the purpose of collecting and remitting adequate funds from health insurers for the cost of vaccines provided to insured children in North Carolina under the Universal Childhood Immunization Program established in G.S. 130A-159.5. The Association shall be comprised of all insurers issuing or renewing health benefit plans in this State, and all third-party administrators conducting business on behalf of residents of this State or on behalf of health care providers and facilities providing health care in this State.

(b) The initial Board of Directors ('Board') of the Association shall be comprised of 11 members, appointed as follows:

- (1) Eight by the General Assembly, four upon the recommendation of the President Pro Tempore of the Senate, and four upon of the recommendation of the Speaker of the House of Representatives. These members shall be selected from health insurers that have the most fully insured and self-funded covered lives in this State. Two of the initial appointees by the Senate and two by the House shall each serve a term of two years. The remainder of the Senate and House initial appointees shall serve a term of one year.

- 1           (2)    Two by the Governor who are physicians licensed in this State, at least one  
2           of whom shall be a board certified pediatrician.
- 3           (3)    The Secretary, or the Secretary's designee with expertise in childhood  
4           immunization purchasing and distribution.
- 5       (c)    The Board shall have the following powers and duties:
- 6           (1)    Adopt articles of incorporation and bylaws.
- 7           (2)    Prepare and adopt a plan of operation, which shall include a dispute  
8           resolution process through which an insurer may challenge an assessment  
9           determination by the Board. The dispute resolution process shall include a  
10          means to bring unresolved disputes to an impartial decision-maker.
- 11          (3)    Conduct all activities in accordance with the approved plan of operation.
- 12          (4)    Enter into contracts as necessary to implement the plan of operation,  
13          including the collection and disbursement of assessments.
- 14          (5)    Sue or be sued, including legal action necessary for the recovery of any  
15          assessment for, on behalf of, or against members of the Association or other  
16          participating person.
- 17          (6)    Obtain liability and other insurance coverage for the benefit of the  
18          Association, its directors, officers, employees, and agents as may in the  
19          judgment of the Board be helpful or necessary for the operation of the  
20          Association.
- 21          (7)    Borrow and repay working capital, reserve, or other funds as, in the  
22          judgment of the Board, may be helpful or necessary for the operation of the  
23          Association.
- 24          (8)    Forward to the Office of State Treasurer annual assessments collected by the  
25          Board as provided in G.S. 130A-159.3.
- 26          (9)    Appoint from among its directors, committees necessary to provide technical  
27          assistance in the operation of the Association, including the hiring of  
28          independent consultants.
- 29          (10)   Provide for audit compliance with reporting obligations established under  
30          the Board's plan of operation. Upon failure of any entity that has been  
31          audited to reimburse the costs of the audit, as certified by vote of the Board  
32          within 45 days of notice of such vote, the Secretary shall assess a civil  
33          penalty of one hundred fifty percent (150%) of the amount of such costs.
- 34          (11)   Establish an interest charge for late payment of an assessment. The Secretary  
35          shall assess a civil penalty in the amount of one hundred fifty percent  
36          (150%) of the assessment amount against a health insurer that fails to pay an  
37          assessment within 45 days of notification of the delinquency.
- 38          (12)   File liens and seek judgment to recover amounts in arrears and civil  
39          penalties, and to recover reasonable collection costs, including reasonable  
40          attorneys' fees and costs. The Secretary is also authorized to recover amounts  
41          under this subdivision. Civil penalties shall be deposited to the Childhood  
42          Immunization Account.
- 43          (13)   Perform other functions as may be necessary or proper to implement the plan  
44          of operation and to affect the purposes for which the Association is  
45          organized.

46       **"§ 130A-159.3. Assessments.**

47       (a)    The Secretary shall establish the total nonfederal program cost for the upcoming  
48       year and provide it to the Board by October 1 of each year. The Board shall establish the  
49       amount of each insurer's assessment needed for the operational period beginning January 1,  
50       2010, through December 31, 2010. By October 15, 2010, the Board shall provide written  
51       notification to each health insurer of the assessment due from each for this period. The Board

1 shall determine the method and timing of assessment collection in consultation with the  
2 Department. The assessment methodology adopted by the Board shall ensure that the  
3 nonfederal costs are based on actual usage of vaccine for a health insurer's covered lives. The  
4 Board shall adopt a formula to ensure the total anticipated nonfederal program cost is collected  
5 and transmitted to the Childhood Immunization Account established under G.S. 130A-159.4 in  
6 order to ensure adequacy of State funds to order State-supplied vaccine from the CDC.

7 (b) The Board shall establish the assessment due from each insurer for the ensuing  
8 operational period and shall provide written notification to each insurer by October 15 of each  
9 year of the total assessment due from the insurer for the ensuing annual period. The insurer  
10 shall have 45 days after receipt of the notification to remit amounts due, or in the case of an  
11 approved payment plan, the initial payment under the approved payment plan.

12 (c) The Board shall develop a mechanism through which the number and cost of doses  
13 of vaccine purchased under the Program that have been administered to children covered by the  
14 health insurer are attributed to each health insurer. The mechanism shall include at least the  
15 date of vaccine administration, patient name, vaccine received, and the patient's coverage under  
16 a health benefit plan. This data shall be collected and maintained in a manner consistent with  
17 applicable State and federal health information privacy laws. The Board shall factor the results  
18 of this mechanism for the previous year into the determination of the appropriate assessment  
19 amount for each health insurer for the ensuing year.

20 (d) For (i) new vaccines recommended by the Advisory Committee for Immunization  
21 Practices of the CDC for which an initial federal contract price is established and (ii) other  
22 vaccine changes received by the Advisory Committee on Immunization Practices of the CDC  
23 between October 1 and July 31 of subsequent fiscal years an interim assessment will be made.  
24 The Department shall determine the dollar amount necessary to purchase, store, and distribute  
25 the vaccine and shall inform the Board of the dollar amount by the first day of the quarter of the  
26 year following the establishment of a federal contract price for the vaccine. The Board shall  
27 determine the appropriate health insurer assessment within 15 days of receiving notice of this  
28 amount from the Department. All health insurer assessments for the vaccine shall be paid to the  
29 Board within 45 days of receiving the assessment from the Board.

30 (e) For any year in which the total calculated cost to be received from Association  
31 members through assessments is less than the total nonfederal program cost, the Association  
32 shall pay the difference to the State for deposit into the Childhood Immunization Account  
33 established under this Part. The Board may assess health insurers their proportionate share of  
34 these costs and appropriate reserves as determined by the Board.

35 (f) The aggregate amount raised by the Association in any year may be reduced by any  
36 surpluses remaining from prior years.

37 (g) The Board shall submit periodic reports to the Secretary listing those health insurers  
38 that failed to remit the required assessment. The Board shall provide for an audit of a health  
39 insurer's books and records to ensure accuracy of assessment payment submission.

40 **"§ 130A-159.4. Childhood Immunization Account established.**

41 There is created in the General Fund a nonreverting restricted receipts account to be known  
42 as the Childhood Immunization Account (Account). Funds in the Account shall be those  
43 forwarded by the Board to the State Treasurer from annual assessments collected by the Board  
44 less administrative costs. Funds in the account may be used only for the purchase, storage,  
45 distribution, and quality assurance of vaccines and other authorized administrative expenses  
46 under the Universal Childhood Immunization Program. No expenditures from the account may  
47 be made unless approved by the Secretary.

48 **"§ 130A-159.5. Universal Childhood Immunization Program; participation.**

49 (a) The Department shall include in the Program those vaccines for childhood  
50 immunizations recommended by the Advisory Committee for Immunization Practices of the  
51 Centers for Disease Control and Prevention (CDC) and designated for coverage by the federal

1 Vaccine for Children Program. Physicians providing these childhood vaccines shall participate  
2 in the Program. The Department shall allow each health care provider participating in the  
3 Program to select vaccines from a list of all vaccines that are (i) approved by the United States  
4 Food and Drug Administration, (ii) recommended by the Advisory Committee on  
5 Immunization Practices, and (iii) made available under contract with the CDC.

6 (b) Not later than October 1, 2010, and annually thereafter, the Department shall  
7 determine the dollar amount appropriate to purchase, store, distribute, and provide quality  
8 assurance for vaccines for routine immunizations, and to support other authorized  
9 administrative expenses under the Universal Childhood Immunization Program. The  
10 Department shall provide the estimates to the Board as soon as possible.

11 (c) All health insurers shall remit payment of the assessment required by the Board for  
12 the health insurer's share of the total amount needed to fund nonfederal program costs  
13 calculated by the Department. The assessment shall include additional funds as determined  
14 necessary by the Board to cover the reasonable administrative expenses of the Association.

15 (d) Physicians and clinics ordering State supplied vaccine must have billing  
16 mechanisms and practices in place that enable the Association to accurately track vaccine  
17 delivered to covered lives and shall submit documentation in such form as may be prescribed  
18 by the Board in consultation with the North Carolina Medical Society. Physicians and other  
19 persons providing childhood immunization are urged to use State supplied vaccine whenever  
20 possible. Health insurers shall deny claims for vaccine serum costs when the serum providing  
21 similar protection is provided or available via State supplied vaccine.

22 **"§ 130A-159.6. Universal Childhood Immunization Program requirements.**

23 (a) Every health insurer shall report annually to the Board the number of covered life  
24 months insured or administered by the health insurer during a period and on a form prescribed  
25 by the Board. The Board shall determine the date on which the annual report is due.

26 (b) Every health care provider that submits a claim to a health insurer for payment for  
27 vaccines administered under the Program shall provide a copy of the claim to the Board at the  
28 same time the claim is submitted to the health insurer. The Board shall maintain a record of  
29 claims for purposes of cross-checking the administration of vaccines with insurer assessments.

30 **"§ 130A-159.7. Reporting requirements; liability.**

31 (a) Not later than 120 days after the close of the Association's fiscal year, the Board  
32 shall submit to the Secretary a financial report in a form approved by the Secretary.

33 (b) No liability on the part of, and no cause of action of any nature, shall arise against  
34 any member of the Board, against an employee or agent of the board or Association, or against  
35 a health care provider for any lawful action taken in the performance of their duties or required  
36 activities under this Part."

37 **SECTION 2.** The Secretary shall convene the initial meeting of the Board of  
38 Directors of the North Carolina Childhood Vaccine Association established in this act.  
39 Thereafter the Board shall meet at the call of the chair.

40 **SECTION 3.** This act is effective when it becomes law.