Draft Fiscal Note Narrative – Proposed Rule with Fiscal Impact
Section .0400 - IMMUNIZATION
10A NCAC 41A .0401 DOSAGE AND AGE REQUIREMENTS FOR IMMUNIZATION

Name of Commission: Commission for Public Health

Agency: Department of Health and Human Services, Division of Public Health

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Impact Summary:

State Impact:	Yes
Federal Impact:	Yes
Local Impact:	Yes
Small Business Impact:	Yes
Substantial Impact:	Yes

Rule Title: 10A NCAC 41A .0401 - Rules Affecting Dosage and Age Requirements for Immunization in North Carolina

Authority: Statutory Authority: G.S. 130A-152 and G.S. 130A-433

***** The agency had specifically requested public comments on the cost-effectiveness of the requirement for the second dose of the varicella vaccine given assumptions and uncertainties surrounding the estimation of costs and benefits. However, no comments regarding the cost-effectiveness were received. The agency received numerous comments, primarily from public school nurses, that the effective date be delayed until July 1, 2015 to provide schools and parents adequate time to meet the new recommendations. The Commission for Public Health adopted the rule amendments at the May 14, 2014 meeting with an effective date of July 1, 2015. The change from the Noticed amendment affects the cost/benefit calculations in this fiscal impact analysis by pushing all cost/benefits out one year.*****

I. Purpose and Summary

Implementation of the proposed rule change (see rule text in Appendix A) will result in a greater number of citizens being immunized against vaccine preventable diseases and will also provide greater protection for unimmunized citizens by strengthening herd immunity. Herd immunity occurs when a critical portion of a community is immunized against a contagious disease, which decreases the opportunity for an outbreak to occur. In turn, infants and immunocompromised individuals are better protected and less likely to come in contact with the disease. Herd immunity is becoming increasingly important with higher levels of religious and philosophical exemptions seen each year in North Carolina and throughout

the United States.[1] Higher vaccination coverage will result in fewer cases of disease and, therefore, lower direct medical costs, and lower indirect societal costs.

This rule change will bring Immunization Branch requirements better in line with recommendations from the Advisory Committee on Immunization Practices (ACIP)[2] and the Centers for Disease Control and Prevention (CDC). The ACIP is a group of medical and public health experts that develop recommendations on the use of vaccines to control diseases in the United States. The recommendations are public health standards designed to result in a reduction in the incidence of vaccine preventable diseases and an increase in the safe use of vaccines and related biological products. This rule change will better align with these standards by:

1) Narrowing the administration window for the booster dose of trivalent type Inactivated Polio Vaccine (IPV) to combat Poliomyelitis to be given on or after the fourth birthday and before enrolling in school (K-1) for the first time;
2) Requiring an additional booster dose of varicella vaccine prior to school entry and a healthcare provider documentation of history of varicella or laboratory finding as verification of history of varicella rather than parental or self-reporting, and;
3) Broadening the vaccine requirements in NC to include 4 doses of the pneumococcal vaccine for children less than five years of age and meningococcal vaccine for adolescents entering the 6th grade and a booster dose before entering 11th grade.

As state under point 1) above, this rule change aims to change the schedule for the booster dose of polio. Currently, the ACIP schedule recommends a booster dose between the ages of 4-6 years.[3] This rule will require the 4th dose (booster) to be given after age 4, but prior to enrollment in kindergarten. The intent of this rule change is to provide immunity to children prior to their integration in a school setting. This rule does not add any additional doses to the schedule nor results in any additional costs, but it just shifts when the costs would be incurred; therefore, this change will not be included as part of the following cost assessment. Additional clarifying changes and language clean-up are not discusses in the analysis either. The analysis addresses the additional 2nd dose of varicella, 4 doses of pneumococcal conjugate, and 2 doses of meningococcal.

As of November 2012, 41 of the 50 states plus the District of Columbia require two doses of varicella for age-specific cohorts. Of these 41, 37 states require two doses of varicella for kindergarten entry (see map of states with this requirement in Appendix B). Furthermore, 37 states require pneumococcal vaccination for enrollment in childcare (see map in Appendix C). Meningococcal vaccination is also on the rise, with 17 states currently requiring documentation of vaccination for school entry, and an additional 6 states requiring education on the disease and vaccine (see map in Appendix D).[4]

By implementing these revisions, the burden will be reduced on the public and medical providers by making the schedule easier to follow and understand. This rule change intends to streamline North Carolina immunization requirements with those of the ACIP and CDC, which in turn will benefit healthcare providers across the state as well as provide better protection against vaccine-preventable diseases.

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[1] CDC MMWR. "Vaccination Coverage Among Children in Kindergarten – United States, 2012-13 School Year" August 2, 2013/62(30); 607-612. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6230a3.htm
CDC. ACIP "Birth-18 Years & "Catch-up" Immunization Schedules," US 2013, http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html (accessed August 7, 2013).

[3] CDC MMWR "Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP) Regarding Routine Poliovirus Vaccination" August 9, 2009/58(30); 829-830 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5830a3.htm

[4] Immunization Action Coalition. Mandates for Vaccine by State. http://www.immunize.org/laws/ (accessed September 4, 2013)

The state government would be impacted by this rule change through the North Carolina Immunization Branch, which helps reduce the spread of vaccine preventable diseases by assisting healthcare providers to assure individuals are age appropriately immunized and by controlling vaccine preventable disease transmission to prevent outbreaks of these diseases. To accomplish this, the Immunization Branch provides vaccines 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.

Table 1 below provides a summary of the costs that would result from the proposed rule changes. The net present value of costs over a 6-year period is estimated to be about $102 million (at a 7% discount rate).

Table 1. Summary of Costs from the Proposed Rule Change*

Description	SFY2014	SFY2015	SFY2016	SFY2017	SFY2018	SFY2019
Federal CMS						
Vaccine, Medicaid Covered Administration Fee, Adverse Events	$10,172,000	$10,391,000	$10,611,000	$10,836,000	$11,066,000	$12,729,000
Shipping & Handling	Unknown					
State						
DMA Administration Fee, Adverse Events	$363,000	$368,000	$376,000	$383,000	$392,000	$439,000
Private Insurers (reimbursement to Providers)	$7,363,000	$7,519,000	$7,678,000	$7,841,000	$8,007,000	$9,955,000
Providers	$700,000	$715,000	$730,000	$746,000	$762,000	$889,000
Public (non-Medicaid VFC)	Tangible costs, deductibles, opportunity cost,					
Total Costs	**$18,598,000**	**$18,993,000**	**$19,395,000**	**$19,806,000**	**$20,227,000**	**$24,012,000**
6-year Net Present Value (NPV) (mil.)	$102.01					
Total Benefits	**$8,602,000**	**$8,739,000**	**$8,884,000**	**$9,029,000**	**$9,173,000**	**$9,313,000**
6-year Net Present Value (NPV) (mil.)	$45.54					

*Assumes a constant annual 2.12% population growth. Also, figures as rounded to nearest thousand.

This analysis presents some rough estimates of potential benefits given some of the unknowns in determining the amount of disease that could potentially be prevented through this rule change. Benefits consist of cost savings in terms of treatment of disease, and any indirect societal costs associated with it. Benefits would also be incurred from potential reduced outbreak, where many suspect cases are ultimately quarantined or given isolation orders, which result in a great deal of time spent away from

work and all other community settings. Furthermore, sick children have to be excluded from school settings, which also results in time spent away from work on the part of the parents. Incidents such as these place a tremendous burden on the public, as well as on the local health departments, who are fully responsible for investigating each case of disease and controlling its spread. When highly contagious diseases take place in North Carolina, health department staff must utilize every resource possible to contain it, which often takes away from surveillance and management of other public health responsibilities. Implementation of this rule change would not only improve the status of vaccine-preventable diseases, but would also allow for better surveillance and monitoring of other public health concerns across the state.

The benefit estimates presented below were based on studies of the proposed vaccine and employed a series of assumptions. The results suggest the pneumococcal vaccine would lead to net societal savings; however, there could be net losses for the meningococcal vaccine requirement and especially for the varicella booster. The analysis used an averted productivity loss approach to estimating the benefits of averted death cases, which puts downward pressure on the estimate. A value of statistical life approach, which most often used a higher value, could result in a net societal benefit conclusion for the requirement.

II. Background

Every year, thousands of people in the United States suffer, and sometimes die from contracting a vaccine preventable disease. In 2012, over 10,000 people, with roughly 10% of the cases being younger than five years of age, contracted *streptococcus pneumonia*, a disease that is preventable with a pneumococcal conjugate vaccine.[5] This bacterial infection can also lead to respiratory tract infections, including acute otitis media (AOM) and sinusitis. In fact, it is estimated that between 30-50% of all AOM infections are caused by *streptococcus pneumonia*.[6] Although these types of infections do not typically progress to invasive disease, they do cause considerable morbidity and result in high medical costs. More than 24 million pediatric visits are made each year in the United States as a result of AOM and sinusitis, with 62% of all children experiencing an AOM episode during their first year of life.[7,8] This disease can also cause many serious complications including meningitis, pneumonia, and bacteremia, and a single case can cost upwards of $875 to treat effectively.[9]

Also in 2012, an additional 10,000 cases of varicella were reported across the country, with an average case costing approximately $200, not including indirect societal costs.[10] In the same year, 550 cases of meningococcal disease were reported. When not fatal, this disease is known to cause serious complications including brain damage, hearing loss, and learning disabilities. In addition to its high fatality rate and serious complications, a single case can easily cost hundreds of thousands of dollars due to long-term hospitalization and extensive supportive care.[11]

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[5] CDC MMWR August 30, 3013/62 (34);ND-466-ND-479 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6234md.htm?s_cid=mm6234md_w (Accessed 8/29/13)
[6] Bluestone CD, ed. Pediatric otolaryngology. 3rd ed. Philadelphia, PA: WB Saunders Company, 1990.
[7] Schappert SM. Office visits for otitis media: United States, 1975-90. Hyattsville, MD: United States Department of Health and Human Services, Public Health Service, Centers for Disease Control, 1992 (Advance data no. 214).
[8] Teele DW, Klein JO, Rosner B, Greater Boston Otitis Media Study Group. Epidemiology of otitis media during the first seven years of life in children in Greater Boston: a prospective, cohort study. J Infect Dis 1989;160:83-94.
[9] Huang, et al. "Healthcare Utilization and Cost of Pneumococcal Disease in the United States". Vaccine. 2011 Apr 18;29(18):3398-412
[10] Lieu, et al. "The Cost of Childhood Chickenpox: A Parent's Perspective". Pediatr Infect Dis J. 1994 Mar; 13(3):173-7.
[11] Shepard, et al. "Cost-effectiveness of conjugate meningococcal vaccination strategies in the United States". Pediatrics. 2005 May;115(5):1220-32. http://pediatrics.aappublications.org/content/115/5/1220.full.pdf+html

Vaccines are one of the most successful and cost-effective tools available for protecting the public's health, both at individual and population levels.[12] According to an extensive cost-benefit analysis by the CDC, every dollar spent on immunization saves $6.30 in direct medical costs. When including indirect costs to society - a measurement of losses due to missed work, death and disability as well as direct medical costs, the CDC notes that every dollar spent on immunization saves $18.40.[13] Another recent economic report indicated that vaccination of each U.S. birth cohort with the current childhood immunization schedule prevents approximately 42,000 deaths and 20 million cases of disease, with net savings of nearly $14 billion in direct costs and $69 billion in total societal costs.[14] When comparing these costs to the current population of North Carolina, it is estimated that vaccination prevents approximately 1,300 deaths and 620,000 cases of disease in North Carolina. Similarly, net savings are estimated at $434,000,000 in direct medical costs and over 2 billion in total societal costs.

The vaccines responsible for helping prevent these infections have been studied extensively and found to be biologically safe and highly effective. Despite this, disease continues to occur across the United States and throughout the world, which highlights the need for greater protection. Following the introduction of the pneumococcal conjugate vaccine, it is estimated that approximately 211,000 serious pneumococcal infections and 13,000 deaths were prevented during 2007-2008. In spite of this overwhelming reduction, pneumococcal infection is still known to account for more deaths annually in the United States than any other vaccine-preventable bacterial disease. It is estimated that over half of these deaths could have been prevented through a more extended use of the vaccine.[15] In regards to varicella, the age-specific mortality for persons age <20 years declined by 97% from 0.65 to 0.02 during 2005-2007, following the introduction of the vaccine.[16] While this reduction can be viewed as a tremendous success, tens of thousands of cases are still reported every year in the United States, which often results in relatively high medical and indirect societal costs. An even greater success was seen with polio in the United States, with over 21,000 paralytic cases reported in 1952, followed by a dramatic decline in incidence (and ultimately eradication) after the introduction of the polio vaccine. Despite this tremendous achievement, polio still remains endemic in certain parts of the world. Afghanistan, Nigeria, and Pakistan still see many cases of the disease today as a result of poor vaccination coverage. As long as a single child remains infected, children in all countries are at risk of contracting polio. According to the World Health Organization (WHO), failure to fully eradicate polio from these last three remaining countries could result in as many as 200,000 new cases every year, within 10 years, all over the world.[17] Lastly, the vaccine responsible for preventing the most common strains (A, C, Y, and W-135) of meningococcal disease has also been extremely effective at bringing incidence levels to historic lows in the United States since 2000.[18] North Carolina, however, still continues to see cases each year, with an average of 16 cases each year from 2008-2012.[19] While the annual case count for this disease may seem relatively low, invasive meningococcal disease most often results in death and exorbitant medical costs.

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[12] "Protecting The Public's Health: Critical Functions of the 317 Immunization Program – A Report of the National Vaccine Advisory Committee" Public Health Rep. 2013 Mar-Apr; 128(2):78-95.
[13] Ross Rapoport, "CDC: Immunizations High But Shot In Arm Still Needed," Cox News Service. August, 1 2003 (Accessed July 29, 2013)
[14] Zhou F. Updated economic evaluation of the routine childhood immunization schedule in the United States. Presented at the 45th National Immunization Conference. Washington, DC; March 28—31, 2011.
[15] Gardner P, Schaffner W. Immunization of adults. N Engl J Med 1993;328:1252-8.
[16] Marin, M, Zhang JX, Seward JF. Near elimination of varicella deaths in the US following implementation of the childhood vaccination program. Pediatrics. In press, 2011.
[17] World Health Organization. Poliomyelitis Media Cente Fact Sheet. http://www.who.int/mediacentre/factsheets/fs114/en/. Accessed on September 25, 2013.
[18] Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Hamborsky J, Wolfe S, eds. 12th ed., second printing. Washington DC: Public Health Foundation, 2012.
[19] North Carolina Communicable Disease Monthly Report. Facts and Figures. July 2013. http://epi.publichealth.nc.gov/cd/figures/cd_jul2013.pdf (accessed September 26, 2013)

While childhood immunization has proven to be one of the biggest contributors in increasing life expectancy and quality of life in the United States, vaccine-preventable diseases still remain a major cause of illness, disability, and death, especially in children. The fact that our society is more mobile than ever before, and many of the diseases that vaccines protect against are still endemic in certain parts of the world, only highlights the need for greater protection through immunization coverage.[20]

III. Cost Analysis

The intent of this rule change is to increase the number of children in North Carolina receiving these three vaccines, thereby reducing and preventing vaccine preventable disease. This analysis presents an estimate of all governmental costs – local, state and federal – related to the implementation of the proposed rule. It also estimates direct consumer costs and costs to healthcare providers and private insurers, to the extent possible from available data. All cost estimates are calculated on the basis of a single birth cohort (e.g. all 2 year olds), and assumes a 2.12% annual, constant population growth, as provided from DMA forecasting. Data used to calculate these estimates are based on the data variables available at the beginning of the analysis process. These variables, including but not limited to, cost per vaccine dose, population, and state Medicaid enrollment, are subject to change over time.

Each year the CDC conducts a National Immunization Survey (NIS) to measure coverage rates for various vaccines. These rates serve as the standard for determining how well the population is vaccinated with the ACIP recommended vaccines. According to the most recent NIS results (2011), current vaccination rates (with a 95% confidence interval) in North Carolina for the three vaccines proposed to be added to the current requirements are as follows:

- Pneumococcal conjugate (4 doses): 84.5%;
- Meningococcal (1st dose): 65.9%; (2nd dose): not available; and
- Varicella (2nd dose): not available.

Vaccine coverage for the three proposed vaccines is calculated based on four doses of pneumococcal conjugate, one dose of meningococcal vaccine, and one dose of varicella. The second dose of varicella was first recommended by the ACIP in 2007 but NIS data is not available to indicate overall coverage. Likewise, the second dose of meningococcal vaccine was first recommended by the ACIP in 2011 but NIS coverage rate data is also not yet available.

In accordance with the Healthy People 2020 immunization goals[21], a coverage rate of 90% was used among all three cohorts for the proposed required vaccines, and this is the assumption regarding coverage that this analysis is adopting to estimate the impact of the rule change. Healthy People 2020 goals for immunization and infectious diseases are rooted in evidence-based clinical services and community activities for the prevention and treatment of infectious diseases. Objectives for 2020 reflect a more mobile society with resulting disease transmission beyond typical geopolitical borders. Therefore, higher or lower vaccination coverage rates will alter costs accordingly.

The following immunization schedules for the proposed vaccines reflect the routine recommendations of the ACIP:

- Varicella (2nd dose): prior to kindergarten entry,[22]
- Pneumococcal conjugate: 4-dose series given at 2, 4, 6 and 12-15 months of age,[23] and

[20] US HHS, HealthyPeople.gov, "Immunization and Infectious Diseases", April 10, 2013, http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=23 (accessed September 4, 2013).
[21] US HHS, HealthyPeople.gov, "Immunization and Infectious Diseases", April 10, 2013, http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=23 (accessed August 7, 2013).
[22] CDC MMWR. "Recommendations for use of Varicella Vaccine". June 22, 2007 /Vol. 56 / No. RR-4) http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf

- Meningococcal (1st dose): 11 years of age and (booster dose): 16 years of age.[24]

A. Number of Doses Required to Achieve Coverage Goal

Data from the 2012 Population Estimate Survey (PES) completed by the CDC was used to determine the size of the birth cohorts receiving the proposed vaccines (Appendix E):[25]

- Varicella: The birth cohort receiving a 2nd dose of varicella vaccine was estimated to be 129,581 in 2014 based on the data for the "3-6" year old subgroup.
- Pneumococcal conjugate: The birth cohort receiving this vaccine was estimated to be 135,513 based on the average of the "<1" year old and "1-2" year old subgroups. The four dose series of pneumococcal vaccine will ultimately be spread out over 12 to 15 months. In other words, each child will receive either one dose, two doses, or three doses each year. In order to facilitate impact estimation, it was assumed that there would be 4 doses administered per child per year, so only one cohort estimate was used as opposed to two.
- Meningococcal: The birth cohort receiving this vaccine (1st and 2nd dose) was estimated to be 128,892 based on the average of the "7-18" year old subgroup. As part of this rule change, the 2nd dose of meningococcal vaccine would not become a requirement until the 11 year old cohort receiving the first required dose in 2014 turns 16 years old, in 2019. This rule change uses a 5-year interval and does not implement a requirement of the 2nd dose until the same cohort is entering the 11th grade, at which time they will also be receiving an already required dose of Tdap (tetanus-Diptheria-acellular pertussis). As a result, the fiscal impact for all seven required doses will not fully be realized until 2019. The cohort used for the 2nd dose of meningococcal is based on the original cohort size, and assumes a 2.12% population increase each year until 2019. In 2019, the population receiving the 2nd dose of meningococcal vaccine is estimated to be 143,147.

Given the above 2011 NIS coverage rates and CDC's PES, the number of doses needed to complete each vaccine series with an overall coverage rate of 90% was calculated (see Table 2 below). Currently, no coverage rate is available for the second dose of varicella; therefore it is assumed that 100% of the respective cohort is in need of immunization. Additionally, the second dose of meningococcal vaccine will not become a requirement until 2019 (when an estimated 31,036 children would receive the second dose). The cohort receiving this dose is based on the cohort receiving the first dose and assumes a five-year interval between the two doses as well as a 2.12% population increase each year until 2019. The number of doses estimated to be administered for each vaccine, as shown in Table 2, is based on the difference between their current coverage rates and the 90% goal. The number of doses estimated to be administered in the first year of implementation of this rule (2014) is 177,499. Six years after the implementation of the proposed rule, in 2019 when all seven of the proposed doses become a requirement, 228,191 doses are estimated to be needed (see Table 3 below).

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[23] CDC MMWR "Recommendations for use of Pneumococcal Conjugate Vaccine" March 12, 2010/59(09); 258-261 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm

[24] CDC MMWR "Updated Recommendations for use of Meningococcal Conjugate Vaccines". January 28, 2011 / 60(03);72-76; http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a3.htm?s_cid=mm6003a3_e

[25] CDC requires all awardees to order vaccine based on their population estimate survey, which is the basis for using this data as opposed to other state demographic resources.

Table 2. Number of Additional Doses Needed – 1st year of Implementation (2014)

Immunization	Doses	Average Cohort Size[1]	2011 NIS Coverage Rate[2]	HP 2020 Coverage Rate Goal[3]	Doses Needed for 90% Coverage
Varicella (2nd Dose)[4]	1	129,581	N/A	90%	116,623
Pneumococcal Conjugate	4	135,513	84.5	90%	29,813
Meningococcal (1st dose)	1	128,892	65.9	90%	31,063
Meningococcal (2nd dose)[4,5]	0	N/A	N/A	90%	0
TOTAL					**177,499**

[1] Average birth cohort size is based on the average of the "<1 "and "1-2" year old subgroups, "3-6" year old subgroup, and "7-18" subgroup (Appendix E).
[2] National Immunization Survey (NIS) is sponsored by the CDC, and it is a list-assisted random-digit-dialing telephone survey followed by a mailed survey to children's immunization providers that began data collection in April 1994 to monitor childhood immunization coverage. http://www.cdc.gov/nchs/nis.htm
[3] The analysis assumes at immunization coverage will reach the Healthy People (HP) 2020 immunization goal of 90% for all childhood and adolescent immunizations.
[4] The second doses of varicella and meningococcal vaccine were first recommended by the ACIP in 2007 and 2011, respectively, and have not yet been assessed for overall coverage.
[5] The second dose of meningococcal does not become a requirement until 2019. The population estimate for this cohort is based on that of the 11 year olds receiving the first dose in 2014.

Table 3. Number of Additional Doses Needed Over a 6-year Period (2014 – 2019)

Immunization	SFY2014	SFY2015	SFY2016	SFY2017	SFY2018	SFY2019
Varicella (2nd Dose)	116,623	119,095	121,620	124,198	126,831	129,520
Pneumococcal Conjugate	29,813	30,445	31,090	31,749	32,422	33,109
Meningococcal (1st dose)	31,063	31,722	32,395	33,082	33,783	34,499
Meningococcal (2nd dose)[5]	0	0	0	0	0	31,063
TOTAL	**177,499**	**181,262**	**185,105**	**189,029**	**193,036**	**228,191**

Next, the allocation of the costs for these doses among payors must be estimated. Vaccine costs will ultimately be paid for by either the federal Vaccines for Children (VFC) entitlement program or by private insurers or parent (in the case on non-VFC eligible uninsured child). The NC Department of Medical Assistance (DMA) does not pay for vaccine, as the federal VFC program provides vaccine for all Medicaid-eligible children. Federal funding for the VFC program is approved by the Office of Management and Budget (OMB) and allocated through the Centers for Medicare & Medicaid Services (CMS) to the Centers for Disease Control and Prevention (CDC). CDC purchases vaccines at a discounted federal contract price and allocates them to the North Carolina Division of Public Health - which in turn determines distribution to those private physicians' offices and public health clinics enrolled in the states immunization program. The actual shipping and distribution of the vaccines is generated centrally from McKesson Corporation, located in Memphis, Tennessee. These shipping costs are paid by the CDC directly to McKesson and are unknown due to the proprietary nature of the contract.

To determine the estimated cost allocation, it is necessary to define the percentage of the childhood and adolescent population eligible to receive vaccines through the 100% federally funded VFC program. The VFC program provides vaccines at no cost to eligible children ages 0 through 18 years who might not otherwise be vaccinated because of inability to pay. To be eligible for VFC vaccines, children must fall into one of the following four categories:

- Medicaid eligible,
- Uninsured,

- American Indian or Alaska Native, or
- Underinsured receiving care through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) or other provider delegated the same authority.

Data from the 2012 PES (see Appendix E) was used to calculate the distribution of VFC eligibility among cohorts, as well as the proportion of children within the VFC eligible population that are covered by Medicaid (see Table 4). The distribution was used to estimate the number of doses for each vaccine over a 6-year period by eligibility, as shown in Table 5 below. As stated previously, DMA also forecasts an additional 2.12% increase each year as a result of overall growth within the general population. The overall percentages are assumed to remain the same as the overall population increases. In 2014, the first year of implementation of the rule change, a total of 115,469 VFC and 62,030 Non-VFC (private) doses are estimated to be administered. In 2019, when all seven doses have become a requirement, a totl of 144,703 VFC doses and 83,489 Non-VFC doses are estimated to be administered.

Table 4. Distribution of Eligibility

	VFC			**Non VFC**
Immunization	**% of Total Population**	% of VFC Covered by Medicaid	% of VCF Not Covered by Medicaid	**% of Total Population**
Varicella (2nd Dose)	67%	61%	39%	33%
Pneumococcal Conjugate	70%	63%	37%	30%
Meningococcal	53%	51%	49%	47%

Table 5. Distribution of Eligibility and Doses Needed Over a 6-year Period (2014 – 2019)*

Immunization	**SFY2014**	**SFY2015**	**SFY2016**	**SFY2017**	**SFY2018**	**SFY2019**
Medicaid VFC DOSES						
Varicella (2nd Dose)	47,664	48,674	49,706	50,761	51,837	52,936
Pneumococcal Conjugate	13,147	13,426	13,711	14,001	14,298	14,601
Meningococcal (1st dose)	8,396	8,574	8,756	8,941	9,131	9,325
Meningococcal (2nd dose)[5]	0	0	0	0	0	8,396
TOTAL (Medicaid VFC)	**69,207**	**70,674**	**72,173**	**73,703**	**75,266**	**85,258**
Non-Medicaid VFC DOSES						
Varicella (2nd Dose)	30,473	31,120	31,780	32,453	33,141	33,844
Pneumococcal Conjugate	7,722	7,885	8,052	8,223	8,397	8,575
Meningococcal (1st dose)	8,067	8,238	8,412	8,591	8,773	8,959
Meningococcal (2nd dose)[5]	0	0	0	0	0	8,067
TOTAL (Non-Medicaid)	**46,262**	**47,243**	**48,244**	**49,267**	**50,311**	**59,445**
Non-VFC DOSES						
Varicella (2nd Dose)[4]	38,486	39,301	40,134	40,985	41,854	42,741
Pneumococcal Conjugate	8,944	9,133	9,327	9,525	9,727	9,933
Meningococcal (1st dose)	14,600	14,909	15,225	15,548	15,878	16,215
Meningococcal (2nd dose)[5]	0	0	0	0	0	14,600
TOTAL (NON-VFC)	**62,030**	**63,343**	**64,686**	**66,058**	**67,459**	**83,489**

* Assumes a constant annual population growth of 2.12%.

B. Vaccine Cost

Next, the cost per dose was determined based on the "CDC Vaccine Price List"[26] dated July 24, 2013 for VFC and non-VFC doses. The VFC program provides all 16 routine childhood vaccinations recommended by the CDC's ACIP to children who are eligible. The VFC program pays for any brand of vaccine recommended by the ACIP. Therefore, individual vaccine costs vary. Since providers select a particular vaccine product based on clinical decisions, a more costly product may be selected. Therefore, the higher priced product was used to calculate the following maximum possible costs. In regards to the varicella vaccine (Varivax), it is priced at $94.14 when purchased for private use, and $75.36 if purchased federally for the VFC program. The pneumococcal conjugate vaccine (PCV13) costs $128.16 when purchased for private use, and $107.12 when purchased by the federal government. Lastly, the meningococcal vaccine (Menveo) has a private retail cost of $114.02 per dose and $82.12 when purchased by the federal government for the VFC program. All vaccine costs are assumed to remain constant throughout the six year time period. Vaccine costs fluctuate frequently, with many increasing or decreasing over time as more vaccines are introduced to the market. For this reason, all vaccine costs are based on the current price list at the time of analysis.

Applying the VFC versus non-VFC percentages to the vaccine-specific costs mentioned above to the number of VFC eligible and non-VFC eligible doses need to achieve 90% coverage shown in Table 5 above, staff estimated the total cost to the federal VFC program (see Table 6) and cost to the private insurers (see Tables 7) from the first year of implementation, 2014, through 2019 when all seven doses will have become a requirement.

Table 6. Cost of Vaccine Accrued to Federal VFC Program Over a 6-year Period (2014 – 2019)

Immunization	SFY2014	SFY2015	SFY2016	SFY2017	SFY2018	SFY2019
Varicella (2nd dose)	$5,888,404	$6,013,276	$6,140,785	$6,271,007	$6,403,942	$6,539,741
Pneumococcal Conjugate	$2,235,487	$2,282,834	$2,331,253	$2,380,635	$2,431,088	$2,482,613
Meningococcal (1st dose)	$1,351,942	$1,380,601	$1,409,836	$1,439,728	$1,470,276	$1,501,482
Meningococcal (2nd dose)*	$0	$0	$0	$0	$0	$1,351,942
TOTAL	**$9,475,833**	**$9,676,711**	**$9,881,874**	**$10,091,370**	**$10,305,306**	**$11,875,778**

* Uses Menveo (Meningococcal vaccine) to reflect highest possible cost.

[26] CDC. "CDC Vaccine Price List", July 24, 2013, http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html (accessed August 7, 2013).

Table 7. Cost of Vaccine Accrued to Private Providers (Reimbursed by Private Insurers) Over a 6-year Period (2014 – 2019)

Immunization	SFY2014	SFY2015	SFY2016	SFY2017	SFY2018	SFY2019
Varicella (2nd dose)	$3,623,072	$3,699,796	$3,778,215	$3,858,328	$3,940,136	$4,023,638
Pneumococcal Conjugate	$1,146,263	$1,170,485	$1,195,348	$1,220,724	$1,246,612	$1,273,013
Meningococcal (1st dose)	$1,664,692	$1,699,924	$1,735,955	$1,772,783	$1,810,410	$1,848,834
Meningococcal (2nd dose)*	$0	$0	$0	$0	$0	$1,664,692
TOTAL	**$6,434,027**	**$6,570,206**	**$6,709,518**	**$6,851,835**	**$6,997,157**	**$8,810,177**

* Uses Menveo (Meningococcal vaccine) to reflect highest possible cost.

C. Vaccine Administration Costs

The next question to address relates to charges for the administration of these vaccines. The administration fee cap is up to, but not exceeding, $13.71 and applies to all VFC-eligible children. This analysis assumes the administration fee covers all tangible and intangible costs (opportunity costs) providers would incur from administering the vaccine. The Centers for Medicare and Medicaid Services (CMS) sets the administration fee cap for all of the states. According to VFC requirements, this administration fee must be waived if the parent/guardian is unable to pay. The majority of VFC-eligible children are also eligible for Medicaid, and for these families this administration fee would be paid by Medicaid, with 34.29 % of the fee covered by DMA (or $4.70 per dose) and 65.71% (or $9.01 per dose) by federal funds from CMS. Beginning in 2015, DMA estimates these proportions to change slightly, with DMA covering 33.99% of the fee (or $4.66 per dose), and the remaining 66.01% (or $9.05 per dose) covered by federal funds. DMA does not estimate an increase in the total administration fee ($13.71) over the course of the next six years, and therefore all annual estimates are based on this amount. The administration fee, proportion of fee borne by CMS versus NC DMA, and the number of Medicaid, VFC eligible doses for need for 90% coverage as shown in Table 4 above were used to estimate the vaccine administration costs that federal CMS and NC DMA would incur as a result of the rule change – see annual estimates in Tables 8 and 9.

Table 8. Cost of Administration Fees to Federal CMS Over a 6-year Period (2014 – 2019)*

Immunization	SFY2014	SFY2015	SFY2016	SFY2017	SFY2018	SFY2019
Varicella (2nd dose)	$429,453	$440,499	$449,838	$459,386	$469,123	$479,069
Pneumococcal Conjugate	$118,454	$121,505	$124,084	$126,709	$129,396	$132,139
Meningococcal (1st dose)	$75,647	$77,594	$79,242	$80,916	$82,635	$84,391
Meningococcal (2nd dose)	$0	$0	$0			$75,984
TOTAL	**$623,554**	**$639,598**	**$653,164**	**$667,011**	**$681,154**	**$771,583**

* In 2014, CMS's portion of the administration fee is 65.71%, or $9.01. All years following 2014, CMS will cover 66.01%, or $9.05.

Table 9. Cost Accrued from Administration Fees to NC DMA Over a 6-year Period (2014 – 2019)*

Immunization	SFY2014	SFY2015	SFY2016	SFY2017	SFY2018	SFY2019
Varicella (2nd dose)	$224,021	$226,822	$231,631	$236,548	$241,562	$246,683
Pneumococcal Conjugate	$61,791	$62,566	$63,894	$65,245	$66,629	$68,041
Meningococcal (1st dose)	$39,461	$39,955	$40,803	$41,665	$42,551	$43,455
Meningococcal (2nd dose)	$0	$0	$0	$0	$0	$39,126
TOTAL	**$325,273**	**$329,343**	**$336,328**	**$343,458**	**$350,742**	**$397,305**

* In 2014, DMA's portion of the administration fee is 34.29%, or $4.70. All years following 2014, DMA will cover 33.99%, or $4.66 per dose.

For VFC-eligible children and adolescents ineligible for Medicaid, the administration fee is either paid by the parent/guardian or waived and accrued by the provider. Staff estimate, particularly during the slow economic recovery with those who are unemployed or underemployed, that fees for the additional VFC vaccines will likely be waived and would in turn, accrue to providers. Applying the $13.71 vaccine administration fee to the VFC eligible doses not covered by Medicaid, as shown in Table 4 above, staff estimate vaccine administration costs that would accrue to either parents/guardians or providers to be about $634,000 in 2014 and $815,000 by 2019. See more details in Table 10.

Table 10. Cost Accrued to Providers or Parents of Non-Medicaid VFC-Eligible Patients* – Over a 6-Year Period (2014-2019)

Immunization	SFY2014	SFY2015	SFY2016	SFY2017	SFY2018	SFY2019
Varicella (2nd dose)	$417,785	$426,655	$435,704	$444,931	$454,363	$464,011
Pneumococcal Conjugate	$105,868	$108,103	$110,393	$112,737	$115,123	$117,563
Meningococcal (1st dose)	$110,599	$112,943	$115,329	$117,783	$120,278	$122,828
Meningococcal (2nd dose)	$0	$0	$0	$0	$0	$110,599
TOTAL	**$634,253**	**$647,701**	**$661,426**	**$675,451**	**$689,764**	**$814,991**

* According to North Carolina Immunization Law, if a child is considered VFC-eligible and is not covered by Medicaid, and the parent is unable to pay for the administration fee, the fee is required to be waived and the cost is accrued by the provider.

With respect to privately insured children who are not VFC eligible, the standard administration fee of $13.71 was also used to calculate additional cost for children receiving privately purchased (i.e. non-VFC) vaccine. This fee would generally not be paid by the parent/guardian at the time of the visit; instead, the parent will generally be responsible for the insurance co-pay already being paid for well-child visit. For this reason, it is estimated that no additional out-of-pocket costs will be experienced by the parent of a non-VFC eligible child (i.e. privately insured) at the time of the visit. These costs will accrue instead to the family's private insurer. The actual amount of payment private insurers pay providers for vaccine administration varies from plan to plan; $13.71 is used as an available proxy amount due to it being a regulated cost set by CMS. Both local health departments and private providers may also provide an immunization only visit that would accrue no cost or co-pay to the parent for an office visit. Applying these parameters, administration costs, which would ultimately accrue to private insurers, for the three proposed vaccines were estimated as shown in Table 11.

Table 11. Cost of Administration Reimbursed by Private Insurers Over 6-year Period (2014 – 2019)

Immunization	SFY2014	SFY2015	SFY2016	SFY2017	SFY2018	SFY2019
Varicella (2nd dose)	$527,643	$538,817	$550,237	$561,904	$573,818	$585,979
Pneumococcal Conjugate	$122,622	$125,213	$127,873	$130,588	$133,357	$136,181
Meningococcal (1st dose)	$200,166	$204,402	$208,735	$213,163	$217,687	$222,308
Meningococcal (2nd dose)	$0	$0	$0	$0	$0	$200,166
TOTAL	**$850,431**	**$868,433**	**$886,845**	**$905,655**	**$924,863**	**$1,144,634**

D. Cost of Adverse Effects

As with any vaccine, there is a possibility that some children would develop adverse effects from the administration of the proposed vaccine doses. Most studies show that the adverse effects from vaccines are generally mild (e.g. fever, rash), however they can also result in more serious events. Based on assumptions made in three different studies that looked at the cost-effectiveness of the vaccines proposed in this rule change, the following assumptions were made in this analysis to estimate the direct medical costs of adverse effects:

- 0.5% of individuals would develop minor complications as a result of the administration of the second varicella dose, leading to a follow-up outpatient visit costing about $75 (cost was determined after adjusting for inflation the 2006 cost of $64.41 used in the study); [27]
- $7 per dose administered would be used to account for the cost of any adverse effects of the pneumococcal conjugate vaccine (cost was adjusted for inflation from the $5 estimate used in the study);[28]
- 0.03% of administered doses of meningococcal would result in mild adverse events having a direct medical cost of about $150 and 0.0002% would result in severe events with associated cost of about $20,000;[29] and
- For simplicity and given the rounding up of the cost estimates from the bullets above, the analysis assumes these costs constant over the next few years.

These assumptions in conjunction with the number of doses that would be administered, as shown in Table 5, and the percentage of Medicaid costs covered by federal CMS and the state's DMA, as mentioned in the vaccine administration cost section, were used to compute the cost estimate shown for adverse effects that would be covered by the federal CMS, DMA, and private insurers or parents (see Table 12). Note these cost estimates do not include any indirect costs related to parents' lost time from work, travel costs for the doctor visits, etc.

[27] Zhou, Fangjun et. al. **"**An Economic Analysis of the Universal Varicella Vaccination Program in the United States," Journal of Infectious Diseases, 2008; 197 (Supplement 2): S156–64. http://jid.oxfordjournals.org/content/197/Supplement_2/S156.full.pdf+html

[28] Lieu, T.A. et. al. "Projected cost-effectiveness of pneumococcal conjugate vaccination of healthy infants and young children," JAMA., 2000, Mar 15; 283(11):1460-8. http://www.ncbi.nlm.nih.gov/pubmed/10732936

[29] Shepard, et al. "Cost-effectiveness of conjugate meningococcal vaccination strategies in the United States". Pediatrics. 2005 May;115(5):1220-32. http://pediatrics.aappublications.org/content/115/5/1220.long#ref-34

Table 12. Cost of Adverse Effects – Over a 6-year Period (2014-2019)

Immunization	SFY2014	SFY2015	SFY2016	SFY2017	SFY2018	SFY2019
Federal CMS						
Varicella	$11,745	$12,049	$12,304	$12,565	$12,832	$13,104
Pneumococcal Conjugate	$60,472	$62,038	$63,354	$64,694	$66,067	$67,467
Meningococcal (1st dose)	$469	$481	$491	$502	$512	$523
Meningococcal (2nd dose)[5]	$0	$0	$0	$0	$0	$471
TOTAL	**$72,686**	**$74,568**	**$76,150**	**$77,761**	**$79,411**	**$81,565**
DMA						
Varicella	$6,129	$6,204	$6,336	$6,470	$6,607	$6,747
Pneumococcal Conjugate	$31,557	$31,944	$32,623	$33,313	$34,019	$34,740
Meningococcal (1st dose)	$245	$248	$253	$258	$264	$270
Meningococcal (2nd dose)[5]	$0	$0	$0	$0	$0	$243
TOTAL	**$37,931**	**$38,396**	**$39,211**	**$40,041**	**$40,890**	**$42,000**
Providers or Reimbursed by Parents						
Varicella	$11,427	$11,670	$11,918	$12,170	$12,428	$12,692
Pneumococcal Conjugate	$54,054	$55,195	$56,364	$57,561	$58,779	$60,025
Meningococcal (1st dose)	$686	$700	$715	$730	$746	$762
Meningococcal (2nd dose)[5]	$0	$0	$0	$0	$0	$686
TOTAL	**$66,167**	**$67,565**	**$68,997**	**$70,461**	**$71,953**	**$74,165**
Reimbursed by Private Insurers)						
Varicella	$14,432	$14,738	$15,050	$15,369	$15,695	$16,028
Pneumococcal Conjugate	$62,608	$63,931	$65,289	$66,675	$68,089	$69,531
Meningococcal (1st dose)	$1,241	$1,267	$1,294	$1,322	$1,350	$1,378
Meningococcal (2nd dose)[5]	$0	$0	$0	$0	$0	$1,241
TOTAL	**$78,281**	**$79,936**	**$81,633**	**$83,366**	**$85,134**	**$88,178**

E. Key Points

For non VFC-eligible children the maximum up-front cost to providers for the newly required vaccines could be as great as $6.4 million in 2014 and close to $9 million in 2019 based on the current retail cost per vaccine (see Table 7). Providers would also incur the cost of administering the vaccine to non-VFC eligible children, estimated to be $850,000 in 2014 and close to $1.2 million by 2019 (see Table 11). Providers will be reimbursed for these expenditures, usually by private insurers. Providers may however incur non-reimbursable expenses of $0.7 million in 2014 and close to $0.9 million in 2019 associated with the administration of the vaccine and treatment for adverse events for VFC eligible children who are not covered by Medicaid (summation of Tables 10 and 12). A part of this expense would be incurred by the parent or guardian of the child, but it is difficult to estimate the proportion. As a result, given the slow economic recovery, this analysis is attributing the entire expense to providers.

The maximum reimbursement cost paid by private insurers to providers for the retail cost of vaccine, the administration fee of $13.71 per vaccine, and treatment of adverse events is estimated to be about $7.4

million in 2014 and increase to about $10 million by 2019 (summation of totals in Tables 7, 11, and 12). Note, that depending on plan deductibles, some parents or guardians of insured children may end up incurring the cost associated with the vaccines and their administration.

For parents of VFC eligible children and adolescents, there will be no up-front cost for vaccine, since the vaccines are provided at no direct cost through the federal VFC program. Also, this analysis assumes the proposed vaccines would be administered during an already planned doctor visit. For the cases where parents or guardians would have to schedule an immunization visit solely for the administration of the proposed vaccines, there would be additional costs such as the opportunity cost of the time to schedule the visit, transport the child to the visit, and the time spent at the doctor's office. There would also be more tangible costs associated with deductibles, if any apply, and transportation, i.e. gas costs or public transportation. A 2008 study of the varicella vaccination program in the US used the assumption of $3.5 cost for the doctor's office trip and close to $20 for the average opportunity cost (foregone wages) of the parent/ guardian.[30] In 2013 dollars, this would amount slightly more than $25 per trip to the doctor.

Of the families eligible for the VFC program, over half of each birth cohort is covered by Medicaid. Consequently, these newly required vaccines will result in the reimbursement of additional administration fees at the rate of $13.71 per vaccine and potential cost of treating adverse events resulting in a total cost to Medicaid of almost $1.1 million in 2014 and $1.3 million by 2019 (sum of Tables 8, 9 and 12). Note that this cost to the provider is eligible for reimbursement. DMA would be responsible for about $363.000 of this expense in 2014 and close to $440,000 by 2019.

Federal funds from the Centers for Medicare and Medicaid Services (CMS) would be responsible for close to $700,000 of the administration fee in 2014 and up to $850,000 by 2019. Additionally, the federal government through the VFC program would incur the expenses of ordering the necessary amount of vaccines and having it shipped to North Carolina. This analysis estimated that the cost of purchasing the vaccine would be close to $9.5 million in 2014 and increase to almost $11.9 million by 2019 (see Table 6). It is unknown what other processing and shipping costs the federal government would incur because of the proposed regulation.

Any private insurer and Medicaid infrastructure costs relating to increased billing volume for the additional vaccines and administration fees associated with the proposed rule change have been determined to be minimal. DMA anticipates that the vaccines in question would typically be administered during routine office visits and would not result in increased billings to Medicaid. These administration fees would be attached to an electronic claim form and would not incur any additional cost.

IV. Estimates of Return on Investment

A. Investing in the Health of North Carolinians and Quality of Life Issues

If a critical number of people within a community are vaccinated against a particular illness, the entire group becomes less likely to get the disease. This herd immunity assures more people are protected from vaccine preventable diseases. On the other hand, if too many people in a community do not get vaccinations, diseases can reappear. Earlier this year, a measles outbreak took place in North Carolina, which resulted in 23 cases of disease, many quarantine/isolation orders, and an exorbitant amount of staff time and resources to contain the disease. This outbreak ranked the second largest outbreak in the country since 1996. While this outbreak initially began as an imported case of disease, it quickly spread

[30] Zhou, Fangjun et. al. **"**An Economic Analysis of the Universal Varicella Vaccination Program in the United States," Journal of Infectious Diseases, 2008; Vol. 197 (Supplement 2): S156–64. http://jid.oxfordjournals.org/content/197/Supplement_2/S156.full.pdf+html

throughout a community of unimmunized individuals due to decreased herd immunity. This outbreak serves as an example of how other vaccine-preventable diseases can quickly spread, regardless of how rare a disease may be in the United States.

Herd immunity is achieved when the vast majority of the population is immune to a disease. Infectious agents cannot readily spread in a highly immune community. Those who are susceptible to the disease will be protected by the immune people around them. With herd immunity, fully vaccinated people help those who do not or cannot receive a vaccine by reducing the likelihood that they will encounter an infected individual. A small number of people cannot be vaccinated (e.g., those who are immunocompromised) and a small percentage of people do not respond to vaccines. Therefore, it is important that immunization rates remain high among all groups of people in North Carolina. High immunization rates result in a decrease of disease rates and, in some cases, disease eradication among entire populations.

Furthermore, this rule change would require adolescents that do not typically make regular visits to their healthcare provider to make appointments for meningococcal vaccination. These additional visits could provide healthcare providers the opportunity to identify other medical conditions not otherwise seen. These conditions could include diabetes, smoking cessation, sexual education, depression, etc. It is in this sense, that this rule change could also provide many indirect benefits.

Staff have conferred closely with CDC Health Economists and with nationally known pediatric infectious disease specialists to determine if the studies required to model return on investment when moving these vaccines from recommended to required status have been performed. Our research and experience with past new requirements indicate moving to requiring vaccines for school and day care entry will significantly increase coverage levels.

B. Cost-Effectiveness

Generally, preventing disease through immunization has proven to be one of the most cost-effective and successful preventive health measures. A study conducted by Dr. J Ehreth estimates that vaccines annually prevent almost 6 million deaths worldwide. In the US, the incidence of nine diseases for which vaccines have been recommended for decades has decreased by 99%, accompanied by a similar decline in mortality and disease sequelae.[31] Furthermore, immunization has been successful in combating complications from the disease the vaccine is preventing, such as congenital rubella syndrome, liver cirrhosis, and cancer caused by chronic hepatitis B infection or neurological lesions secondary to measles or mumps, which can have a greater long-term impact than the acute disease. Up to 40% of children who survive meningitis due to Hib may have life-long neurological defects.[32]

Vaccine-preventable diseases not only harm and sometimes kill their victims, but also have high financial and societal costs. Therefore, immunizations can save parents/guardians time and money. Also, a child with a vaccine-preventable disease is denied attendance at school or day care facilities. Some vaccine-preventable diseases can result in prolonged disabilities and can take a financial toll because of parents' lost time at work, medical bills, or long-term disability care. For example, resurgence in measles in the United States in the early 1990s resulted in more than 55,467 measles cases, 132 measles-related deaths, and 11,251 hospitalizations, resulting in more than 44,100 hospital days, with an estimated $150 million in direct medical costs.[33] In contrast, immunizations against these diseases serve as an investment.

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[31] Ehreth J. "The Global Value of Vaccination". Vaccine 2003/21/596-600, January 30, 2003, http://www.uvm.edu/~bwilcke/ehreth.pdf (accessed July 31, 2013).
[32] Ibid.
[33] Robinson C, Sepe SJ, Lin KFY. et al. The President's Child Immunization Initiative – A Summary of the Problem and Response. Public Health Reports 1993;108(4): 419-425.

Various cost-benefit analyses produce similar measurements; in fact, the U.S. saves almost $14 billion and $69 billion (in 2001 dollars) in direct and indirect costs, respectively, each year as a result of the pediatric vaccination program.[34]

When a vaccine is first introduced into use, it is common practice to analyze the return on investment, benefit cost ratio, or the cost per Quality-Adjusted Life Years (QALY – a standard measure of health outcome) of the vaccine by looking at the incidence and cost of the disease prior to the vaccine versus the cost of the vaccine. Trial studies also compare the decrease in incidence, and thus cost of the disease, to the uptake and cost per vaccine. Studies that show such effectiveness help vaccines to become recommended by the ACIP. Table 13 below compares some metrics of effectiveness of the proposed vaccines from different studies.

Table 13. Vaccine Cost-effectiveness

Vaccine to Prevent Disease	Average Reported NC Cases of Disease, 2018-2012[1]	Average Reported Deaths in NC, 2008-2012	Cost of Vaccine/ Case Prevented[2]	Cost of Vaccine/ QALY	Cost of Vaccine/ Life-Year Saved	Societal Benefit Cost Ratio	Direct Benefit Cost Ratio
Varicella[3]	Not Reportable	Not Reportable	$384	$122,000	$999,000	0.56	0.13
Pneumococcal Conjugate[4]	30	4			$104,000		
Meningococcal[5]	16	2	$779,000	$170,000	$149,000	0.27	0.08

[1] General Communicable Diseases – September 2013 Monthly Report, North Carolina DPH. http://epi.publichealth.nc.gov/cd/figures/cd_sept2013.pdf

[2] Dollar figures are in 2013 dollars and were adjusted using GDP deflator data from IHS Global Insight database. Also, the sources used employed a 3% discount rate to compute the cost-effectiveness estimates.

[3] Cost-effectiveness measures assume a vaccine cost of $56.9 for public sector and $66.8 for privates (this analysis assumes $75 and $94, respectively). Source: Zhou, Fangjun et. al. **"**An Economic Analysis of the Universal Varicella Vaccination Program in the United States," Journal of Infectious Diseases, 2008; 197 (Supplement 2): S156–64. http://jid.oxfordjournals.org/content/197/Supplement_2/S156.full.pdf+html

[4] Cost-effectiveness measures assume a vaccine cost of $58 (much lower than the $107-128 cost assumed by this analysis). Source: Lieu, T.A. et. al. "Projected cost-effectiveness of pneumococcal conjugate vaccination of healthy infants and young children," JAMA., 2000, Mar 15; 283(11):1460-8. http://www.ncbi.nlm.nih.gov/pubmed/10732936

[5] Cost-effectiveness measures assume the cost of vaccine plus cost to administer it is $82.5 (this analysis assumes $95-127 for vaccine plus administration). Source: Shepard, et al. "Cost-effectiveness of conjugate meningococcal vaccination strategies in the United States". Pediatrics. 2005 May;115(5):1220-32.

The cost-effectiveness measures presented for Table 13, aside from the direct benefit cost ratio, include both direct and indirect (societal) costs. The studies generally used a cost for vaccination that included the cost of vaccine, administration, travel to appointment, parents' time lost, and adverse events. The cost per disease incidence included hospitalization, ambulatory visit, cost to public health department from outbreaks, economic value of life lost prematurely, loss from permanent disability, and parents' time lost from caring for sick child.[35],[36]

[34] Ross Rapoport, "CDC: Immunizations High But Shot In Arm Still Needed," Cox News Service. August, 1 2003 (Accessed July 29, 2013)

[35] Zhou, Fangjun et. al. **"**An Economic Analysis of the Universal Varicella Vaccination Program in the United States," Journal of Infectious Diseases, 2008; Vol. 197 (Supplement 2): S156–64. http://jid.oxfordjournals.org/content/197/Supplement_2/S156.full.pdf+html

[36] Shepard, et al. "Cost-effectiveness of conjugate meningococcal vaccination strategies in the United States". Pediatrics. 2005 May;115(5):1220-32. http://pediatrics.aappublications.org/content/115/5/1220.full.pdf+html

The varicella vaccine study concludes that while in the absence of any varicella vaccination the 2-dose vaccine leads to substantial societal cost savings, adding the second dose to the first dose requirement is not cost saving, and has a higher cost per QALY than a number of ACIP recommended vaccines. Similarly, the study estimating the cost-effectiveness of the meningococcal vaccine concedes the vaccine is less cost effective than most of the other routine childhood vaccination.

While the cost-effectiveness information presented above could be a useful tool in decision-making, those numbers may be overestimating the costs and in some cases underestimating the benefits. The varicella, study does not account for potential benefits from fighting the varicella-zoster virus, reduced susceptibility in adulthood, and decreased public health department costs from outbreaks in highly vaccinated populations. Also, the meningococcal study did not include any benefits from potential reduction in meningococcal disease outbreaks. Additionally, the cost-effectiveness measures presented above include the cost of lost productivity of the parents or guardians and travel costs for the doctor's appointment. As mentioned above, these costs are not likely to be incurred since the doses of the proposed vaccines can be integrated in the current immunization schedule resulting in few, if any, additional healthcare apportionments.

Immunization administration is an evidence-based practice. Therefore, benefits are predictable from the new vaccine requirements. However, the total cost-effectiveness of this effort to expand vaccine requirements in NC cannot be determined with limitations on time and resources. Large-scale studies to present the economic benefits of vaccines by using the value-of-statistical- life approach child survival cost modeling tools are very costly, complex, and time consuming.[37] The section below attempts to provide rough estimates of potential benefits.

C. Benefit Estimates

Potential Benefit of Varicella Booster Vaccine

The introduction of new vaccines has led to a substantial decline in medical spending for some conditions. For example, in 1995, a vaccine to protect against varicella (chickenpox) was added to the childhood schedule. In 1994-1995, the total estimated direct medical cost of varicella hospitalizations and ambulatory visits was almost $85 million; in 2002, after the vaccine was introduced, the cost declined to $22.1 million.[38]

Based on assumptions from the Zhou et. al. (2008), this analysis tries to estimate the potential decrease in costs if the varicella booster were introduced as proposed in this rule change.[39] Assumptions from the paper were used regarding the annual incidence rates of varicella with a 2-dose versus 1-dose vaccine, the direct medical costs and lost productivity costs of varicella related cases, and the probabilities of occurrence of each case outcome (hospitalization, ER visits, outpatient visits, acyclovir treatment, etc.). These assumptions were adjusted to NC levels using 2014 NC population estimates. No population growth was assumes as the number of cases prevented are an annual average. Also, cost estimates from the study were adjusted from 2006 dollars to current year and then inflated each year using a forecast of the consumer price index from IHS Global Insight. It is important to note that the potential cost savings figures presented in Table 14 may be overestimating the impact since there is currently some coverage for

[37] Emma Hitt, PhD , Medscape Medical News ,"Decade of Vaccines Will Save Lives and Money Globally", June 09, 2011, http://www.medscape.com/viewarticle/744285 (accessed July17, 2013)
[38] Zhou F, Harpaz R, Jumaan AO, Winston CA, Shefer A. Impact of varicella vaccination on health care utilization. JAMA.2005;294(7):797-802.
[39] Zhou, Fangjun et. al. **"**An Economic Analysis of the Universal Varicella Vaccination Program in the United States," Journal of Infectious Diseases, 2008; Vol. 197 (Supplement 2): S156–64. http://jid.oxfordjournals.org/content/197/Supplement_2/S156.full.pdf+html

the 2-dose vaccine in NC; however, that rate of coverage is unknown. Also, the first few years may be overestimating the benefit since it would likely take some time to achieve the reduction in cases.

Table 14. Potential Savings from the Varicella Vaccine*

Event	2014	2015	2016	2017	2018	2019
ER visit	$568,000	$577,000	$587,000	$596,000	$606,000	$615,000
Outpatient Visit	$19,000	$19,000	$19,000	$20,000	$20,000	$20,000
Nonprescription Medication	$9,000	$10,000	$10,000	$10,000	$10,000	$10,000
Acyclovir Treatment	$33,000	$33,000	$34,000	$35,000	$35,000	$36,000
Hospitalization - Uncomplicated	$87,000	$89,000	$90,000	$92,000	$93,000	$94,000
Hospitalization - Pneumonia	$58,000	$59,000	$60,000	$61,000	$62,000	$63,000
Hospitalization - Encephalitis	$14,000	$14,000	$14,000	$14,000	$15,000	$15,000
Total Direct Medical Cost Savings (mil.)	**$0.79**	**$0.80**	**$0.81**	**$0.83**	**$0.84**	**$0.85**
Productivity lost by parent	$730,000	$742,000	$754,000	$766,000	$778,000	$791,000
Productivity lost by patient	$459,000	$466,000	$474,000	$482,000	$489,000	$497,000
Total Lost Productivity (mil.)	**$1.19**	**$1.21**	**$1.23**	**$1.25**	**$1.27**	**$1.29**
TOTAL (mil.)	**$1.98**	**$2.01**	**$2.04**	**$2.08**	**$2.11**	**$2.14**

***** Given lack of information, events related to calling doctor's offices for advice (estimated to cost up to $13 in 2013 dollars) were excluded; and the assumption was made that all patients that required an outpatient visit would have chosen to use nonprescription medication (average cost of about $37 per case). Numbers rounded to nearest thousand.

The National Business Group on Health suggests a cost-savings estimate should include reduced costs from lost productivity.[40] Zhou et. al. employ loss of productivity estimates of close to $345 and $13,000 (in 2013 dollars) for parents/guardians caring for a sick child and for sick adults, respectively. These estimates, in conjunction with assumptions made about the number of varicella cases in NC, were used to compute the total lost productivity shown above. Given the lack of information regarding number of outbreaks public health departments' potential savings from fewer outbreaks are not included in the savings estimate in Table 14. Zhou et. al. estimate that the cost to manage an outbreak is more than $6,600 per outbreak (in 2013 dollars).

Potential Benefit of Pneumococcal Conjugate Vaccine

Lieu et.al. (2000) estimated that a routine pneumococcal vaccine would lead to a reduction of more than 1,122,000 cases of pneumococcal related diseases and of 116 associated death events annually, resulting

[40] National Business Group on Health, "Child, Adolescent, Adult Immunizations (Immunizations)", November 23, 2011, http://www.businessgrouphealth.org/preventive/topics/immunizations.cfm#26 (Accessed on August 1, 2013)

in societal savings of $757 million annually. Of these savings, $342 million are in direct medical costs, $285 million in parent opportunity costs and other family borne costs, and $130 million in loss of children's future productivity.[41] Assumptions in the Lieu et. al (2000) study regarding the number of cases prevented and societal cost (including direct medical costs, work-loss costs, and other costs borne by the family of the patient) per type of disease event were used to provide rough estimates for how the savings might look in North Carolina – see Table 15. As in the case of the varicella benefit estimates, the numbers may be overestimating the savings in the first few years as the computed number of averted cases is an annual average. The estimates presented below account for the fact that:

- there is a close to 85% pneumococcal conjugate vaccine coverage in NC currently that significantly decreases the number of prevented outcomes of pneumococcal disease,
- there were an average of 30 cases of meningitis per year reported in NC between 2008-2012, and
- the costs estimates presented in the study are in terms of 1997 dollars and needed to be inflated to current year dollars and then inflated each year using the IHS Global Insight consumer price index forecast.

The estimates in the table below, however, do not account for any annual increases in medical costs.

Table 15. Potential Societal Cost Savings from the Pneumococcal Vaccine

Event	2014	2015	2016	2017	2018	2019
Meningitis	$46,000	$47,000	$48,000	$48,000	$49,000	$50,000
Bacteremia	$212,000	$215,000	$219,000	$222,000	$226,000	$229,000
Pneumonia	$608,000	$617,000	$628,000	$638,000	$648,000	$658,000
Simple Otitis Media Episodes	$2,021,000	$2,053,000	$2,087,000	$2,121,000	$2,155,000	$2,188,000
Complex Otitis Media Episodes	$1,247,000	$1,267,000	$1,288,000	$1,309,000	$1,330,000	$1,351,000
Otitis Media Episodes with Tube Placement	$561,000	$570,000	$579,000	$588,000	$598,000	$607,000
Deaths	$0	$0	$0	$0	$0	$0
TOTAL (mil.)	**$4.70**	**$4.77**	**$4.85**	**$4.93**	**$5.01**	**$5.08**

Potential Benefit of Meningococcal Vaccine

Shepard et. al. (2005) estimated that the introduction of the meningococcal vaccine in the US would prevent 270 disease events and 36 death annually, leading to more than $22.1 million in averted medical costs and an additional $61.5 million in opportunity costs (estimates were adjusted to 2013 dollars).[42] Similarly, Ortega-Sanchez et. al. (2008) studying the cost effectiveness of a meningococcal vaccination catch-up campaign for adolescents in the US estimated 8251 cases of meningococcal disease would be prevented over 10 years (a 48% decrease), and the cost savings would amount to $592 million in direct costs and $983 million in indirect costs (figures are in 2013 dollars).[43]

[41] Lieu, T.A. et. al. "Projected cost-effectiveness of pneumococcal conjugate vaccination of healthy infants and young children," JAMA., 2000, Mar 15; 283(11):1460-8. http://www.ncbi.nlm.nih.gov/pubmed/10732936

[42] Shepard, et al. "Cost-effectiveness of conjugate meningococcal vaccination strategies in the United States". Pediatrics. 2005 May;115(5):1220-32. http://pediatrics.aappublications.org/content/115/5/12 20.full.pdf+html

[43] Ortega-Sanchez, I.R. et. al. "Economics of an Adolescent Meningococcal Conjugate Vaccination Catch-up Campaign in the United States." Clinical Infectious Diseases, 2008, 46:1-13. http://cid.oxfordjournals.org/content/46/1/1.full.pdf

Based on the number of death and cases averted, probability of different disease outcomes, and medical costs (including public health department response) and parents' lost time from work per outcome estimated in the two studies mentioned above, Table 16 presents estimates for potential medical cost savings from requiring the vaccine in NC. The related medical costs and productivity losses averted assumed in these studies were inflated to 2013 dollars and then inflated annually. As a result, it was estimated that more than $10 million would be saved in NC because of the meningococcal vaccine requirement over the next 6 years. This estimate includes an assumption of 8 cases and one death averted per year, which may be overestimating benefits, especially initially. However, the benefit estimate per death averted may be biased downward as it uses the cost of the loss in productivity approach accounting for the value of potential future earnings from premature death, which these studies estimate at between $0.2 and $1.6 million depending on the age of the individual. This is a much lower estimate that the $7 million which is used on average in federal government when employing the value of a statistical life.[44]

Table 16. Potential Cost Savings from the Meningococcal Vaccine

Event	2014	2015	2016	2017	2018	2019
Cases						
- No Sequelae	$259,000	$263,000	$267,000	$272,000	$276,000	$280,000
- Skin Scarring	$50,000	$51,000	$52,000	$53,000	$54,000	$54,000
- Single Amputation	$0	$0	$0	$0	$0	$0
- Multiple Amputations	$0	$0	$0	$0	$0	$0
- Hearing Loss	$499,000	$507,000	$515,000	$524,000	$532,000	$540,000
- Neurological Disability	$0	$0	$0	$0	$0	$0
Death Cases	$1,122,000	$1,140,000	$1,159,000	$1,178,000	$1,197,000	$1,215,000
TOTAL (mil.)	**$1.93**	**$1.96**	**$1.99**	**$2.03**	**$2.06**	**$2.09**

Based on the rough estimates of benefits from above, the introduction of the proposed vaccine requirements could result in total annual cost savings of $8.6-$9.3 million. The 6-year net present value of these potential cost savings is close to $45.5 million. These benefit estimates indicate a possible net societal cost from the varicella booster ($49 million) and meningococcal vaccine ($11 million) and a net benefit from the pneumococcal vaccine (3 million). The benefit cost ratios are 0.2, 1.2 and .5 respectively. These results seem agree with the conclusions in other studies.

V. Uncertainties

Due to gaps in data and information, this analysis has made some assumptions in determining estimate costs of the proposed rule change. For example, staff decided for the sake of uniformity to use only one source for coverage data – the National Immunization Survey (NIS). This source, however, does not have separate coverage data for the two different doses of the varicella vaccine. Therefore, this analysis made the very conservative assumption that no child is receiving the varicella booster (i.e. 0% coverage). This assumptions leads to an overestimation of the costs of the varicella booster requirement, especially since the NIS data shows 88% of children receive at least the first dose, if not both. Furthermore, a CDC

[44] Robinson, L. "How US Government Agencies Value Mortality Risk Reduction." *Review of Environmental Economics and Policy*, 2007, 1(2): 283–299. https://www.law.upenn.edu/institutes/regulation/papers/RobinsonValues.pdf

document looking at vaccine coverage among adolescents quotes a rate of 62.8% for the varicella booster coverage in NC.[45] Table 17 below shows how the total cost of the proposed rule amendments (as shown in Table 1) changes with different assumptions about coverage.

Table 17. Sensitivity Analysis for Coverage of 2nd Varicella Dose in NC

2nd Varicella Dose Coverage	6-year Net Present Value of Cost of All Proposed Vaccines (mil.)
0%	**$102.01**
25%	$85.42
50%	$68.82
63%	$60.34
75%	$52.23
88%	$43.61

Other assumptions in this analysis include fixed vaccine prices and fixed fee for vaccine administration. The cost of administration of the vaccine for the private sector was assumed to equal the $13.71 cap set by CMS. Certain studies have used cost of administration in private health clinics that are three to four times higher than cost of administration in public health clinics. Also, vaccine prices CDC historic price data for the proposed vaccines[46] shows an increase over the last 5 years at a rate of 2-6% per year, with the exception of the meningococcal vaccine price for the federal government, which has remained fairly unchanged. Table 18 below presents a two-way sensitivity analysis of the net present value of the costs presented in Table 1 around these two assumptions regarding vaccine price and administration.

Table 18. Sensitivity Analysis for Vaccine Price and Private Vaccine Administration Cost

6-year NPV of Cost of Proposed Vaccines (mil.)			Annual Growth in Vaccine Prices			
			0.00%	2.00%	4.00%	6.00%
Cost of Private Vaccine Administration	Fee Assumed in Analysis	**$13.71**	**$102**	$106	$111	$116
	Twice CMS Fee	$27	$107	$111	$116	$120
	Three Times CMS Fee	$41	$111	$116	$120	$125
	Four Times CMS free	$55	$116	$121	$125	$130

The analysis also employed the assumption of constant population growth of 2.12% based on data from CMS. State demographic data indicates that rate of growth on the population 16 years and under may be much smaller. This would imply an overestimation of the costs presented in this analysis above. Table 19 shows how the net present value of the costs estimate in this analysis would change if a different annual growth rate were employed.

[45] US Center for Disease Control. "National and State Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2011." http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6134a3.htm?s_cid=mm6134a3_e

[46] CDC. Vaccines for Children Program. VFC CDC Vaccine Price List Archives. http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/archive.html

Table 19. Sensitivity Analysis for Population Growth Rate

Constant Annual Population Growth	6-year NPV of Cost of Proposed Vaccines (mil.)
2.12%	**$102.01**
1.50%	$100.59
1.00%	$99.46
0.75%	$98.91
0.50%	$98.35

It is important to note that given the lack of recent studies on the estimated benefits of the proposed vaccine requirements, especially in the context of relatively high existing coverage, there is considerable uncertainty related to the benefits presented in the section above. As mentioned above some of the estimated benefits do not include all societal costs, like additional varicella prevention from the herpes-zoster virus and shingles in adults, or secondary benefits from adolescent doctor visits; therefore, the benefits may be underestimating the total potential savings. Also, using the $1.1 weighted average for the value of an averted productivity loss due to premature death may further underestimate the meningococcal benefits. Using a value greater than $3 million, while maintaining the assumption of one death case averted per year, would lead to a net societal benefit from the requirement.

However, there are also uncertainties in the benefit method that could lease to overestimation. These estimates may not be adequately taking into account the current coverage and the gradual effect an increase in coverage would actually have on the current incidences of the related diseases, and may be overestimating the number of cases prevented. The cost per case of disease averted were based on older studies that may no longer truly reflect actual cost.

An additional uncertainty relates to the fact that by 2014, the Affordable Care Act (ACA) will begin to require all public and private health insurance plans to voluntarily provide first-dollar coverage (i.e., no deductibles or co-pays) for all ACIP-recommended vaccines and their administration for children and adolescents at no cost-sharing.[47] Depending on the number of insurance plans that opt to provide first-dollar coverage, someone of the costs paid by parents or guardians may be incurred by insurances. Also, as a result of the ACA, most of the costs to providers from administering the vaccines to non-VFC eligible uninsured children, estimated at $634,000-815,000 annually, would actually be reimbursed by insurance providers.

VI. Alternatives

The Department considered two other alternatives to the proposed rules changes but dismissed them based on the concerns discussed below:

1. No Changes to the rule

   Add no new vaccine requirements. There has been a moratorium on rule changes for a number of years with the risk of increases in vaccine preventable diseases. While money could be saved in the short term, costs would be saved in direct medical and societal costs when individuals are vaccinated as outlined in the analysis above. Currently, the three vaccines proposed for requirement are recommended in North Carolina. While many parents do choose to vaccinate their children with all recommended vaccines, we are not able to achieve the appropriate levels for herd immunity or meet

[47] Tan, Litjen (L.J.), American Medical Association (AMA), "Impact of the Affordable Care Act on Immunization", http://www.preventinfluenza.org/NAIS_2012/NAIS-1_tan_impact.pdf, (accessed August 7, 2013)

the Healthy People 2020 immunization goal of 90%. Pockets of disease still occur in North Carolina today and travel rates continue to increase each year, with more and more people traveling to areas where many vaccine preventable diseases are still endemic.

2. Require all ACIP Recommended Vaccines

Currently, North Carolina requires all but 6 of the ACIP recommended vaccines. The Public Health Commission suggested that all ACIP recommended vaccines be required. However, it was decided that adding all 6 vaccines at one time would place a significantly increased burden on schools, providers, parents/guardians, and insurers. It was determined to propose the three most critical vaccines and to add the others later. These three vaccines were identified as being the most critical for several reasons. In regards to varicella, the first dose of this series is currently already required, yet an increased number of breakthrough cases of varicella are being observed today, which highlights the need for a required booster dose. Secondly, the pneumococcal conjugate vaccine is well known at being extremely cost-effective and successful at preventing many diseases. Nearly half of all AOM events can be attributed to this disease as well as a large number of sinusitis episodes. Lastly, the meningococcal vaccine is considered critical due to the high fatality rate and cost of disease. Furthermore, each of these three vaccines have been extensively studied and found to be medically sound and non-controversial.

VII. Endorsements

A number groups and individuals have publicly declared support of proposed changes to the immunization rules:

- North Carolina Pediatric Society,
- North Carolina Academy of Family Physicians,
- North Carolina Commission for Public Health,
- North Carolina Immunization Advisory Committee,
- North Carolina Department of Public Instruction, and
- Novartis.

APPENDIX A. Proposed Rule Text

10A NCAC 41A .0401 Is proposed for amendment as follows:

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 pertussis (whooping cough) - 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~~ 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 vaccine; ~~toxoid and a booster dose of tetanus/diphtheria/pertussis vaccine if a tetanus/diphtheria toxoid or~~ one of which must be tetanus/diphtheria/pertussis; ~~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 have not previously received it and are entering the sixth grade or by 12 years of age (whichever comes first); ~~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.~~

(D) The sixth grade booster dose does not apply to individuals who enrolled in sixth grade before August 1, 2008.

(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 the 4th birthday and 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) The requirements for the booster does on or after the 4th birthday do not apply to individual who began school before August 1, 2014;

(C) ~~(B)~~ Individuals who receive the third dose of poliomyelitis vaccine on or after the fourth birthday are not required to receive a fourth ~~dose;~~ dose if third dose is given at least six months after the second 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 or laboratory confirmation of disease is not required to receive measles vaccine;

(B) An individual who has been diagnosed prior to January 1, 1994, by a physician (or designee such as a nurse practitioner or physician's assistant) ~~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 laboratory confirmation of disease is not required to receive rubella vaccine;

(B) An individual who has attained his or her 50th ~~fiftieth~~ birthday is not required to receive rubella vaccine except in outbreak situations; Birth before 1957 is not acceptable evidence of rubella immunity for women who could become pregnant.

(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, or laboratory confirmation of disease 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 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; ~~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;~~ 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* conjugate vaccines; ~~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—Two doses ~~1 dose~~ 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 enrolling in school for the first time. ~~months.~~ However:

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

~~(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.~~

(C) ~~(B)~~ An individual born prior to 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 enroll in school (K-1) for the first time before August 1, 2014.

(9) Pneumococcal conjugate vaccine – Four doses; three doses by age seven 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 two 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 two 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 one dose to complete the series;

(D) No individual who has passed their fifth birthday shall be required to be vaccinated against pneumococcal disease;

(E) An individual born prior to April 1, 2014 shall not be required to receive pneumococcal conjugate vaccine.

(10) Meningococcal conjugate vaccine – Two doses: one dose is required for individuals entering the sixth grade or by 12 years of age (whichever comes first) on or after August 1, 2014. A booster dose is required by 16 years of age or by entering the 11th grade. However:

(A) The first dose does not apply to individuals who enrolled in sixth grade before August 1, 2014;

(B) The booster dose does not apply to individuals who enrolled in the 11th grade before August 1, 2019;

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

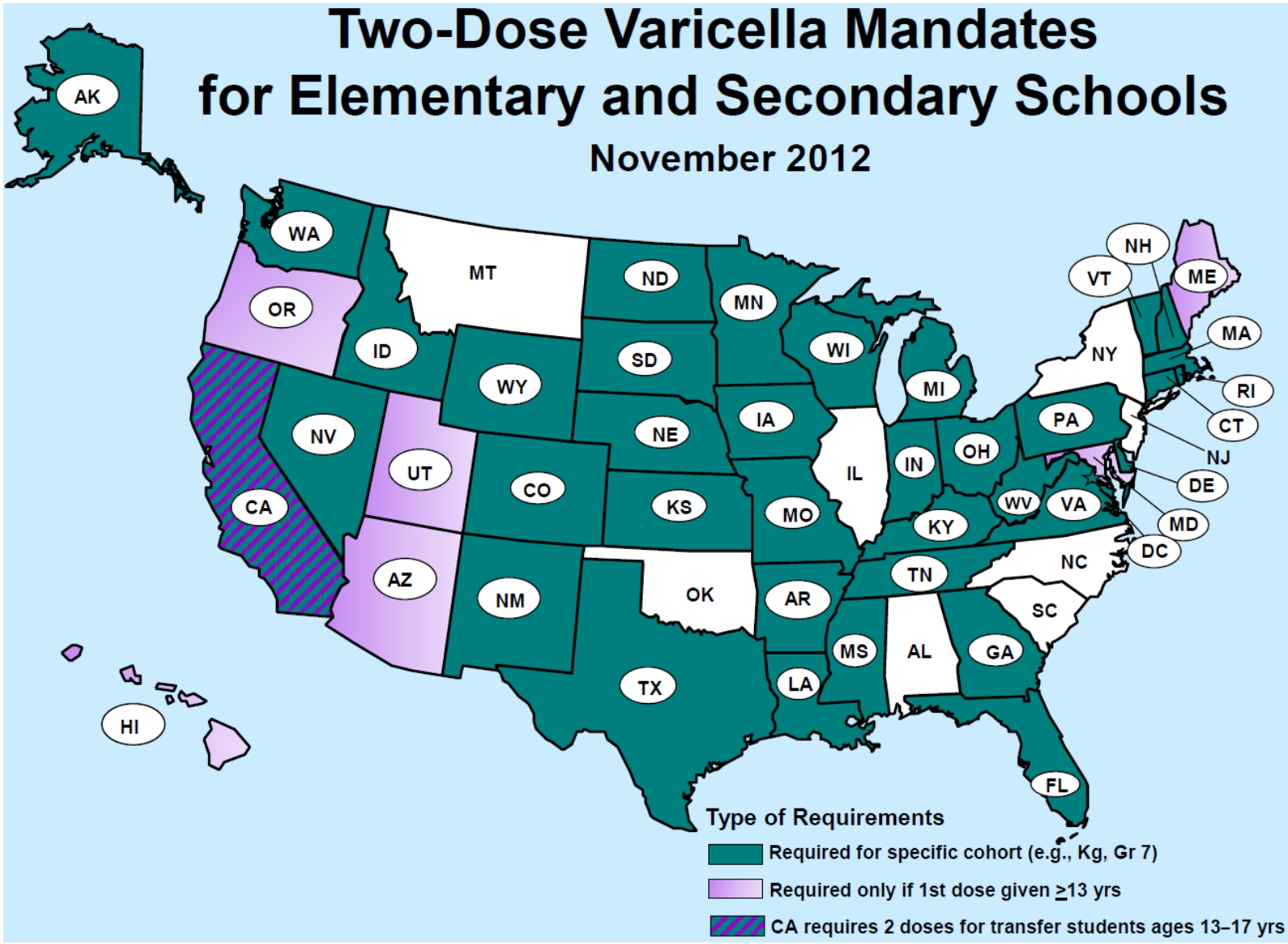
(D) An individual born prior to January 1, 2003 shall not be required to receive meningococcal conjugate vaccine.

(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 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.

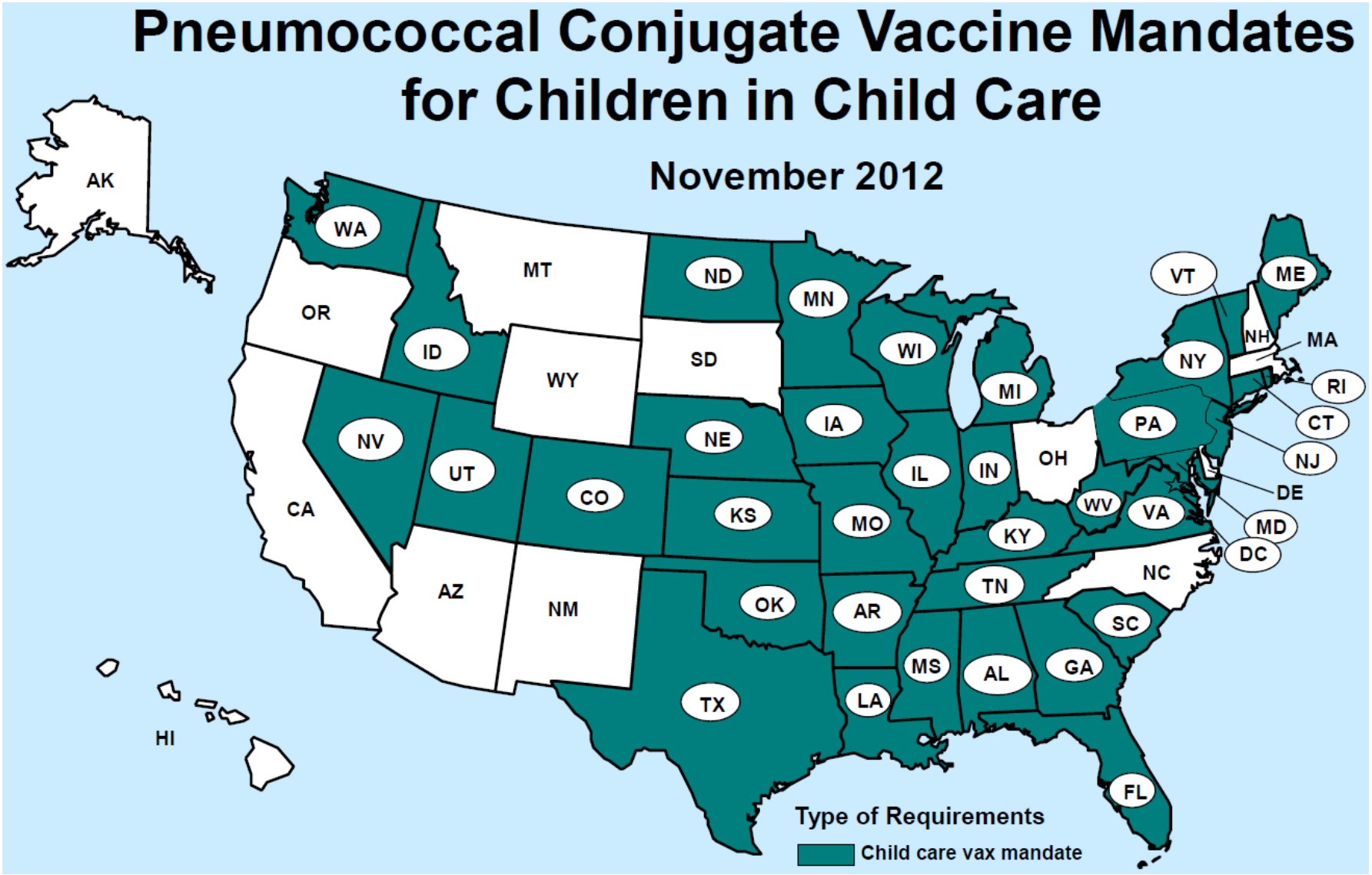
History Note: *Authority G.S. 130A-152(c); 130A-155.1*
Amended Eff. _____

APPENDIX B



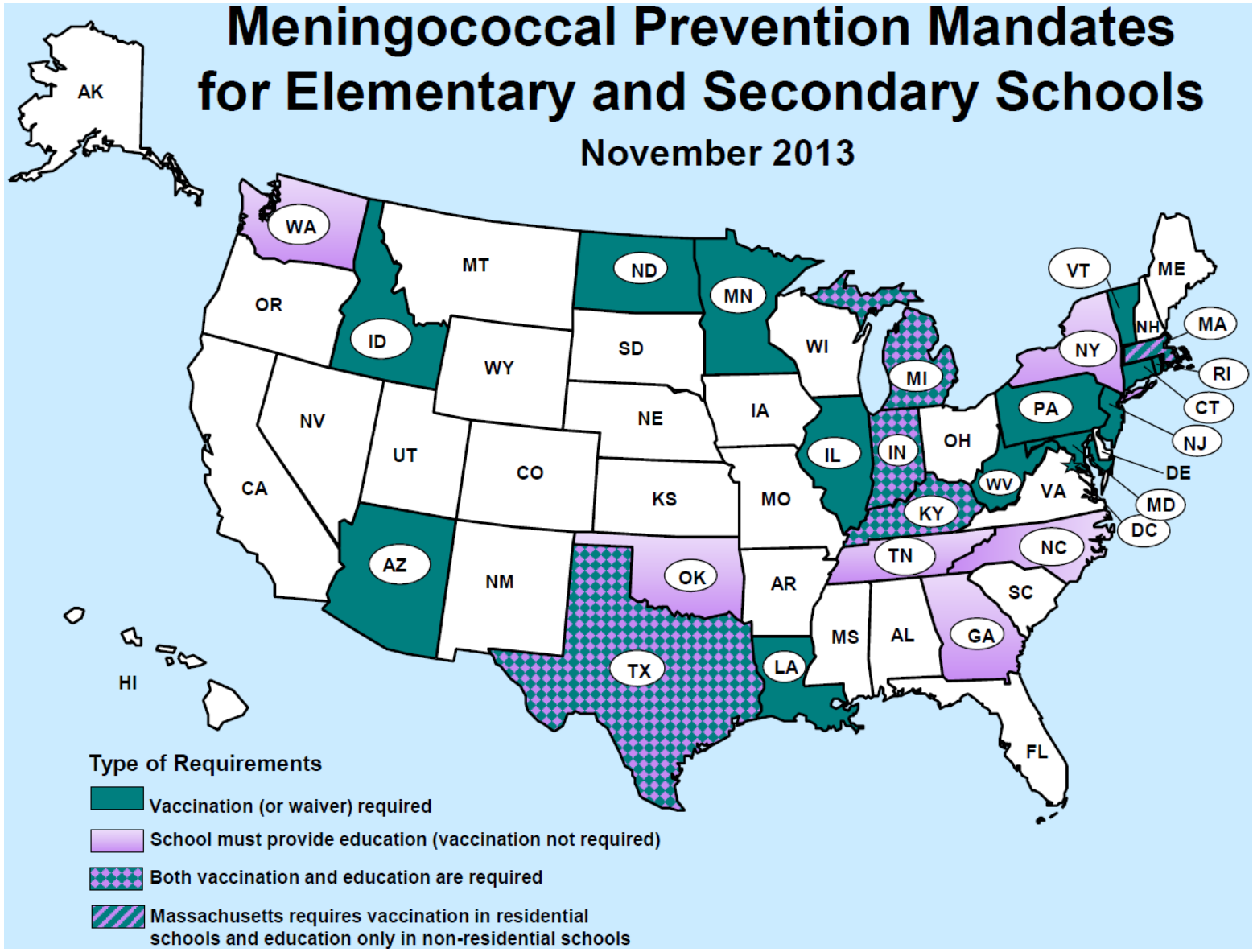
Source: Immunization Action Coalition. Mandates for Vaccine by State. Varicella. http://www.immunize.org/laws/vari_two.pdf

APPENDIX C



Source: Immunization Action Coalition. Mandates for Vaccine by State. Varicella. http://www.immunize.org/pdfs/pcv7.pdf

APPENDIX D



Source: Immunization Action Coalition. Mandates for Vaccine by State. Varicella. http://www.immunize.org/laws/menin_sec.pdf

APPENDIX E. VFC Annual Population Estimates Report for Calender Year 2012

Annual Population Estimates Report for CY2012

Grantee Population Estimate for CY 2012

VFC Vaccines for Children

contact information

Grantee	North Carolina	CDC Project Consultant	Harry McKinght
State Medicaid Contact	Maclyn Powell	State Medicaid ContactPhone	(336) 849-1060
Immunization Contact	Amy Grimshaw	Immunization Contact Phone	(919) 707-5550

grantee population estimates

TABLE I - TOTAL POPULATION ESTIMATE FOR CY 2012

Population Estimate

	Years of Age				
	0-1	1-2	3-6	7-18	Total
Grantee population estimate for CY 2012	136,312	270,227	518,323	1,546,698	2,471,560
Grantee approved population estimate for CY 2011	134,195	270,227	518,212	1,530,314	2,452,948

vfc eligibility summary

TABLE II - VFC ELIGIBLE FOR CY 2012

VFC Eligibility Definitions

	Years of Age				
	0-1	1-2	3-6	7-18	Total
Medicaid estimate for CY 2012	64,164	115,832	211,165	415,976	807,137
The number of American Indians/Alaska Natives	3,069	5,975	10,671	30,230	49,946
The number of children without health insurance	14,745	29,231	56,069	167,311	267,357
FQHC/RHC	409	811	1,555	10,827	13,601
Delegated Authority (DA)	17312	34319	65827	190244	307702
DA Data Source Comments	SCHS, Statistical Brief, Health Costs in North Carolina				
Sub-total VFC Eligible	99699	186168	345287	814588	1445742
NON-VFC Eligible	36613	84059	173036	732110	1025818

Please select "Final" when you have completed all data entry for the CY2012 Population Estimates section.

(•) In-process ( ) Final

Save Public/Private Estimates

View Summary