2016 Annual Review of Statutory Childhood Immunization Requirements

Section 32.1-46 F of the Code of Virginia requires the State Board of Health to perform an annual review of the childhood immunization requirements specified in § 32.1-46, and to make recommendations for revision. This statute requires that parents, guardians and persons standing in loco parentis shall cause their children to be immunized in accordance with the immunization schedule developed by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics and the American Academy of Family Physicians (*Recommended Childhood and Adolescent Immunization Schedule*). This section also states that vaccines required for school and day care attendance are those contained in the State Board of Health's Regulations for the Immunization of School Children (Regulations) and specifies those vaccines, at a minimum, that must be required by the Regulations.

Meningococcal Vaccine

Meningococcal conjugate vaccine (MCV) was added to the ACIP *Recommended Childhood* and *Adolescent Immunization Schedule* in 2006. Meningococcal disease is an acute, potentially severe illness and is a leading cause of bacterial meningitis and sepsis in the United States. Ten cases of meningococcal disease were reported in Virginia in 2015. There were three cases reported in the 10-19 year age group. Two cases each were reported in the 0-9 year age group, the 30-39 age group, and in the group over 60 years of age. One case was reported in the 50-59 age group. Of these, three deaths were reported: one each in the 0-9 year age group, the 10-19 age group and the 50-59 age group.

Per the ACIP recommendation, the optimal age to administer meningococcal vaccine to children is at 11-12 years of age with a booster dose given at 16-18 years of age. Per the 2014 National Immunization Survey-Teen (NIS-Teen), 72.5% of adolescents ages 13-17 in Virginia received at least one dose of the routinely recommended meninogoccal vaccine. This is lower than the national vaccine coverage rate of 79.3%.

Legislation was introduced during the 2015 General Assembly session to require one dose of quadrivalent meningococcal conjugate vaccine (MCV4) before entry into sixth grade. The legislation also proposed to require two age-appropriate doses of MCV4 before entry into the twelfth grade unless the first dose was administered after the sixteenth birthday; then only one dose is required. The legislation was laid on the table in both the House and the Senate, due to the estimated fiscal impact. VDH recommends revisions in the Code to require this vaccine for children at 6th grade entry only. If vaccine continues to be purchased from federal procurement contracts, implementing a school requirement for quadrivalent meningococcal vaccine in Virginia would require approximately \$427,300 annually in additional state general funds in order to cover the increased costs estimated to be incurred to provide the vaccine to clients not eligible for the Vaccines for Children program. (Projected costs were calculated based on vaccine acquisition costs and administration costs for insured clients, minus projected reimbursement for administration costs billed to third party payers as required by § 32.1-46, Section A, Item 12. Immunization of patients against certain diseases.) This would require a budget amendment to supplement current immunization funding. If vaccine were also required before entry into the twelfth grade, the costs to implement requirements for two

grade levels would be approximately double or \$854,600 annually.

In 2015, two additional meningococcal vaccines have been licensed to protect against a strain (serogroup B) that is not included in the MCV4 vaccine. ACIP has recommended that the serogroup B meningococcal (MenB) vaccine be given only to certain high risk individuals and recently approved a "permissive" recommendation for children aged 16-23 years for short-term protection. MenB vaccine can also be given at 11-12 years of age, as a series of either two or three doses, depending on brand, given over a period of one to six months. At this time, there is no indication for additional doses at later ages. Because the MenB vaccine is not recommended routinely at this time, VDH does not recommend revisions to the Code to require this vaccine for school entry. VDH will carefully watch for any changes in ACIP recommendations to see if this requirement should be revisited at a later date.

Human Papillomavirus (HPV) Vaccine

In December, 2011, the ACIP recommended the routine use of the HPV vaccine in males aged 11 or 12 years; the current ACIP immunization schedule now recommends HPV vaccine for boys as well as girls. In the 2014 NIS-Teen, 35.9% of girls ages 13-17 in Virginia had received the recommended 3-dose series of HPV vaccine. Coverage for boys is even lower: only 22.5% of boys 13-17 in Virginia had received the recommended 3-dose series.

The Code and the Regulations currently require HPV vaccine only for girls. To be consistent with the ACIP schedule, revisions to the required immunizations for school and daycare attendance in the Code and Regulations would be necessary. VDH recommends revisions in the Code that would require HPV vaccine and related review of educational materials for boys, to mirror the current language relevant to the requirements for girls. Based on historical "doses administered" data for HPV vaccine over the last two years, implementing this requirement would require approximately \$112,400 in additional state general funds annually in order to cover the increased costs estimated to be incurred by the local health departments. A budget amendment would not be required to support this effort.

Language in the Code does not require tangible documentation of a parent's decision to opt out of the requirement. Lack of this tangible documentation precludes an accurate determination of valid opt-outs versus those student records lacking HPV documentation. If documentation were required (i.e., a signed waiver form) for opting out of the HPV vaccine requirement, VDH would be better able to determine local immunization coverage data for this important cancer-prevention vaccine. VDH recommends amending the Code to add a signed waiver requirement for the HPV vaccine. It is possible that adding the waiver requirement could increase the number of children vaccinated at local health departments but potential fiscal impact of this change is unknown at this time.

Influenza Vaccine

In 2010, ACIP expanded the influenza vaccine recommendation to include that all children older than 6 months of age should receive seasonal influenza vaccine annually. Influenza

vaccination coverage estimates indicate that 65.0% of Virginia children aged 6 months -17 years received vaccine in the 2014-15 influenza season (the latest available data) compared to 59.3% of children nationally.

Annual influenza vaccine for children is certainly good public health practice. Due to complexity of implementation and cost of supporting an annual vaccine for all school children, however, an influenza requirement is not recommended for enactment in the coming year. Local health departments will continue to respond to the need for seasonal influenza vaccine by offering expanded clinic hours and supporting school-based influenza clinics around the state.

Hepatitis A Vaccine

In 2006, ACIP recommended hepatitis A vaccine for all children, to be given beginning at 1 year of age. The National Immunization Survey (2014) data show that Virginia's coverage rate for this vaccine is near the national average for children 19-35 months of age (57.5% United States; 55.2% Virginia). The 2015 Virginia Immunization Survey reported that 70.2% of children in daycare had documentation of two doses of hepatitis A vaccine at the time of the assessment. It is likely that even more children have received this vaccine but it is not documented in the daycare facility's record because there is no requirement to do so. In 2015, there were 50 cases of acute hepatitis A reported in Virginia; only one of those cases was in a preschool-aged child less than 4 years old. Because of the high vaccine coverage rate, particularly in the pre-school population at highest risk for acquiring hepatitis A infection in the school setting, a revision to the requirement for school and day care attendance is not recommended.

Status of Recent Statutory and Regulatory Actions

In 2014, legislation was enacted to amend § 32.1-46 as recommended in the 2013 Annual Review. Pursuant to Executive Order 14 (2010) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, a periodic review of the Regulations (12VAC5-110) was also conducted in April, 2014. Regulatory actions were submitted in 2014 to amend the Regulations as a result of these activities. The exempt action to amend the regulations to conform to the enacted legislation became effective on October 10, 2014. The fast-track action to amend as a result of the periodic review became effective on January 14, 2016.