Economic Impact Analysis Virginia Department of Planning and Budget

12 VAC 5-110 – Immunization of School Children Virginia Department of Health December 22, 2008

Summary of the Proposed Amendments to Regulation

The State Board of Health (Board) proposes to amend its regulations governing the immunization of school children to incorporate immunization requirements enacted by the legislature in 2006 and 2007 and to reflect changes in the current immunization schedule recommended by the American Academy of Pediatrics and the American Academy of Family Physicians (this is also required by statute). The Board also proposes to add registered nurses to the list of entities that can administer immunizations and can provide certification that required vaccines would be detrimental to a child's health.

Result of Analysis

There is insufficient information to accurately gauge whether benefits will outweigh costs for this proposed regulatory action. Benefits and costs are discussed below.

Estimated Economic Impact

Currently, parents must make sure that their children have received a specified number of immunizations for specified diseases before they are enrolled in school (and continue receiving specified immunizations as a condition for staying enrolled). Alternately, parents may present a Certificate of Religious Exemption (CRE), certification from a physician or local health department that the required vaccines would be detrimental to their child's health or, for rubeola and rubella, proof that the child already has antibodies and would not, therefore need to be vaccinated.

The current regulatory vaccination schedule requires:

- Three doses of Diphtheria and Tetanus toxiods and Pertussis vaccine (DPT) before the child is seven years old; One of these doses must be administered after the child is four years old,
- A minimum of three doses of the polio vaccine, one of which must be administered after a child is four years old,
- Two doses of live Rubeola (measles) vaccine, one administered at age 12 months or older and one administered prior to entering kindergarten (this requirement is clarified in the proposed regulations and will have the second dose administered between the ages of four and six),
- A minimum of one dose of Rubella (German measles) vaccine administered at age 12 months or older,
- A minimum of one dose of mumps vaccine administered at 12 months of age or older,
- A maximum of four doses of Haemophilus Influenza type b (Hib) vaccine on an approved schedule that is "appropriate to the age of child and the age at which the immunization series was initiated" and
- A minimum of three doses of the Hepatitis B vaccine.

According to current regulatory text, a physician or his designee or a local Departments of Health can attest to the administration of immunizations (or attest that a child would be harmed by same).

The Board proposes to update this regulatory vaccination schedule to reflect changes in statutory requirements and changes in the current immunization schedule recommended by the American Academy of Pediatrics and the American Academy of Family Physicians. The Board proposes to list the three component parts of the DPT vaccine separately and add the requirement that a booster of each must be given prior to a child's enrollment in sixth grade, provided that at least five years had passed since the child's last dose of each. Even though these components will be listed separately in these regulations, they are normally combined into one shot for the purposes of childhood immunization. The proposed regulations include a required second dose of the mumps vaccine, to be administered between the ages of four and six, and an addition to the requirements for the Hepatitis B vaccine that allows children between the ages of 11 and 15

to only take two (rather than three) doses of this vaccine so long as they are taking the newly approved RECOMBIVAX HB produced by Merck.

The proposed regulations also include recently (in the last two years) passed legislative requirements that children born on or after January 1,1997 receive two doses of the Varicella (chickenpox) vaccine, one dose on or after the age of 12 months and one dose between the ages of four and six, that all children under the age of 24 months receive a maximum of four doses of Pneumococcal Conjugate Vaccine (PCV) to protect against pneumonia and that girls must have three doses of the Human Papillomavirus (HPV), the first of which must be administered before admittance to sixth grade. Because HPV is not a disease that is communicable in a school setting and because requiring this vaccine is not without controversy, parents (guardians) may choose not to allow the HPV vaccine to be give to their daughters (charges). These parents (guardians) must review materials describing the link between certain HPV strains and cervical cancer prior to deciding whether to allow the vaccine to be given but do not have to sign a waiver.

The proposed regulations also includes chickenpox among the diseases for which a child does not need the vaccine if he already has antibodies and clarifies by explicitly listing registered nurses as individuals empowered to give vaccines or to certify, when necessary, that vaccines cannot be given because they would be harmful to a child.

Requiring a booster of each of the components of the DPT vaccine before a child enters sixth grade currently entails either an extra visit to the child's doctor (either completely paid for by the parent or with the cost split between the parent and their insurance company) or a visit to a local Department of Health where the vaccine will be given at no fee to the parent but where the parent may spend many hours waiting for the shot to be given. Parents who choose to allow their daughters to receive the HPV vaccine would likely choose to have this vaccine given at the same time as the DPT booster and , so, could lower the per shot cost (of time or money or both). Parents who do not choose to allow their daughters to receive the HPV virus will incur the cost of time spent reading Board approved materials about the link between HPV and cervical cancer.

Parents who will be immunizing infants and toddlers with the PCV vaccine, and parents whose children will be required to be vaccinated against chickenpox, will likely be able to have these vaccines administered with other required vaccines at normal well child visits. Any costs for parents for the PCV and chickenpox vaccines will likely be limited to any out of pocket costs

for the vaccine doses themselves (this would likely only be an issue for parents paying all costs themselves since most insurance plans cover vaccines in the copay cost of well child visits).

The requirement for an additional dose of mumps vaccine and the allowance for a two dose course of Hepatitis B vaccine will likely not raise the total cost (in time or money) of immunization for parents who are having their children immunized on the recommended schedule because the recommended schedule already includes two doses of the of the combined measles, mumps and rubella (MMR) vaccine and because parents are unlikely to choose the two dose Hepatitis B vaccine unless they receive some benefit over the normal three dose course.

The Virginia Department of Health (VDH) reports that the state will incur extra costs for vaccines paid for by the state, and administered through local Departments of Health, and that local Departments of Health will likely lose revenue (costs for office visit and administration of vaccine) that they have received from parents paying for the optional second dose of chickenpox vaccine. The state has budgeted \$1.4 million per year to cover the cost of the HPV vaccine and \$280,110 per year to cover the (local Department of Health) cost of requiring the DPT booster before sixth grade. Local Departments of Health currently charge approximately \$30 per child for administering a second chickenpox immunization; the state already pays for the actual vaccine doses.

To the extent that the new immunization schedule lowers the incidence of the diseases covered by the required vaccines, the public will benefit from fewer costs for illness (misery, permanent injury or death for the sick children, costs for medication to ameliorate symptoms and lost wages for parents) and, for diseases that are easily spread in a school setting, greater herd immunity. Any extra benefit from the changes to required immunizations have to be weighed against the not insignificant increases in costs to the state, to parents and to insurance companies.

Businesses and Entities Affected

VDH reports that these proposed regulations will affect parents and their children, all public and private health care providers who administer covered vaccines as well as school staff who must verify that children are in compliance with the required vaccine schedule. These proposed regulations will also likely affect insurance companies that cover required vaccinations.

Localities Particularly Affected

All local Departments of Health will likely lose revenue (costs for office visit and administration of vaccine) that they have received from parents paying for the optional second dose of chickenpox vaccine. Local Departments of Health currently charge approximately \$30 per child for administering a second chickenpox immunization; the state pays for the actual vaccine doses.

Projected Impact on Employment

This regulatory action will likely have no impact on employment in the Commonwealth.

Effects on the Use and Value of Private Property

This regulatory action will likely have no effect on the use or value of private property in the Commonwealth.

Small Businesses: Costs and Other Effects

Small businesses in the Commonwealth are unlikely to incur any costs on account of this regulatory action.

Small Businesses: Alternative Method that Minimizes Adverse Impact

Small businesses in the Commonwealth are unlikely to incur any costs on account of this regulatory action.

Real Estate Development Costs

This regulatory action will likely have no effect on real estate development costs in the Commonwealth.

Legal Mandate

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.H of the Administrative Process Act and Executive Order Number 36 (06). Section 2.2-4007.H requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the

regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, Section 2.2-4007.H requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.