Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Department of Health/Office of Epidemiology/ Division of Immunization
Virginia Administrative Code (VAC) citation	12 VAC 5-115
Regulation title	Virginia Immunization Information System
Action title	Regulations for the Virginia Immunization Information System (VIIS)
Date this document prepared	May 27, 2009

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The purpose of this regulatory action is to comply with two bills dealing with the statewide immunization registry, SB 1132 and HB 2519. The identical bills were presented by Senator Howell and Delegate John O'Bannon, III during the 2005 session of the General Assembly, and called for the establishment of the Virginia Immunization Information System (VIIS). VIIS contains the birth to death immunization histories of participants and merges this immunization data from all health care providers for that patient into one complete, accurate and definitive record. This consolidated record is made available to participating health care providers throughout the state. § 32.1-46.01 of the Code of Virginia requires the State Board of Health to establish regulations for VIIS.

An accurate patient immunization record allows health care providers to diagnose more effectively and to recommend immunizations to ensure patients receive all of the age-appropriate vaccines that are recommended by the Advisory Committee on

Immunization Practices at the Centers for Disease Control and Prevention (CDC). Accurate information also decreases costs in the areas of duplicated immunizations, reminders of vaccinations that are due, manufacturer recall procedures, and data collection for identifying and targeting immunization rate improvement activities.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The creation of these regulations was mandated by legislation during the 2005 session of the General Assembly. Identical bills, SB 1132, sponsored by Senator Howell (Chapter 684) and HB 2519, sponsored by Delegate John O'Bannon, III (Chapter 643), resulted in § 32.1-46.01 of the Code of Virginia. This legislation requires the Board of Health to promulgate the regulations for VIIS.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

Regulations are essential for the successful operation of VIIS and for achievement of the goals of VIIS. These goals are to protect the public health of citizens by ensuring up-to-date recommendations for age-appropriate immunizations; by preventing under- or over-immunization of children; by generating parental reminder and recall notices and manufacturer recalls of vaccines; by producing immunization coverage rates and reports; by identifying areas of under-immunized populations, and by providing in the event of a public health emergency, a mechanism for tracking the distribution and administration of immunizations, immune globulins, or other preventive medications or emergency treatment. The regulations will address the assurance of system security and patient confidentiality.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

Regulations for VIIS will include all necessary definitions and cover three main areas: 1) users of the VIIS application; 2) data entry by organizations exchanging immunization data with VIIS; and, 3) approved uses of VIIS data.

The regulations will define who may be an authorized user of VIIS; describe the voluntary enrollment process and the necessary registration procedures, including any forms or agreements for compliance with regulations of the Department of Health & Human Services concerning patient privacy; and describe the process for confirming, continuing and terminating participation in VIIS. They will also include opt-out procedures for clients who choose not to be included in VIIS

Regulations dealing with the exchange of immunization information from other electronic systems will include ensuring secure data exchange and entry and will also address patient confidentiality. The regulations will describe reporting procedures, including timelines and formats; the use of data from Vital Statistics in populating VIIS; and the incorporation of existing immunization data into VIIS. They will also define patient-identifying information and immunization data.

The approved uses of data both with and without personal identifiers will be defined and will include handling requests for immunization records as well as requests for aggregate data. The procedures for requesting data, the identity of qualified recipients, the purpose and mechanism for its release will be defined. Disciplinary procedures for unauthorized use or disclosure of data will be stated. Mechanisms for entering into data-sharing agreements with other state and regional immunization registries or organizations on a non-emergency basis, as well as the accessing/releasing of data in public health emergencies by the Commissioner of Health will be included.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

No feasible alternative exists. Legislation enacted by the 2005 General Assembly requires these regulations. CDC also requires a statewide immunization registry as a means of protecting public health through appropriate immunizations and of promoting activities that improve immunization rates.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action including, but not limited to, ideas to assist in the development of the proposal.

Anyone wishing to submit written comments may do so by mail, email or fax to **James Farrell, 109 Governor Street, Room 314 West, Richmond, Virginia 23219; phone (804) 864-8055 or (800) 568-1929; fax (804) 864-8089 or James.Farrell@vdh.virginia.gov**. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

In addition, the agency is seeking information on (1) the continued need for the regulation; (2) the complexity of the regulation; (3) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

A public hearing will not be held during this stage.

Participatory approach

Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, technical advisory committees) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

Many professional organizations supported the legislation of VIIS. These include:

- Virginia Chapter of the American Academy of Pediatrics
- Virginia Pediatric Society
- Medical Society of Virginia
- Medical Society of Northern Virginia
- Virginia Association of Health Plans
- VOICES for Virginia's Children
- Bon-Secours Care-a-Van
- National Association of Pediatric Nurse Practitioners
- Aetna Health Plan
- Anthem Health Plan
- Coventry/Southern Health Plan
- Virginia Hospital and Healthcare Association
- Virginia Nurses Association
- Virginia Association of Physician Assistants

In 2003, a Registry User Group (RUG) of professionals representing the public and private health sectors was created. The RUG was originally composed of about 50 individuals including doctors, nurses, business managers, representatives from health care plans, health departments, etc., who were interested in a statewide immunization registry in Virginia. The RUG has provided guidance for many issues concerning the development of VIIS.

In 2006, the RUG was expanded to include representatives from organizations having an interest in VIIS, and included medical professional organizations, pharmaceutical companies, federal and state government agencies, school systems, hospitals and others. There are currently approximately 150 stakeholders. An advisory meeting was held of all stakeholders in May 2007.

In addition, this group will be consulted and will serve as the Regulatory Advisory Panel in the development of the regulations.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

No adverse impact on the institution or the family or family stability is anticipated in writing the regulations for VIIS. VIIS will protect and improve the health of the people of the Commonwealth. The most obvious benefit to the family is to provide a complete immunization history for the child, which allows the physician to provide all of the age-appropriate immunizations recommended by the Advisory Committee on Immunization Practices (ACIP). An incomplete immunization history can lead to under- or over - immunized children. Under-immunized children are those who do not receive the recommended ACIP vaccines and are vulnerable to preventable and serious illness, and over-immunized children have received duplicate vaccines. Over-immunization is costly because of unnecessary healthcare visits with time off from work for the parent or guardian; unnecessary discomfort to the child with an increased chance of reaction to the unnecessary vaccine; wasted vaccine and unnecessary administrative costs and staff time.

Additional benefits include:

- Removing the parental requirement to take the immunization record to each visit to the child's provider(s);
- Preventing additional visits to the child's provider(s) by identifying all age-appropriate immunizations that may be given during the current visit;

- Providing emergency room access to check the child's immunization status at the time of an injury or illness;
- Providing information needed to create reminder/recall notices for recommended immunizations that are due or overdue;
- Simplifying the process for obtaining the child's immunization history for admission to schools, daycares, camps, etc.;
- Identifying and recalling the child who may need additional vaccines due to:
  - Having received a vaccine that was later recalled, or
  - Not having received a recommended vaccine due to short supply; and
- Guaranteeing lifetime access to the client's immunization history even if the health care provider's office is no longer in operation**.**