Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	Department of Health/Office of Epidemiology/Division of Immunization
Virginia Administrative Code (VAC) citation	12 VAC5-115
Regulation title	Virginia Immunization Information System
Action title	Regulations for the Virginia Immunization Information System (VIIS)
Date this document prepared	09/14/2010

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

Section 32.1-46.01 of the *Code of Virginia* requires the State Board of Health to establish regulations for the Virginia Immunization Information System (VIIS). VIIS is a voluntary, statewide immunization registry that consolidates patient immunization histories from birth to death into a complete, accurate, and definitive record that is available to Virginia's participating health care providers. The VIIS regulations are designed to: (1) define who is allowed access to VIIS; (2) specify requirements for this access; (3) ensure compatibility with current state and federal guidelines in the areas of patient data confidentiality and system security; (4) discuss the security features of the application; (5) define the data to be collected; (6) state the mechanisms for populating and capturing data; (7) define the approved use of data, the authorized recipients, and the procedure for obtaining the data; and, (8) discuss the use of VIIS in a public health emergency.

Acronyms and Definitions

"ACIP" means Advisory Committee on Immunization Practices

"CDC" means Centers for Disease Control and Prevention

"Data exchange" means electronically sending immunization information from an

existing information system to VIIS and being able to retrieve information from VIIS

"DOE" means Department of Education

"DMAS" means Department of Medical Assistance Services

"DSS" means Department of Social Services

"EHR" means electronic health record

"FQHC" means a Federally Qualified Health Center

"HIPAA" means the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C.P.L.104-191; 42 C.F.R. Part 164)

"IIS" means an immunization information system

"RHC" means a Rural Health Clinic

"UTD" or "Up-to-date" means the client has received all age-appropriate vaccines

"VDH" means the Division of Immunization within the Virginia Department of Health

"VIIS" means the Virginia Immunization Information System

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., the agency, board or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Statutory authority to promulgate these regulations is granted to the State Board of Health by §32.1-46.01 of the *Code.*

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

The purpose of this regulatory action is to comply with two bills dealing with VIIS passed by the 2005 General Assembly: SB 1132 and HB 2519. The identical bills were presented by Senator Janet D. Howell and Delegate John M. O'Bannon, III, MD, and called for the establishment of VIIS. The statewide immunization information system contains birth-to-death immunization histories of participating clients and merges this data from all healthcare providers for that patient into one record. This consolidated record, which is available to participating health care providers in Virginia, will help providers identify appropriate

immunizations to give their patients. It will help to increase immunization rates and protect the public health of all citizens of Virginia in the following ways: (1) ensure that children receive vaccines appropriately, as currently recommended by ACIP; (2) prevent the under- and over-immunization of children; (3) generate parental reminders, recall notices and manufacturer recalls; (4) produce immunization coverage reports; (5) identify areas of under-immunized populations for educational purposes and other immunization rate improvement activities; and, (6) provide, 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 treatments.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

Regulations for VIIS will cover five main areas: 1) authorized participants of VIIS and their registration procedure; 2) data entry by participants either through user interface or data exchange; 3) requirements for patient confidentiality and system security; 4) approved and non-approved use of VIIS data; and, 5) use of VIIS in a public health emergency.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.

If the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

VIIS regulations will pose no disadvantage to the public or the Commonwealth. Many advantages will occur for both the general public and to the Commonwealth. An accurate patient immunization record allows health care providers to diagnose vaccine preventable diseases more effectively and to recommend immunizations that ensure patients receive all the age-appropriate vaccines recommended by ACIP. Accurate immunization information also decreases costs by preventing unnecessary duplicated immunizations, reminding clients of vaccines that are due or were recalled by the manufacturer, and identifying areas of need for increased education and other activities that may lead to improved immunization coverage rates.

There are also benefits to parents or guardians, which include the following:

- removes the need to provide their child's immunization record to the healthcare provider(s);
- prevents additional visits to the child's provider(s) by identifying all age-appropriate immunizations that may be given during the current visit;
- provides emergency department ability to assess the child's immunization status at the time of an injury;
- provides information needed to create reminder/recall notices for recommended immunizations that are due or overdue;
- simplifies the process for obtaining the child's immunization history for admission to schools, daycares, camps, etc.;
- enables identification and recall of the child who:

- received a vaccine that was later recalled; or,
- did not receive a recommended vaccine due to short supply;

o guarantees lifetime access to the client's immunization history even if the health care provider's office is no longer in operation.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

VIIS is a partnership between the public and private health sectors of Virginia; however, participation in VIIS is voluntary for healthcare providers and citizens. Therefore, no locality would be disproportionately affected by VIIS.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the *Code*.. Information may include 1) projected reporting, recordkeeping and other administrative costs; 2) probable effect of the regulation on affected small businesses; and, 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or 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**. 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. A public hearing is not planned.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirements create the anticipated economic impact.

<table>
<tr><td>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.</td><td>There are three types of costs incurred with VIIS: building costs for the construction, maintenance costs for the continued operation (including costs for improving and upgrading the application), and user costs for participants. As VIIS has been operational since 2006, building costs have been met with 100% federal financial assistance and only ongoing maintenance will be discussed here.

Historically, the maintenance costs for the operation of VIIS are approximately $2.3 M per year. The federal funding codes are 607 40502 1000. This figure includes the following ongoing expenditures: management of VIIS by an outside vendor; salaries for VDH staff necessary for program management, including the planning and performing of daily operations, as well as quality assurance and improvement activities, and recruitment, training and monitoring of participants; adequate technical support for analysis of data and coordination of data exchange with VIIS; program supplies; hardware upgrades for the application's operation, and travel expenses for necessary visits to the participant's offices, and continuing education of staff.</td></tr>
<tr><td>Projected cost of the new regulations or changes to existing regulations on localities.</td><td>There are no projected costs to localities for VIIS. Enrollment in VIIS is voluntary, and the web-based application is available free of charge. If qualified persons elect to participate, the costs incurred by them are limited and include: a computer with Internet access (high-speed connection is desirable, but not necessary); staff time to complete forms for participation; training and customizing the application for their facility, for adding users within their facility, and, if they elect to do so, for entering the past immunization history of their clients.</td></tr>
<tr><td>Description of the individuals, businesses or other entities likely to be affected by the new regulations or changes to existing regulations.</td><td>Various categories of persons and entities giving immunizations or processing immunization information would be affected by VIIS regulations.
CHART 1- Typical users of VIIS<table><tr><th>VIIS users/sites</th><th>Approximate number</th></tr><tr><td>Private doctors, including pediatricians, family medicine practices, internal medicine physicians and OB/GYN practices.</td><td>4,500 doctors within 1700 sites that may be large or small medical practices</td></tr><tr><td>Community Health Centers, RHCs and FQHCs</td><td>200</td></tr><tr><td>Mobile Vans</td><td>5</td></tr></table></td></tr>
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<tr><td>Local health departments and clinics</td><td>135</td></tr>
<tr><td>Hospitals</td><td>200</td></tr>
<tr><td>Pharmacies providing immunizations</td><td>1000</td></tr>
<tr><td>Schools, Colleges and Universities</td><td>4,000</td></tr>
<tr><td>Health Care Plans</td><td>100</td></tr>
<tr><td>Detention centers and other government agencies such as DMAS, DSS and DOE</td><td>NA</td></tr>
<tr><td>Military</td><td>NA</td></tr>
<tr><td>TOTAL SITES</td><td>10,140</td></tr>
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<tr><td>Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.</td><td>Over 10,140 sites will be affected by VIIS. Many of these sites would be small medical practices or pharmacies.
(See Chart 1 for details).</td></tr>
<tr><td>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</td><td>VIIS is free to all users who have been approved by VDH. VIIS may be used in two ways: direct entry of immunization data into the application through user interface or by data exchange of immunization data from other information systems (e.g., billing systems, or EHRs). The organization has the cost of staff time for completing registration and security forms and creating a file that puts the data from their existing system in the format that is accepted by VIIS.

For persons electing to use VIIS by user interface, there would be the cost of additional staff time to complete registration and security forms for participation, training and customizing the application for their facility, adding users within their facility, and, if they elect to do so, entering the previous immunization history of their clients. After VIIS access is granted to the provider, the staff must enter their vaccine inventory into the system and when giving an immunization, register the client (if not already in the system) and enter the immunization data. A computer with Internet access is necessary (a high-speed connection is desirable but not necessary).</td></tr>
<tr><td>Beneficial impact the regulation is designed to produce.</td><td>1. To provide accurate immunization records
2. To identify age-appropriate vaccines for specific clients
3. To reduce duplicate vaccines
4. To recall recipients of recalled vaccines or recipients not receiving vaccines due to vaccine shortages
5. To improve inventory management
6. To identify areas of the state in need of increased</td></tr>
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	immunization services 7. To provide official immunization records for parents/guardians 8. To improve health by the use of health information technology 9. To increase immunization rates 10. To provide a means of communication to healthcare providers in a public health emergency 11. To save the state an estimated one million dollars annually * * documentation available from VDH/DOI

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

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

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There is no alternative to developing the VIIS regulations because the *Code* requires it. Participation in VIIS is voluntary, so neither health care practices nor patients are required to participate.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

No comments were received following the publication of the NOIRA.

Family impact

Please assess the 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 of the family or family stability is anticipated in developing the regulations. VIIS should protect and improve the health of Virginians. The most obvious benefit to the family is the provision of complete immunization histories for children, which allows physicians to provide all age-appropriate immunizations recommended by ACIP. For additional benefits, see the "Issues" section.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact if implemented in each section. Please describe the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For new chapters, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
12VAC5-115-10	Definitions of words and terms used in chapter 115	§ 32.1-46.01	To ensure consistency in interpretation of VIIS regulations
12VAC5-115-20	Authority granted to promulgate regulations for the operation of VIIS	§ 32.1-46.01	To allow the Board of Health to develop regulations for the operation of VIIS
12VAC5-30	The purpose of addressing the policies and procedures of VIIS	§ 32.1-46.01	To state the purpose of the regulations
12VAC5-115-40	Authorized participants of VIIS must require immunization data to perform their job function and must be licensed or certified in Virginia to deliver or support health care services or public health. These participants include but are not limited to, any physician, physician assistant, nurse practitioner, registered nurse, school nurse, pharmacist or any entity listed in § 8.01-581.1. Health care entities may only use VIIS for exchanging	§ 32.1-46.01 § 8.01-581.1	To identify persons or organizations who are allowed to use VIIS

	information on persons for whom they provide services. Other state or regional immunization registries may share data or have access to VIIS data.		
12VAC5-115-50	Those persons electing to participate in VIIS must complete registration forms and assure compliance with necessary confidentiality and security access provisions. VDH will train and provide VIIS access after approval. Participants must designate an administrator who may allow VIIS access by other organization employees and in doing so shall assume responsibility for those users.	§ 32.1-46.01	To identify registration forms, agreements and security conditions necessary to gain access to VIIS and to identify the responsibilities of the participants.
12VAC5-115-60	Patients shall have the opportunity to opt-out of VIIS by contacting VDH or their healthcare provider. Confidentiality of patient VIIS data shall be assured by all users who shall comply with VIIS regulations and state and federal laws, including HIPAA. VIIS records shall be treated with the same confidentiality and privacy as any other patient records. Any inappropriate use shall result in immediate suspension of participant privileges and additional actions may be taken pursuant to Virginia Code § 32.1-27.	§ 32.1-46.01 § 32.1-127.1:03 § 32.1-27	To assure parents/guardians and healthcare providers of children enrolled in VIIS of the confidentiality of the data and, if they elect to do so, to provide them with an opt-out procedure.
12VAC5-115-70	Each approved participant is assigned a security role level in VIIS and there is immediate suspension following any violation of security or misuse of data. Participants shall also have password-enabled screen savers, make every effort to protect VIIS screens from unauthorized view and log off whenever leaving the VIIS workstation. Data shall be encrypted and exchanged via a secure connection. The VIIS application, located on a secure website, includes additional security features, including an organizational code, user ID and password. It inactivates after a set period of time and disallows entry of participants if not used for a period of time.	§ 32.1-46.01	To assure the parents/guardians/providers of patients enrolled in VIIS of the security of the data.
12VAC5-115-80	Birth certificate data are used to populate VIIS and death certificate data are used to make the VIIS record no longer viewable. Enrolled participants or organizations shall report data either by online data entry or by data exchange of files from other information systems. Both demographic and immunization data shall be reported by the participant. The social security number, if provided, is encrypted by the application, appears as asterisks, and does not print out on reports for that client. The application allows only exact matches when the social security number is used for search purposes.	§ 32.1-46.01	To discuss the sources of VIIS data, including the initial population of the application, the ongoing input of data and the inactivation of deceased patients.

	Participants shall make every effort to ensure the accuracy of all immunization and demographic information and shall include enough identifying information to allow for de-duplication of clients. Participants in data exchange shall provide an acceptable level of data quality, such as correct data fields, data accuracy and enough information to correctly merge with existing clients.		
12VAC5-115-90	Specific patient data shall be released to that patient or his parents/guardian only after contacting VDH, who will verify the source and comply with federal and state regulations when releasing the information. Requests for patient-level data from health care entities providing health care services or processing health information for that patient must be in writing to VDH, who will authorize the request. The data shall be erased when no longer needed or when the computer is being terminated, due to replacement or the resignation, retirement or dismissal of the participant. Aggregate data from which personal identifying data has been removed or redacted may be released only after approval by VDH. Any inappropriate use of VIIS data shall result in immediate suspension of user privileges and result in an investigation conducted by VDH.	§ 32.1-46.01 § 32.1-127.1:03 § 32.1-27	To assure the public that VIIS data will be shared only with appropriate recipients after authorization by VDH and to explain the mechanisms and requirements for requesting data, and the penalties for misuse of data.
12VAC5-115-100	In the event of a public health emergency, the Commissioner may access VIIS by contacting the Division of Immunization. If additional persons are designated by the Commissioner to view VIIS information during the emergency, VDH shall contact these users, provide instruction and activate their account. The Commissioner, by notifying the Division of Immunization, may include public health emergency information on the main screen which may be viewed immediately by the VIIS participants.	§ 32.1-46.01 § 32.1-40	To define procedures for the State Health Commissioner to access VIIS or to designate others to view VIIS in a public health emergency.