



Virginia

Regulatory
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V

Final Regulation Agency Background Document

Agency name	Department of Health/Office of Epidemiology/Division of Immunization
Virginia Administrative Code (VAC) citation	12VAC5-115
Regulation title	Virginia Immunization Information System
Action title	Regulations for the Virginia Immunization Information System (VIIS), the statewide registry for private and public healthcare systems
Date this document prepared	05/17/2013

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

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

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 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.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

The State Board of Health approved the final regulations for the Virginia Immunization Information System on April 12, 2013.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

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

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal 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 and called for the establishment of VIIS. The statewide immunization information system contains birth to death immunization histories of participating patients and merges this data from all participating providers for that patient into one record. This consolidated record, which is available to participating providers in Virginia, will help providers identify appropriate immunizations to give their patients. It will 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 the Advisory Committee for Immunization Practices (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 population 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 identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" 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 there are 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 participating 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 patients 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:

- to remove the requirement to provide their child's immunization record to the participating provider(s);
- to consolidate the immunization histories from multiple providers into one record and therefore eliminate duplicate immunizations due to no known history of having received them
- to prevent additional visits to the child's participating provider(s) by identifying all age-appropriate immunizations that may be given during the current visit;
- to provide emergency room access to assess the child's immunization status at the time of an injury;
- to provide information needed to create reminder/recall notices for recommended immunizations that are due or overdue;
- to simplify the process for obtaining the child's immunization history for admission to schools, daycares, camps, college, etc.;
- to identify and recall the child who:
 - § received a vaccine that was later recalled by the manufacturer, or
 - § did not receive a recommended vaccine due to short supply;
- to guarantee lifetime access to the client's immunization history even if the participating provider's office is no longer in operation.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

Minor wording changes, such as “client to patient”, “health record to patient record”, “health care provider to participating provider”, “designated health plan to health plan”, and “must to shall”, that were suggested by the Attorney General’s office have been made since the proposed stage. In addition several changes regarding the clarification of definitions, the VIIS registration procedure, and the population and release/use of VIIS data were made. These are listed below:

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC5-115-10	<u>“Patient” means the client who is receiving health services or his parent or guardian.</u>	Elimination of <u>or his parent or guardian</u> from the sentence.	Based on recommendations from the AG’s office
12VAC5-115-10)	<u>“VDH” or “Department of Health” means the Division of Immunization within the Virginia Department of Health.</u>	Elimination of <u>Division of Immunization within the Virginia Department of Health</u>	Based on recommendations from the AG’s office
12VAC5-115-30 (C)	<u>Once the participant is approved,</u>	Addition of <u>the participant shall sign a participant registration agreement with VDH to the statement.</u>	Based on recommendations from the AG’s office
12VAC5-115-60 (E)	<u>VDH may suspend system privileges and refer to § 32.1-27 of the Code of Virginia for additional action</u>	Elimination of Code reference and replacement with “take” to say <u>VDH may suspend system privileges and take additional action...</u>	Based on recommendations from the AG’s office
12VAC5-115-70 (A)	<u>Specific patient data shall be disclosed...</u>	Changed to <u>Specific patient data shall not be disclosed except...</u>	Based on recommendations from the AG’s office
12VAC5-115-70 (B)	<u>See § 32.1-127.1:03 of the Code of Virginia</u>	Addition of a code to the statement so that it says <u>See §§ 32.1-46 (E) and 32.1-127.1:03 of the Code of Virginia.</u>	Based on recommendations from the AG’s office
12VAC5-115-70 (C)	<u>Patient data shall be erased when no longer needed or when the computer is being terminated due to the replacement of the computer or the resignation, retirement or dismissal of the participant:</u>	Replacement of wording “in accordance with a data sharing agreement or a participant registration agreement with VDH” so that it says <u>Patient data shall be erased when no longer needed, when the computer is being terminated, or in accordance with a data sharing agreement or a participant registration agreement with VDH.</u>	Based on recommendations from the AG’s office
12VAC5-115-80 (A)	<u>In the event of an epidemic or an outbreak of a vaccine preventable disease or any disease of public health</u>	Elimination of sentence from the section.	Based on recommendations from the AG’s office

	<u>significance or threat, the commissioner may access VIIS in accordance with § 32.1-40 of the Code of Virginia by contacting the Division of Immunization.</u>		
12VAC5-115-80 (A)	<u>The commissioner may release VIIS data in accordance with § 32.1-41 of the Code of Virginia.</u>	Wording changes and addition of § 32.1-40 to this statement so that it says <u>The commissioner may access and release VIIS data in accordance with §§ 32.1-40 and 32.1-41 of the Code of Virginia.</u>	Based on recommendations from the AG's office
12VAC5-115-80 (C)	<u>The commissioner by notifying the Division of Immunization may include public health emergency announcements...</u>	Elimination of "by notifying the Division of Immunization" so it says <u>The commissioner may include public health emergency announcements...</u>	Based on recommendations from the AG's office

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
Stephen	<p>Immunizations required for school attendance.</p> <p>There are substantial numbers of students attending schools that are at risk for contacting diseases for which there are immunizations available. These students have received the immunization treatments but remain unprotected. In light of the fact that there is no concern for these students attending school, why then is there so much effort placed on forcing a few students to get immunized whose parents do not want them immunized? If they were not immunized, they would be no more at risk than the many children that are not protected by the immunizations. "Requiring" immunizations and then quietly, through medical records privacy, allowing those that object to attend (based on religious or health issues or what ever) would seem reasonable. The purely fear tactics used over this issue to get a public out cry for forced immunizations, while there is no concern for exposure to those uneffected after</p>	<p>School immunization requirements are addressed in Virginia Administrative Code 12VAC5-110. These regulations (12VAC5-115) refer to VIIS, the information system for the deposit for immunization data. This comment does not relate to VIIS and cannot be addressed in this regulatory process.</p>

	receiving immunizations, is about government control rather than about health concerns.	
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All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	12VAC5-115-10	None	<u>Definitions.</u> Definitions of words and terms used in chapter 115 to ensure consistency in interpretation of VIIS regulations.
	12VAC5-115-20	None	<u>Authorized participants.</u> Persons or organizations must first seek authorization before they are allowed to use VIIS. 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 information on persons for whom they provide services. Other state or regional immunization registries may share data or have access to VIIS data after approval from VDH.
	12VAC5-30	None	<u>Registration procedures.</u> Registration forms, agreements and security conditions are necessary to gain access to VIIS and participants have responsibilities which are listed in this section. 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.
	12VAC5-115-40	None	<u>Patient confidentiality.</u> This section assures parents/guardians and healthcare providers of persons enrolled in VIIS of the confidentiality of the data and, if they elect to do so, provides them with an opt-out procedure. Patients shall have the opportunity to opt-out of VIIS by contacting VDH or their healthcare provider. Confidentiality of VIIS patient data shall be assured by all users who must comply with VIIS regulations and state and federal laws. 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.
	12VAC5-115-50	None	<u>Security.</u> This section assures the parents/guardians/providers of patients enrolled in VIIS of the security of the data. 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 designated period of time.
	12VAC5-115-60	None	<u>Population of VIIS.</u> This section discusses the sources of VIIS data, including the initial population of the application, the ongoing input of data and the inactivation of deceased patients. 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

			<p>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. Participants shall make every effort to ensure the accuracy of all immunization and demographic information and shall include enough identifying information to allow for deduplication 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.</p>
	12VAC5-115-70	None	<p><u>Release of VIIS data.</u> This section assures the public that VIIS data will be shared only with appropriate recipients after authorization by VDH and explains the mechanisms and requirements for requesting data, and the penalties for misuse of data. 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, when the computer is being terminated, or in accordance with a data sharing agreement or a participant registration agreement with VDH. Aggregate data from which personal identifying data have 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.</p>
	12VAC5-115-80	None	<p><u>Data access in public health emergency.</u> This section defines the procedures for the State Health Commissioner to access VIIS or to designate others to view VIIS in a public health emergency. The Commissioner may access and release VIIS data. If additional</p>

			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 may include public health emergency information on the main screen which may be viewed immediately by the VIIS participants.
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Enter any other statement here