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Fast-Track Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-115
VAC Chapter title(s)	Virginia Immunization Information System (VIIS) Regulations
Action title	Amend Regulation Following Periodic Review
Date this document prepared	7/26/24

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The Virginia Immunization Information System (VIIS) Regulations (12VAC5-115) address the effective administration of a system containing birth to death immunization histories of individuals by merging data from various sources. The regulations described in 12VAC5-115 set clear guidance for all providers and health care entities on the appropriate use of the Virginia Immunization Information System by defining protocols related to authorized participants, registration procedures, patient confidentiality, security, data entry and quality assurance, data release, data access, and forms.

The regulations described in 12VAC5-115 are necessary to protect the public health, safety, and welfare of individuals in the Commonwealth of Virginia by ensuring that public health information associated with immunization records is kept in an efficient, inclusive, and secure system. This system is vital to ensure immunization data is readily available to providers and other health care entities to ensure they can provide timely and appropriate patient care. Public health efforts to control and prevent vaccine-

preventable diseases and effectively respond to public health emergencies (e.g., pandemics) could be negatively affected without VIIS regulations in place.

The impetus for this regulatory action is the periodic review of 12VAC5-115, which resulted in a decision to amend the regulation. This amendment adds, removes, and updates regulatory language to enhance clarity; clarifies required and authorized participants in the VIIS system; updates the VIIS registration, onboarding, and training processes; clarifies authorized use of VIIS to protect patient confidentiality; updates the VIIS opt-out process; clarifies VIIS access and reactivation processes; and updates the list of demographic information required to be reported and the timing of VIIS immunization data reporting.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

Board – State Board of Health
VDH – Virginia Department of Health
VIIS – Virginia Immunization Information System

Statement of Final Agency Action

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 taking the action; and 3) the title of the regulation.

The State Board of Health approved these Fast Track Amendments to 12VAC5-115 - Virginia Immunization Information System (VIIS) Regulations, on September 19, 2024.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

Consistent with Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track rulemaking process.

The impetus for this regulatory action is the periodic review of 12VAC5-115, which resulted in a decision to amend the regulation.

This regulatory amendment includes 1) technical changes to regulatory language; 2) clarifications on VIIS required and authorized participants, authorized use, and access and reactivation processes; 3) updates to registration, onboarding, and training processes, as well as to demographic information and timing of VIIS immunization data reporting. This rulemaking is expected to be noncontroversial as amendments to the regulations are either 1) technical or clarifying in nature or 2) intended to align the regulations with current standards of practice. Further, no comments were received during the periodic review public comment period. Therefore, this action is appropriate for the fast-track rulemaking process.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

The State Board of Health is the promulgating agency. Va. Code § 32.1-12 authorizes the Board to "make, adopt, promulgate and enforce such regulations and provide for reasonable variances and exemptions therefrom as may be necessary to carry out the provisions of [Title 32.1] and other laws of the Commonwealth administered by it, the Commissioner or the Department."

Va. Code § 32.1-46.01 requires the Board to establish the VIIS and to promulgate regulations to implement the VIIS.

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.

The impetus for this regulatory action is the periodic review of 12VAC5-115, which resulted in a decision to amend the regulation. This regulatory action is needed to clarify and update the regulation for the regulated public to reflect current VIIS practices, and to maximize VIIS capabilities to positively impact public health. The regulatory changes include streamlined immunization data record-keeping and provider access to comprehensive immunization records, leading to better informed patient care and, potentially, improved patient outcomes, and are essential to protect the health, safety, or welfare of citizens.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

The amendments will:

- Update three definitions;
- Add, remove, and update regulatory language to enhance clarity;
- Clarify required and authorized participants in the VIIS system;
- Update the VIIS registration, onboarding, and training processes;
- Clarify authorized use of VIIS to protect patient confidentiality;
- Update the VIIS opt-out process;
- Clarify the VIIS access and reactivation processes; and
- Update list of demographic information required to be reported and the timing of VIIS immunization data reporting, including the removal of social security number as a required field to reduce regulatory burden.

Issues

Identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

The primary advantages to the public include 1) streamlined immunization data record-keeping and provider access to comprehensive immunization records, leading to better informed patient care and, potentially, improved patient outcomes; 2) improved electronic VIIS registration, onboarding, and training processes that may reduce costs to health care providers and health care entities through increased efficiency and reduced manual paperwork; and 3) simplified patient opt-out of VIIS through an electronic form.

The primary advantages to the agency or the Commonwealth include 1) clarification of the regulation to improve regulatory understanding and compliance by regulants; 2) streamlined immunization data record-keeping and provider access to comprehensive immunization records, leading to better informed patient care and, potentially, improved patient outcomes; 3) improved electronic VIIS registration, onboarding, and training processes that may reduce costs to health care providers and health care entities through increased efficiency and reduced manual paperwork; and 4) simplified patient opt-out of the VIIS through an electronic form.

No disadvantages to the public or the Commonwealth have been identified.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

None of these requirements is more restrictive than federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

No other state agency would be particularly affected by this regulatory change.

Localities Particularly Affected

All localities who are subject to these regulations would be equally affected by these regulatory changes.

Other Entities Particularly Affected

All health care entities and health care providers who are subject to these regulations would be equally impacted by these regulatory changes.

Economic Impact

Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	No direct or indirect economic impact.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	No direct economic impact. There may be indirect economic impact to state agencies required to report immunization data to VIIS. State agencies required to report immunization data to VIIS may incur personnel costs related to mandatory input of patient immunizations if they are reporting manually. Conversely, a savings may be realized as electronic registration, onboarding, and reporting of immunization-related data may be more cost effective than faxing or mailing paper reports. There may also be a reduction in staffing costs through more efficient processes and a reduction in labor necessary to process paper forms.
For all agencies: Benefits the regulatory change is designed to produce.	Benefits the regulatory change is designed to produce for state agencies include 1) clarification of the regulation to improve regulatory understanding and compliance by regulants; 2) streamlined immunization data record-keeping and provider access to comprehensive immunization records, leading to better informed patient care and, potentially, patient outcomes; 3) improved electronic VIIS registration, onboarding, and training processes that may reduce costs to health care providers and health care entities through increased efficiency and reduced manual paperwork; and 4) simplified patient opt-out of the VIIS through an electronic form.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees or revenues resulting from the regulatory change.	Analysis provided on Table 2 of the ORM Economic Impact form.
Benefits the regulatory change is designed to produce.	Analysis provided on Table 2 of the ORM Economic Impact form.

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Analysis provided on Tables 3 and 4 of the ORM Economic Impact form.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	Analysis provided on Tables 3 and 4 of the ORM Economic Impact form.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	Analysis provided on Tables 3 and 4 of the ORM Economic Impact form.
Benefits the regulatory change is designed to produce.	Analysis provided on Tables 3 and 4 of the ORM Economic Impact form.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

There are no viable alternatives to the regulatory change. The Board is required, pursuant to § 32.1-46.01 to promulgate regulations to implement the VIIS.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B of the Code of Virginia, 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) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.

There are no alternative regulatory methods to achieve the statutory requirement in § 32.1-46.01 of the Code of Virginia. The regulations are already designed to minimize administrative burden and achieve the intent of the legislative mandate.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

Consistent with § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The State Board of Health is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Karen Mask, Senior Policy Analyst for the Virginia Department of Health Office of Epidemiology, 109 Governor Street, Richmond, VA, 23219, (804) 654-9351, and Karen.Mask@vdh.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or

agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
115-10	N/A	This section includes definitions	**Change:** The definitions for "heath care entity", "health care provider", and "health plan" were updated to reference the respective definitions in § 32.1-127.1:03 of the Code of Virginia. **Intent:** The intent is to tie the definitions to the Code definitions. There is no substantive change to the meaning or use of the terms. **Rationale:** The rationale is to ensure consistency with the Code. Subsection B of § 32.1-46.01 requires that those three terms be defined as in the cited Code section. **Likely Impact:** The likely impact of this change is improved consistency with the Code.
115-20	N/A	This section addresses authorized participants in the VIIS system.	**Change:** Updates language to reflect health care provider and health care entities required or authorized to participate in VIIS per §§ 32.1-127.1:03, 8.01-581.1, and 32.1-46.01 of the Code of Virginia. **Intent:** The intent of this change is to clarify both the required and authorized VIIS user populations for the regulated public. **Rationale:** The rationale for this change is to improve the clarity of the regulation and to align the regulation with §§ 32.1-127.1:03, 8.01-581.1, and 32.1-46.01 of the Code of Virginia. **Likely Impact:** The likely impact of this change is better understanding of who is

			required and who is authorized to utilize VIIS.
115-30	N/A	This section addresses VIIS registration procedures and requirements.	**Change:** Section edits: • Relocates provisions from subsection A to section 115-20 • Updates language to reflect current electronic VIIS registration versus paper forms. • Clarifies VDH and participant organization responsibilities regarding VIIS training and onboarding. • Specifies that all data entered by an organization or participant will remain in the system in the event that organization or participant access is terminated. **Intent:** The intent of the change is to reflect current VIIS electronic registration, onboarding, and data retention procedures and to clarify VDH and participant organization VIIS training and onboarding responsibilities. **Rationale:** The rationale for this change is to improve the clarity of the regulation and update the regulation to reflect current VIIS practice. **Likely Impact:** The likely impact of the change is a reduction in regulatory burden on regulants due to fewer required forms and more streamlined electronic VIIS processes and better regulation clarity among regulants.
115-40	N/A	This section addresses patient confidentiality in VIIS	**Change:** Section edits: • Adds language stating that VIIS patient level data may only be used for purposes listed in § 32.1-46.01 of the Code of Virginia. • Adds language clarifying that VIIS patient level data may not be used to determine if an employee is in compliance with the immunization policies of the employer (this is not a purpose listed in § 32.1-46.01). • Updates language regarding the VIIS opt-out process. • Relocates examples of activities that may jeopardize the security of VISS from subsection B of section 50 to subsection B of section 40.

			• Adds pulping and incineration as acceptable methods of immunization record destruction. **Intent:** The intent of the change is to clarify allowable use of VIIS and the VIIS opt-out process. The change expands pathways to compliance with secure record disposal methods. **Rationale:** The rational for this change is to improve the clarity of the regulation and align the regulation with § 32.1-46.01 of the Code of Virginia; and to allow additional methods of secure document disposal. **Likely Impact:** The likely impact of this change is better understanding of allowable usage of VIIS and better clarity among the regulants. Regulants may begin to pulp or incinerate copies of immunization records.
115-50	N/A	This section addresses the security requirements to participate in the VIIS system	**Change:** Updates language to reflect current VIIS sign-on, data protection, and account reactivation requirements. Removes nonregulatory language in subsection A. Relocates provisions from subsection B to section 40. **Intent:** The intent of the change is to update the regulation to reflect current VIIS practice and provide clarity to regulants. Remove nonregulatory or unnecessary language. Clarify reactivation procedures after account is automatically inactivated. **Rationale:** The rationale for this change is to improve the clarity of the regulation and update the regulation to reflect current VIIS practice. **Likely Impact:** The likely impact of this change is better clarity among the regulants.
115-60	N/A	This section addresses data population of VIIS.	**Change:** Section edits: • Updates language to reflect current titles of VDH offices. • Clarifies existing data transmission methods, including with VDH vital statistic information.

			• Changed timing of immunization data reporting to within three days of vaccine administration. • Updates patient demographic information required to be reported to VIIS: Patient name and birth date are the only two fields required for record acceptance. Gender, telephone number, email, home address, race, ethnicity, birthplace, and mother's maiden name are now only required if available. • Removes patient social security number as a field required for reporting. • Clarified data quality review and notice procedures, including adding a 30-day requirement to resolve rejected records. Additional updates to this section include non-substantive changes for language and style consistency. **Intent:** The intent of this change is to update the regulation to reflect current VIIS practice and to conform to the Virginia Registrar's *Form, Style and Procedure Manual for Publication of Virginia Regulations*. The change also reflects the existing operation of the system with regard to record rejection and minimum data field requirements. **Rationale:** The rationale for this change is that these changes reflect current standards of practice, reduce data reporting requirements, reflect data reporting capabilities in the current environment, and align the regulation with § 32.1-46.01 of the Code of Virginia. Most data submissions occur on a daily basis, changing the submission window from 7 to 3 days aligns the few manual submissions with the rest of the data reported to VIIS. The current language requires rejected record resolution "in a timely way," which is not an objective or enforceable standard. 30 days is objective, enforceable, and a reasonable amount of time. **Likely Impact:** The likely impact of this change is better clarity of the regulation and better understanding of the data

			reporting requirements by regulants. Manual data submissions will be sent within 3 days of vaccination administration. Rejected records will be updated by the participant within 30 days of notice that the record was rejected.
115-70	N/A	This section specifies requirements regarding the release of VIIS data.	**Change:** Updates language to reflect current technology and consistent use of the term VIIS "participant" throughout the regulation. Removes subsection B. Removes requirement to contact VDH before disclosing data as required or permitted by state or federal law. **Intent:** The intent of this language is to conform to current industry practice and to the Virginia Registrar's *Form, Style and Procedure Manual for Publication of Virginia Regulations*. **Rationale:** The rationale for this change is to improve the clarity of the regulation and conform to the form and style guidelines. Subsection B was duplicative of the information in subsection A, and was unnecessary. If VDH or an external participant in VIIS were to disclose VIIS information for a purpose explicitly required or permitted by state or federal law, VDH does not need to approve that disclosure in advance. **Likely Impact:** The likely impact of this change is better clarity among the regulants. Required or permitted disclosures may take place with a lower administrative burden.
Forms (12VAC5-115)	N/A	Current documents listed in the Forms section: • Administrator Information • Electronic Data Exchange with VIIS • Information Systems Security Access Agreement • Organization Information, VIISORG • Memorandum of Agreement between Virginia Department of Health/Division of Immunization (VDH/DOI) and VIIS Organization	**Change:** Removes all forms except the VIIS patient opt-out form. Replaces the opt-out form with a link to the new electronic form. **Intent:** The intent of this change is to remove VIIS-related forms that are no longer used by VDH from the regulation. **Rationale:** The rationale for this change is that the VIIS system collects necessary registration, user, security, and confidentiality agreement information electronically, removing the need for paper forms and manual processes. The electronic opt-out form will be much easier to use for patients.

		Interested in Data Exchange • Virginia Immunization Information System (VIIS) Opt-In of VIIS • Virginia Immunization Information System (VIIS) Opt-Out of VIIS • VIIS Security Policy and User Confidentiality Agreement • VIIS User Acknowledgement Page • VIIS User Signature Page	**Likely Impact:** The likely impact is a reduction in regulatory burden on regulants due to fewer required forms and more streamlined electronic VIIS processes.