

Office of Regulatory Management
Economic Review Form

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	Amendment Resulting from Periodic Review
Date this document prepared	7/22/24
Regulatory Stage (including Issuance of Guidance Documents)	Fast Track

Cost Benefit Analysis

Complete Tables 1a and 1b for all regulatory actions. You do not need to complete Table 1c if the regulatory action is required by state statute or federal statute or regulation and leaves no discretion in its implementation.

Table 1a should provide analysis for the regulatory approach you are taking. Table 1b should provide analysis for the approach of leaving the current regulations intact (i.e., no further change is implemented). Table 1c should provide analysis for at least one alternative approach. You should not limit yourself to one alternative, however, and can add additional charts as needed.

Report both direct and indirect costs and benefits that can be monetized in Boxes 1 and 2. Report direct and indirect costs and benefits that cannot be monetized in Box 4. See the ORM Regulatory Economic Analysis Manual for additional guidance.

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

<p>(1) Direct & Indirect Costs & Benefits (Monetized)</p>	<p><u>Overall changes in the action</u></p> <p>Direct Costs: There are no direct monetized costs associated with any of the proposed regulatory changes.</p> <p>Indirect Costs: There are no indirect monetized costs associated with any of the proposed regulatory changes.</p> <p>Direct Benefits: Replacing or removing seven VIIS-related manual forms/processes and transitioning activities to the electronic portal is likely to improve efficiency of VIIS registration, onboarding, and reporting of immunization-related data. For health care providers and health care entities required to report, it could be more cost effective compared to faxing or mailing paper reports because those methods cost money for postage, fax lines, and paper. There may also be a reduction in staffing costs through more efficient processes and a reduction in labor necessary to process paper forms.</p> <p>Indirect Benefits: There are no indirect monetized benefits associated with any of the proposed regulatory changes.</p> <p><u>Specific changes</u></p> <p>Amended regulation to change VIIS registration, onboarding, and training from a manual process with paper forms to an electronic process to reflect current practice.</p> <ul style="list-style-type: none"> • Direct monetized benefits: Streamlining VIIS registration, onboarding, and training processes electronically may reduce costs to health care providers and health care entities through improved processes, increased efficiency, and reduction in manual paperwork. VDH is not able to quantify the direct monetary benefit of this regulatory change. The potential cost savings are difficult to quantify as costs will vary based on the salary of the employee entering data, the volume of immunizations administered at a practice, data exchange costs from electronic health record vendors, and employee efficiency while entering VIIS data. <p>Amended language to transition the VIIS opt-out process from a written notification to an electronic form.</p> <ul style="list-style-type: none"> • Direct monetized benefits: Streamlining the VIIS opt-out processes electronically may reduce costs to health care providers and health care entities through improved processes, increased efficiency, and reduction in manual paperwork. VDH is not able to quantify the direct monetary benefit of this regulatory change.
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	<p>The following changes have no direct or indirect monetized costs or benefits:</p> <ul style="list-style-type: none"> • Updated definitions for “health care entity”, “health care provider”, and “health plan” to reference the respective definitions in § 32.1-127.1:03 of the Code of Virginia • Clarifications to the regulatory language were made to ensure consistency throughout the regulation, provide clarity to regulants, and to conform to the Virginia Registrar’s <i>Form, Style and Procedure Manual for Publication of Virginia Regulations</i>. • Clarified required and authorized VIIS participant groups and VIIS purpose to align with §32.1-127.1:03, §8.01-581.1, and §32.1-46.01 of the Code of Virginia. • Amended language to reflect that the use of VIIS is limited to purposes listed in subsection A of §32.1-46.01 and does not include employers using VIIS to verify vaccination status of employees. • Added pulping and incineration as acceptable methods of immunization record destruction. • Amended language to reflect current standards of practice for VIIS system sign-on and account reactivation. • Clarified the demographic information that is required to be reported and removed demographic data that is not required to be reported to VIIS and changed reporting timeline to within three days of vaccine administration, which affects only manual data submissions. • Replaced the patient opt-out form with a link to the new electronic form. Removed references to unnecessary documents listed in the Forms Section. 	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$0
(3) Net Monetized Benefit	\$0	
(4) Other Costs & Benefits (Non-Monetized)	Non-monetized benefits: Some of these changes could result in more efficient reporting practices and eliminate redundant data reporting.	
(5) Information Sources	N/A	

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs: The current regulation affects health care providers, local health departments, and other entities that provide patient immunizations. These health care entities incur personnel costs related to mandatory input of patient immunizations into VIIS if they are reporting manually. Over 90% of immunization records received in VIIS are sent electronically through data exchange. The actual costs are difficult to quantify as costs will vary based on the salary of the employee entering data, the volume of immunizations that are administered at a practice, data exchange costs from electronic health record vendors, and employee efficiency while entering VIIS data. Additional costs may include computer equipment and internet access, but these costs would be negligible as health care entities would likely have computer equipment and internet access with or without these requirements.</p> <p>Indirect Costs: There are no monetized indirect costs associated with maintaining the current regulations.</p> <p>Direct Benefits: There are no monetized direct benefits associated with maintaining the current regulations.</p> <p>Indirect Benefits: There are no monetized indirect benefits associated with maintaining the current regulations.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$0
(3) Net Monetized Benefit	\$0	
(4) Other Costs & Benefits (Non-Monetized)	<p>If the regulations are maintained as currently written, health care providers, local health departments and other health care entities will maintain the same level of burden associated with immunization data reporting and efficiencies and modernization of the immunization data reporting process (VIIS) will be thwarted. This will result in less timely data, a decreased ability for health care providers to make appropriate immunization decisions for their patient population, and potential negative impact on the reduction of vaccine-preventable diseases.</p>	
(5) Information Sources	N/A	

Table 1c: Costs and Benefits under Alternative Approach(es)

(1) Direct & Indirect Costs &	VDH has not identified any viable alternative approaches beyond those described in the proposed action.
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Benefits (Monetized)		
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$0
(3) Net Monetized Benefit	\$0	
(4) Other Costs & Benefits (Non-Monetized)	N/A	
(5) Information Sources	N/A	

Impact on Local Partners

Use this chart to describe impacts on local partners. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 2: Impact on Local Partners

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs: Any clinics owned/operated by local government, such as local health departments, are affected by this regulation. Health care clinics will incur personnel costs related to mandatory input of patient immunizations into VIIS if they are reporting manually. Over 90% of immunization records received in VIIS are sent electronically through data exchange. The actual costs are difficult to quantify as costs will vary based on the salary of the employee entering data, the volume of immunizations administered at a practice, data exchange costs from electronic health record vendors, and employee efficiency while entering VIIS data. Additional costs may include computer equipment and internet access, but these costs would be negligible as clinics would likely have computer equipment and internet access with or without these requirements. For the purposes of this Form, VDH has assumed that all monetizable costs will be borne by health care providers. Some or all the costs may, however, be passed along to families in the form of higher health care costs.</p> <p>Indirect Costs: There are no monetized indirect costs on local partners associated with this action.</p> <p>Direct Benefits: This amendment streamlines VIIS through the use of electronic processes reducing the use of paper forms and manual registration, training, and data submission processes. This amendment</p>
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	<p>may reduce costs to local partners through improved processes and increased efficiency. The potential cost savings are difficult to quantify as costs will vary based on the salary of the employee entering data, the volume of immunizations administered at a practice, data exchange costs from electronic health record vendors, and employee efficiency while entering VIIS data.</p> <p>Indirect Benefits: There are no monetized indirect benefits on local partners associated with this action.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0 (but see explanation above)	(b) \$0 (but see explanation above)
(3) Other Costs & Benefits (Non-Monetized)	<p>Benefits:</p> <ul style="list-style-type: none"> (1) Health care providers have access to complete patient immunization records, enabling them to make appropriate and timely patient care decisions when treating patients. (2) VDH has access to patient immunization data, enabling the state agency to make appropriate and timely public health decisions, assess immunization coverage rates, and provide direction to health care providers and the public. (3) Enables VDH the ability to provide insurance carriers with Healthcare Effectiveness Data and Information Set (HEDIS) data which is used to evaluate program effectiveness. (4) Enables VDH to create and publish vaccination dashboards to inform the public about coverage for vaccine-preventable diseases in Virginia. 	
(4) Assistance	N/A	
(5) Information Sources	N/A	

Impacts on Families

Use this chart to describe impacts on families. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 3: Impact on Families

(1) Direct & Indirect Costs &	Direct Costs: There are no monetized direct costs on local partners associated with this action.
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Benefits (Monetized)	<p>Indirect Costs: Any costs incurred by families would be a result of a business choosing to pass staff costs along to consumers. These costs should be negligible.</p> <p>Direct Benefits: There are no monetized direct benefits on local partners associated with this action.</p> <p>Indirect Benefits: There are no monetized indirect benefits on local partners associated with this action.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0 (but see explanation above)	(b) \$0 (but see explanation above)
(3) Other Costs & Benefits (Non- Monetized)	<p>Benefits:</p> <ul style="list-style-type: none"> (1) Enhanced health care services - health care providers have access to complete patient immunization records, enabling them to make appropriate and timely patient care decisions when treating patients. (2) Enhanced public health services - VDH has access to patient immunization data, enabling the state agency to make appropriate and timely public health decisions and provide direction to health care providers and the public. (3) Patients have direct access to COVID-19 immunization records through a VDH-created electronic interface and all immunization records through a request process. 	
(4) Information Sources	N/A	

Impacts on Small Businesses

Use this chart to describe impacts on small businesses. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 4: Impact on Small Businesses

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs: Small Businesses, such as health care providers, are affected by this regulation. Small businesses will incur personnel costs related to mandatory input of patient immunizations into VIIS if they are reporting manually. Over 90% of immunization records received in VIIS are sent electronically through data exchange. The actual costs are difficult to quantify as costs will vary based on the salary of the employee entering data, the volume of immunizations that are</p>
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	<p>administered at a practice, data exchange costs from electronic health record vendors, and employee efficiency while entering VIIS data. Additional costs may include computer equipment and internet access, but these costs would be negligible as clinics would likely have computer equipment and internet access with or without these requirements. For the purposes on this Form, VDH has assumed that all monetizable costs will be borne by health care providers. Some or all the costs may, however, be passed along to families in the form of higher health care costs.</p> <p>Indirect Costs: There are no monetized indirect costs on local partners associated with this action.</p> <p>Direct Benefits: This amendment streamlines VIIS through the use of electronic processes reducing the use of paper forms and manual registration, training, and data submission processes. This amendment may reduce costs to local partners through improved processes and increased efficiency. The potential cost savings are difficult to quantify as costs will vary based on the salary of the employee entering data, the volume of immunizations administered at a practice, data exchange costs from electronic health record vendors, and employee efficiency while entering VIIS data.</p> <p>Indirect Benefits: There are no monetized indirect benefits on local partners associated with this action.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0 (but see explanation above)	(b) \$0 (but see explanation above)
(3) Other Costs & Benefits (Non-Monetized)	<p>Benefits:</p> <ul style="list-style-type: none"> (1) Health care providers have access to complete patient immunization records, enabling them to make appropriate and timely patient care decisions when treating patients. (2) VDH has access to patient immunization data, enabling the state agency to make appropriate and timely public health decisions, assess immunization coverage rates, and provide direction to health care providers and the public. (3) Enables VDH the ability to provide insurance carriers with Healthcare Effectiveness Data and Information Set (HEDIS) data which is used to evaluate program effectiveness. <p>Enables VDH to create and publish vaccination dashboards to inform the public about coverage for vaccine-preventable diseases in Virginia.</p>	

(4) Alternatives	N/A
(5) Information Sources	N/A

Changes to Number of Regulatory Requirements**Table 5: Regulatory Reduction**

For each individual action, please fill out the appropriate chart to reflect any change in regulatory requirements, costs, regulatory stringency, or the overall length of any guidance documents.

Change in Regulatory Requirements

VAC Section(s) Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
12VAC5-115-10	(M/A):	0	0	0	0
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
12VAC5-115-20	(M/A):	0	0	0	0
	(D/A):	2	+1	0	+1
	(M/R):	0	+1	0	+1
	(D/R):	0	0	0	0
12 VAC5-115-30	(M/A):	0	0	0	0
	(D/A):	3	0	0	0
	(M/R):	1	0	-1	-1
	(D/R):	11	0	-3	-3
12VAC5-115-40	(M/A):	0	0	0	0
	(D/A):	3	0	0	0
	(M/R):	0	0	0	0
	(D/R):	7	0	0	0
12VAC5-115-50	(M/A):	0	0	0	0
	(D/A):	4	0	0	0
	(M/R):	0	0	0	0
	(D/R):	5	0	-4	-4
12VAC5-115-60	(M/A):	0	0	0	0
	(D/A):	11	0	-3	-3
	(M/R):	0	0	0	0
	(D/R):	9	+1	0	+1
12VAC5-115-70	(M/A):	1	0	0	0
	(D/A):	3	0	-1	-1
	(M/R):	1	0	0	0

	(D/R):	1	0	0	0
	Grand Total of Changes in Requirements:	(M/A): 0			
		(D/A): -3			
		(M/R): 0			
		(D/R): -6			

Key:

Please use the following coding if change is mandatory or discretionary and whether it affects externally regulated parties or only the agency itself:

(M/A): Mandatory requirements mandated by federal and/or state statute affecting the agency itself

(D/A): Discretionary requirements affecting agency itself

(M/R): Mandatory requirements mandated by federal and/or state statute affecting external parties, including other agencies

(D/R): Discretionary requirements affecting external parties, including other agencies

Cost Reductions or Increases (if applicable)

VAC Section(s) Involved*	Description of Regulatory Requirement	Initial Cost	New Cost	Overall Cost Savings/Increases

Other Decreases or Increases in Regulatory Stringency (if applicable)

VAC Section(s) Involved*	Description of Regulatory Change	Overview of How It Reduces or Increases Regulatory Burden
12VAC5-115-40 (D)	Added pulping and incineration as acceptable methods of immunization record destruction.	Increases available pathways to compliance for regulants,
12VAC5-115-60 (C)	Decrease immunization administration reporting time frame from seven (7) days to three (3) days.	The regulatory change reduces the amount of time health care providers have to report to VIIS any immunizations administered. This change is minimal as the immunization data exchange occurs automatically each night. The reduced submission timeframes will only affect a small number of manual data submissions.
12VAC5-115-60 (D)	Remove social security number from the list of demographic information to be reported to VIIS.	Removal of one of the pieces of demographic information required to be reported to VIIS.

Length of Guidance Documents (only applicable if guidance document is being revised)

Title of Guidance Document	Original Word Count	New Word Count	Net Change in Word Count

*If the agency is modifying a guidance document that has regulatory requirements, it should report any change in requirements in the appropriate chart(s).