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## Periodic Review and Small Business Impact Review Report of Findings

<b>Agency name</b>	State Board of Health
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	12 VAC 5-218
<b>VAC Chapter title(s)</b>	Rules and Regulations Governing Outpatient Data Reporting
<b>Date this document prepared</b>	October 19, 2022

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*.

## Acronyms and Definitions

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

VDH- Virginia Department of Health

## 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 or 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, pursuant to § 32.1-12 of the Code of Virginia, is authorized 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.”

Section 32.1-276.2 of the Code of Virginia requires that the Board administer the health care data reporting initiatives established by Chapter 7.2, Title 32.1 of the Code.

Section 32.1-276.6 of the Code of Virginia requires the Board of Health to promulgate regulations specifying the format for submission of outpatient data.

**Alternatives to Regulation**

*Describe any viable alternatives for achieving the purpose of the regulation that were considered as part of the periodic review. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving its purpose.*

There are no viable alternatives for achieving the purpose of the existing regulations. Section 32.1-276.6 of the Code of Virginia requires the Board of Health to promulgate regulations specifying the format for submission of outpatient data. Amending the regulation is the least burdensome and most efficient approach to obtaining the desired outcome of VDH collecting more robust outpatient data and having consistency of definitions within its regulations.

**Public Comment**

*Summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency’s response. Be sure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. Indicate if an informal advisory group was formed for purposes of assisting in the periodic review.*

Commenter	Comment	Agency response
James B. Andrews III	<p>On behalf of the Virginia Hospital &amp; Healthcare Association’s (VHHA) 29 member health systems, representing 110 community, psychiatric, rehabilitation, and specialty hospitals, thank you for the opportunity to comment on the periodic review of regulations affecting the Virginia Department of Health and multiple regulations affecting data reporting.</p> <p>For 12 VAC 5-218, we would like to propose several modifications and additions in order that this chapter matches up more closely with chapter 217, which pertains to inpatient data. Since the establishment of these regulations, the place of service for patients has moved from the inpatient setting with a substantial and growing volume being performed on an</p>	<p>It is the decision of the Virginia Department of Health to amend the regulation and accept the Commenter’s recommended changes.</p>

	<p>outpatient basis. Accordingly, it is in the best interest of the Commonwealth to expand the data being collected in the outpatient setting, and the regulations should be adjusted to allow the ability to capture this information.</p> <p>In 12 VAC 5-218-10, the last sentence in the definition of “outpatient surgical procedures” which references a pilot study should be deleted.</p> <p>Two sections need to be added to chapter 218 so that the outpatient filing matches that of the inpatient filing. Sections 217-70 and 217-100 should be added to chapter 218 in order to allow VDH the opportunity to collect more robust outpatient data. The potential language would read:</p> <p><b>12VAC5-218-70. Establishment of Annual Fee.</b>  <i>The board shall not assess any fee against any health care provider that submits data under this chapter that is processed, verified, and timely in accordance with standards established by the board. The board shall prescribe a reasonable fee not to exceed \$1.00 per discharge for each outpatient provider submitting patient-level data pursuant to this chapter that is not processed, verified, or timely to cover the cost of the reasonable expenses in processing and verifying such data. The fee shall be established and reviewed annually by the board.</i></p> <p><b>12VAC5-218-100. Late Charge.</b>  <i>A late charge of \$25 per working day shall be paid to the board by an outpatient provider that does not submit, in aggregate, a complete filing of the patient-level data required by 12VAC5-218-20 for all outpatient procedures in a calendar year quarter pursuant to the times established in 12VAC5-218-60. This requirement may be waived by the board if a provider can show that an extenuating circumstance exists. Examples of an extenuating circumstance include, but are not limited to, the installation of a new computerized billing system, a bankruptcy proceeding, closure of the institution, change of ownership in the institution, or the institution is a new facility that has recently opened.</i></p> <p>Thank you for the opportunity to comment on these notices posted on June 9, 2019. Should you have any questions or require any additional information regarding our comments</p>	
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	<p>please do not hesitate to contact me at jandrews@vhha.com, 804-965-1229 at your convenience.</p>	
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**Effectiveness**

*Pursuant to § 2.2-4017 of the Code of Virginia, indicate whether the regulation meets the criteria set out in the ORM procedures, including why the regulation is (a) necessary for the protection of public health, safety, and welfare, and (b) is clearly written and easily understandable.*

The regulations meet the criteria set out in Executive Order 19 (2022) as they are necessary for the protection of public health, safety, and welfare of the citizens of the Commonwealth. The establishment of effective health care data analysis and reporting initiatives is essential to improving the quality and efficiency of health care, fostering competition among health care providers, and increasing consumer choice with regard to health care services in the Commonwealth. Accurate and valuable health care data can best be identified by representatives of state government and the consumer, provider, insurance, and business communities.

The regulations are clearly written and understandable.

**Decision**

*Explain the basis for the promulgating agency’s decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).*

*If the result of the periodic review is to retain the regulation as is, complete the ORM Economic Impact form.*

VDH is recommending the regulations be amended to reflect current outpatient data reporting requirement needs. Amending will also allow the language to be updated for consistency of the definitions within the regulation and allow for the consideration of public comments received.

**Small Business Impact**

*As required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency’s decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.*

The regulations are needed because the establishment of effective health care data analysis and reporting initiatives is essential to improving the quality and efficiency of health care, fostering competition among health care providers, and increasing consumer choice with regard to health

care services in the Commonwealth. The comments received from the Virginia Hospital & Healthcare Association (VHHA) reflect the need to amend the regulations, as they no longer accurately reflect the current outpatient data reporting needs. The regulations are clearly written and are not overly complex. The regulations do not overlap, duplicate, or conflict with federal or state law or regulation. The regulations have not been updated since 2015 and no longer accurately reflect the current outpatient data reporting landscape. VDH will convene an advisory panel to ensure the regulations minimize the economic burden on small businesses.

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