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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12-VAC5-218
VAC Chapter title(s)	Rules and Regulations Governing Outpatient Health Data Reporting
Action title	Amend Regulations Following Periodic Review 2022
Date this document prepared	October 27, 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*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation).

The intent of amending the Regulations Governing Outpatient Health Data Reporting 12VAC5-218 is to better align the chapter with inpatient-level data reporting requirements and to expand outpatient data reporting. Since the initial promulgation of these regulations, the provision of patient care has shifted away from the inpatient setting with a substantial and growing volume being provided in an outpatient setting.

While the inpatient-level data reporting requirements have consistently resulted in timely, comprehensive, and high-quality data collection, the current outpatient-level data collection standards have not achieved the same desired outcomes. The regulatory changes that will be proposed will leverage the knowledge gained over the past decades on the ideal scope and structure of the outpatient-level data system to make it consistent with mature programs in other states and to account for the trend of migration from inpatient to outpatient services. 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. [RIS2]
Acronyms and Definitions

Define all acronyms or technical definitions used in this form.

There are no acronyms or technical definitions used in this form.

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."

The Virginia Department of Health conducted a periodic review of the chapter pursuant to Executive Order 19 and § 2.2-4017 of the Code of Virginia. This periodic review resulted in the recommendation to amend 12VAC5-218 to reflect current outpatient data reporting requirement needs.

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, 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 State Board of Health 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 State Board of Health to promulgate regulations specifying the format for submission of outpatient data.

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

The inpatient-level data system has provided vital insights to the Virginia Department of Health, healthcare providers, health plans, and the medical research community for over 25 years. By

standardizing and expanding the outpatient level system, these groups will have access to comprehensive and trustworthy data to drive quality improvements in outpatient data procedures. While the collection of this data is very valuable to the Commonwealth, it does require time and resources on behalf of healthcare providers to submit. The level of effort required of facilities that have traditionally not submitted inpatient or outpatient-level data in the past should be monitored. VDH will also consider the increased cost of reporting and processing more data as part of a comprehensive outpatient-level system.

Substance

Briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

In order for 12VAC5-218 to more closely align with 12VAC5-217, VDH is considering the following modifications and additions that pertain to data collection:

- The establishment of new requirements in order to allow VDH to collect more robust outpatient data.
- The establishment of an annual fee for providers who do not submit their data in a timely manner.
- The establishment of a late fee for an outpatient provider that does not submit a complete filing of patient-level data required by 12VAC5-218-20 pursuant to the times established in 12VAC5-218-60.
- The deletion of the last sentence in the definition of “outpatient surgical procedures” in 12VAC5-218-10 due to its reference to a pilot study.
- Any other revisions to the regulations that may be proposed based on public comment or the regulatory advisory panel.

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 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. During this rulemaking process, the Board will consider all public comment received and will consult stakeholders to discuss any potential less intrusive or less costly alternatives for regulated entities, including small businesses.

Periodic Review and Small Business Impact Review Announcement

If you wish to use this regulatory action to conduct, and this NOIRA to announce, a periodic review (pursuant to § 2.2-4017 of the Code of Virginia and the ORM procedures), and a small business impact review (§ 2.2-4007.1 of the Code of Virginia) of this regulation, keep the following text. Modify it as

necessary for your agency. Otherwise, delete the paragraph below and insert “This NOIRA is not being used to announce a periodic review or a small business impact review.”

This NOIRA is not being used to announce a periodic review or a small business impact review.

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. In addition, as required by § 2.2-4007.02 of the Code of Virginia, describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

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, (ii) any alternative approaches, and (iii) the potential impacts of the regulation.

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 or email to:

Dr. Kindall Bundy, Office of Information Management
109 Governor Street, 4th floor
Richmond VA, 23219
vdh_oim_regulations@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.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.

A regulatory advisory panel will be convened to discuss the expansion of outpatient data reporting requirements.