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Fast-Track Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12-VAC5-217-20
VAC Chapter title(s)	Regulations of the Patient Level Data System
Action title	Amend Regulation to Update Data Element Reporting and Conform to Item 307 D1 of Chapter 1289 of the 2020 Acts of Assembly.
Date this document prepared	April 24, 2023 (updated February 6, 2024)

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 State Board of Health ("Board") proposes to amend 12VAC5-217-20, Regulations of the Patient Level Data System by permanently adopting the emergency regulation promulgated in January 2022 and updating the language to reflect current inpatient data reporting practices. Item 307 (D1) of Chapter 1289 of the 2020 Acts of Assembly ("2020 Appropriation Act") require**s** inpatient hospitals to report to the Board the admission source of any individuals meeting the criteria for voluntary or involuntary psychiatric commitment. To conform to this mandate, the emergency regulation was promulgated effective January 17, 2022. To make this regulation permanent, the Board proposes to adopt the emergency language through this Fast-Track action.

Additional amendments are proposed to conform the regulations to reflect the data reporting elements currently submitted by inpatient hospitals to Virginia Health Information (VHI). Non-regulatory language is

also being removed from 12VAC5-217-20 to conform to the *Form and Style Requirements* set forth by the Virginia Registrar of Regulations.

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.

DBHDS – Department of Behavioral Health and Developmental Services

VHI – Virginia Health Information

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 the Regulations of the Patient Level Data System (12VAC5-217-20) on June 15, 2023.

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.

Item 307 D1 of the 2020 Appropriation Act requires inpatient hospitals to report the admission source of any individuals meeting the criteria for voluntary or involuntary psychiatric commitment. Item 307(D2) required the Department of Health to promulgate regulations within 280 days from enactment of Chapter 1289 of 2020. A six-month extension to the emergency regulations was granted by the Governor, and the emergency regulation will expire January 15, 2024. The requirement in the 2020 Appropriation Act is also found in Item 307 D1 of Chapter 552 of the 2021 Acts of Assembly, Item 299 C1 of Chapter 2 of the 2022 Acts of Assembly, Special Session I (2022 Appropriation Act), and Item 299 C1 of the 2023 Acts of Assembly, Special Session I (2023 Appropriation Act.) To conform to the Acts of Assembly mandate, the Board is proposing to make the regulatory language permanent using this Fast-Track action.

Non-substantive changes are being made to conform the language to the Registrar of Regulation's *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

The rulemaking is expected to be noncontroversial because it is being utilized to conform the regulation to the legislative mandates and the existing data elements currently submitted by the inpatient hospitals in Virginia. Regulated entities are already submitting the data elements being added to the regulatory text because they are required by federal rules or because the data elements are part of the Uniform Billing Form, which is the standard claim form that hospitals use for all data related to hospital admissions and would be collected even if the Board did not require reporting of the data elements to VHI.

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 Code of Virginia § 32.1-12 gives the Board the responsibility to make, adopt, promulgate, and enforce regulations. Virginia Code § 32.1- 276.6(A) requires the Board to establish and administer an integrated system for collection and analysis of data which is used by consumers, employers, providers, purchasers of health care and state government. Section 32.1-276.6(B) of the Code of Virginia requires that every inpatient hospital shall submit to the Board patient level data containing the elements set forth in the regulations.

Item 307 (D1) of the 2020 Appropriation Act, Item 307 (D1) of the 2021 Appropriation Act, Item 299 (C1) of the 2022 Appropriation Act, and Item 299 (C1) of the 2023 Appropriation Act require inpatient hospitals to report the admission source of any individuals meeting the criteria for voluntary or involuntary psychiatric commitment as outlined in §§ 16.1-338, 16.1-339, 16.1-340.1, 16.1-345, 37.2-805, 37.2-809, or 37.2-904 of the Code of Virginia to the State Board of Health through the creation of the "Legal Status" field. The Board shall collect and share any and all data regarding the admission source of individuals admitted to inpatient hospitals as a psychiatric patient, pursuant to Virginia Code § 32.1-276.6, with the Department of Behavioral Health and Developmental Services (DBHDS).

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 justification for the regulatory change is that the regulation should incorporate all legislative mandates and existing data reporting requirements in order to be clear and understandable for regulated entities. The regulatory change is essential to protect the health, safety, or welfare of citizens because the current regulation does not reflect current data elements submitted by inpatient hospitals or the mandates set forth by the Acts of Assembly, therefore burdening the regulated community. The goals of the regulatory change are to make the mandates incorporated by the Acts of Assembly permanent before the expiration of the emergency extension deadline, and to conform the Regulations to reflect current data reporting elements submitted. The problems it is intended to solve is the understandability and clarity of the regulations, as well as the impending expiration deadline for the emergency regulation and the language within it. Amending the regulation to include the language mandated by the Acts of Assembly, updated data elements, and technical changes for form and style will ensure that the language from the emergency regulation is permanently adopted, that data elements reflect current industry practices, and that the regulation is clear and uniform.

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.

12VAC5-217-20. Reporting Requirements for patient level data elements

A new legal status field was added through the emergency language to include the provision of information required by Item 307 (D1) of the 2020 Appropriation Act. This change adds codes for the "legal status" of voluntary or involuntary psychiatric admissions. During the review of the emergency language, changes were proposed to it in order to conform the language to the Form and Style requirements.

During that review of the emergency language, the data element table is proposed to be replaced with a new table consisting of all data elements currently submitted by inpatient hospitals to VHI, as well as removal of non-regulatory references to the Uniform Billing Form and Manual.

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 are removal of non-regulatory language, addition of legislative mandates that had previously had not been incorporated into the regulations, and the addition of data elements currently submitted by inpatient hospitals. The primary advantages to VDH and the Commonwealth are increased clarity of the minimum requirements for the reporting requirements of inpatient hospitals of patient level data elements, hopefully reducing the staff time associated with reviewing incorrect or incomplete submissions, as well as the time associated with having those entities resubmit their data submissions. There are no disadvantages to the public or the Commonwealth. The new proposed data elements located in the data elements table and the "legal status" of admission are already submitted by hospital systems, therefore no additional regulatory burdens will result in this change to the regulation. VDH is not aware of any pertinent matters of interest to the regulated community, government officials, or the public.

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.

There are no regulatory requirements that exceed applicable federal requirements in this action.

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

There are no other state agencies that will be affected by this action.

Localities Particularly Affected

There are no localities that will be affected by this action.

Other Entities Particularly Affected

Other entities that could be affected by this proposed change are inpatient hospitals that submit patient data. However, all inpatient hospitals already submit each proposed data element, so amending the regulation will result in increased clarity of submission requirements, not an additional regulatory burden faced by the inpatient hospitals.

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	For VDH, the projected cost savings for updating the regulation are associated with complete and correct data submissions to VHI/VDH from inpatient hospitals. Submissions that are complete and correct take less time by a contracted vendor to review, and facilities will not have to take time to submit again, saving money for both the agency and hospitals.
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.	There are no known projected savings, fees, or revenues resulting from the regulatory change.
For all agencies: Benefits the regulatory change is designed to produce.	These amendments will conform the regulations to current practice and therefore will not have an economic impact on any state agencies. Amending the regulation to reflect current practice will increase clarity among the regulants and potentially decrease the number or incorrect, or incomplete data submissions received by VDH and VHI. Amending the regulation to adhere to the legislative mandate ensures the regulations stay in compliance, benefiting all agencies who utilize the regulatory chapter.

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.	There are no projected costs, savings, fees, or revenues resulting from the regulatory change.
Benefits the regulatory change is designed to produce.	These amendments will conform the regulations to current practice and therefore will not have an economic impact on affected entities. Removing non-regulatory language will increase the clarity and understandability of the Regulation. Amending the regulation to adhere to the legislative mandate ensures the regulations stay in compliance.

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.	Entities likely to be affected are inpatient hospitals in Virginia.
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.	There are 102 hospitals that submitted patient level data to VHI in Q3 of 2022, none of which qualify as small businesses. Therefore, no small businesses will be affected by the proposed changes.
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.	Inpatient hospitals are likely to experience a decrease in time spent towards data submission due to clearer element requirements. Hospitals will not have to resubmit their data more than once, saving time for the staff who prepare and submit the data. In FY2022, Inpatient hospitals were invoiced $22,614 due to incorrect or incomplete data reports. The proposed changes will address discrepancies in the regulation and make it clearer, which may help reduce the cost of correction for those data submissions currently faced by inpatient hospitals.
Benefits the regulatory change is designed to produce.	These amendments will conform the regulations to current practice and therefore will not have an economic impact on affected entities. Removing non-regulatory language will increase the clarity and understandability of the Regulation. Amending the regulation to adhere to the legislative mandate ensures the regulations stay in compliance.

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.

No alternative was considered because the General Assembly requires the Board to adopt regulations governing the reporting requirements for patient level data, and amending the regulation is the least burdensome, least intrusive, and less costly method to accomplish the purpose of this action. Amending the regulation to meet the Form and Style Requirements allows for the regulation to be more uniform and easier to understand.

The only alternative to amending the regulations by updating the data elements submitted by inpatient hospitals is the status quo, however, the status quo option does not accurately reflect in the regulations the data that inpatient hospitals submit.

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.

The Board is required to regulate the reporting requirements for patient level data elements pursuant to § 32.1-276.6 of the Code of Virginia. This regulatory action is the least burdensome method to conform the Regulations of the Patient Level Data System (12VAC5-217-20) to the statute. The proposed amendments are the least stringent method to ensure that the regulations accurately reflect current data submission elements and conform to the legislative mandates. The removal of non-regulatory language allows for regulants to comply with regulatory requirements without reading through unnecessary regulatory text or a separate document (i.e., The Uniform Billing Manual) to understand the reporting requirements.

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 Board 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: Townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Dr. Kindall Bundy, Policy Analyst, Virginia Department of Health, Office of Information Management, 109 Governor Street, 4th Floor, Richmond VA 23219; email: kindallbundy@vdh.virginia.gov; fax: (804) 229-0517. 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
217-20 (Emergency Regulation Language)	N/A		**Change:** Patient legal status has been added to the table of data elements submitted by inpatient hospitals. **Intent:** The intent of these changes is to conform to Chapter 1289 of 2020, Item 307(D1). **Rationale:** The patient-level discharge data submitted to VHI currently includes the patient's legal status due to the addition of this element through the previous emergency action. **Likely Impact:** The legal status field will be permanently adopted to the Regulation, allowing for better clarity among regulants and ensuring the

			Board is in compliance with the legislative mandates set forth by the Acts of Assembly.

*If the regulatory change is replacing an **emergency regulation**, and the proposed regulation is identical to the emergency regulation, complete Table 1 and/or Table 2, as described above.*

*If the regulatory change is replacing an **emergency regulation**, but changes have been made since the emergency regulation became effective, also complete Table 3 to describe the changes made since the emergency regulation.*

Table 3: Changes to the Emergency Regulation

Emergency chapter-section number	New chapter-section number, if applicable	Current emergency requirement	Change, intent, rationale, and likely impact of new or changed requirements since emergency stage
217-20	N/A	The current emergency requirement adds the Legal Status field to the reporting requirements.	**Change:** The emergency regulation language was updated with non-substantive changes **Intent:** The intent of this change is to conform to the Form and Style Guidelines **Rationale:** Conforming to the Form and Style Guidelines allows for better clarity among the regulants and allows for consistency in the Regulations **Likely Impact:** The likely impact of this change is better clarity among the regulants.
217-20	N/A	The regulatory text contains references to the Uniform Billing Form and Uniform Billing Manual. Additionally, for required elements not in the Uniform Billing Form, the text contains instructions to comply with the table's instructions for format of submitted data.	**Change**: References to the Uniform Billing Form (UB) are removed **Intent**: The intent of these changes is to conform to the form and style guidelines and remove non-regulatory language. **Rationale**: Removing non-regulatory language improves clarity of the regulation and conforms to the form and style guidelines. It appears that it was previously the Board's intent that the language served to incorporate the UB by reference to ensure that the data elements on the form and the instructions for submission of those elements. The regulation used to reference specific versions of the UB and contained cross-references between the listed data elements and their UB counterparts. The purpose of

			removing specific versions and instead referencing the ”latest publication of the Uniform Billing Manual…” was to “prevent the regulations from becoming outdated when changes are made to the billing forms,” as stated in the Agency Background Document of the regulatory action effective February 1, 2016. At the time that action was submitted for publication, 1VAC7-10 had not yet been promulgated; the Final exempt action which created the chapter was published in the following issue of the *Register* and went into effect January 1, 2016, subsequently prohibiting the adoption of prospective changes to an incorporated document. It is still the Board’s intent to require submission of the data elements contained in the UB, along with the additional elements otherwise required by state law or federal law or regulation. Pursuant to 1VAC7-10-140 and 1VAC7-10-160, the Board may not reference the “latest publication” of the UB, and thus would be required to pursue a regulatory action each time the UB is updated to add data elements. Because the Board is also requiring data elements beyond those included in the UB, it is most efficient to list all required data elements in the table in Section 20, which similarly require a regulatory action to update. This way, all requirements are listed in one place and the Board complies with the Virginia Code Commission’s regulations. **Likely Impact**: The likely impact of this change is better clarity among the regulants.
217-20		Current data elements listed in the stricken table: • Hospital identifier • Attending physician identifier • Other physician identifier • Payor identifier • Employer identifier • Patient identifier (SSN) • Patient sex • Race code	**Change**: Data elements listed in the new table (new elements bolded, emergency regulation language italicized): 1. Provider Number 2. Provider National Provider Identifier (NPI) **3. Patient Control Number** Part of the UB. This is how the hospitals identify specific medical records when they need to be re-accessed for any reason. Both VHI and hospitals find reporting this valuable.

		• Date of birth • Street address, city of county, and zip code • Employment status code • Patient status • Birth weight • Admission type • Admission source • Admission date • Admission hour • Admission diagnosis code • Discharge date • Principal diagnosis code • External cause of injury code • Co-morbid conditions existing but not treated • Principal procedure code and date • Revenue code Total charges	4. Discharge Date 5. Patient Zip Code 6. Patient Date of Birth 7. Patient Sex 8. Admission Date and Hour 9. Admission Type 10. Admission Source 11. Patient Discharge Status **12. Medical Record Number** Similarly to the Patient Control Number, this value is a submission associated with the UB and helps hospitals identify specific medical records. 13. Revenue Center Code 14. Revenue Center Units 15. Revenue Center Charges 16. Total Charges **17.** Payor Identifier **18. Patient Relationship to Insured A** This used to be in the Virginia Administrative Code but was removed for some reason in 2016. The agency background document submitted does not address the reason for the removal in the 2016. This value is part of how the "Payor Identifier" is reported. 19. Patient Social Security Number (SSN) 20. Employment Status Code 21. Employer Identifier 22. Principal Diagnosis Code **23. Other Diagnosis Code** 24. Admitting Diagnosis Code 25. External Cause of Injury 26. Principal Procedure Code 27. Principal Procedure Date 28. Other Procedure Code 29. Other Procedure Dates 30. Attending Physician 31. Operating Physician **32. Other Physician/Provider** 33. Infant Birth Weight 34. Patient Race 35. Patient Street Address 36. Patient City or County ***37. Patient Legal Status*** Added to conform to the 2021 Appropriation Act. **Intent**: The intent of these changes is to add data elements that are already submitted by inpatient hospitals to VHI.

			Rationale: Inpatient hospitals already submit this data to VHI. **Likely Impact**: The likely impact of this change is better clarity of the regulations and better understanding of the data element reporting requirements by the regulated community.