Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-217
Regulation title	Regulations of the Patient Level Data System
Action title	Amend regulation for clarity, efficiency and effectiveness following periodic review
Date this document prepared	July 23, 2013

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.

The State Board of Health (board) proposes to amend 12VAC5-217, Regulations of the Patient Level Data System by making corrections to outdated citations and to enhance the clarity of the regulations.

Statement of final agency action

Please 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.

These amendments to the Regulations of the Patient Level Data System (12VAC5-217) were approved by the State Health Commissioner, on behalf of the board while the board was not in session, on August 28th, 2013.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The regulation is promulgated under the authority of §32.1-12 and §32.17-276.2 of Chapter 7.2 of Title 32.1 of the Code of Virginia (Code). Section 32.1-12 grants the board the legal authority "to make, adopt, promulgate, and enforce such regulations necessary to carry out the provisions of Title 32.1 of the Code." Section 32.1-276.2 requires the board to administer the health care data reporting initiatives established by Chapter 7.2 of Title 32.1.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

To fulfill the statutory mandate to review regulations and to protect the citizens of the Commonwealth, the Department conducted a periodic review of 12 VAC 5-217 *et seq*. "Regulations of the Patient Level Data System" pursuant to Executive Order (EO) 14 (2010). As a result of this review, the Department determined it was necessary to use the regulatory process to amend these regulations. It is necessary to amend these regulations to make corrections to outdated citations and to enhance the clarity of the regulations in order to achieve improvements that will be reasonable, prudent and will not impose an unnecessary burden on the Virginia Department of Health or the public.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Please note: 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 (i) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

These amendments simply update the regulations to reflect current practice. The Department does not expect that this regulatory action will be controversial.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

12VAC5-217-10. Definitions. Amend this section to make corrections to three definitions and remove an unnecessary definition.

12VAC5-217-15 Requirements of Processed Verified Data - Create a new section. The substance of this section comes from the previous definition of Processed Verified Data. The definition had numerous substantive requirements which were not appropriate to be located in the definitions section.

12VAC5-217-20. Reporting requirements for patient level data elements. Amend this section to remove outdated citations. Add language to ensure the section does not become outdated due to later publications from the National Uniform Billing Committee. Add language clarifying that reporting requirements require a complete filing submitted in electronic format.

12VAC5-217-30. Options for filing format. Repeal this section.

12VAC5217-70. Establishment of annual fee. Amend this section to reflect current practice.

12VAC5-217-80. Payment of fee to nonprofit organization. Repeal this section.

12VAC5-217-90. Waiver or reduction of fee. Repeal this section.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

The purpose of the proposed regulatory action is to comply with the Code and to remove outdated regulations which no longer reflect current practice. There are no known disadvantages to the public, the regulated entities, business entities or the Commonwealth. The advantage will be greater clarity of the regulations.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.

There are no requirements in this proposal that exceed federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No locality will be particularly affected by the proposed regulation.

Regulatory flexibility analysis

Please 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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

The alternative regulatory methods are not applicable.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	Projected cost to the state is negligible.
Projected cost of the *new regulations or changes to existing regulations* on localities.	None
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	Virginia Health Information (VHI) and inpatient hospitals across the state.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are approximately 105 licensed hospitals in the Commonwealth.
All projected costs of the *new regulations or*	These amendments will conform the regulations to

***changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	current practice and therefore will not have an economic impact on affected entities.
Beneficial impact the regulation is designed to produce.	Greater clarity of the regulations as well as conforming the regulations to current practice.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

There are no other viable alternatives other than the proposed amendments to simplify the current regulations to be less burdensome, while also continuing to fulfill the board's statutory mandate to protect the citizens of the Commonwealth.

Periodic review/small business impact review result

If this fast-track regulation is <u>not the result</u> of a periodic review/small business of the regulation, please delete this entire section.

If this fast-track regulation <u>is</u> the result of a periodic review/small business impact review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, please include, pursuant to § 2.2-4007.1 E and F, a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the 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.

No comments were received from the public during the recent periodic review. There is a continued need for the regulation as it is mandated by law. The Department has not received any complaints or comments concerning the regulation from the public. The regulation is clearly written and easily understandable and the Department is confident based on this most recent review that the regulation does not overlap, duplicate or conflict with federal or state law or regulation.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The board has assessed the impact the proposed amendments will have on the institution of the family and family stability. The board anticipates no impact to the family or family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre**-emergency regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10 - Definitions		The following words and terms, when used in this chapter, shall have the following meanings: "Board" means the Virginia Board of Health. "Complete filing" means that patient level data of at least 99% of a hospital's inpatient discharges for a calendar year quarter are submitted. "Inpatient hospital" means a hospital providing inpatient care and licensed pursuant to Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia, a hospital licensed pursuant	The following words and terms, when used in this chapter, shall have the following meanings: "Board" means the Virginia Board of Health. "Complete filing" means that patient level data of at least 99% of a hospital's inpatient discharges for a calendar year quarter are submitted. "Inpatient hospital" means a hospital providing inpatient care and licensed pursuant to Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia, a hospital licensed pursuant to Article 2 (§ 32.2-403 et seq.) of Chapter 4 of Title 37.2 ~~Chapter 8 (§ 37.1-179 et seq.) of Title 37.1~~ of the Code of Virginia, a hospital operated by the

		to Chapter 8 (§ 37.1-179 et seq.) of Title 37.1 of the Code of Virginia, or a hospital operated by the University of Virginia or Virginia Commonwealth University. "Nonprofit organization" means a nonprofit, tax-exempt health data organization with expertise and capacity to execute the powers and duties set forth for such entity in Chapter 7.2 (§ 32.1-276.2 et seq.) of Title 32.1 of the Code of Virginia and with which the Commissioner of Health has entered into a contract as required by the Code of Virginia. "Processed, verified data" means data on inpatient records which have been subjected to edits. These edits shall be applied to data elements which are on the UB-92 Billing Form (or a successor Billing Form adopted by the Virginia Uniform Billing Committee for use by inpatient hospitals in Virginia). The edits shall have been agreed to by the board and the nonprofit organization. Inpatient records containing invalid UB-92 codes or all blank fields for any of the data elements subjected to edits shall be designated as error records. To be considered processed and verified, a complete filing of all records which are submitted by an inpatient hospital in aggregate per calendar year quarter and which are subjected to these edits must be free of error at a prescribed minimum rate. The prescribed minimum error rate shall be 95% overall, with patient identifier	Department of Behavioral Health and Developmental Services for the care and treatment of individuals with mental illness, or a hospital operated by the University of Virginia or Virginia Commonwealth University Health System Authority. "Nonprofit organization" means a nonprofit, tax-exempt health data organization with the characteristics, expertise and capacity to execute the powers and duties set forth for such entity in Chapter 7.2 (§ 32.1-276.2 et seq.) of Title 32.1 of the Code of Virginia and with which the Commissioner of Health has entered into a contract as required by § 32.1-276.4 the Code of Virginia. "Processed, verified data" means data on inpatient records which have been subjected to the edits which have been specified in 12VAC5-217-15. ~~These edits shall be applied to data elements which are on the UB-92 Billing Form (or a successor Billing Form adopted by the Virginia Uniform Billing Committee for use by inpatient hospitals in Virginia). The edits shall have been agreed to by the board and the nonprofit organization. Inpatient records containing invalid UB-92 codes or all blank fields for any of the data elements subjected to edits shall be designated as error records. To be considered processed and verified, a complete filing of all records which are submitted by an inpatient hospital in aggregate per calendar year quarter and which are subjected to these edits must be free of error at a prescribed minimum rate. The prescribed minimum error rate shall be 95% overall, with patient identifier separately calculated at 95% or a minimum rate recommended by the board of directors of the nonprofit organization and approved by the Virginia Board of Health. The error rate shall be calculated on only those fields designated in 12VAC5-217-20 or as subsequently approved by the board through the process specified in 12VAC5-217-20.~~ ~~"System" means the Virginia Patient Level Data System.~~

		separately calculated at 95% or a minimum rate recommended by the board of directors of the nonprofit organization and approved by the Virginia Board of Health. The error rate shall be calculated on only those fields designated in 12VAC5-217-20 or as subsequently approved by the board through the process specified in 12VAC5-217-20. "System" means the Virginia Patient Level Data System.	Intent: Amend the definition of "inpatient hospital" to reflect the definition in the Code of Virginia. Amend the definition of nonprofit organization to reflect the definition in the Code of Virginia. Remove the substantive requirements from the definition of processed verified data and remove the unnecessary definition of system. Impact: Greater clarity of the regulations.
	15 - Requirements of Processed Verified Data	N/A	Inpatient hospitals shall submit only processed verified data from inpatient records. To be considered processed and verified, a complete filing of all records which are submitted by an inpatient hospital in aggregate per calendar year quarter must be free of error at a prescribed minimum rate. The prescribed minimum accuracy rate shall be 95% overall, with patient identifier separately calculated at 95% or a minimum rate recommended by the board of directors of the nonprofit organization and approved by the Virginia Board of Health. The accuracy rate shall be calculated on only those fields designated in 12VAC5-217-20. Inpatient records containing invalid codes or blank fields for any of the data elements shall be designated as error records. Intent: To remove the substantive requirements of Processed Verified data from the definitions section. Impact: Greater clarity of the regulations.
20 - Reporting requirements for patient level data elements.		Every inpatient hospital shall submit each patient level data element listed below for each hospital inpatient, including a separate record for each infant, if applicable. Most of these data elements are currently collected from a UB-92 Billing Form. The	Every inpatient hospital shall submit a complete filing of each patient level data element listed below for each hospital inpatient, including a separate record for each infant, if applicable. Most of these data elements are currently collected from a Uniform~~UB-92~~ Billing Form located in the latest publication of the Uniform Billing Manual prepared by the

		column for a "Form Locator" indicates where the data element is located on the UB-92. For elements collected on the UB-92, the column "Page Number" refers to the Uniform Billing Manual (UB-92), revised May, 1993. The Uniform Billing Manual UB-92, prepared for Virginia hospitals by the Virginia Uniform Billing Committee, provides a detailed field description and any special instructions pertaining to that element. An asterisk (*) indicates when the required data element is either not on the UB-92 or in the Uniform Billing Manual. The instructions provided under that particular data element should then be followed. If a successor billing form to the UB-92 form is adopted by the Virginia Uniform Billing Committee for use by inpatient hospitals in Virginia, information pertaining to the data elements listed below should be derived from that successor billing form.	National Uniform Billing Committee. ~~The column for a "Form Locator" indicates where the data element is located on the UB-92. For elements collected on the UB-92, the column "Page Number" refers to the Uniform Billing Manual (UB-92), revised May, 1993.~~ The Uniform Billing Manual ~~UB-92, prepared for Virginia hospitals by the Virginia Uniform Billing Committee,~~ provides a detailed field description and any special instructions pertaining to that element. An asterisk (*) indicates when the required data element is either not on the Billing Form ~~UB-92~~ or in the Uniform Billing Manual. The instructions provided under that particular data element should then be followed. Inpatient hospitals that submit patient level data directly to the board or the nonprofit organization shall submit it in an electronic data format. ~~If a successor billing form to the UB-92 form is adopted by the Virginia Uniform Billing Committee for use by inpatient hospitals in Virginia, information pertaining to the data elements listed below should be derived from that successor billing form.~~ Intent: Amend this section to update citations to the Uniform Billing Manual and remove the field locators from the chart. VDH anticipates the proposed change will prevent the regulations from becoming outdated when changes are made to the billing forms. Remove citations to the Virginia Uniform Billing Committee as this Committee no longer exists. Also add language clarifying that the data must be submitted in electronic format Impact: Greater clarity.
30- ~~Options for filing format.~~		Inpatient hospitals of 100 beds or more that submit patient level data directly to the board or the nonprofit organization shall submit it in an electronic data format. Hospitals of less than 100 beds that submit patient level data directly to the board or the nonprofit organization may directly submit it in electronic data	~~Inpatient hospitals of 100 beds or more that submit patient level data directly to the board or the nonprofit organization shall submit it in an electronic data format. Hospitals of less than 100 beds that submit patient level data directly to the board or the nonprofit organization may directly submit it in electronic data format or in hard copy. If hard copy is utilized the hospital shall submit, for each inpatient discharged, a copy of the UB-92 and an addendum sheet for~~

		format or in hard copy. If hard copy is utilized the hospital shall submit, for each inpatient discharged, a copy of the UB-92 and an addendum sheet for those data elements not collected on the UB-92 or defined in the Uniform Billing Manual. These hospitals must submit all patient level data in electronic data format by January 1, 1995. If a hospital submits processed, verified data directly to the nonprofit organization, it shall be in electronic format	~~those data elements not collected on the UB-92 or defined in the Uniform Billing Manual. These hospitals must submit all patient level data in electronic data format by January 1, 1995.~~ ~~If a hospital submits processed, verified data directly to the nonprofit organization, it shall be in electronic format.~~ Intent: Repeal an unnecessary section of the regulations. The requirement for filing format has been moved to Section 20 as it is not necessary for filing format to be a separate section. Impact: Greater clarity and accuracy of the regulations.
70 - Establishment of annual fee.		The board shall prescribe a reasonable fee not to exceed $1.00 per discharge for each inpatient hospital submitting patient level data pursuant to this chapter 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. Payment of the fee by a hospital shall be at the time quarterly inpatient data is submitted.	The board shall <u>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</u> prescribe a reasonable fee not to exceed $1.00 per discharge for each inpatient hospital submitting patient level data pursuant to this chapter <u>which is not processed, verified and/or timely</u> 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. ~~Payment of the fee by a hospital shall be at the time quarterly inpatient data is submitted.~~ Intent: Amend this section so that a fee is only assessed on those institutions which submit data which is not processed, verified and/or timely. This change reflects current practice. Impact: Greater clarity and accuracy of the regulations
80 - ~~Payment of fee to nonprofit organization.~~		If an inpatient hospital chooses to submit its patient level data directly to the nonprofit organization, that hospital may pay the fee described in 12VAC5-217-70 to the nonprofit organization at the time it submits its quarterly data. If	~~If an inpatient hospital chooses to submit its patient level data directly to the nonprofit organization, that hospital may pay the fee described in 12VAC5-217-70 to the nonprofit organization at the time it submits its quarterly data. If a hospital pays its fee directly to the nonprofit organization, the requirements of a fee to be paid to the board, as~~

		a hospital pays its fee directly to the nonprofit organization, the requirements of a fee to be paid to the board, as described in 12VAC5-217-70, shall be waived by the board.	~~described in 12VAC5-217-70, shall be waived by the board.~~ Repeal this section. This process is not utilized. Impact: Greater clarity and accuracy of the regulations.
90 - ~~Waiver or reduction of fee.~~		If a hospital submits processed, verified patient level data to the nonprofit organization, the nonprofit organization may, in its discretion, grant a waiver or reduction of the fee if it determines that the hospital has submitted properly processed, verified data.	~~If a hospital submits processed, verified patient level data to the nonprofit organization, the nonprofit organization may, in its discretion, grant a waiver or reduction of the fee if it determines that the hospital has submitted properly processed, verified data.~~ Intent: Repeal this section. The non-profit does not charge a fee to inpatient hospitals which submit processed, verified and timely data. Impact: Greater clarity and accuracy of the regulations.