Form: TH-04 April 2020



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Fast-Track Regulation Agency Background Document

Agency name	Virginia Board of Health		
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC5-410-10 et seq.		
VAC Chapter title(s)	Regulations for the Licensure of Hospitals in Virginia		
Action title	Amend Regulations to Conform to Ch. 433 of the 2019 Acts of Assembly		
Date this document prepared	November 5, 2020		

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), 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.

Ch. 433 of the 2019 Acts of Assembly amended and reenacted Va. Code § 32.1-134.01 to add perinatal anxiety to the list of information hospitals are required to make available to maternity patients, the father of the infant, and other relevant family members or caretakers prior to such patients' discharge. The existing list of information from that Code section is not currently included in the hospital regulations and the Board is using this action to conform to the requirements of Va. Code § 32.1-134.01. The Board is also using this action to correct a spelling error in 12VAC5-410-441.

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.

"Board" means the Virginia Board of Health.

Statement of Final Agency Action

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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.

Enter statement here

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 Executive Order 14 (as amended, July 16, 2018), "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."

As required by Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

Ch. 433 of the 2019 Acts of Assembly amended and reenacted Va. Code § 32.1-134.01 to add perinatal anxiety to the list of information hospitals are required to make available to maternity patients, the father of the infant, and other relevant family members or caretakers prior to such patients' discharge. The existing list of information from that Code section is not currently included in the hospital regulations.

As the rulemaking is being utilized to conform to the statute and no new requirements are being developed, it is expected to be noncontroversial.

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.

Va. Code § 32.1-12 gives the Board the responsibility to make, adopt, promulgate, and enforce such regulations as may be necessary to carry out the provisions of Title 32.1 of the Code of Virginia. Va. Code § 32.1-127 requires the Board to adopt regulations that include minimum standards for (i) the construction and maintenance of hospitals, nursing homes and certified nursing facilities to ensure the environmental protection and the life safety of its patients, employees, and the public; (ii) the operation, staffing and equipping of hospitals, nursing homes and certified nursing facilities; (iii) qualifications and training of staff of hospitals, nursing homes and certified nursing facilities, except those professionals licensed or certified by the Department of Health Professions; (iv) conditions under which a hospital or nursing home may provide medical and nursing services to patients in their places of residence; and (v) policies related to infection prevention, disaster preparedness, and facility security of hospitals, nursing homes, and certified nursing facilities.

Purpose

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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's intended to solve.

This regulation is being amended due to the changes to Va. Code § 32.1-143.01. The Board is required by Va. Code § 32.1-127 to promulgate regulations for the licensure of hospitals in order to protect the health, safety, and welfare of citizens receiving care in hospitals. The goal of the regulatory change is to conform the regulations to the statute. It is intended to increase maternity patients' knowledge and awareness of certain information that protects the health, safety, and welfare of new mothers and their infants.

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.

12VAC5-410-441: A new subdivision is added to require the provision of information pursuant to Va. Code § 32.1-134.01.

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.

This action is being used to conform the regulations to existing requirements in the statute. The advantage to the public and the Commonwealth is that the regulations are in compliance with legislative changes enacted by the 2019 General Assembly. There are no disadvantages to the public, the agency, or the Commonwealth.

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 requirements in this proposal that exceed applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "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

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regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

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Other State Agencies Particularly Affected

No other state agency is particularly affected.

Localities Particularly Affected

No locality is particularly affected.

Other Entities Particularly Affected

The 106 licensed inpatient hospitals and 63 outpatient surgical hospitals will be required to comply with the provision.

Economic Impact

Pursuant to § 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 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	None
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.	None
For all agencies: Benefits the regulatory change is designed to produce.	None

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
<u> </u>	
Benefits the regulatory change is designed to	None
produce.	

Impact on Other Entities

Description of the individuals, businesses, or other	Licensed inpatient hospitals and licensed
entities likely to be affected by the regulatory	outpatient surgical hospitals.

change. If no other entities will be affected, include a specific statement to that effect.	
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.	106 inpatient hospitals and 63 outpatient surgical hospitals. Three of the outpatient surgical hospitals are estimated to meet the definition of "small business"
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.	As all licensed hospitals are required to comply with the Code of Virginia, there are no projected costs for compliance with the regulatory change.
Benefits the regulatory change is designed to produce.	The regulatory change is designed to conform the regulations to the Code of Virginia.

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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 to conform the regulations to the statutes. As the requirement to provide information on perinatal anxiety is already present in statute, there are no additional costs for small businesses associated with compliance with the regulation.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B 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 licensure of hospitals consistent with the provisions of Article 1 (Va. Code § 32.1-127 *et seq.*) of Chapter 5, Title 32.1 of the Code of Virginia. Initiation of this regulatory action

is the least burdensome method to conform the Regulations for the Licensure of Hospitals in Virginia (12VAC5-410) to the statute.

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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.

As required by § 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: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Rebekah E. Allen, Senior Policy Analyst, Virginia Department of Health, Office of Licensure and Certification, 9960 Mayland Drive, Suite 401, Henrico, VA 23233; email: regulatorycomment@vdh.virginia.gov; fax: (804) 527-4502. 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 <u>existing</u> 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 <u>and replaced</u>, 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 section	New	Current requirement	Change, intent, rationale, and
number	section		likely impact of new
	number, if		requirements
	applicable		

12VAC5-408-10. Definitions	N/A	There is no existing definition for "health care provider" or "provider," "managed care plan," "new provider applicant," or "participating provider."	CHANGE: The following definitions have been added: "Health care provider" or "provider" has the same meaning ascribed to the term in subsection B of § 32.1-127.1:03 of the Code of Virginia.
			"Managed care plan" means a health benefit plan, as defined in § 38.2-3407.10:1 of the Code of Virginia, that requires a covered person to use, or creates incentives, including financial incentives, for a covered person to use health care providers managed, owned, under contract with, or employed by the MCHIP licensee.
			"New provider applicant" means a provider who has submitted a completed credentialing application to an MCHIP licensee.
			"Participating provider" means a provider who is managed, under contract with, or employed by an MCHIP licensee and who has agreed to provide health care services to covered persons with an expectation of receiving payments, other than coinsurance, copayments, or deductibles, directly or indirectly from the MCHIP licensee.
			INTENT: The intent of these changes is to conform to § 38.2-3407.10:1, pursuant to Ch. 703 of the 2018 Acts of Assembly and to ensure the scope of definitions are in line with the Board's existing authority to regulation MCHIP licensees.
			RATIONALE: Where Ch. 703 (2018 Acts of Assembly) uses the word "carrier," the Board is using the term "MCHIP licensee" as it is already defined in the regulations and refers to the same entity; additionally, the Board presently

			only has regulatory authority over MCHIPs and not all health insurance entities. Where Ch. 703 (2018 Acts of Assembly) uses the word "physician," the Board is using the word "provider" for consistency with the MCHIP licensees' current credential practice that covers all providers. Where Ch. 703 (2018 Acts of Assembly) uses the term "health benefit plan," the Board is using the term "managed care plan" as it is more specific to the regulated health benefit plans being offered by MCHIP licensees. As it relates to the Board's regulation of MCHIP licensees, the Board confines the term "covered person" in the regulations to residents of the Commonwealth, as the Board has no enforcement mechanisms to regulate the coverage of out-of-state persons. LIKELY IMPACT: These proposed changes will provide clarity as to whom and what is covered by the new credentialing changes in Section 170.
12VAC5-408-170. Provider credentialing and recredentialing.	N/A	A. The MCHIP licensee shall establish and maintain a comprehensive credentialing verification program to ensure its providers meet the minimum standards of professional licensure or certification. Written supporting documentation for providers who have completed their residency or fellowship requirements for their specialty area more than 12 months prior to the credentialing decision shall include: 1. Current valid license and history of licensure or certification; 2. Status of hospital privileges, if applicable; 3. Valid DEA certificate, if applicable;	CHANGE: The following subsections have been struck from the regulatory text and the remaining subsections have been re-lettered: F. The appropriate credentialing process shall be completed before the provider: 1. Begins seeing covered persons; 2. Enters into the employment or contractual relationship with the MCHIP licensee; and 3. Is included in the listing of health care providers as a participating provider in any marketing and covered person materials.

- 4. Information from the National Practitioner Data Bank, as available:
- 5. Education and training, including post graduate training, if applicable;
- 6. Specialty board certification status, if applicable;
- 7. Practice or work history covering at least the past five years; and
- 8. Current, adequate malpractice insurance and malpractice history of at least the past five years.
- B. The MCHIP licensee may grant provisional credentialing for providers who have completed their residency or fellowship requirements for their specialty area within 12 months prior to the credentialing decision. Written supporting documentation necessary to provisionally credential a practitioner shall include:
- 1. Primary source verification of a current, valid license to practice prior to granting the provisional status:
- 2. Written confirmation of the past five years of malpractice claims or settlements, or both, from the malpractice carrier or the results of the National Practitioner Data Bank query prior to granting provisional status; and
- 3. A completed application and signed attestation.
- C. Providers provisionally credentialed may remain so for 60 calendar days.

The following subsections have been added to the regulatory text:

- O. The MCHIP licensee shall establish protocols and procedures for reimbursing new provider applicants, after being credentialed by the MCHIP licensee, for health care services provided to covered persons during the period in which the new provider applicant's completed credentialing application was pending. At a minimum, the protocols and procedures shall:
- 1. Apply only if the new provider applicant's credentialing application is approved by the MCHIP licensee;
- 2. Permit provider reimbursement for services rendered from the date the new provider applicant's completed credentialing application is received for consideration by the MCHIP licensee;
- 3. Apply only if a contractual relationship exists between the MCHIP licensee and the new provider applicant or entity for whom the new provider applicant is employed or engaged; and
- 4. Require that any reimbursement be paid at the innetwork rate that the new provider applicant would have received had the provider been, at the time the covered health care services were provided, a credentialed participating provider in the network for the applicable managed care plan.
- P. Nothing in this section shall require:
- 1. Reimbursement of providerrendered services that are not benefits or services covered by

- D. Policies for credentialing and recredentialing shall include:
- 1. Criteria used to credential and recredential:
- 2. Process used to make credentialing and recredentialing decisions;
- 3. Type of providers, including network providers, covered under the credentialing and recredentialing policies;
- 4. Process for notifying providers of information obtained that varies substantially from the information provided by the provider;
- 5. Process for receiving input from participating providers to make recommendations regarding the credentialing and recredentialing process; and
- 6. A requirement that the MCHIP licensee notify the applicant within 60 calendar days of receipt of an application if information is missing or if there are other deficiencies in the application. The MCHIP licensee shall complete the credentialing process within 90 calendar days of the receipt of all such information requested by the MCHIP licensee or, if information is not requested from the applicant, within 120 calendar days of receipt of an application. The department may impose administrative sanctions upon an MCHIP licensee for failure to credentialing complete the process as provided herein if it finds that such failure occurs with such frequency as to constitute a general business practice.

The policies shall be made available to participating

the MCHIP licensee's managed care plan.

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- 2. An MCHIP licensee to pay reimbursement at the contracted in-network rate for any covered health care services provided by the new provider applicant if the new provider applicant's credentialing application is not approved or the MCHIP licensee is otherwise not willing to contract with the new provider applicant.
- Q. Payments made or retroactive denials of payments made under this section shall be governed by § 38.2-3407.15.
- R. If a payment is made by the MCHIP licensee to a new provider applicant or any entity that employs or engages a new provider applicant under this section for a covered service, the patient shall only be responsible for any coinsurance, copayments, or deductibles permitted under the insurance contract with the MCHIP licensee or participating provider agreement with the provider.
- S. A new provider applicant, in order to submit claims to the MCHIP licensee pursuant to this section, shall provide written or electronic notice to covered persons in advance of treatment that:
- 1. The provider has submitted a credentialing application to the MCHIP licensee of the covered person; and
- 2. The MCHIP licensee is in the process of obtaining and verifying the written documentation from the new provider applicant, pursuant to 12VAC5-408-170 A.

The written or electronic notice shall conform to the requirements

providers and applicants upon written request.

E. A provider fully credentialed by an MCHIP licensee, who his changes place employment or his nonMCHIP licensee employer, shall, if within 60 calendar days of such change and if practicing within the same specialty, continue to be credentialed by that MCHIP licensee upon receipt by the MCHIP licensee of the following:

- 1. The effective date of the change;
- 2. The new tax ID number and copy of W-9, as applicable;
- 3. The name of the new practice, contact person, address, telephone and fax numbers; and
- 4. Other such information as may materially differ from the most recently completed credentialing application submitted by the provider to the MCHIP licensee.

This provision shall not apply if the provider's prior place of employment or employer had been delegated credentialing responsibility by the MCHIP licensee.

Nothing in this section shall be construed to require an MCHIP licensee to contract or recontract with a provider.

- F. The appropriate credentialing process shall be completed before the provider:
- 1. Begins seeing covered persons;
- 2. Enters into the employment or contractual relationship with the MCHIP licensee: and

in § 38.2-3407.10:1 G of the Code of Virginia.

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Statutory Authority § 32.1-12 and 32.1-137.3 of the Code of Virginia.

INTENT: Subsection F of the existing regulation is inconsistent with the new § 38.2-3407.10:1 of the Code of Virginia. The intent is to allow physicians and non-physician providers to provide care to covered persons of an MCHIP during the pendency of their credentialing application and to receive reimbursement from the MCHIP carrier, provided that their application is approved

RATIONALE: MCHIP licensees presently credential and contract physicians and other healthcare providers: to differentiate between physician and non-physicians for the purposes of credentialing would require MCHIP licensees to set up two separate credentialing procedures. protocols and including two different billing practices. Aside from being administratively burdensome for the MCHIP licensee, it would also complicate VDH's annual regulatory examination of the MCHIP licensees.

LIKELY IMPACT: It is expected that physicians and non-physician providers will exercise this new ability and begin to see MCHIP-covered persons while their completed credentialing application is pending. The MCHIP licensees will have to establish the protocols and procedures outlined by § 38.2-3407:10.1.

3. Is included in the listing of health care providers as a participating provider in any marketing and covered person materials.

- G. The providers shall be recredentialed at least every three years. Recredentialing documentation shall include:
- 1. Current valid license or certification;
- 2. Status of hospital privileges, if applicable;
- 3. Current valid DEA registration, if applicable;
- 4. Specialty board eligibility or certification status, if applicable;
- 5. Data from covered person complaints and the results of quality reviews, utilization management reviews and covered persons satisfaction surveys, as applicable; and
- 6. Current, adequate malpractice insurance and history of malpractice claims and professional liability claims resulting in settlements or judgments.
- H. All information obtained in the credentialing process shall be subject to review and correction of any erroneous information by the health care provider whose credentials are being reviewed. Nothing in the previous sentence shall require an MCHIP or MCHIP licensee to disclose to a provider, or any other person or party, information or documents: (i) that the MCHIP or the MCHIP licensee, itself, develops or causes to be developed as part of the MCHIP's credentialing process or (ii) that are privileged under applicable law. The

department may require the MCHIP licensee to provide a copy of its credentialing policies.

- I. Providers shall be required by the MCHIP licensee to notify the MCHIP of any changes in the status of any credentialing criteria.
- J. The MCHIP licensee shall not refuse to initially credential or refuse to reverify the credentials of a health care provider solely because the provider treats a substantial number of patients who require expensive or uncompensated care.
- K. The MCHIP licensee shall have policies and procedures for altering the conditions of the provider's participation with the MCHIP licensee. The policies shall include actions to be taken to improve performance prior to termination and an appeals process for instances when the MCHIP licensee chooses to alter condition of provider participation based on issues of quality of care or service, except in circumstances where an covered person's health has been jeopardized. Providers shall have complete and timely access to all data information used by the licensee to identify or determine the need for altering the conditions of participation.
- L. The MCHIP licensee shall retain the right to approve new providers and sites based on quality issues, and to terminate or suspend individual providers. Termination or suspension of individual providers for quality of care considerations shall be supported by documented records of noncompliance with specific MCHIP expectations and requirements for providers. The provider shall have a prescribed system of appeal of

this decision available to them as prescribed in the contract between the MCHIP or its delegated service entity and the provider.

M. Providers shall be informed of the appeals process. Profession

- M. Providers shall be informed of the appeals process. Profession specific providers actively participating in the MCHIP plan shall be included in reviewing appeals and making recommendations for action.
- N. The MCHIP licensee shall notify appropriate authorities when a provider's application or contract is suspended or terminated because of quality deficiencies by the health care provider whose credentials are being reviewed.
- O. There shall be an organized system to manage and protect the confidentiality of personnel files and records. Records and documents relating to a provider's credentialing application shall be retained for at least seven years.