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Fast-Track Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-410-10 <i>et seq.</i>
VAC Chapter title(s)	Regulations for the Licensure of Hospitals in Virginia
Action title	Amend Regulation after Enactment of Chapters 712 and 772 of the 2022 Acts of Assembly
Date this document prepared	November 16, 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 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.

Chapters 712 and 772 of the 2022 Acts of Assembly require the State Board of Health to amend its hospital regulation to exempt from licensure temporary increase in the total number of beds in an existing hospital to include “a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the hospital..., provided that the ability remains to safely staff services across the existing hospital...” These acts also amended the exemption to now also be triggered by an emergency order entered pursuant to Va. Code § 32.1-13 or 32.1-20 for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health.

The duration of this exemption was amended to be either “a period of no more than the duration of the Commissioner's determination plus 30 days...when the Commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health

emergency exists due to a shortage of hospital or nursing home beds” or “a period of no more than the duration of the emergency order entered pursuant to § 32.1-13 or 32.1-20 plus 30 days.”

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 State Board of Health.

“Commissioner” means the State Health Commissioner.

“VDH” means the Virginia Department of Health.

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 Board approved the fast-track amendments for 12VAC5-410-10 *et seq.*, Regulations for the Licensure of Hospitals in Virginia on June 23, 2022.

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.

Chapters 712 and 772 of the 2022 Acts of Assembly require the State Board of Health to amend its hospital regulation to exempt from licensure a temporary increase in the total number of beds in an existing hospital to include “a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the hospital..., provided that the ability remains to safely staff services across the existing hospital...” These acts also amended the exemption to now also be triggered by an emergency order entered pursuant to Va. Code § 32.1-13 or 32.1-20 for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health. These acts also amended the duration of the exemption.

It is anticipated that this action will be noncontroversial and therefore appropriate for the fast-track process because the minimum information required when requesting temporary beds and the process described in the regulatory action is consistent with the minimum information that was requested of hospitals and the process that was utilized during the COVID-19 pandemic pursuant to Executive Orders 52 (2020), 84 (2022), 11 (2022), and 16 (2022).

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.

This regulation is promulgated under the authority of Va. Code §§ 32.1-12 and 32.1-127(B)(24). Va. Code § 32.1-12 grants the Board the legal authority “to make, adopt, promulgate, and enforce such regulations...as may be necessary to carry out the provisions of this title and other laws of the Commonwealth administered by it, the Commissioner, or the Department.”

Va. Code § 32.1-127(B)(24) states that the Board shall promulgate regulations that “establish an exemption from the requirement to obtain a license to add temporary beds in an existing hospital..., including beds located in a temporary structure or satellite location operated by the hospital..., provided that the ability remains to safely staff services across the existing hospital..., (i) for a period of no more than the duration of the Commissioner's determination plus 30 days when the Commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds or (ii) for a period of no more than the duration of the emergency order entered pursuant to § 32.1-13 or 32.1-20 plus 30 days when the Board, pursuant to § 32.1-13, or the Commissioner, pursuant to § 32.1-20, has entered an emergency order for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health [.]”

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 rationale or justification of the regulatory change is that the General Assembly has mandated that the existing regulatory flexibilities for hospital licensure for man-made or natural disasters be modified in light of the Commonwealth’s experience during the COVID-19 pandemic and the impact of hospital licensure statues and regulations on the ability of hospitals to rapidly expand bed capacity.

The specific reason the regulatory change is essential to protect the health, safety, or welfare of citizens are that normal state controls on the hospital and nursing home bed inventory in the Commonwealth have proven to be too inflexible during certain public health emergencies where demand for beds outstrips both the current inventory and the mandated processes by which additional inventory can be authorized. These amended exemption regulations will allow hospitals to temporarily increase their bed inventory in response to disasters and other public health emergencies, while still allowing the Commissioner sufficient oversight to ensure the beds are being operated and staffed safely.

The goals of the regulatory change is to create an expeditious process by which hospitals can request temporary beds while ensuring that the Commissioner and VDH have sufficient information to take action on the request.

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.

12VAC5-410-110. Bed capacity.

Creates a new process that is exempt from licensure to allow hospitals to temporarily increase their bed inventory during disasters or other public health emergencies.

12VAC5-410-9998. FORMS.

A new section created to include the new form specified in Section 110.

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 of implementing the amended provisions are the ability to rapidly and temporarily increase hospital and nursing home bed inventory during disasters or other public health emergencies while preserving life safety code protections and safe staffing. The primary advantages to the Commonwealth of implementing the amended provisions are a new exemption process that grants more discretion and flexibility to the Board and Commissioner in responding to public health emergencies for which additional bed inventory is needed without needing either a legislative amendment to the Code of Virginia or an executive order from the Governor. There are no primary disadvantages to the public or the Commonwealth. The Board is not aware of any other pertinent matters of interest to the regulated community, government officials, and 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 applicable federal requirements.

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

Virginia Commonwealth University (VCU) Health Systems Authority would be particularly affected by this proposed regulatory change.

Localities Particularly Affected

Lee County Hospital Authority and Chesapeake Hospital Authority may be particularly affected by this proposed regulatory change since it operates a general hospital and would be subject to the new regulatory requirements, unlike other localities that do not operate a hospital.

Other Entities Particularly Affected

The 106 licensed general hospitals (including those operated by VCU Health Systems Authority, Lee County Hospital Authority, and Chesapeake Hospital Authority) are particularly affected by this proposed regulatory change as they would be subject to the new regulatory requirements.

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

<p><i>For your agency:</i> 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</p>	<p>There are no projected costs, savings, fees or revenues resulting from the regulatory change.</p>
<p><i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>There are no projected costs, savings, fees or revenues resulting from the regulatory change.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>The benefits of this regulatory change is creation of an expeditious process by which hospitals can request temporary beds during disasters or emergencies.</p>

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.

<p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p>	<p>There are no projected costs, savings, fees or revenues resulting from the regulatory change.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The benefits of this regulatory change is creation of an expeditious process by which hospitals can request temporary beds during disasters or emergencies.</p>

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.

<p>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.</p>	<p>Existing general hospitals. VDH does not anticipate that outpatient surgical hospitals will likely be affected because these medical care facilities do not have beds and would be unlikely to be able to adequately staff beds in situations where a disaster has forced an evacuation or where an emergency order is needed. No outpatient surgical hospitals were approved to have temporary beds during the COVID-19 pandemic.</p>
<p>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:</p> <ul style="list-style-type: none"> 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. 	<p>There are 106 general hospitals that are licensed. Based on anecdotal accounts, VDH does not have reason to believe any of the 106 hospitals would be "small businesses."</p>
<p>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:</p> <ul style="list-style-type: none"> 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. 	<p>There are no projected costs, savings, fees or revenues resulting from the regulatory change.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The benefits of this regulatory change is creation of an expeditious process by which hospitals can request temporary beds during disasters or emergencies.</p>

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 the regulatory change as the Board has no other method other than the promulgation or amendment of regulations to create the mandated regulatory exemption from hospital licensure.

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.

There are no alternative regulatory methods that will accomplish the objectives of applicable law. The Board is required by the General Assembly to regulate the hospitals under a licensure program. The Board has no other method other than the promulgation or amendment of regulations to create the mandated regulatory exemption from hospital licensure. The Board has put forth thoughtful consideration about the burdens of the new regulatory requirements and has limited these amendments to those necessary to protect the health, safety, and welfare of the public.

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: <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.

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
410-110	N/A	<p>12VAC5-410-110. Bed capacity.</p> <p>A. Each license issued by the commissioner shall specify the maximum allowable number of beds. The number of beds allowed shall be determined by the OLC and shall so appear on the license issued by the OLC.</p> <p>B. Request for licensed bed increase or decrease shall be made in writing to the OLC. No increase will be granted without an approved Certificate of Public Need.</p> <p>C. Hospitals shall be exempt from the requirement to obtain a license to add temporary beds, for a period of no more than 30 days, when the commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p>	<p>CHANGE: The Board is proposing the following change:</p> <p>12VAC5-410-110. Bed capacity.</p> <p>A. Each license issued by the commissioner shall specify the maximum allowable number of <u>beds, excluding temporary beds added pursuant to subsection C of this section.</u> The number of beds allowed shall be determined by the OLC and shall so appear on the license issued by the OLC.</p> <p>B. Request for licensed bed increase or decrease shall be made in writing to the OLC. No increase will be granted without an approved Certificate of Public <u>Need, except as provided in subsection C of this section.</u></p> <p>C. <u>Provided that a hospital complies with subsections D, E, G, and H of this section, Hospitals a hospital shall be exempt from the requirement to obtain a Certificate of Public Need or a license to add temporary beds, including beds located in a temporary structure or satellite location operated by a hospital:</u></p> <ol style="list-style-type: none"> <u>1. for a period of no more than 30 days, when</u> If the commissioner has determined that a natural <u>disaster</u> or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds; <u>and</u> <u>2. If the board has entered an emergency order pursuant to § 32.1-13 of the Code of Virginia or if the commissioner has entered an emergency order pursuant to §§ 32.1-13 and 32.1-20 of the Code of Virginia for the purpose of suppressing:</u> <ol style="list-style-type: none"> <u>a. A nuisance dangerous to public health;</u>

			<p><u>b. A communicable, contagious, or infectious disease; or</u></p> <p><u>c. Other danger to the public life and health.</u></p> <p><u>D. A hospital may request temporary beds by filing a Request for Temporary Beds, OLC-1009-F (eff. 06/22), with the OLC that includes:</u></p> <ol style="list-style-type: none"><u>1. The hospital's name;</u><u>2. The hospital's license number;</u><u>3. The hospital chief executive officer's or his designee's name;</u><u>4. The hospital chief executive officer's or his designee's telephone number;</u><u>5. The hospital chief executive officer's or his designee's email address;</u><u>6. The number and type of temporary beds the hospital anticipates adding;</u><u>7. The planned use of the temporary beds;</u><u>8. The plans for staffing the temporary beds;</u><u>9. The efforts undertaken or to be undertaken to reduce or eliminate the number of temporary beds needed;</u><u>10. The address of the building, temporary structure, or satellite location where the hospital intends to locate the temporary beds;</u><u>11. The specific locations within the building, temporary structure, or satellite location where the hospital intends to locate the temporary beds;</u><u>12. Whether the locations identified in subdivision D 11 of this section meet life safety code requirements for the type of patients expected to occupy those temporary beds;</u><u>13. If life safety code requirements are not currently met for the locations identified in subdivision D 11 of this section,</u>
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			<p><u>what action the hospital will take to meet life safety code requirements; and</u></p> <p><u>14. Any other information that the board or commissioner may request.</u></p> <p><u>E. The hospital shall provide additional information as may be requested or required by the commissioner to evaluate the temporary bed request.</u></p> <p><u>F. The commissioner shall notify the hospital in writing of the commissioner's decision on the temporary bed request. If granted, the commissioner may attach conditions to the approval that, in the sole judgment of the commissioner, protects the public's or patients' health, safety, or welfare.</u></p> <p><u>G. The hospital may not add temporary beds unless its request has been granted and may not operate temporary beds more than 30 days after the expiration of:</u></p> <ol style="list-style-type: none"><u>1. The commissioner's determination pursuant to subdivision C 1 of this section; or</u><u>2. The board's or the commissioner's emergency order pursuant to subdivision C 2 of this section.</u> <p><u>H. The hospital shall notify the OLC in writing within 24 hours of opening a temporary bed and within 24 hours of closing a temporary bed.</u></p> <p><u>I. The OLC shall promptly inform the Department of Medical Assistance Services and the Centers for Medicare and Medicaid Services of the identity of any hospital certified as a Medicare provider or Medicaid provider or both that fails to comply with subsection G of this section.</u></p> <p><u>J. The commissioner may rescind or modify the approval of a temporary bed request if:</u></p> <ol style="list-style-type: none"><u>1. Additional information becomes known that alters the basis for the original approval, including if the hospital added</u>
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			<p><u>temporary beds prior to receiving the approval; or</u></p> <p><u>2. The hospital fails to meet any conditions attached to the approval.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p>INTENT: The intent of the new requirements is detail the minimum required information to request temporary beds, the process for requesting temporary beds, and what the obligations are of each party in the process.</p> <p>RATIONALE: The rationale for the new requirements is to recreate a level of information-sharing and processes familiar to hospitals that were utilized during the COVID-19 pandemic to temporary increase bed capacity.</p> <p>LIKELY IMPACT: The likely impact of the new requirements is clarity regarding what hospitals should do when temporary beds are needed when a disaster has caused an evacuation of another hospital or nursing home or when an emergency order from the Board or the Commissioner has been issued.</p>
<p>N/A</p>	<p>410-9998</p>	<p>This is a new section.</p>	<p>CHANGE: The Board is proposing the following change:</p> <p><u>FORMS (12VAC5-410)</u> <u>Request for Temporary Beds, OLC-1009-F (eff. 06/22).</u></p> <p>INTENT: The intent of the new requirements is for hospitals to use this form when requesting temporary beds.</p> <p>RATIONALE: The rationale for the new requirements is to standardize the information being provided to VDH when temporary beds are being requested.</p> <p>LIKELY IMPACT: The likely impact of the new requirements is consistency in the information and data being received by VDH.</p>