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Exempt Action: Final 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 Chapter 417 of the 2023 Acts of Assembly
Final agency action date	June 15, 2023
Date this document prepared	May 11, 2023

This information is required for executive branch review pursuant to 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. In addition, this information is required by the Virginia Registrar of Regulations pursuant to the Virginia Register Act (§ 2.2-4100 *et seq.* of the Code of Virginia). Regulations must conform to 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.

Chapter 417 of the 2023 Acts of Assembly requires the State Board of Health to amend its hospital regulations to require hospitals with emergency departments “to establish a security plan...using standards established by the International Association for Healthcare Security and Safety or other industry standard” and that is “based on the results of a security risk assessment of each emergency department location of the hospital.” This security plan must “include the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times as indicated to be necessary and appropriate by the security risk assessment.” Chapter 417 further enumerates what identified risks that hospitals must consider when developing security plans and training requirements for security personnel. Chapter 417 authorizes the State Health Commissioner to “provide a waiver from the requirement that at least one off-duty law-enforcement officer or trained security personnel be present at all times in the emergency department if the hospital demonstrates that a different level of security is

necessary and appropriate for any of its emergency departments based upon findings in the security risk assessment.”

The second enactment clause of Chapter 417 exempts this regulatory action from the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), provided that the State Board of Health gives an opportunity for public comment prior to adoption. The State Board of Health published a general notice in *The Virginia Register of Regulations* on April 10, 2023 containing the proposed regulatory text; this general notice had a 30-day public comment period during which three comments were received. On June 15, 2023, the State Board of Health convened one of its quarterly meetings, during which a public comment period was held prior to adoption to this regulatory action; no comments were received regarding this regulatory action during that public comment period. Between the close of the 30-day public comment period and the start of the quarterly meeting, two written comments were received.

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, internal staff review, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, “mandate” has the same meaning as defined in the ORM procedures, “a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part.”

The mandate for this change is found in Chapter 417 of the 2023 Acts of the Assembly.

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 Final Exempt amendments to the Regulations for the Licensure of Hospitals in Virginia (12VAC5-410) on June 15, 2023.

Supplemental Information for Exempt Action: Final Regulation

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage and provide the agency's response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

The "Exempt Action: Final Regulation Agency Background Document" does not have a section devoted to public comment as those actions typically do not require an opportunity for public comment prior to adoption. Since this opportunity was required for this action and public comment was received, a summary of the comments received and response to those comments have been prepared as a courtesy to the public.

Commenter	Comment	Agency response
<p>Aimee Perron Seibert, Virginia College of Emergency Physicians (VACEP)</p>	<p>VACEP supports the draft regulations as written and urges the State Board of Health (Board) to adopt them, including the process outlined for waivers in the draft.</p> <p>VACEP worked in conjunction with the Virginia Nurses Association and the Medical Society of Virginia (MSV) to negotiate the compromise with the Virginia Hospital & Healthcare Association (VHHA) on Chapter 417 of the 2023 Acts of Assembly that passed both houses of the General Assembly unanimously. VACEP believes Chapter 417 allowed for the requested flexibility by hospitals for the varying needs of different communities by including a waiver option.</p> <p>VACEP firmly and wholeheartedly disagrees with the VHHA's interpretation of Chapter 417 contained in VHHA's public comment on the draft regulations. VACEP believes it was very clear from numerous discussions, including with the patron Senator Favola, that the security risk assessment would guide the creation of a security plan, but that it was never the intent--nor does VACEP believe it to be the plain reading of the law—to permit hospitals to (1) never need security in their emergency departments (EDs) or (2) exempt them from obtaining a waiver from the 24/7/365 security personnel requirement if there was a different need shown by the security risk assessment.</p>	<p>The agency notes the support of VACEP for the regulations as drafted. The agency also notes the additional information regarding the threat of violence in emergency departments and the work that stakeholders engaged in during the 2023 Regular Session to reach a compromise regarding the mandates in Chapter 417 of the 2023 Acts of Assembly. The agency further notes VACEP's opposition to the comments provided by VHHA.</p>

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	<p>VACEP states the clear purpose of the waiver was to acknowledge that some EDs might need security on one or two shifts a day, rather than the entire day. VACEP disagrees vehemently with the notion that an ED has no need for any security personnel to be present, and points to national trends and anecdotal evidence from its members about feeling unsafe in their EDs and about the violence they experience not being taken seriously.</p> <p>VACEP encourages the State Board of Health to focus on the purpose of the bill to ensure safe workplaces for doctors and nurses and safe places for patients to be cared for who are experiencing life threatening emergencies.</p>	
<p>Clark Barrineau, Medical Society of Virginia (MSV)</p>	<p>MSV supports the draft regulations as written and urges the State Board of Health (Board) to adopt them, including the process outlined for waivers in the draft. MSV believes the draft regulations align with the legislative intent of Chapter 417 of the 2023 Acts of Assembly—which MSV believes is to make hospitals and emergency rooms more secure.</p> <p>MSV expresses regret and surprise at the public comments offered by the Virginia Hospital & Healthcare Association (VHHA) as VHHA was an active stakeholder in conversations regarding Chapter 417 throughout the 2023 General Assembly session. MSV shares that VHHA expressed no public opposition to the final version of Chapter 417, despite having opportunity to do so in subcommittees and committees in both the House of Delegates and Senate.</p> <p>MSV believes VHHA’s newly expressed concern about the 24/7/365 security presence requirement is already assuaged by the legislative compromise of the waiver that VHHA agreed to with the bill patron, Senator Favola. MSV points out that Chapter 417 gives the State Health Commissioner (Commissioner) the ability to provide a waiver from that requirement, and the draft amendments for 12VAC5-410-10 <i>et seq.</i> give the Commissioner appropriate oversight to follow that provision.</p> <p>MSV asserts that any effort to water down the intent of Chapter 417 places patients and healthcare providers in jeopardy. MSV pointed to VHHA’s proposed changes for the drafted L.5.c that would prevent the Commissioner from rescinding or modifying a waiver unless the Commissioner could prove the <i>absence</i> of a</p>	<p>The agency notes the support of MSV for the regulations as drafted. The agency also notes the additional information regarding the threat of violence against healthcare providers and the work that stakeholders engaged in during the 2023 Regular Session to reach a compromise regarding the mandates in Chapter 417 of the 2023 Acts of Assembly. The agency further notes MSV’s opposition to the comments provided by VHHA.</p>

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	<p>security guard led to one or more incidents that jeopardized the health or safety of patients, employees, contractors, or the public. MSV contends that VHHA’s suggestion amounts to requiring the Commissioner to prove a negative, with the sole intent of keeping the standard for security in Virginia’s hospitals low.</p> <p>MSV provides several statistics from the Bureau of Labor Statistics about the growing rate of injuries from violent attacks against medical professionals over the last decade and the rate of workplace violence for healthcare providers compared to other industries. MSV also referenced the 2022 Tulsa hospital shooting where a disgruntled patient killed a surgeon, physician, receptionist, and visitor. MSV asserts that this data and types of tragedies were the impetus of Chapter 417 and weakening Chapter’s 417 intent is irresponsible.</p>	
<p>R. Brent Rawlings, Virginia Hospital & Healthcare Association (VHHA)</p>	<p>VHHA does not support the draft regulations as written and provided suggested changes in its public comment, along with more general comments about the draft regulation. VHHA specifically opposes any requirement for 24/7/365 security presence in emergency departments (EDs)</p> <p>VHHA asserts that federal regulations and accreditation standards do not require or assume the need for security personnel to be always present in the hospital or any given department. VHHA states that it and its members have concerns with mandating the 24/7/365 presence of at least one off-duty law-enforcement officer or trained security personnel at every ED, as many hospitals have determined that this requirement is not appropriate or necessary at some EDs.</p> <p>VHHA points to the 24/7/365 requirement as presenting significant cost and workforce concerns because the cost of off-duty law enforcement officers has escalated, and the additional demands placed on police has reduced the availability of officers for off-duty assignments. VHHA contends that private security firms are subject to the same workforce challenges that make recruitment and retention difficult and more costly.</p> <p>VHHA’s specific suggestions are as follows:</p> <p><i>(i) 12VAC5-410-280.I.1 and J.2 – Other Industry Standards</i></p>	<p>The agency notes that VHHA does not the regulations as drafted. The agency support also notes the alternative interpretation of Chapter 417 of the 2023 Acts of Assembly offered by VHHA and the impact of that interpretation on the draft regulations. The agency further notes VHHA’s specific suggested changes, which are addressed in greater detail below.</p>

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	<p>VHHA disagrees with this regulation and suggests that individual hospitals should be provided with the flexibility to determine the industry standard to apply in its organization. VHHA contends that the requirement for each hospital to request permission from OLC to use a different standard is administratively burdensome and not required by statute. VHHA proposes that OLC could develop a list of acceptable industry standards that are the same or similar based upon input from hospitals to include in its guidance that could be updated from time to time as new standards are developed and identified.</p> <p>VHHA proposed the following language at I.1 “Is developed using standard established by the Healthcare Security Industry Guidelines 13th Edition (International Association for Healthcare Security and Safety), or other standard identified by the Department.” VHHA further proposes eliminating J.2 entirely.</p> <p><i>(ii) 12VAC5-410-280.I.3 – Security Personnel Requirement</i></p> <p>VHHA opposes the requirement to have 24/7/365 security presence in EDs and proffers an alternative interpretation of Chapter 417 of the 2023 Acts of Assembly. VHHA contends that hospitals should be permitted to operate without 24/7/365 ED security presence without any waiver from the State Health Commissioner (Commissioner) if the risk assessment conducted by the hospital conclude 24/7/365 security is not necessary. VHHA contends that a waiver from the Commissioner would only be needed if the risk assessment did conclude 24/7/365 security was necessary if a hospital demonstrates it could take other measures to ensure ED security.</p> <p>VHHA suggests the reference to subsection K should be changed to subsection L.</p> <p><i>(iii) 12VAC5-410-280.L – Waiver Process</i></p> <p>L.1: VHHA opposes with the requirement that a copy of the security risk assessment must have been “reviewed and approved by the governing body or its designee” because VHHA contends that security risk assessments or documents of this nature are a function of day-to-day management and would constitute an additional regulatory burden not required by statute and inconsistent with existing business practices.</p>	<p><i>(i) 12VAC5-410-280.I.1 and J.2 – Other Industry Standards</i></p> <p>The agency notes VHHA’s suggestion. Guidance documents are created by agencies to provide interpretation or implementation of the law but cannot be used to impose regulatory requirements on the public. Further, the Virginia Code Commission in 1VAC7-10-140(A) authorizes the incorporation by reference of all or any part of a publication or document, with the incorporated text “becom[ing] the text of the regulation and an enforceable part of the regulation.” In the absence of known alternative standards that can be incorporated by reference into the regulatory text and knowing the limitations of guidance documents, the agency included a process in the draft regulations by which a hospital may request to use a different standard. If one or more alternative standards are commonly requested by hospitals, the agency will revisit 12VAC5-410-280.I.1 in the future to explicitly incorporate those alternative standards into the regulation and eliminate the need for further individual hospital requests.</p> <p><i>(ii) 12VAC5-410-280.I.3 – Security Personnel Requirement</i></p> <p>The agency notes VHHA’s comment regarding its interpretation of the ED</p>
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	<p>VHHA proposes eliminating “that has been reviewed and approved by the governing body or its designee” and corresponding changes should be made to subsection L.3.b below.</p> <p>VHHA would support including in the regulation at L.1 a requirement that the hospital specify the rationale for the request for waiver, supported by the results of the security risk assessment and information on any alternative measures or mitigating strategies proposed to address the subject or intent of the regulatory requirement requested to be waived.</p> <p>L.2: VHHA proposes it should be revised to state that “The commissioner shall grant a waiver pursuant to this section, and shall specify . . .” because VHHA interprets this to mean that the Commissioner is required to grant a waiver where the hospital demonstrates that a different level of security is necessary and appropriate for any of its emergency departments based upon findings in the security risk assessment. VHHA further proposes that L.2 should be further revised to state: “The commissioner shall grant a waiver pursuant to this subsection upon receipt of information and rationale demonstrating that a different level of security is necessary and appropriate for the emergency department.” This would continue to provide the Commissioner with the authority to require additional information from the hospital as determined appropriate to demonstrate that a different level of security is necessary and appropriate for the emergency department prior to granting a waiver.</p> <p>L.3: VHHA proposes that notice of a changed security risk assessment should only be required where such change impacts when and how many off-duty-law-enforcement officers or trained security personnel should be present at the emergency department. This could be accomplished by eliminating the word “and” in the first instance in L.3.</p> <p>L.5.a: VHHA opposes permitting the Commissioner to modify or rescind a waiver if the security risk assessment changes. There could be changes to the security risk assessment that would have no bearing on the determination of whether at least one off-duty law-enforcement officer or trained security personnel be present at all times in the emergency department. The underlying concern, that there is a change to a security risk</p>	<p>security presence requirement. The Commissioner’s waiver authority is for “the requirement that at least one off-duty law-enforcement officer or trained security personnel be present at all times in the emergency department.” A hospital bears the burden of proving “a different level of security is necessary and appropriate for any of its emergency departments based upon findings in the security risk assessment”, i.e., something other than 24/7/365 ED security presence is necessary per the security risk assessment. It would be nonsensical for the Commissioner to have the authority to waive a 24/7/365 ED security presence requirement if Chapter 417 did not contain any such requirement.</p> <p>The agency notes VHHA’s comment about the subsection cross-reference and has corrected this.</p> <p><i>(iii) 12VAC5-410-280.L – Waiver Process</i></p> <p>L.1: The agency notes VHHA’s suggestions. The agency would highlight that the draft regulations provide for review and approval of the security plan by “the governing body or its designee” (emphasis added) so that a hospital’s governing body has the flexibility to designate someone else to carry out this function. All general hospitals in Virginia are certified by the Centers for Medicare and Medicaid Services (CMS), which has extensive emergency preparedness requirements that call for both risks assessments and the involvement of facility leadership in the review and update/approval of these assessments and plans. The draft regulation gives hospitals the flexibility—if it wishes to utilize it—to align staff responsibilities so that the state and federal risk assessments may be reviewed and approved/updated by the same person(s). Alternatively, the hospital’s</p>
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	<p>assessment that indicates that a different level of security may now be necessary and appropriate, is already captured by L.5.b “Additional information becomes known with alters the basis for the original decision” so VHHA proposes that L.5.a be eliminated.</p> <p>L.5.c: VHHA opposes giving the Commissioner the authority to modify or rescind a waiver where “results of the waiver jeopardize the health or safety of patients, employees, contractors, or the public” because of concerns regarding subjectivity and ambiguity. VHHA proposes the text be revised to read “The commissioner can demonstrate that the waiver directly results in jeopardizing the health or safety of patients, employees, contractors, or the public.”</p> <p>L.6: VHHA agrees that all information that a hospital discloses pursuant to this subsection pertaining to waiver should not be released to the public. VHHA suggests eliminating the language “to the extent those records are exempt from disclosure.”</p>	<p>leadership can designate someone else in “day-to-day management” if the hospital determines that to be more appropriate.</p> <p>The agency notes that the intent of the regulation is to identify the minimum information a waiver request must have, and a hospital is not limited in the information it wishes to provide to the Commissioner in evaluating a waiver request. It has been the agency’s experience that requesters of variances (which are functionally the same as a waiver) nearly always supplement the minimum information required by regulation with additional information they believe will support their request and that mandating further regulatory burden is not needed for most requesters.</p> <p>L.2: The agency notes VHHA’s suggestion. The agency does not disagree with VHHA that the waiver must be given if the hospital makes the requisite demonstration, which is already addressed in subsection L. The authority to request additional information to evaluate a hospital’s requested waiver is already address in L.4.</p> <p>L.3: The agency notes VHHA’s suggestion and has removed the “and” in the first instance of L.3.</p> <p>L.5.a: The agency notes VHHA’s suggestion and has revised L.5.a and L.5.b into a single subdivision and added clarity regarding what security risk assessment changes are of pertinent interest.</p> <p>L.5.c: The agency notes VHHA’s suggestion. This language is similar to variance language used for other medical care facility licensing programs administered by the Virginia Department of Health and the State Health Commissioner. These concerns about subjectivity and ambiguity have not manifested for variances, which are functionally the same as a waiver.</p>
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