



Virginia  
Regulatory  
Town Hall

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## Notice of Intended Regulatory Action (NOIRA) Agency Background Document

<b>Agency name</b>	Virginia Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12VAC5-410 (current) 12 VAC 5-411 (proposed)
<b>Regulation title</b>	Regulations for Inpatient Hospital Licensure
<b>Action title</b>	Repeal of sections on 12VAC5-410 Promulgation of a comprehensive new regulation
<b>Date this document prepared</b>	December 3, 2007

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Purpose

*Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.*

The department plans to comprehensively revise the current inpatient hospital regulations. The existing regulation governing both inpatient and outpatient hospitals (12VAC5-410) has not been comprehensively revised since first promulgated in the 1980's. This revision is intended to develop a new regulation (12VAC5-411 *Regulations for Inpatient Hospital Licensure*) that is more reflective of the changes occurring in the inpatient hospital industry while providing the necessary consistency in the provision of acute care services and assuring safe, adequate and efficient hospital operation. To accomplish this, it will be necessary to repeal sections of the current hospital regulation (12VAC5-410) as the proposed regulation is promulgated.

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

The regulation is promulgated under the authority of §32.127 of the Code of Virginia which grants the Board of Health the legal authority to promulgate hospital regulations “in substantial conformity to the standards of health, hygiene, sanitation, construction and safety as established in matters of public health and safety.”

### Need

*Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.*

Responsible for regulating medical care facilities and related services, the department recognizes the need to update the hospital regulation to better reflect national standards of care for individuals receiving services in Virginia’s 115 inpatient hospitals. At the same time, the department wants to develop a more provider-oriented document. Merely revising the current regulation, however, will not achieve the goal of developing a document that can serve as a customer service manual for providers while concurrently upgrading the current regulatory controls. Therefore, the department chooses to replace the current inpatient hospital standards by promulgating a new regulation.

### Substance

*Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.*

Except for changes required by legislative mandate, the hospital regulation has not undergone a comprehensive review and update in some time. The goal of this project is actually twofold: (i) to separate the current single regulation addressing both inpatient and outpatient hospitals into distinct regulations addressing each type of hospital and (ii) to be more reflective of the changes occurring in the acute care industry, especially in the areas of: (i) quality assurance, (ii) patient safety, (iii) emergency preparedness, (iv) perinatal services, (v) patient complaint management, (iv) hospital management and organization, and (vi) infection control. In addition, the department intends to reorganize the regulation into a user-friendlier format and reconcile state regulatory requirements with federal regulations, where appropriate, to eliminate contradiction and duplication.

A final phase of this project will be a comprehensive revision to the outpatient hospital regulations. However, that will be accomplished under a separate regulatory action following completion of the revision to the inpatient hospital regulation.

### Alternatives

*Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the*

*agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.*

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The regulation is clearly and directly mandated by law.

### Public participation

*Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.*

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The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to:

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Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will not be held.

### Participatory approach

*Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, technical advisory committees) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.*

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The department intends to convene a work group of interested parties, stakeholders and patient/family advocates to discuss issues related to hospital regulation.

### Family impact

*Assess the potential 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.*

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There is no direct impact on the family or family stability.