



townhall.virginia.gov

## Fast-Track Regulation Agency Background Document

<b>Agency name</b>	Virginia Department of Health
<b>Virginia Administrative Code (VAC) citation(s)</b>	12VAC5-410
<b>Regulation title(s)</b>	Regulations for the Licensure of Hospitals in Virginia
<b>Action title</b>	Update the Regulations to reflect a CMS issued final rule enabling registered dietitian nutritionists in the hospital setting to order therapeutic diets
<b>Date this document prepared</b>	May 12, 2015

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.*

The State Board of Health (Board) proposes to amend 12VAC5-410 et. seq. Regulations for the Licensure of Hospitals in Virginia to reflect changes to federal regulations. The Centers for Medicare and Medicaid Services (CMS) issued a final rule on May 12, 2014, which enables a qualified dietitian or qualified nutrition professional to become privileged to independently order both standard and therapeutic diets within the hospital and critical access hospital settings (<https://www.federalregister.gov/articles/2014/05/12/2014-10687/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and#h-22>). This rule change became effective on July 11, 2014. The Regulations for the Licensure of Hospitals in Virginia, 12VAC5-410-260 is

currently written in a manner that is more restrictive than the federal regulations. This regulatory action will amend the regulations to remove restrictions that are more stringent than federal law.

### Acronyms and Definitions

*Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the “Definition” section of the regulations.*

---

CMS means the Centers for Medicare and Medicaid Services

### Statement of final agency action

*Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.*

---

These amendments to the Regulations for the Licensure of Hospitals in Virginia (12VAC5-410) were approved by the State Board of Health on June 4, 2015.

### Legal basis

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

---

The regulation is promulgated under the authority of §§ 32.1-12 and 32.1-127 of Chapter 5 of Title 32.1 of the Code of Virginia (Code). Section 32.1-12 grants the board the legal authority “to make, adopt, promulgate, and enforce such regulations necessary to carry out the provisions of Title 32.1 of the Code.” Section 32.1-127 of the Code of Virginia directs the Board to promulgate regulations with minimum standards for the construction and maintenance of hospitals, the operation, staffing and quipping of hospitals, qualifications and training of staff of hospitals, conditions under which a hospital may provide medical and nursing services to patients in their places of residence and policies related to infection prevention, disaster preparedness and facility security.

### Purpose

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

---

CMS issued a final rule on May 12, 2014, which enables a qualified dietitian or qualified nutrition professional to become privileged to independently order both standard and therapeutic diets within the hospital and critical access hospital settings. According to the CMS rule, hospitals will have the flexibility to either appoint registered dietitians to the medical staff and grant them specific nutritional ordering privileges or authorize ordering privileges without appointment to the medical staff through the hospital’s

appropriate medical staff rules, regulations and bylaws. This rule change became effective on July 11, 2014. The Regulations for the Licensure of Hospitals in Virginia, 12VAC5-410-260 is currently written in a manner that is more restrictive than the federal regulations. The Regulations only allow registered dietitians to write independent nutrition orders in hospitals if they are appointed to the medical staff. This regulatory action will amend the regulations to remove restrictions that are more stringent than federal law. This regulatory action will protect the health and welfare of Virginians by ensuring that patients within a hospital setting are able to obtain the proper standard and therapeutic diets within the Commonwealth.

### Rationale for using fast-track process

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

---

These amendments simply ensure that the Commonwealth's regulations are not more restrictive than federal regulations. These amendments have also been prepared with input from the Virginia Academy of Nutrition and Dietetics. Therefore, the Department does not expect that this regulatory action will be controversial.

### Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.*

---

12VAC5-410-260. Remove the requirement that all patient diets be ordered in writing by a member of the medical staff. Add language which allows practitioners responsible for the care of the patient, or dietitians authorized by the medical staff, to order patient diets. Add a subsection which allows a hospital or medical staff to privilege qualified dietitians to prescribe diets and order tests to determine appropriate diets for the patient. Add a subsection to specify that therapeutic diets include the provision of enteral and parenteral nutrition

### Issues

*Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.*

---

The primary advantage to the agency, the Commonwealth and the public of the proposed regulatory action will be less burdensome regulations. The proposed regulatory action will also lead to greater access to well rounded patient care. There are no known disadvantages to the agency, the Commonwealth or the public.

**Requirements more restrictive than federal**

*Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.*

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

**Localities particularly affected**

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

No locality will be particularly affected by the proposed regulatory action.

**Regulatory flexibility analysis**

*Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

The alternative regulatory methods are not applicable. The regulations are required by the Code and the proposed amendments are attempting to reduce the burden of the existing requirements.

**Economic impact**

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

<p><b>Projected cost to the state to implement and enforce the proposed regulation, including:</b>  <b>a) fund source / fund detail; and</b>  <b>b) a delineation of one-time versus on-going expenditures</b></p>	<p>None</p>
<p><b>Projected cost of the new regulations or changes to existing regulations on localities.</b></p>	<p>None</p>

<p><b>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</b></p>	<p>Qualified dietitians throughout the Commonwealth, Hospitals licensed within the Commonwealth, Patients served by hospitals throughout the Commonwealth</p>
<p><b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> 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.</p>	<p>There are 106 licensed hospitals and critical access hospitals within the Commonwealth.</p>
<p><b>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including:</b>  a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and  b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>No projected cost</p>
<p><b>Beneficial impact the regulation is designed to produce.</b></p>	<p>Less burdensome nature of the regulations.</p>

### Alternatives

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

There are no other viable alternatives other than the proposed amendments to obtain the objectives of the board.

### Public participation notice

*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.*

### Family impact

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

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

### Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre-emergency** regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-410-260. Dietary Service.		A. Each hospital shall maintain a dietary service directed by a full-time person, qualified as allowed in 12VAC5-421. B. Each hospital shall have at least one dietitian, meeting the criteria of § 54.1-2731 of the Code of Virginia, employed on either a full-time, part-time or on a consultative basis, to direct nutritional aspects of patient care and to advise on food preparation and service. C. Space, equipment and supplies shall be provided for the efficient, safe and sanitary receiving, storage, refrigeration, preparation and serving of food. D. The hospital food service operation shall comply with applicable standards in 12VAC5-421.	A. Each hospital shall maintain a dietary service directed by a full-time person, qualified as allowed in 12VAC5-421. B. Each hospital shall have at least one dietitian, meeting the criteria of § 54.1-2731 of the Code of Virginia, employed on either a full-time, part-time or on a consultative basis, to direct nutritional aspects of patient care and to advise on food preparation and service. C. Space, equipment and supplies shall be provided for the efficient, safe and sanitary receiving, storage, refrigeration, preparation and serving of food. D. The hospital food service operation shall comply with applicable standards in 12VAC5-421. E. A diet manual, approved by the medical staff shall be maintained by the dietary service. Diets served to patients shall comply with the principles set forth in the diet manual. F. All patient diets, including therapeutic diets, shall be ordered in

		<p>E. A diet manual, approved by the medical staff shall be maintained by the dietary service. Diets served to patients shall comply with the principles set forth in the diet manual.</p> <p>F. All patient diets shall be ordered in writing by a member of the medical staff.</p> <p>G. Pertinent observations and information relative to the special diets and to dietetic treatment shall be recorded in the patient's medical record. A hospital contracting for food service shall require, as part of the contract, that the contractor comply with the provisions of this section.</p>	<p><u>writing by a practitioner responsible for the care of the patient or by a dietitian as authorized by the medical staff. shall be ordered in writing by a member of the medical staff.</u></p> <p><u>1. Hospitals and their medical staffs may grant privileges to dietitians meeting the criteria of § 54.1-2731 of the Code of Virginia to order patient diets, including therapeutic diets, and to order laboratory tests to help determine appropriate diets for the patient.</u></p> <p><u>2. Therapeutic diets include the provision of enteral and parenteral nutrition.</u></p> <p>G. Pertinent observations and information relative to the special diets and to dietetic treatment shall be recorded in the patient's medical record.</p> <p>A hospital contracting for food service shall require, as part of the contract, that the contractor comply with the provisions of this section.</p>
--	--	--	---