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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-230
Regulation title(s)	State Medical Facilities Plan
Action title	Update the regulatory chapter following SMFP Task Force Review
Date this document prepared	13 November 2018

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 (1 VAC 7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation).

Any decision to issue a certificate of public need (COPN) shall be consistent with the most recent applicable provisions of the State Medical Facilities Plan (SMFP). The SMFP is a set of regulations providing service/facility specific criteria for determining public need. In making a determination of need for a requested project the State Health Commissioner must take into consideration each of eight statutory criteria for determining need, including consistency with the SMFP. This Notice of Intended Regulatory Action begins the process of fulfilling the statutory mandate for the SMFP Task Force to complete a review to update or validate the existing criteria in the SMFP at least every four years. The last SMFP Task Force update to the SMFP was initiated in 2014, which resulted in a pending regulatory action to amend the SMFP related to cardiac catheterization and nursing home beds.

Acronyms and Definitions

Please define all acronyms or technical definitions used in the Agency Background Document.

COPN: certificate of public need
SMFP: State Medical Facilities Plan
Board: Board of Health
Department: Virginia Department of Health

Mandate and Impetus

Please 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, board decision, etc.). 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."

Section 32.1-102.2:1 of the Code of Virginia requires that the SMFP Task Force review the SMFP every four years to update or validate the SMFP. It has been nine years since the last comprehensive revision to the SMFP became effective.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.

This regulation is promulgated by the Board of Health (Board) under the authority of § 32.1-102.2 of the Code of Virginia requiring the Board to promulgate regulations with concise procedures for the prompt review of applications for certificates of public need consistent with Article 1.1 of Chapter 4 of Title 32.1. Section 32.1-102.2 of the Code of Virginia further requires the Board to promulgate regulations that establish specific criteria for determining need in rural areas, giving due consideration to distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care in such areas. Section 32.1-102.2:1 of the Code of Virginia requires the formation of a task force of at least 15 individuals to review and update or validate the existing criteria in the SMFP at least every four years.

Purpose

Please describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.

To fulfill the statutory mandate to review regulations and to protect the citizens of the Commonwealth, the Virginia Department of Health (Department) convened the SMFP Task Force to review 12VAC5-230 et seq., the "State Medical Facilities Plan." As a result of this ongoing review, the Department determined it was necessary to utilize the regulatory process to amend the regulations. It is necessary to amend the regulations to update each section within the regulations.

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

This regulatory action will update an existing regulatory chapter in order to correct numerous sections in the regulations and update standards to reflect current clinical application and technical capability based on the language developed by the SMFP Task Force, the Board and from public comment.

Alternatives

Please 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 other than the intended regulatory action to carry out the Board’s and the SMFP Task Force’s statutory mandates to promulgate regulations with concise procedures for the prompt review of applications for certificates of public need consistent with Article 1.1 of Chapter 4 of Title 32.1 and regulations which establish specific criteria for determining need in rural areas, giving due consideration to distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care in such areas. The regulations are mandated by § 32.1-102.2 of the Code of Virginia. This statutory requirement provides little regulatory flexibility.

Periodic Review and Small Business Impact Review Announcement

If you wish to use this regulatory action to conduct, and this NOIRA to announce, a periodic review (pursuant to § 2.2-4017 of the Code of Virginia and Executive Order 14 (as amended, July 16, 2018)), and a small business impact review (§ 2.2-4007.1 of the Code of Virginia) of this regulation, keep the following text. Modify as necessary for your agency. Otherwise, delete the paragraph below and insert “This NOIRA is not being used to announce a periodic review or a small business impact review.”

This NOIRA is not being used to announce a periodic review or a small business impact review.

Public Participation

Please indicate whether the agency is seeking comments on this regulation, including ideas to assist the agency in the development of the regulation 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. Please include one of the following choices: 1) a panel will be appointed and the agency’s contact if you’re interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulation.

The Board is seeking comments on this regulation, including but not limited to: ideas to be considered in the development of this regulation, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation. Also, the Board 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) the probable effect of the regulation on affected small businesses; and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

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://www.townhall.virginia.gov>. Written comments must include the name and address of the commenter. Comments may also be submitted by mail, email or fax to Erik Bodin, at 9960 Mayland Drive, Suite 401, Henrico, Virginia 23233; (804) 367-1889; (804) 527-4502 Fax; or Erik.Bodin@VDH.Virginia.gov. To be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.