



Virginia
Regulatory
Town Hall

Final Regulation Agency Background Document

Agency Name:	Virginia Department of Health
VAC Chapter Number:	12 VAC 5-220-10, 90, 105, 150, 160, 180, 200, 230, 270, 280, 355, 385, 420, 470 12 VAC 5-230-10, 20; 12 VAC 5-240-10, 20, 30; 12 VAC 5-250-10, 30, 40; 12 VAC 5-260-30, 40, 80, 100; 12 VAC 5-270-30, 40; 12 VAC 5-280-10, 30, 70; 12 VAC 5-290-10, 30; 12 VAC 5-300-30; 12 VAC 5-310-30; 12 VAC 5-320-50, 150, 430; 12 VAC 5-340-30; 12 VAC 5-360-30, 40
Regulation Title:	Virginia Medical Care Facilities Certificate of Public Need (COPN) Rules and Regulations State Medical Facilities Plan
Action Title:	Promulgating a final permanent regulation
Date:	October 25, 2002

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

The proposed amendments to selected sections of the Certificate of Public Need (COPN) regulation and the State Medical Facilities Plan (SMFP) are in response to changes in the Code of Virginia. The overall impact of the changes is a reduction in the scope of the Certificate of Public Need program. In addition, a provision of the SMFP regarding liver transplantation services was found to be outdated, inadequate and otherwise inapplicable and in need of revision. The current volume standard (12) for liver transplantation procedures needed to ensure a successful liver transplantation program is far below the nationally recommended number of procedures (20).

No substantive changes have been made since published as a proposed action on May 22, 2002.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

Changes made were editorial and claritive in nature and did not alter the regulation as proposed.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On October 25, 2002, the Board of Health adopted as final the proposed amendments to the COPN regulation and the SMFP.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law.

The Department is proposing these amendments under the following three legal authorities:

1. Statutory changes to the COPN law, specifically sections 32.1-102.1, 32.1-102.1:1, 32.1-102.2, 32.1-102.3, 32.1-102.6, and 32.1-102.12 of the Code, affected regulatory criteria requiring amendment to the COPN regulation and the SMFP.
2. The State Health Commissioner's authority, in section 32.1-102.3 of the Code, to "initiate procedures to make appropriate amendments to" the SMFP when "the provisions of [the SMFP] are inaccurate, outdated, inadequate, or otherwise inapplicable."
3. The Board of Health's authority to promulgate regulations granted under section 32.1-12 of the Code.

Sections 32.1-12, 32.1-102.1, 32.1-102.1:1, 32.1-102.2, 32.1-102.3 and 32.1-102.6, and 32.1-102.12 of the Code are available through the Virginia Department of Legislative Services LIS web site (<http://leg1.state.va.us/lis.htm>).

The proposed amendments do not exceed federal minimum requirements. The Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulations and that they comport with applicable state law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The Virginia Medical Care Facilities Certificate of Public Need program was designed to promote comprehensive health planning to meet the health care needs of the public, while avoiding duplication of specified medical care services. The amendments to the regulation ensure timely decision making regarding those services requiring a COPN and address the issue of barriers to service delivery in rural areas. In addition, Virginia's liver transplantation volume criterion does not meet nationally recommended transplantation volumes to maximize survival rates and professional competency. Therefore, the criterion is being amended.

These amendments to the Certificate of Public Need Rules and Regulations and the State Medical Facilities Plan address service availability and delivery and ensure better access to medical care for Virginia's citizens.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

The amendments to the COPN regulation: (i) address the special needs of rural localities when making COPN decisions, (ii) reduce the scope of the regulatory program, (iii) mandate an annual report on program activities, (iv) simplify the fee schedule, and (v) modify the response time by which decisions on disputed projects must be issued. The essence of the amendments reduces the burden imposed by the COPN program on persons subject to the regulation.

There are only two topical changes made to the SMFP: (i) consideration of the barriers to health care access for populations in rural areas when making COPN decisions, and (ii) increasing the minimum number of transplantation procedures from twelve (12) to twenty (20) to ensure successful liver transplants.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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 include a sentence to that effect.

The primary advantage of the amendments is an overall reduction in the scope of the COPN program. Other advantages include a simplified fee structure, revised project review deadlines to ensure timely decision making, and inclusion of rural localities in the decision making process. Amendments to selected sections of the SMFP establish criteria for determining need in rural areas, giving due consideration to distinct and unique geographic, cultural, transportation, and other barriers to access to care, and provide for weighted calculations of need based on the barriers to health care access in rural areas.

The organ transplantation services component of the SMFP is intended to provide a rational basis for considering the public need for new or expanded organ transplantation services in Virginia. The health, safety, and welfare of Virginia's citizens will be enhanced by assuring that the standards used in review of proposed organ transplantation projects reflect the most current national experience in transplantation program performance. This is a highly specialized medical service that only a few large hospitals have or will seek to offer, based on the available technology in the field.

The standards for approval of such services are intended to require new programs to provide a sufficient number of transplants to help ensure maximum survival rates, professional competence, and economies of scope in operations. An article in the New England Journal of Medicine, on December 30, 1999 (vol. 341, no. 27, pp. 2049-53) reported that: "as a group, liver-transplantation centers in the United States that perform 20 or fewer transplantations per year have mortality rates that are significantly higher than those at centers that perform more than 20 transplantations per year." Currently, the SMFP calls for only 12 procedures per year, far below the standard needed to assure successful outcomes. Therefore, the department, as the state's advocate for public health, safety, and welfare, has determined it is necessary to increase the state's criteria to 20 procedures per year.

There are no disadvantages to the public, the Commonwealth, or businesses as a result of these amendments to selected sections of the COPN regulation and SMFP.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

A public comment period was held from May 20, 2002 to July 22, 2002 to receive comments regarding the proposed changes to the Certificate of Public Need regulation and the SMFP. No comments were received.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

The amendments to the COPN regulation are made as a direct result of changes in the COPN law (section 32-102.1 et seq.) as follows:

12 VAC 5-220-10 Definitions. The definitions of “medical care facility” and “project” were modified to reflect the language of the law. In addition, the definition of “planning district” was clarified, a definition for “rural” was added, and the definition of “standard review process” was technically amended.

12 VAC 5-220-90 Annual report. Permissive language regarding the COPN annual report was changed to require an annual report. The eight criteria to be addressed in the report were also added.

12 VAC 5-220-105 Requirements for registration of the replacement of existing medical equipment. The law no longer requires a COPN for replacement equipment. However, such equipment is to be registered with the department.

12 VAC 5-220-150 Reserved for future use. The requirement for emergency replacement of equipment has been eliminated from the law. Therefore, the text of this section was deleted and the section number held for future use.

12 VAC 5-220-160 Required considerations. Language addressing the needs of rural populations was inserted into the appropriate factors for consideration of the need for a project.

12 VAC 5-220-180 Application form. The application fee schedule was simplified to assess 1% of the proposed expenditure for the project, capped at \$20,000. Criteria for applicant mailing were inserted.

12 VAC 5-220-200 One hundred ninety-day review cycle. The review cycle was changed from 120 days to 190 days with new “cycle end” dates inserted. Equipment replacement language was deleted. An exclusion of nuclear medicine imaging equipment used for nuclear cardiac imaging was inserted. Other corrections are technical.

12 VAC 5-220-230 Review of complete application. The project review cycle deadlines were adjusted to ensure timely decision making, including decisions on disputed projects. The language on special provisions for “good cause” cases was modified. The criteria regarding the “proceeding for mandamus” were deleted and language for “petition for immediate injunctive relief” in cases of disputed projects was inserted. An allowance for “deemed approval” and issuance of the COPN, if a decision is not reached within 70 days after the closing of the project record, was inserted. An allowance for “bond filing,” as permitted by law and determined by the courts, was inserted for the protection of all parties interested in a case decision by individuals appealing that case decision.

12 VAC 5-220-270 Action on an application. The same amendments reflected in 12 VAC 5-220-230 are repeated as a result of changes in the COPN law and are necessary for consistency in the document.

12 VAC 5-220-280 Applicability. The replacement of equipment requirement was deleted as result of changes in the law. Other changes are technical.

12 VAC 5-220-355 Application forms. The amendment reflects an increase in fees omitted from the 1997 revision to the regulation. Criteria for applicant mailing were inserted.

12 VAC 5-220-385 Review of complete application. The same amendments reflected in 12 VAC 5-220-230 are repeated as a result of changes in the COPN law and are necessary for consistency in the document.

12 VAC 5-220-420 Action on application. This section, applicable to nursing facility COPN applications, mirrors 12 VAC 5-220-270. Therefore, the amendment is necessary for consistency in the document.

12 VAC 5-220-470 Court review. Language pertaining to “good cause” petitioners was inserted.

12 VAC 5-230-10, 20; 12 VAC 5-240-10, 20, 30; 12 VAC 5-250-10, 30, 40; 12 VAC 5-260-30, 40, 80, 100; 12 VAC 5-270-30, 40; 12 VAC 5-280-10, 30, 70; 12 VAC 5-290-10, 30; 12 VAC 5-300-30; 12 VAC 5-310-30; 12 VAC 5-320-50, 150, 430; 12 VAC 5-340-30; 12 VAC 5-360-30, 40. Language was added to emphasize consideration of distinct and unique geographic, cultural, transportation, and other barriers to access to care and to provide for weighted calculations of need based on the barriers to health care access in rural areas.

12 VAC 5-280-70 Quality; minimum utilization. Liver transplantation volumes were increased from 12 to 20 procedures.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which 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.

No longer required per Executive Order 21, dated June 26, 2002.