



Virginia
Regulatory
Town Hall

**Proposed Regulation
Agency Background Document**

Agency Name:	Department of Health (State Board of)
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:	(i) Virginia Medical Care Facilities Certificate of Public Need (COPN) Rules and Regulations and (ii) the State Medical Facilities Plan (several chapters)
Action Title:	Promulgating permanent regulations from an emergency action
Date:	April 6, 2001

This information is required pursuant 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*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

This action is to finalize the emergency regulatory action that became effective on January 3, 2000. 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 legislative changes in the law as a result of the 1999 and 2000 sessions of the General Assembly. 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In addition, a provision of the SMFP regarding liver transplantation services was found to be outdated, inadequate and otherwise inapplicable and in need of revision.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 to ensure a successful liver transplantation program is far below the nationally recommended number of procedures (20).

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 must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

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

1. The enactment clauses of Senate Bill 1282 (SB1282), House Bill 2543 (HB2543), and House Bill 2369 (HB2369) of the 1999 session of the General Assembly mandated the implementation of the “provisions of [the] act within 280 days of the date of enactment,” which occurred on March 29, 1999. The Department responded to this directive by promulgating emergency regulations that became effective on January 3, 2000. The Administrative Process Act, specifically section 9-6.14:4.1 C5 of the Code, states that emergency regulations may not exceed 12 months in duration. If an agency decides to continue regulating the subject matter governed by the emergency regulation, a regulation to replace the emergency regulation shall be promulgated. Because section 32.1-102.2 of the Code requires permanent changes to the COPN regulation and the SMFP, the Department must now take action to convert the emergency action to permanent regulations.
2. House Bill 1270 (HB1270) of the 2000 Session of the General Assembly also affected regulatory criteria requiring amendment to the COPN regulation.
3. 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.”
4. 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 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 proposed 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 Law, which is codified in Chapter 4 of Title 32.1 of the Code, requires the owners or sponsors of medical care facility projects to secure a certificate of public need from the State Health Commissioner prior to initiating such projects. The criteria of the law are defined in the SMFP and the COPN regulation. When the law is amended or changed, amendments to the corresponding regulatory document are required to ensure the intent of the law is carried out.

Legislation from the 1999 and 2000 sessions of the General Assembly directly impacted the procedures and deadlines defined in the COPN regulation and the SMFP. Therefore, the purpose of the proposed amendments is to ensure consistency with the law.

In addition, Virginia's liver transplantation volume criterion does not meet nationally recommended transplantation volumes to assure successful procedures. Consequently, it should be amended.

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 providing detail of the regulatory action's changes.

The amendments 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 proposed regulatory action. The term "issues" means: 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 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.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

The proposed amendments to the SMFP and the COPN regulation implement recent changes in the Medical Care Facilities Certificate of Public Need law. Therefore, any fiscal impact on the program, localities, or businesses to accommodate those changes is a result of changes to the law, not the proposed amendments to the regulation. Since there was an overall reduction in the scope of the program, COPN applicants should find it easier to comply with the mandated requirements of the law.

The SMFP is the planning document by which the Commonwealth determines whether a medical care facility or service project would meet the medical services needs in communities across the Commonwealth. As such, providers of medical care facilities and services are not required to “implement” these amendments as regulations. However, they are required to prepare any application for obtaining a Certificate of Public Need according to the criteria stated in the SMFP.

Since the proposed amendments only modify the criteria by which medical care facilities and services apply for a Certificate of Public Need, there are no projected cost increases to the Commonwealth, localities, or businesses to accommodate the changes to selected sections of the SMFP.

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 cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

The amendments to the COPN regulation are made as a direct result of changes in the COPN law (§ 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.

Alternatives

Please describe the specific 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.

As stated previously, the authority to promulgate the amendments to the regulation is found in the Code. The proposed amendments are clearly and directly mandated by law. The proposed amendments honor the Department’s statutory charge and are the least burdensome or intrusive alternative available for adequately addressing the mandate of the law.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

A NOIRA was published on September 25, 2000 to receive public comments. Kenneth Cook, President, Jerry Kirk & Associates, submitted the following comments:

The 10-day window between the 80th and 90th day of the cycle has the potential to be a bit restrictive, especially if four of those days fall on weekends and there are a large number of projects in a given batch. . . With respect to the time frame to allow those seeking to demonstrate good cause, the four days allowed for the opposition to file written notification may be too short. . . We suggest that the language allow four working days, rather than calendar days. . . We also concur with the portions of the regulations relating

to the refunding of fees as a penalty on the part of the Department for not completing the review in a timely manner. . . We are opposed to the continuation of the fee schedule as changed by these regulations. . . We suggest that the changes in 12 VAC 5-220-180.B. be eliminated and the pricing for the old fee schedule be returned.

Recommend a change in the definition of “rural” [as] . . . the present definition restricts rural areas to those which lie outside of a Metropolitan Statistical Area (MSA). We suggest that the definition be changed so that rural areas include those localities which are not “urbanized” areas, as defined by the US Census. The use of the MSA designation may unintentionally restrict the development of some health services which are needed to meet access issues. . . there are a number of counties which are not part of the MSAs where a maldistribution of health care resources exists, including Washington, Scott, Pittsylvania, Botetourt and a number of counties in the northern Virginia MSA, all of which have population densities consistent with non-MSA counties. The number of counties in state which are part of MSAs is likely to grow within the next couple of years as new census figures are released.

The administrative timeframes for project review were clearly and specifically mandated by the changes to the COPN law in 1999 and are the reason for the emergency regulatory action. Therefore, they cannot be changed without changes to the COPN law. In the 2000 session of the General Assembly, however, additional changes to the timeframes were made and address many of the concerns expressed by Mr. Cook. The changes to the law are reflected in the proposed amendments. The department reviewed the Census Bureau definition of “rural” and found that it does not restrict “rural” to the non-MSAs; therefore, no change has been made to the definition.

Mr. Cook continues:

Include a definition of “maldistribution”. Section 12 VAC 5-360-30.D. states that preference will be given to applications which correct any maldistribution of beds within a planning district, and section 12 VAC 5-360-40.D. states that the minimum size of new facilities can be reduced to 90 beds when it can be demonstrated that there is a lack of demand for a larger facility and a maldistribution of nursing home facility beds within a planning district. A definition of maldistribution should be included, either in the general definitions or in those specifically related to nursing home beds. . . a definition that compare the ratio of services to a population (e.g. greater than 25% variance from the planning district average) with consideration of the availability of services in a contiguous jurisdiction would be appropriate. . . With respect to section 12 VAC 5-360-30.D., we recommend the elimination of the statement “and a maldistribution of nursing home facility beds within the planning district.” . . Given the continuing reduction in demand for nursing home beds that is being seen across the state, it may be better in the long run to encourage the development of smaller nursing homes in rural areas.

The department does not consider a definition of “maldistribution,” beyond what is found in a common dictionary, to be beneficial to the overall clarity of the regulation. Further definition of “maldistribution” would impose a “bar” that would not be flexible enough to address the unique characteristics of Virginia’s diverse population and geographic structure and may disserve recent

amendments to the law that encourage special consideration of geographic and other barriers that affect rural areas.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The amendments to the COPN regulation and the SMFP are clearly written and easily understandable by the individuals and entities affected.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

The whole COPN program was legislatively reviewed as a result of the passage of Senate Bill 337 (SB337) of the 2000 session of the General Assembly. SB337 called for a plan to address the gradual elimination of the COPN program by 2004. The plan was completed by December 1, 2000 for review and approval by the 2001 General Assembly. The plan did not receive the necessary legislative support for passage due to budgetary constraints.

Historically, the Certificate of Public Need law has been susceptible to amendment during each legislative session resulting in the need to promulgate amendments to the SMFP and the COPN regulation each year. The Department predicts that, with the failure of the plan mandated by SB337, the program will again be subject to legislative review and amendment. Each time this occurs, a certain level of review necessarily occurs, obviating to a degree the need for a scheduled review. In any case, the department will continue to monitor the SMFP and the COPN regulation to ensure consistency with the law.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential 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.

There is no direct impact to Virginia families as a result of these amendments. Therefore, proposed amendments do not erode the authority and rights of parents in the education,

nurturing, and supervision of their children; discourage economic self-sufficiency, self-pride, and their assumption of responsibility for oneself, one's spouse, one's children and one's parents; it does not erode the marital commitment, and does not decrease the family's disposable income.

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