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Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-230
Regulation title	State Medical Facilities Plan (SMFP)
Action title	Comprehensive Revision
Date this document prepared	October 1, 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.*

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

NOTE: This stage is a *reproposal* of a proposed regulation for public comment, developed after considerable public comment and lengthy stakeholder discussions.

Because of stakeholder interest in this project and the comprehensive revision as a result of that interest, it was determined that an additional review of the proposed document was appropriate to assure consensus prior to proceeding with the final promulgation stage. Except for changes required by legislative mandate, the State Medical Facilities Plan (SMFP) has not been reviewed and updated since it was first promulgated in 1993. The SMFP is one of twenty criteria used to determine public need in eleven categories of medical care facilities subject to the Certificate of Public Need (COPN) law. The goal of the revision project is to update the criteria and standards to reflect current national and health care industry standards, remove archaic language and ambiguities, and consolidate all portions of the SMFP into one comprehensive document. Because of the consolidation of the current 14 separate regulations into one comprehensive document, 12 VAC 5-240 through 12 VAC 5-360 are being repealed as 12 VAC 5-230 is amended and promulgated.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., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The State Medical Facilities Plan (SMFP) is promulgated by the Office of Licensure and Certification of the Virginia Department of Health, for the Board of Health, under the authority of §§ 32.1-102.1 through 32.1-102.3 of the *Code of Virginia*. Section 32.1-102.1 defines the SMFP as a planning document adopted by the Board of Health (Board); 32.1-102.2 mandates that the Board promulgate regulations to implement Virginia's Medical Care Facilities Certificate of Public Need (COPN) law in which, as set out in § 32.1-102.3 of the Code, any decision to issue or approve the issuance of a certificate shall be consistent with the most recent applicable provision of the State Medical Facilities Plan." Existence of the SMFP, therefore, is mandated.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

The Virginia Medical Care Facilities Certificate of Public Need law requires owners or sponsors of medical care facility projects to secure a COPN from the State Health Commissioner prior to initiating such projects. The SMFP is essential to the implementation of the COPN program as it provides the criteria and standards for the full range of capital expenditure project categories that require review, including general acute care services, perinatal services, diagnostic imaging services, cardiac services, general surgical services, organ transplantation services, medical rehabilitation services, psychiatric/substance abuse services, mental retardation services, lithotripsy services, miscellaneous capital expenditures and nursing facility services. The SMFP provides applicants and reviewing agencies with a framework for examining the need for these projects.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

The substantive changes are technical in nature, providing clarity, continuity and better direction than the proposed draft. For example, a number of sections have been created from existing text

or added to each Part to facilitate identification of specific topics to ease the use of the SMFP as a planning document. As a result, sections beginning with Part II have been renumbered. Changes include:

Part I. Definitions and General Information.

Definitions added, deleted, and amended. 'Preface' section repealed. Sections on guiding principles, application filing, project costs, and competing applications technically amended to provide better direction and clarify intent. 'Emerging technologies' section reallocated to 'prorating of mobile service'. 'Compliance with terms of condition' section deleted.

PART II. Diagnostic Imaging.

Article 1. Computed Tomography: 'Need for new services,' section amended, e.g. increasing volume standard to 10,000 procedures, and standards rearranged; technical amendments to 'expansion of services' and 'staffing' sections; section on mobile CT services added; 'space' section deleted.

Article 2. Magnetic Resonance Imaging: 'Need for new services,' 'expansion,' and staffing sections technically amended; section on mobile MRI services added; 'space' section deleted.

Article 3. Magnetic Source Imaging: No Change

Article 4. Positron Emission Tomography: 'Need for new service,' and 'expansion of services' sections technically amended for clarity, in addition to increasing the service volume standards; section added to address mobile PET services; 'staffing' section amended to reflect current law regarding professional credentials.

Article 5. Non-cardiac nuclear Imaging: 'Need for new service' section technically amended for clarity; 'staffing' section amended to reflect current law regarding professional credentials.

Part III. Radiation therapy services.

Article 1. Radiation therapy services: 'Need for new services section technically amended for clarity; ''staffing' section amended to reflect current law regarding professional credentials; 'expansion' section created from existing text; 'Equipment' section deleted.

Article 2. Stereotactic radiosurgery: "Need for new services' section amended and standards added to clarity and facilitate service identification; 'expansion of services 'section added; 'staffing' section amended to reflect current law regarding professional credentials

PART IV. Cardiac Services.

Article1. Cardiac catheterization services: "Need for new service' sections technically amended for clarity and to increase the service volume standard; 'pediatric catheterization,' 'expansion of

services' and 'non-emergent catheterization' sections created from existing text for continuity and clarity; 'staffing' section amended to reflect current law regarding professional credentials.

Article 2. Open heart surgery: "Travel time' and 'need for new services' sections amended for clarity and to increase the service volume standard; 'expansion' and 'pediatric open heart' section created from existing text; 'staffing' section amended to reflect current law regarding professional credentials.

PART V. General Surgical Services.

Formula for determining need amended to change population data source; 'staffing' section added for consistency.

PART VI. Inpatient Bed Requirements.

New formulas to determining need created and added; new population data source referenced; three sections created from existing text for clarity and identification of service category; 'expansion,' 'long-term acute care beds,' and 'staffing' added for clarity and to facilitate identification of services.

PART VII. Nursing Facilities.

Two sections created from existing text with concurrent deletion to the original section; new population data source referenced; 'staffing' section added for document continuity and to reflect current law regarding professional credentials.

PART VIII. Lithotripsy Services.

'Expansion' and 'mobile services' sections created from existing text; 'need for new services' section technically amended for clarity and consistency.

PART IX. Organ Transplant Services.

'Expansion' section added from existing text; 'staffing' section added for consistency within the document; 'need for new service' and 'volumes' section technically amended for clarity.

PART X. Miscellaneous Capital Expenditures.

Technical amendments made.

PART XI. Medical Rehabilitation.

'Expansion' section created from existing text; formula for determining need amended to change population data source amended in 'need for new service' section.

PART XII. Mental Health Services.

Article 1. Acute psychiatric and acute substance abuse disorder treatment services. 'Intermediate care substance abuse disorder treatment' standards deleted (F thru J); technical amendments made for clarity and consistency.

Article 2. Mental retardation. Technical amendments made for clarity and consistency.

PART XIII. Perinatal Services.

Article 1. Obstetrical services. Technical amendments made; 'staffing' section added for consistency.

Article 2. Neonatal special care services. 'Need for new service' section added to clarity COPN requirements for providing such service; individual sections created from existing text for each level of special care (i.e., intermediate, specialty and subspecialty); 'staffing section added for consistency.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

Since the SMFP is such an integral part of the COPN process, no discussion of the SMFP can be conducted without mentioning the COPN program. The COPN law states the program objectives: (i) promote comprehensive health planning to meet the needs of the public; (ii) promote the highest quality of care at the lowest price; (iii) avoid unnecessary duplication of medical care facilities; and (iv) provide an orderly procedure for resolving questions concerning the need to construct or modify medical care facilities. In other words, the program seeks to contain health care costs while ensuring financial viability and access to health care for all Virginians at a reasonable cost. The COPN program has long been a controversial feature of government efforts to contain health care costs. However, lacking a consensus on what might work better, Virginia, like 36 other states, has chosen to maintain its COPN program. That decision, however, does not prevent the department from taking steps to address and alleviate, where possible, some of the on-going controversy regarding the COPN program. There are two issues surrounding the COPN program and subsequently the SMFP: (i) the perception that the COPN program ensures quality health care services, and (ii) the perception that the program has become a guarantor of "franchise" providers, i.e., those providers already holding a COPN, making it difficult for new health care providers to enter the health care market in Virginia.

Over time, the COPN program has garnered a reputation as a program that monitors and ensures quality health care services to Virginia's citizens. In reality, the COPN program

addresses but a small portion of the burgeoning health care market and only legislatively mandated licensure programs can actually assure quality health care service delivery. Since the COPN quality misperception stems from some of the criteria in the current SMFP, one of the objectives of the SMFP revision project was to remove criteria that the program does not revisit once the certificate has been granted, such as meeting specific staffing requirements or requiring national accreditation. The COPN law does not provide enforcement of the individual sections of the SMFP. Rather, a COPN can be revoked only when: (i) substantial and continuing progress towards project completion has not been made; (ii) the maximum capital expenditure is exceeded, (iii) the applicant has willfully or recklessly misrepresented intentions or facts to obtain a COPN, or (iv) a continuous care retirement community has failed to establish a nursing facility as required by law. However, it is unlikely that VDH would seek revocation of a COPN pursuant to 'willful or reckless misrepresented intentions' because a provider fails to obtain national accreditation. The COPN law does not permit inspection after issuing the COPN, which is the only method by which such 'quality' failures can be identified. The SMFP impacts quality only through the service volume and utilization standards established within each of the services specific sections. It is well known in the health care industry that the volume of service provision results in better outcomes and survival rates for patients and service recipients. Therefore, as part of the revision project, the service volume and utilization standards were carefully reviewed and adjusted to meet nationally accepted practices.

Those same 'quality of care' standards in the current SMFP act as a deterrent or barrier for new providers applying for a COPN as they would have no quality service history. Therefore, it can be posited that the current 'quality of care standards' contribute to the perception of the COPN program as a "franchise guarantor" as only those current COPN holders can meet the quality standards. This has the effect of limiting the field of health care services to Virginia's citizens, while denying access to legitimate health care providers. As has been stated, one of the goals of the revision project has been to assure equal access to *all* applicants for COPN.

The department believes the revised SMFP assists in correcting the perception that COPN restricts such fair market competition. By eliminating criteria that can only be measured after a COPN has been granted, such as the national accreditation standards, and adjusting quality to focus on measurable standards, such as volume and utilization criteria, the process is now open to a broader range of applicants which will provide greater choices for Virginia's citizens. Since all service volume and utilization criteria were carefully reviewed, with appropriate adjustments made, and criteria that were outdated or not applicable to the application review process were deleted, VDH believes many of the difficulties to obtaining a COPN have been removed.

A third objective of the effort to revise the SMFP was to ensure the resultant document is clearly written and understandable. Much work was necessary to bring the SMFP up to currently accepted standards and practice. The approach used was to strive for simplicity, and avoid being burdensome, while meeting the requirements of the law. The department was careful to replace archaic language, which was ambiguous and subject to interpretation, with common vernacular to ensure the document's readability.

After the public comment period and because of continuing concerns expressed by stakeholders to the Board of Health at its October 2005 meeting, the Board directed department staff to reconvene the advisory committee with the intent of discussing responses to the public comments received. That process was accomplished over the course of eight months and ten meetings. Using a series of matrices of the public comments received, stakeholders had an opportunity to fully express their concerns and suggest improvements. Consensus was achieved on the majority of concerns; 'no consensus' meant there was no consensus from the stakeholder community. The completed matrices are available on the web at: www.townhall.virginia.gov.

As a result of the overall project objectives and the reconvened advisory committee meetings, the department considers the proposed SMFP to fulfill its commitment to develop a document that addresses the myriad concerns expressed during development of the final document while being user-friendlier and providing more opportunity for new health facility and service providers to obtain a COPN. Therefore, the proposed SMFP is advantageous for Virginia's citizens as well as the health care industry as it has the potential for allowing more competition.

Small businesses or organizations contracting with COPN applicants for development services would be affected by the revised document. This would include consultants and lawyers hired to help guide applicants through the COPN process.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which are 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 federal requirements related to the Certificate of Public Need Program or the Virginia State Medical Facilities Plan. Therefore, there are no standards in the proposed draft that exceed applicable 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.

There is no single locality that would bear a disproportionate material impact that would not be experienced by other localities.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is 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:

Carrie Eddy, Senior Policy Analyst
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9960 Mayland Drive, Ste. 401
Richmond, Virginia 23233

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Email: **carrie.eddy@vdh.virginia.gov**

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

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	None – the SMFP is one of 20 criteria used in determining the public need for a project requiring a Certificate of Public Need. There are costs for applying for a certificate; the revised SMFP will not affect those costs.
Projected cost of the regulation on localities	None, unless the locality chooses to own or operate a medical care facility requiring a COPN. There are 5 nursing facilities and 5 hospitals owned or operated by located governments.
Description of the individuals, businesses or other entities likely to be affected by the regulation	Nursing Facilities, hospitals, other medical care facility providers, rural citizens and indigent patients.
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. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	Approximately 100 applications are received each year.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	Non- however, there are costs to apply for the Certificate of Public Need of which the SMFP is a part.

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.

The department is required to regulate the medical care facility projects defined in § 32.1-102.1 of the Code. The SMFP is necessary to carry out the mandate of the COPN law.

Regulatory flexibility analysis

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 department is required to regulate medical care facility projects under the Certificate of Public Need program as defined in § 32.1-102.1 of the Code. The SMFP is one part of the larger COPN program that includes twenty criteria used for determining a need for medical care facilities. As stated under "Issues," a goal of the SMFP revision project has been to assure equal access for all applicants, regardless of their size or complexity.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
These comments were made by more than one respondent. Rather than repeat, they are consolidated here.	Quality: Support the inclusion in both the general and service-specific sections of quality criteria and standards. Beyond facility licensure, applicants should demonstrate their attention to generally accepted quality standards for the requested services. Removing both general and service-specific quality criteria and standards undermines effective population-based community planning.	The COPN law does not allows for inspection after issuing a COPN, the only means by which 'quality' failures can be identified. The SMFP impacts quality through the services volume and utilization standards established within each of the service specific sections. It is well known in the health care industry that the volume of service provision results in better outcomes and survival rates for patient and service recipients. Therefore, as part of the revision project, the services volume and utilization standards were carefully reviewed and adjusted to meet nationally accepted standards. Other 'quality' standards, such as national accreditation or meeting specific staffing requirements were deleted.
	Service and facility inventories: Recommend that the SMFP include inventories and historical use data for the regulated services and facilities, updated annually. VHI data is not available for all COPN regulated services because many providers are not required to submit data. It would be helpful to have a common source of use data, maintained by each planning district, for all medical care facilities.	The suggestion is beyond the scope of this project. However, VDH has addressed the issue with Virginia Health Information.
	In order for it to be fully useful, data should also be collected from all free standing medical care facilities, including grand-fathered diagnostic imaging centers and radiation therapy centers that opened when COPN regulations were suspended. We realize this may require legislation, but feel that it is a significant point worth making in the review of this documents.	Yes, it would require legislation.

Commenter	Comment	Agency response
	Future plan changes: Recommend that the sections addressing areas experiencing rapid change in the last few years be retained in the main body of the SMFP, while service specific volume standards could be in a separate document that would be reviewed and revised periodically. This would provide for a plan that could be updated in a more responsive fashion to the technology and patient care delivery changes. This arrangement would be similar to how the RFAs are now handled for nursing homes beds, permitting adjustments to be made relatively quickly as technology and medical practices change.	Such a suggestion is not practical. The only means available having the force of law is regulation. Therefore, service specific volume standards must be promulgated through the Administrative Process Act and "cannot be a separate document that would be reviewed and revised periodically." In addition, to have the service specific standards as a separate regulation would negate one of the goals of this revision project, to have all projects requiring review via the SMFP to be available under one comprehensive document. The comparison to the RFA process is not applicable. VDH has been striving for regular review of the SMFP, which is certainly sensible as well as required through Executive Order of the Governor. Unfortunately, the frequency of legislatively mandated revisions regarding the Certificate of Public Need Program and the complexities of the regulatory process have prohibited VDH from keeping to a regular revision schedule. It is hoped that with the completion of this comprehensive review, that a more timely review will be possible.
	230-10: Recommend adding a definition of "charges" and retaining the definition of "costs." "hospital-based" is too broad, suggest deleting "legally associated with" "indigent and uninsured": the term "uninsured" should be deleted because it does not necessarily mean that a patient is indigent. Support language that reflects the amount of uncompensated care being provided rather than strictly defining it as a percentage of the federal poverty guidelines.	We disagree, 'charges' and 'costs' are not reflected in the final draft; therefore definitions have been deleted. The definition has been deleted as it is understood within the context of the final plan. The definition has been amended to address 'indigent'' as a person meeting a percentage of the poverty level and who is uninsured.
	"Lithotripsy;" should distinguish between renal and orthopedic lithotripsy. "Operating rooms" There are many interpretations of operating rooms. Recommend: "a room, located in a fully controlled sterile environment, specifically designed for the performance of surgical procedures, meeting the minimum requirements and conditions of the	While we believe the proposed definition does distinguish between renal and orthopedic lithotripsy, the definition was amended to provide clarification. The definition has been standardized to be consistent with the adoption of the American Institute of Architects "Guidelines for the Design and Construction."

Commenter	Comment	Agency response
	Virginia Code, and involving the administration of anesthesia." The definition should explicitly exclude minor procedure rooms such as gastrointestinal and endoscopy suites. The list of definitions of service, facilities and processes related to COPN needs to be expanded substantially and revised.	Without further clarification of what the commenter would like to have defined, it is difficult to respond. Each definition in the current SMFP was carefully screened for applicability within the document. Those definitions that had no application in the proposed SMFP were deleted. The commenter should be aware that a regulatory definition section will not contain definitions of general understanding or definitions that can be located in a dictionary in general circulation.
	230-40.B: Further discussion is needed regarding the intent of the requirements to provide facilities and services "in location that meet established zoning regulations." This could be interpreted as barring any application by a facility that does not meet zoning criteria prior to application.	Upon reflection, it has been determined that zoning practices are the purview of local governments and would be addresses through the processes conducted by the health systems agencies. The section was deleted.
	230-80: This is drafted too broadly. Unfairly protects non-network hospitals. Institutional need must be weighted against and balanced in the context of the regional need for regulated services. Recommend removal of the section because there is a lack of data or criteria by which to measure institutional need. Because this favors existing providers, we believe this makes the process a very unlevel [sic] playing field and is not in the spirit of the COPN law. We also request that the sentence" if a facility with an institutional need is part of a network, the under-utilized services at the other facilities within the network should be relocated to the facility within the planning district with the institutional need when possible." This seems to nullify most of the other provision of the plan.	We disagree and believe there may be some confusion regarding the section. The section addresses 2 core principles of the COPN program: (i) the promotion of comprehensive health planning to meet the needs of the public, and (ii) improves the cost-effectiveness of health care delivery by relocating or removing under-utilized services. An applicant cannot apply for expanded services based solely on this section. It rests with the applicant to demonstrate via the filed application that their proposed expansion should be granted based on institutional need. Therefore, we believe there are sufficient safeguards in place to prevent an uneven playing field as suggested.
	230-450.D: Suggest a 10-year planning horizon in keeping with the Commissioner's recent	We disagree; the Commissioner's decision is pertinent to a particular project only and should not be considered a 'set aside,' but assurance

Commenter	Comment	Agency response
	decisions.	that the proposed project, should it succeed, appropriately meets its projected goals. After four years, that project is still in litigation making the decision to require a 10-year planning horizon prudent. However, that case cannot be considered routine and should not be taken as precedence for future proposals. We believe a 5-year planning horizon is more realistic for determining actual need. That decision has been re-enforced by the reconvened advisory committee.
Floyd Heater Shenandoah Memorial Hospital James Woodward Winchester Medical Center Michael Halseth Valley Health	Many of the recommendations in the [SMFP] will greatly reduce the ability of non-profit hospitals to be competitive with other service providers who are not required to accept all patients. The draft also appears to have other inadequate or improper definitions as well as a lack of access and quality standards.	Thank you for responding. However, as we stated in our initial justification for this project the SMFP has not been updated since first promulgated in 1993. We understand and appreciate the unique concerns of Virginia's non-profit hospitals; the issue of all hospitals to provide services was discussed at length during sessions of the reconvened advisory committee. We are confident that the revisions made will allay those concerns.
Daniel O'Brien Erikson Retirement Communities Ian Lee Brown Greenspring (an Erikson Reitement Community)	470.C and E: If this applies to CCRCs, it could significantly diminish the ability of rapidly developing CCRCs to meet the life-care obligation to their residents. Suggest adding: Only [subsection] F in 12VAC5-230-470 applies to development of new nursing facilities or the expansion of existing facilities at [CCRCs].	The entire Part VI has been amended; CCRCs were moved to a separate section for clarity.
Dana Steger Va. Assoc. Of Non-Profit Homes for the Aging	470.F1: Oppose as it's in direct conflict with § 32.1-102.3:2 D and E to reduce nursing facilities bed capacity from 20% to 10%. This prevents CCRCs from meeting their contractual obligations resulting in unmet resident nursing care needs. 470.F.4: Incorrectly implies that a CCRC would require a resident to leave a facility based the resident's financial status. Suggest deleting "and that, in the event such resident becomes a Medicaid recipient and is eligible for nursing facility placement, the resident will not be eligible for placement in the CCRCs nursing facility unit."	The text of the standard has been amended to conform to the law. The entire subsection has been amended to conform to the law.

Commenter	Comment	Agency response
	470.G: the current capital cost reimbursement mythology utilized by [DMAS] should apply to CCRCs that are precluded from Medicaid. Since CCRCs do not participate in Medicaid, there is no public interest in limiting the amount of capital invested in their nursing facilities. Suggest solution as proposed above.	Since CCRCs are not eligible to receive public funding such as Medicaid, it does not make sense that their capital costs be included in the methodology utilized by DMAS. The "public interest" regarding CCRC capital costs comes from a CCRCs target population and how much those individuals are willing to pay for the privilege of living in a CCRC. To implement this suggestion would harm CCRCs and would not benefit non-CCRC facilities significantly.
Doug Suddreth Virginia Health Care Assoc.	470.B: This restriction will prevent state planners from addressing a fast-growing area's nursing bed need. Suggest the prohibition last for only 3 years after approval of new beds and that the occupancy of a newly licensed facility not count for the first full year of operation in computing the NF bed occupancy.	We believe the text of PART VII has been suitably amended to address the concerns expressed. In addition, the RFA process, as required by law, allows providers the opportunity to argue for a "fast-growing area's nursing bed need."
Edward George Virginia Oncology Assoc.	Suggest that the SMFP be placed on an update schedule for each covered service every 2 or 3 years.	We agree and have been striving for that goal, which is certainly sensible as well as required through Executive Order of the Governor. Unfortunately, the frequency of legislatively mandated revisions and the complexities of the regulatory process have prohibited VDH from keeping to a regular revision schedule. It is hoped that with the completion of this comprehensive review, that a more timely review will be possible.
	VOA appreciates the Department's efforts to remove lingering doubts of some in the health care community as to the efficiency and fairness in the Virginia COPN process. VOA is supportive of the Department's position that the SMFP should provide "more opportunity for new facility and service providers to obtain a COPN." VOA applauds the proposed revision to the standard on radiation therapy services.	Thank you. We appreciate the recognition and support of our efforts on this project.
	290.C: Suggest removing the special allowance for general hospitals, i.e., do not specify a required setting for radiation services. In addition, the 60-minute drive time one way is somewhat arbitrary and may be difficult for patients needing repeated access to services.	The subsection appears to have been taken out of context, resulting in some confusion. It is not intended that patients should have to travel 60 minutes for treatment, but that treatment services should be *no more* than 60 minutes away. Such a standard serves to ensure that patients have a choice of providers.

Commenter	Comment	Agency response
	Question the necessity to specify a particular class of providers that can apply for PET imaging services	The section has been suitably amended.
	Suggest allowing the incorporation of integral imaging technologies [i.e., CT & PET] in comprehensive cancer centers.	The applicable standards have been amended for clarification.
Bruce Hillman Va. Chapter, American College of Radiology	Suggest defining supervision as CT/MRI & PET: suggest Unless the imaging unit is located in a hospital, the unit should be under the supervision of a board certified radiologist. Direct and on-site supervision by a physician shall be required during examinations utilizing parental contrast administration.	The section has been suitably amended.
	Many analysts believe that the increased utilization of CT/MRI and PET is driven by non-radiologist physicians, with an ownership interest in imaging equipment who can refer their own patients for imaging examinations.	That is a prohibited practice; see Chapter 24.1 (§ 54.1-2410 et seq.) of Title 54.1 of the Code of Virginia, and should be reported to the Board of Medicine of the Department of Health Professions.
	Suggest that imaging facilities be accredited by the American College of Radiology or an equivalent agency.	As explained previously, the SMFP is not the correct tool for establishing such criteria, as there is no "after the fact" enforcement capability. Such criteria can only be established through licensing programs and independent imaging centers do not require licensure to operate in Virginia.
Deborah Oswalt Virginia Health Care Foundation Neal Graham Virginia Association for Primary Care Karen Cameron Central Virginia Health Planning Agency, Inc.	90.B and C: Suggest clarifying that, for the purposes of meeting charity care obligations, a facility can only count any free or reduced rate care provide to indigent patients. Suggest striking [in B] "to patients with specialized needs, or by the facilitation of primary care services in designated medically underserved areas" and inserting "indigent patients" in C.1 and 2. 90.D: Suggest changing "services should render" to "services must render"	During discussion with the reconvened advisory committee, it was determined that the SMFP was not the proper venue for addressing charity care obligations. Therefore the section has been deleted in favor of the guideline addressing compliance with charity care obligations.

Commenter	Comment	Agency response
Karen Cameron Central Virginia Health Planning Agency, Inc.	There is no definition of "regional standard" and there is no means to verify the financial information provided to VHI from which the regional standard is developed. While this may be difficult to address in the context of the SMFP revision, it needs to be addressed by VDH to insure accuracy and fairness of the standard to be used.	Since the section on charity care has been deleted as explained, there is no need for a definition of regional standard.
	Suggest that the SMFP actually reflect appropriate volume changes in the use of technology for CT, MRI, lithrotripsy and other equipment types.	The applicable standards have been suitably amended.
John T. Stone Bon Secours Health System	230-10: "Hospital-based" should also include <u>any entity, facility or location that qualifies under Medicare to bill under the Medicare provider number of the hospital to which such entity, facility or location is "hospital-based.</u> "Open heart surgery" should be modified to cover those procedures requiring the use of heart-lung bypass machines and those that require the bypass to be immediately available.	Medicare is a federal reimbursement program. The intent of the standard is to address the proximity of hospital services, not reimbursement. In addition, it has been determined that a definition of 'hospital-based' is not necessary; therefore the definition has been deleted. The definition has been suitably amended.
James Dahling Children's Hospital of the King's Daughters Jamil Khan EVMS/Children's Hospital of the King's Daughters Glen Green Children's Specialty Group, PLLC	230-690: Oppose the deletion of the requirements of current 12 VAC 5-250-80.B and 90.B through D relating to specialty and subspecialty neonatal special care. Specialty level or subspecialty level nurseries should be within 90 minutes drive time one way; limit the 45 minute drive time to intermediate level service 690.A: Average annual occupancy should be 85% for specialty and subspecialty level nurseries. 690.B: Specialty and subspecialty beds should contain a minimum of 15 [infant] stations. In addition, there should be no more than 4 bassinets per 1,000 live births for specialty or subspecialty services in each	Part XIII has been amended as suggested.

Commenter	Comment	Agency response
	planning region, and current services should not be negatively impacted by any new services.	
John Duval VCU Health System	The calculation of inpatient days and discharges should include observation patients, when such patients occupy licensed beds.	The formula has been amended.
	Any calculation of charity care should continue to include the care provided by academic medical centers and be based on the mean. Calculations eliminating the AMCs or moving to a median level of care will only lower the charity care standard community-wide.	We agree, and there has been no proposal to exclude the AMCs from the charity care calculations. However, it has been determined that the SMFP is not the proper venue for addressing charity care obligations. Therefore the section has been deleted, in favor of the guideline addressing compliance with charity care obligations.
	Cardiac qualifications are not specific regarding interventional cardiology or participants in interventional procedures.	The specifics of staff qualifications are a licensure issue. Staffing requirements for COPN have been addressed in a broad sense, as there is no ability for COPN follow-up.
	Surgical back-up needed for facilities performing interventions without in-house cardiac surgery. Recent articles in JAMA noted an increased risk to patients undergoing interventions in such facilities.	The section has been amended as appropriate.
	Suggest the SMFP exempt equipment used for medical research from the COPN Process.	That must first be addressed through the legislative process, as currently the law does not permit such an exemption.
Thomas Stallings McGuireWoods	230-40.B: Appears to bar any application that does not meet zoning criteria. An applicant may have an option to purchase contingent upon COPN approval. The SMFP should allow for this.	The requirement regarding zoning has been deleted as previously explained.
	230-390: Appears to allow at least one open-heart surgery program in each planning district. This would be an unwise policy as some planning districts can be served by programs in nearby planning districts.	We believe the section was read out of context, the standard does not read 'within the same planning district as the open-heart surgery program.' Rather, the determinant is that services be available within 60 minutes, which includes services across planning district lines.
	230-450.B.3 and G: The proposed language is inconsistent with recent decisions by the Commissioner. Suggest deleting sections.	The subsections have been amended and clarified.
	Once the SMFP [is adopted] we ask the [VDH] to coordinate with VHI so that data collection is relevant to the SMFP. This would help eliminate the data problems in the current system.	This suggestion is beyond the scope of this project. However, VDH has addressed the issue with Virginia Health Information.

Commenter	Comment	Agency response
R. Edward Howell University of Virginia Health Systems	230-370.F.3: Suggest adding without reducing the utilization of existing pediatric cardiac catheterization laboratories in the Commonwealth below 100 pediatric catheterization procedures.	The subsection has been amended accordingly.
	230-390: Suggest striking the reference to planning district. Given that the number of open-heart surgeries is declining [in Virginia], the [SMFP] should not be relaxed.	The section appears to have been read out of context. We do not believe that any reduction in open-heart surgery is the result of the COPN program.
	230-400.A.3: Suggest adding per room after "400 open heart procedures" making this subsection consistent with subsections A.2 and B.	The subsection has been clarified.
Virginia Hackney Hunton & Williams for Loudoun Hospital Center	230-40: Strongly endorse the requirement that an applicant show that a proposed facility meets established zoning regulation. It gives the Commissioner the benefit of knowing beforehand of the local government has any concerns or objections to the proposed location.	The zoning requirement has been deleted as previously explained.
	230-60: Suggest preference also be given to applicants who consistently demonstrate that the information and testimony the present represents a complete and accurate presentation of the issues.	Such a standard is not practical. However, applicants are required to certify that the information provided on any application is accurate and true.
	230-370: Suggest inserting subject to the provision of 12 VAC 5-230-80 at the beginning of the section. Also suggest: A.1: Delete A.2: Delete after "500 diagnostic equivalent procedures" B: Delete after "350 diagnostic equivalent procedures" C: Delete after "400 diagnostic equivalent procedures" D: Delete after "400 diagnostic equivalent procedures"	We disagree. An important part of the process is to assure that new services do not negatively impact existing services. As part of the process, applicants must prove that their new service is responding to an increased need within a community or locality. To do otherwise would simply be a sanction to lure patients away from established providers. VDH cannot support such a principle.

Commenter	Comment	Agency response
	230-450: Suggest adding except in cases where (i) such relocation can be shown to be a public benefit based on particular conduct or practices of the existing hospital provider, or (ii) it can be clearly demonstrated that the proposed relocation will not materially harm the existing hospital provider, or (iii) the new location is within a thirty minute drive of the existing beds proposed to be relocated.	We disagree. As explained, the purpose of COPN is not to guarantee the "franchise" of any one provider group as appears to be suggested.
Deb Anderson Sentara Health Care	A utilization database in which all providers are required to participate is necessary. Currently there are several diagnostic centers and outpatient surgery centers that are not required to report separately and do not. This gap needs to be filled.	Thank you, but these suggestions are beyond the scope of this project. They must first be addressed through the legislative process
	It is important that the SMFP, the COPN, and licensure regulations be consistent with each other, that definitions be uniform, and that the uniformity includes the data reporting components	We are beginning the process of revising the hospital regulation in which definitions will be conformed.
	This revision is an excellent opportunity to provide more uniformity and to ensure that each plan component addresses all possible project scenarios.	We agree that uniformity is important and we believe we have been successful in achieving more uniformity with this draft than is available with the current SMFP. Uniformity, to the extent possible while recognizing the uniqueness of individual services, is a goal of OLC for all its regulations, not just the SMFP
	A process should be in place to review the SMFP on a regular basis.	We agree and have been striving for that goal, which is certainly sensible as well as required through Executive Order of the Governor. Unfortunately, the frequency of legislatively mandated revisions and the complexities of the regulatory process have prohibited VDH from keeping to a regular revision schedule. It is hoped that with the completion of this comprehensive review, that a more timely review will be possible.
	230-10: Suggest retaining the definition of "accessibility" from the current SMFP	The definition has deleted as 'accessibility' is defined in any dictionary of common usage.
	"Charges" should be costs	We disagree; however, 'charges' has been deleted as unnecessary to the draft.
	"pediatric" references should be for 15 and under, not 21	The definition was amended to reflect Virginia's legal age of 18.

Commenter	Comment	Agency response
	"hospital" should include outpatient surgical hospitals and delete reference to "community" to make consistent with licensure regulation	The definition was suitably amended.
	"uninsured" should be deleted.	We agree for the reasons stated previously.
	"inpatient beds" should include long term acute care beds {LTACHs]	The definition has been amended to address 'inpatient' with a new definition for 'beds' added. A section on LTACHs has been added under inpatient bed requirements.
	"MRI relevant patients" should be deleted	We agree.
	"Nursing facilities" should include nursing facility beds	The definition of "nursing facility beds" was deleted as unnecessary. A definition of 'bed' has been added.
	"Pediatric cardiac catheterizations" should refer to patient 15 and under, rather than 21	The definition was amended to reflect the legal age in Virginia of 18.
	The definition of "quality of care" should be retained	We disagree for the reasons stated previously.
	230-30: Reference to quality of care should be retained. Also suggest: The COPN program seeks to promote rational reallocation of existing resources to meet evolving community needs.	The SMFP impacts quality only through the services volume and utilization standards established within each of the service specific sections. The entire section has been amended to include the suggestion for reallocation of resources.
	230-90.D.1: Add or local clinics	During discussion with the reconvened advisory committee, it was determined that the SMFP was not the proper venue for addressing charity care obligations. Therefore the section has been deleted in favor of the guideline addressing compliance with charity care obligations.
	230-120:Increase the volume to reflect changes in CT technology, suggest 4,500	The section has been suitably amended as agreed by the reconvened advisory committee.
	230-130 [and 180]: Suggest physicians with documented formal training in the production and interpretation of cross-sectional CT [MRI] images rather than" broad certified diagnostic radiologists"	We disagree. Specific staffing standards are licensing issues for those entities that require licensure under the law. As explained previously, the COPN program has no means of enforcing compliance with staffing standards.
	230-290:Lowering the volume standard is a constructive change from the existing plan.	Thank you

Commenter	Comment	Agency response
	230-370:include a formula for calculating diagnostic equivalent procedures (DEP), e.g., diagnostic is 1DEP, therapeutic is 2 DEPs, same session is 3 DEPs, pediatric is 2 DEPs	We agree and have included the suggestion as a definition in section 12 VAC 5-230-10.
	230-430: clarify the formula so that only general purpose operating rooms visits and hours are used, i.e., exclude open heart surgery	The subsection has been suitably amended.
	230-450.B: Add <u>the relocation results in improved distribution of existing resources to meet community need</u>s. Suggest lengthening the planning horizon to 10 years. G: delete	We agree and have amended the subsection accordingly. We disagree as previously explained. We disagree, but have clarified the intent of the subsection
	230-520.A: Suggest changing transplant services to reflect Medicare and national trends, i.e.: Heart s/be 12, not 17 Heart/lung no minimum, but require an active heart program Lung s/be 10, not 12 Liver s/be 12, not 21 Pancreas or pancreas/kidney no minimum, but an active kidney program Pt survival for heart/lung s/be increased to 70%	We disagree; the proposed standards meet the recommendations of UNOS. Medicare is a federal reimbursement program. The intent of the standard is to address service proficiency and patient survival rates, not reimbursement.
	230-580: Change “planning region” to <u>planning district</u>.	The section has been amended.
	230-670: Suggest reducing the minimum volume of deliveries for new services	The need for new obstetrical services is now based on population and utilization of current services, which will appropriately address any need for new services in urban, suburban and rural areas.

Commenter	Comment	Agency response
William Downey Riverside Health System	The revision contains only a few general definitions without the service-specific guidelines. Suggest these sections be left in so that applicants and DCOPN have a mutual understanding.	Without further clarification by the commenter of the "deleted" definitions, it is difficult to respond. However, each definition in the current SMFP was carefully screened for applicability in the revision. Those words that were not used in the text were deleted. The commenter should also be aware that a regulatory definition section will not contain definitions of general understanding or definitions that can be located in a dictionary in general circulation.
	230-10: "Charges" are not properly defined. "Costs" s/be defined as in the current SMFP	The definition of charges has been deleted as previously explained.
	"hospital-based" does conform to the Medicaid definition and is inconsistent with the current definition in 12 VAC 5-320-10. Include a definition of operating room.	That is correct, nor was the intent to mirror either Medicare or the current SMFP. However, the term when used is clearly understood within the text, therefore the definition was deleted as previously explained. A definition was included in the draft; as a result of comments received it has been amended for clarification.
	"Radiation therapy" delete "ingestion of isotopes" and add <u>implantation of isotopes</u> Ingestion of isotopes is appropriately used in diagnostic procedures, not therapeutic use.	The definition has been suitably amended for clarification.
	"Stereotactic radiosurgery" as <u>radiotherapy</u> meaning more than one session of fractionalization. Radiosurgery is a one-session process.	The definition was suitably amended for clarification.
	230-20.D: Add <u>regional health planning agencies</u>	The section has been deleted as previously explained.
	230-30.5: "needs" should be identified by regional health systems agencies and DCOPN as well as by applicants. This assumes a proactive approach to health planning.	The entire section has been amended and clarified.
	230-40.B: Appears to bar any application by a facility that did not, prior to the application, meet zoning criteria.	The zoning criterion was deleted as previously explained.
	230-200: suggest moving under [emerging technologies] as no FDA approval has been granted, nor have CMS codes for MSI been approved.	We disagree. The section on emerging technologies has been reassigned.
	230-290: The volume decrease from 9,000 to 8,000 is appropriate; this [section] should be reviewed	We agree.

Commenter	Comment	Agency response
	carefully in view of the emergence IMRT and IGRT.	
	230-330: The definitions of radiosurgery and radiotherapy determines whether an applicant requests fall in this section or radiation therapy.	This was clarified in the definition.
	230-370.E & G: The intent of these is apparent, but the language is confusing, need to clarify Emergency availability of open-heart surgery has been eliminated and needs to be retained. It is considered a significant safety issue.	The intent of the subsections has been clarified. We believe the issue of emergency availability is suitably addressed via the requirement that open-heart surgery be available 24 hours, 7 days a week. That would cover any emergency contingencies.
	230-430: Since operating rooms for trauma services, open-heart procedures, and caesarian sections have been deleted from the inventory; statistics will have to be revised. Open heart and trauma s/be recognized only in facilities that have approved and designated open heart and trauma programs. Consider extending the need threshold to 10 years in line with the recent decision by the Commissioner. In light of 230-80, is this section applicable if the applicant can show institutional need?	We agree. We disagree as previously explained. The Commissioner's decision is pertinent to a particular project only and should not be considered a 'set aside,' but assurance that the proposed project, should it succeed, appropriately meets its projected goals. After four years, that project is still in litigation making the decision to require a 10-year planning horizon prudent. However, that case cannot be considered routine and should not be taken as precedence for future proposals. We believe a 5-year planning horizon is more realistic for determining actual need. That decision has been re-enforced by the reconvened advisory committee. Yes, as the applicant would be using this section to show a need.

Commenter	Comment	Agency response
	230-450: There is no provision for retention of beds due to surge capacity requirements on homeland security	Nor would there be, surge capacity is for emergency preparedness purposes.
	G: is inconsistent with other parts of the draft.	The subsection was moved and clarified.
	Conversion of beds within the medical-surgical category should be addressed, i.e., if less that the threshold cost ($5 million), no COPN is required to convert acute care beds to categories.	Such a standard in the SMFP is not necessary as hospitals can designate beds as needed to suit the needs of their patients.
	230-620: Suggest some clarification under "needs" section should be included to facilitate in-state placement of children and adolescents.	Response from DMHMRSAS: Although state agencies have complained that there is a shortage of children and adolescent (C&A) beds, we have no information to substantiate the complaint. To address this issue the 2002 General Assembly passed legislation requesting that the DMHMRSAS track and report on the number of available beds and staffed beds in the system to serve children. The Legislation required that all Community Policy and Management Teams (CPMTs) and each operating community services board (CSB), administrative policy board, local government departments with a policy-advisory board, or behavioral health authority report to the Department instances of a child or adolescent for whom admission to an acute care psychiatric hospital or residential treatment facility was sought but was unable to be obtained by the reporting entities as well as the reasons these admissions were denied. The legislation also requested the Department to identify and track requests for acute psychiatric beds and acute residential treatment facilities on a quarterly bases. We have no data to support that there is a shortage of C& A beds based on the data that we have been collecting.
	Suggest thought be given to separating geriatric psychiatric services from general psychiatric services. Geriatric involves significantly different patient care parameters.	Response from DMHMRSAS: We agree that the geriatric population may require specialized care that is not provided in general acute psychiatric facilities. We have provided language to give special consideration to projects that involve the addition of dedicated beds for geriatric patients.

Commenter	Comment	Agency response
	230-670:Suggest lowering the minimum number of deliveries even lower than 2, 5000.	The section has been amended to reflect need based on population and utilization of existing services, which accommodates all areas of the state equally.
	There is no discussion of high-risk patients and transfer agreements with regional NICU units. Safety and quality have apparently been disregarded in terms of plans and protocols.	We can assure the commenter that safety and quality of services are paramount to VDH. However, transfer agreements are addressed in the hospital licensure regulations, which is the proper venue for assessing quality and safety.
Don Harris INOVA Health Systems	Part II, Articles 1 thru 5: Suggest leaving the MRI threshold at 4,000 or increase to 5,00 and raise the CT volume to 6,000.	The sections have been suitably amended.
	Suggest the CT and MRI are not a purely diagnostic modality, recommend CT simulation be excluded from the COPN application process.	Currently the Code of Virginia does not make exceptions for CT simulation; such exclusion would require legislative action. However, we have addressed simulation within the SMFP.
	Please clarify whether PET/CT machines are embedded in the PET criteria.	The definition has been amended for clarification.
	230-450.A and B: Recommend combining general medical/ surgical, pediatric, “step-down” or “ intermediate care,” and intensive care beds and a single occupancy standard of 80% as the threshold for adding new inpatient beds.	Per the reconvened advisory committee, the agreed upon occupancy (midnight census) is 80% of med/surge/pediatric and 65%for intensive care
	E & F: Recommend 80% threshold for adding new beds.	We disagree and lowered the occupancy to 70%.
	Since VEC data shows lower population than actual experience, suggest allowing substitution of local data, if it results in substantially larger need calculation.	As a result of perceived flaws in the VEC data, OLC has plans to contract with a national demographic entity to obtain population data.
	Part VIII: Suggest distinguishing between renal and orthopedic lithrotripsy. It is unclear if approved provider of renal lithrotripsy will be permitted to add orthopedic lithrotripsy without COPN.	While we believe the proposed definition does distinguish between renal and orthopedic, the definition has been clarified.
	Part XIII: there is no occupancy standard to guide projection of needed obstetrical beds.	The need for new obstetrical services is now based on population and utilization of current services, which will appropriately address any need for new services in urban, suburban and rural areas.

Commenter	Comment	Agency response
	Recommend getting expert consensus on minimum standard of deliveries from a quality and efficiency perspective.	We disagree; we contacted the stakeholder organizations to nominate members to the advisory committee. Therefore, the choice of members was the decision of the stakeholder associations. Additional expert consensus was also obtained through the exposure draft process, in addition to the 60-day comment period required by the APA. VDH is confident ample and sufficient opportunity has been provided for "expert consensus."
Margaret King Northern Virginia Health Systems Agency, Inc.	Concerned about the lack of accessibility and quality standards and the low numerical volume standards for services such as CT, MRI and Lithotripsy. Suggest inserting <u>per machine</u>	As part of the revision project, the services volume and utilization standards were carefully reviewed and adjusted to meet nationally accepted standards. Other 'quality' standards, such as national accreditation or meeting specific staffing requirements were deleted. As previously explained, sections that were not enforceable as allowed by law were deleted. That includes the sections on "accessibility." The volume standards for CT, MRI and Lithotripsy have been amended to include the suggested "per machine."
	Definition of "competing applications" limits competition to planning districts, where some types of services call for evaluation on a regional basis.	The definition was amended for clarification.
	There is no definition of "emerging technologies"	Correct – the applicable section has been reassigned.
Paul Boynton Eastern Virginia Health Systems, Inc.	Request that quality standards be reinserted in the SMFP	The SMFP impacts quality through the services volume and utilization standards established within each of the service specific sections. It is well known in the health care industry that the volume of service provision results in better outcomes and survival rates for patient and service recipients. Therefore, as part of the revision project, the services volume and utilization standards were carefully reviewed and adjusted to meet nationally accepted standards. Other 'quality' standards, such as national accreditation or meeting specific staffing requirements were deleted.

Commenter	Comment	Agency response
	230-10: Suggest including definitions of "cardiac capacity," cardiac capacity for open heart surgery programs" be included.	A definition of diagnostic equivalent procedure has been added to 12 VAC 5-230-10.
	"Charges" is the definition of costs – charges would be the prices set by the provider.	As previously stated, 'charges' has been deleted.
	"hospital" should include outpatient surgical hospitals	The definition has been corrected.
	"hospital-based" should include: whether located on the hospital's campus or at a site not on the hospital's campus.	As previously stated, the definition has been deleted.
	"planning year" should include and services after "which bed"	The definition was amended as suggested.
	"Positron emission tomography" should include: imaging modality after invasive diagnostic"	The definition was amended as suggested.
	"Radiation therapy" delete: "and by the ingestion of radioisotopes"	The definition was amended as suggested.
	"Stereotactic radiosurgery" insert: one session after "means a"	The definition has been amended for clarification.
	230-40.B: insert or will meet after "locations that meet"	The subsection was reassigned as previously explained.
	[charity care] 230-90.D.1: insert or local clinics that are members of the Association after "Free Clinics" [charity care] 230-90.E: insert and the appropriate Regional Health planning Agency after "filed with the Center,"	During discussion with the reconvened advisory committee, it was determined that the SMFP was not the proper venue for addressing charity care obligations. Therefore the section addressing compliance terms of condition has been deleted in favor of the guideline addressing charity care.
	230-110.A.2: suggest deleting	The subsection was moved within the context of the section.
	230-120: suggest increasing volume to 4,500 for CT scans and 4,000 MRI scans	The section was suitably amended.

Commenter	Comment	Agency response
	230-280: Suggest amending to include 95% of rural and and be available within 30 minutes driving time one way, under normal conditions, for 95% of the urban and suburban population of the planning district.	We do not believe it is necessary to differentiate between rural, urban and suburban; as a planning district may be some of each type of locality.
	230-360: suggest amending to include rural and and be available within 30 minutes driving time one way, under normal conditions, for 95% of the urban and suburban populations of the planning district	We do not believe it is necessary to differentiate between rural, urban and suburban; as a planning district may be some of each type of locality.
	230-370.D: suggest amending as follows: Proposals for the expansion of an existing cardiac catheterization service shall not be approved unless all of the existing cardiac catheterization laboratories operated by that service have performed… Add subsection H: Non-emergent interventional cardiology services should only be provided at hospitals having open heart surgery services available.	The subsection has been suitably amended for clarification. Non-emergent services standards have been placed in a separate section and amended as suggested.
	230-400.B: suggest moving "to less than 400 procedures per room" to after " service location" C.1 and C.2: Suggest drive time be 1 hour, not 2	The subsection was amended as suggested. We agree.
	230-430:.C: Suggest adding However, existing surgical services may be expanded when all of the applicant's existing general purpose operating rooms have experienced an average of at least 1,600 service hours per operating room for the relevant reporting period.	Such expansion needs can be requested under the new section 12 VAC 5-230-80, relating to institutional need.

Commenter	Comment	Agency response
	230-450.D.1: Suggest adding: However, the medical/surgical and pediatric bed capacity of a hospital or the ICU bed capacity of a hospital, may be allowed to increase when existing beds in those categories have experienced respectively and average of 80% and 65% occupancy for the relevant reporting period and when no beds exist at the hospital or at any other hospital within the same hospital system in the planning district which can be converted to, or relocated to, the hospital that is in need of such expansion. 450.G: Suggest deleting or change to read "less than 80% average annual occupancy" so it is consistent with 12 VAC 5-230-450.E.2.b	It's not clear whether the comment suggests expansion/institutional need or that hospitals should be allowed to increase beds as needed without benefit of COPN review. Expansion/ institutional need is covered in respective sections. Uncontrolled expansion is not permitted by law. The section regarding 'need for new service' has been suitably amended for clarity and consistency.
	230-490: suggest adding subsection E. Proposed orthopaedic lithrotripsy services may be located at the offices of physicians and podiatrists, and a new service may be approved of the applicant can demonstrate that it can reasonably be expected that the proposed new service would have a volume of at least 100 orthopaedic lithrotripsy patients annually.	We believe it is not necessary to distinguish specific provider sites, the language of the standards is broad enough to address all providers of lithotripsy services.
	230-520.A: Suggest 12 pancreas or kidney/pancreas transplants be deleted and add: Any proposed pancreas transplant program must be part of a kidney transplant program that has achieved at least the SMFP's minimum volume standard for kidney transplants as well as the minimum transplant survival rates stated in 12 VAC 5-230-520.C	The subsection has been amended as suggested.
	230-660: Suggest driving time be 60 minutes for rural areas	We disagree. The Governor's Task Force on Obstetrical Services indicates a lack of available services in rural areas. We believe it to be counterproductive to further restrict access to care in rural areas.
	230-670.B: Suggest 2,500 deliveries may be too high. More reasonable may be 1,9000 or 2,000 deliveries.	The subsection has been amended to reflect population and utilization of current services, a better indicator of need for new services for all geographic areas, i.e., urban, suburban and rural.

Commenter	Comment	Agency response
Virginia Association of Regional Health Planning Agencies	Suggest service inventories be developed and maintained by regional and state planners, with the existing services providers.	Establishing a process for developing those inventories is beyond the scope of this project. However, the staff of the DCOPN is happy to discuss this with the Association once the SMFP has been promulgated.
	Suggest provisions for consideration of exceptions to planning district averages for non-tertiary services where there is substantial distance and travel time within the planning district and there are not significant overlaps in services areas. This would permit expansion regardless of high use rates in another part of the district that does not share the market area.	We believe the concern has been suitably addressed by inserting: 'The utilization of existing services and serving as area distinct from the proposed new service site may be disregarded in computing . . . ', where appropriate.
	230-10: There is no definition of emerging technologies, Suggest "medical technologies that have advanced beyond basic to applied research, but as yet to attain wide diffusion in the health care delivery system."	The applicable section has been deleted; therefore a definition is not necessary.
	Acute Care Beds: Recommend minimum planning district occupancy level of 80% to add beds	We agree.
	Long term acute care hospital: No need to reduce regional occupancy levels, 85% is readily achievable in LTAC beds. Current occupancy levels have worked well. No basis for reduced occupancy levels presented. Would permit unwarranted excess capacity and facilities to be develop, especially in urban areas. Recommend keeping 85% occupancy standard.	We disagree, believing that LTACH beds are part of the total inventory of inpatient beds. The utilization rate of 80% for inpatient beds was agreed upon by the reconvened advisory committee, of which the Association was a part. In addition, a section specific to LTACHs beds has been added.
	Psychiatric Facilities: No need to reduce regional occupancy levels substantially. The purpose of the change is unclear. Perhaps it is assumed that a lower occupancy standard will make it more likely that needed psychiatric beds will be developed. Occupancy levels of determining need should be no lower than 80%	The changes to Part XII- Mental Health Services were requested by the Department of Mental Health, Mental Retardation, and Substance Abuse Services.

Commenter	Comment	Agency response
	Obstetrical Services/Beds: No need to change regional standard. Recommend retaining existing planning standards. A bed standard [for rural areas] is needed and should be based on occupancy levels.	Given that there is a shortage of obstetric services and beds in Virginia, as stated in the Governor's Task Force Report, the intent of this statement is unclear. As stated previously, a goal of the revision project has been to provide access to needed services. Holding to previous regional standards when facilities are closing is counterproductive.
	Organ Transplant program: Support as proposed, except change the pancreas transplant standard to require that the procedures occur in a program that meets the kidney transplant standard of 30 cases per year (based on Medicare program policy).	The subsection has been amended as suggested.
	Nursing homes and nursing home beds: The CCRC bed ratio limitation is needed. Calculation of bed need under the RFA process should be based in regional use rates trends rather than the current fixed-point historical use rate.	The bed ratios for CCRCs is prescribed in law and the sections were amended accordingly. Changes can only be made legislatively. The RFA bed need calculation is beyond the scope of this project.
	Diagnostic imaging: Raise the CT standard to 6,000 scans/year. Raise the MRI standard to 4,5000 scans/year, with exceptions for rural areas. Changing the [PET] standard is not necessary.	The diagnostic imaging section was suitable amended as agreed upon by the reconvened advisory committee, of which the Association was a part.
	Radiation therapy: Formulae should reflect regional patterns, which vary considerably.	We disagree; believing the existing formula appropriately allows for the variability in regions as suggested in the comment.
	Cardiac Catheterization: Need to develop plans/exceptions protocols for both primary and elective angioplasty. A number of successful state models are available as examples, i.e., NJ, NY, MD. Need to include practitioner minimum volume standards.	We believe the sections on cardiac catheterization appropriately address and allow for angioplasty procedures. These same sections already provide volume standards.
	Neonatal Special Care Services: Neonatal special care services are volumes sensitive of quality and financial viability. The perinatal services subcommittee recommended keeping the 85% occupant standard. There is no reference to travel times in rural areas.	The subsection on neonatal services has been suitably amended to assure access to care for women and their infants, when needed. We believe it is counterproductive to establish an occupancy level or rural travel times when services are closing.

Commenter	Comment	Agency response
Susan Ward Virginia Hospital & Healthcare Association	Intra-planning-district exception process: Suggest a provision for exception to planning district averages for non-tertiary services where there are not significant overlaps in service areas. This would allow for expansions in capacity when justified.	The intent of the comment is not clear, however, we believe the draft provides sufficient opportunities for expansion as suggested.
	230-10: Suggest "Accessibility read: "the ability of a population or segment of a population to obtain appropriate and available services. This ability is determined in part by temporal, economic, cultural, locational and architectural factors that may be barriers or facilitators to obtaining services. It is also determined by the ability of people to obtain the services within a reasonable time in relation to their medical need.	'Accessibility' is defined in any dictionary of common usage; therefore the definition has been deleted.
	Suggested defining appropriate as: suitable for the purpose intended.	We disagree: "appropriate" is generally understood and its definition can be located in a dictionary in general circulation.
	"Competing applications:" should reflect competition on a regional basis, not solely within a planning district.	The definition has been amended as suggested.
	"Computed tomography:" retain current definition; under proposed definition MRI also fits the definition of a CT.	The definition has been amended for clarification.
	"General inpatient beds:" pediatric patients should be under 15 years of age rather than 21 years of age	We have added a definition of pediatric to reflect the legal age of 18.
	"Hospital:" should refer to and be consistent with § 32.1-123	The definition has been clarified; however referencing § 32.123 would omit psychiatric hospital licensed by DMHMRASA.
	"Indigent or uninsured:" suggest adding: or underinsured	The section in which 'indigent and uninsured' is used has been deleted, as the SMFP is not considered the appropriate venue for criteria related to COPN conditioning criteria. Therefore, the definition of 'indigent' has been deleted.

Commenter	Comment	Agency response
	"Magnetic resonance imaging:" use the current definition, as studies indicate the MRIs may be invasive.	That is not correct, while the MRI may be used to assist in conducting invasive procedures; the MRI itself is not invasive, producing images external to the patient's body.
	MRI relevant patients:" delete	We agree.
	"Network:" as defined is confusing, suggest referring to a planning district or make the definition flexible depending on whether a particular application is reviewed on a planning district or health planning region basis.	We have determined to use the term 'health system,' the term coined by the hospital industry itself, when referencing multi-hospital systems. Therefore, the definition of network has been deleted. No definition of 'health system' appears necessary at this time.
	"Off-site replacement:" delete "within the same planning district"	We disagree, believing such a change counterproductive to good health planning.
	"Open-heart surgery:" suggest <u>also referred to as advanced cardiac surgery, means operations on the valve and septa of the heart, coronary artery bypass procedures, implantation of heart and circulatory assist systems, or any other procedures that would require availability of the heart-lung bypass machine or pump</u>.	We determined to use a more general definition to describe open-heart surgery, since COPN does not determine what constitutes medical practice.
	"Operating room" means <u>a room located in a fully controlled sterile environment specifically designed for the performance of surgical procedures and involving the administration of anesthesia</u>. This would include open-heart surgery and trauma rooms, but not include endoscopy, cystoscopy, C-section and procedure rooms.	Defining operating rooms has proven problematic. We chose to utilize the definition in the AIA medical facility design and construction standards, since VDH has been legislatively mandated to adopt those standards for medical care facility licensure purposes. We did add an exclusion for procedure rooms and rooms dedicated for cesarean sections. In addition, the 'General Surgical Services' section provides exclusions for dedicated cardiac and trauma rooms.
	Pediatric cardiac catheterization:" pediatric patients are considered to be those less than 15 years of age, not 21 as proposed.	The pediatric age was amended to reflect the legal age in Virginia of 18.
	"Physician:" suggest including <u>allopathic or osteopathic medicine</u>.	The definition has been deleted as unnecessary.
	"Positron emission tomography:" suggest striking the 2nd sentence as not all PET scanners contain both elements.	The definition has been amended to address both types of PET machines.
	"Radiation therapy:" delete "ingestion of radioisotopes"	The definition has been amended as suggested.

Commenter	Comment	Agency response
	"Stereotactic radiosurgery:" delete "non-invasive" as it is considered an invasive procedures. Also a cyber-knife" does not use an external frame. Also suggest additional review needed as recent technology has made terms less meaningful and confusing when applying standards and criteria.	The definition has been amended as suggested.
	"Study or scan:" please clarify as the draft uses "single patient visit" while VHI collects "procedures" Hence during a patient encounter, multiple procedures, studies or scans may be performed.	As a result of the reconvened advisory committee, it was agreed to replace 'study/scan' with 'procedure.' Therefore, 'study/scan' has been was deleted and replaced with the definition used by VHI, thus codifying the definition of 'procedure.'
	230-20: Suggest adding <u>Each regional health planning agency shall assist the Commissioner in determining whether a certificate should be granted by reviewing applications and making recommendations to the department as provide in § 32.1-102.5.</u>	The section has been deleted per direction from the Code Commission.
	230-30.3: reinsert "and optimal quality of care." 30.5: delete "elimination", insert <u>reduction</u>; delete identified, insert <u>needs as identified pursuant to this chapter</u>.	Section 30 has been redrafted for clarity of intent. We believe it now addresses the concerns expressed.
	230-60:.2 Suggest deleting as the Commissioner should be a position to take the project most beneficial to the public, not necessarily the cheapest. 60.3: deleted this preference. 60.5: preference should be to applicants who best demonstrate a commitment to serving their community as evidence by charity care, community outreach programs and by subsidization of needed but unprofitable services.	The subsection appears to be taken out of context, resulting in some misrepresentation. It is not intended that a COPN would be granted based solely on lowest cost. We agree. The subsection has been amended as suggested.
	230-70: The Board must first designate a new technology for registration before it can be required.	While we disagree with this interpretation, we have determined to delete this section, as most new technologies would cost below the $5 million miscellaneous capital expenditure threshold.
	230-80: Suggest <u>Institution-specific exception</u>; deleting "consideration	The section has been amended as suggested.

Commenter	Comment	Agency response
	will be given" and inserting the Commissioner may grant an exception for	
	230-90.B: suggest including or underinsured; deleting "free of charge to patients; adding to accept patients; delete "by the facilitation of;" add to facilitate; add as defined by the U.S. Department of Health and Human Services Human Resources and Services Administration. 90.C: revise sentence to read the Center shall. Also suggest adding: For the purposes of this subsection, reduced rate or uncompensated care shall include operating losses, determined under generally accepted accounting principles of a provider network's facility located in a medically underserved area as defined by the U.S. Department of Health and Human Services' Human Resources and Services Administration. Without this addition, a hospital could be faced with the perverse incentive of qualifying a patient for Medicaid at 72% of cost or having 100% of cost credited to the charity care condition. Please clarify "regional standard" Recommend the SMFP include a definition of "uncompensated care costs" and that the median value of this measure be used to form the base for the regional standard. 90.C.2: add including in-kind financial support after " direct financial support" 90.D: Suggest the list is too narrow, precluding the addition of any additional recipients without burdensome regulatory change. Recommend that "accurately and fairly represent the net value of services" provided by hospitals, VDH should also take into account:	As previously explained, the text for 'compliance with terms of a condition' has been deleted.

Commenter	Comment	Agency response
	(i) the value of Medicaid losses and (ii) net payments or subsidies provided to compensate hospitals for care of the uninsured, including Medicaid DSH payments, state and local hospitalization payments and receipts from the Indigent Health Care Trust Fund.	
	Staffing for all diagnostic imaging: Suggest reinserting the current standards; the proposal eliminates the requirement of sub-specialization that could result in the proliferation of resources.	We disagree, as staffing qualifications is a facility licensure criterion. However, as a result of the reconvened advisory committee broader staffing language was added.
	230-230: a) Request clarification of how standards apply to mobile PET. b) Will there be specific criteria applied to PET/CT or continue to be embedded in the PET criteria? C) Suggest CT procedures performed during PET/CT downtime be reflected as part of the CT utilization, not the PET/CT utilization.	A section on pro-rating mobile services has been added. In addition, standards regarding the application of mobile services have been added, as applicable.
	230-290: Recommend the state convene a panel of experts to develop consensus recommendations for [radiation therapy] 290.B: the reduction in population from 150,000 to 75,000 is inappropriate and could result in the proliferation of low usage, poorly staffed facilities. Additionally, the current statement regarding decommissioning of replaced units should be retained.	We disagree; we contacted the stakeholder organizations to nominate members to the advisory committee. Therefore, the choice of members was the decision of the stakeholder associations. Additional expert consensus was also obtained through the exposure draft process, in addition to the 60-day comment period required by the APA. VDH is confident ample and sufficient opportunity has been provided for “expert consensus.” The subsection was amended to reflect a population of 150,000, as suggested.
	Stereotactic radiosurgery: suggest that additional review and consideration is needed in the definition and use of these terms	The section on stereotactic radiosurgery has been amended as discussed by the reconvened advisory committee.
	Cardiac Services: Recommend convening an expert panel to develop consensus recommendations on cardiac catheterization services.	We disagree; we contacted the stakeholder organizations to nominate members to the advisory committee. Therefore, the choice of members was the decision of the stakeholder associations. Additional expert consensus was also obtained through the exposure draft process, in addition to the 60-day comment period required by the APA. VDH is confident

Commenter	Comment	Agency response
		ample and sufficient opportunity has been provided for "expert consensus."
	230-370: Recommend defining "diagnostic equivalent catheterization procedures"	A definition has been provided in 12 VAC 5-230-10.
	370.D: For consistency, recommend: Proposals for the <u>expansion</u> of cardiac catheterization <u>services by existing providers</u> shall not be approved unless…	A separate section on expansion of services has been added; this section addresses the concern expressed.
	230-450: Appears to be an inconsistency in subsection A2 and 3 and E2b.	The inconsistency has been addressed.
	Lithotripsy services: the standards should distinguish between renal and orthopedic lithotripsy.	While we believe the standards are clear, clarification has been provided.
	Miscellaneous capital expenditures: Suggest that the $5 million threshold is too low or that some projects be carved out to eliminate COPN review. We understand that legislative change is necessary to implement this recommendation.	That is correct, legislation is necessary to implement this change.
	Perinatal services: Suggest the addition of occupancy standards for obstetrical beds	The need for new obstetrical services is now based on population and utilization of current services, which will appropriately address any need for new services in urban, suburban and rural areas.
	230-670: Suggest the driving time be consistent with neonatal services at 45 minutes.	We disagree. The need for obstetrical services should not be confused with the need for specialized care for the sickest infants.
	Neonatal services: Suggest retaining the current neonatal sections including the definition of "regional neonatal services." Refer to the State Perinatal Plan, which is consistent with the perinatal regionalization scheme of the AAP and ACOG. The regional plan is critical for maintaining quality and should be preserved.	The referenced State Perinatal Plan was developed in 1988 and never officially adopted.

Commenter	Comment	Agency response
	NICU definitions should be consistent with AAP definitions outlining the appropriate level of care provided at the NICU level.	Such change must be accomplished through the hospital licensure regulation since the SMFP references that regulation.
	Suggest the inclusion of requirements regarding high-risk patients and transfer agreements with regional NUCU units.	We disagree; those are hospital licensure issues.
	Suggest the standards be reviewed with the recommendations of the Governor's Working Group on rural Obstetrical Care to ensure consistency.	The suggestion is duly noted.

Family impact

Please assess the 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.

There is not direct impact on the institution of the family or family stability as a result of revising the SMFP.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

The substantive changes are technical in nature, providing clarity, continuity and better direction than the initial draft. For example, a number of sections have been created from existing text or added to each Part to facilitate identification of specific topics to ease the use of the SMFP as a planning document. As a result, sections beginning with Part II have been renumbered. Changes include:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
230-10 240-10 250-10 260-10 270-10 280-10 290-10 300-10 310-10 320-10 330-10 340-10 360-10	230-10	Definitions amended: "Cardiac Catheterization,"" "Computed tomography," "Health planning regions," "Hospital," "Indigent," "Inpatient beds," "Intensive care beds," "Lithotripsy," "Neonatal special care," "Open heart surgery," "Operating room," "Operating room use," "operating room visit," "Outpatient surgery," "Pediatric cardiac catheterization," "Perinatal services," "Population," "Positron emission tomography," "Radiation therapy," "Relevant reporting period," "State medical facilities plan/SMFP," and "Stereotactic radiosurgery."	All definitions were combined into one section at the front of the document. Obsolete or non-related definitions were removed. These definitions were amended as a result of the public comment period.
		Definitions added: "Bassinets," "Beds," "COPN," "Diagnostic equivalent procedures," "Health system," "ICF/MR," "Long term acute care hospital," "Medical/surgical," "Pediatric," "PET/CT," "Primary service area," "Procedure," "Qualified," and "VHI."	New definitions added to aid clarification.
		Definitions deleted: "Acceptability," "Accessibility," "Applicant," "Availability," "Certificate of Public Need," "Charges," "Condition," "Department," "General inpatient hospital beds," "hospital-based," "Intermediate care substance abuse disorder treatment services," "MRI relevant patients," "Network," "Nursing facility beds," "Physician," "Quality of care," "Study," and "The center" were deleted.	These definitions were determined unnecessary, other definitions were eliminated pursuant to the initial draft.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
230-20 State Medical Facilities Plan	230-20	Preface	Does not relate to regulatory standards, section repealed upon instruction from the Code Commission.
230-30	230-30	Technical amendments made	Amendments made at request of Board of Health member.
	230-40	N/A	Section contains "general application filing criteria;" the first of the new general information sections to reduce redundancy in the document. Section title amended. States that applicants must comply with all 20 COPN criteria; that the burden of proof rests with the applicant to provide the necessary required information, and that the Commissioner may 'condition' a COPN upon agreement of the applicant to provide a level of indigent or uncompensated care.
	230-50	N/A	Section addresses "project costs;" one of the new general criterion sections developed to consolidate redundancy in related standards throughout the current SMFP. Section has been technically amended for clarity.
	230-60	N/A	Section addresses "preferences" to granting a COPN when competing applications are received; this section was developed to consolidate and decrease redundancy of all preferences scattered throughout the current SMFP. Section title and section technically amended for clarity.
	230-70	N/A	Section addresses "prorating mobile services" to provide prorating formula for determining need for mobile services rather than fixed site services. This is an enhancement to the SMFP.
	230-80	N/A	Section addresses "institutional need" in granting a COPN; this is an enhancement to the current SMFP requested by providers by allowing providers to apply for additional services when data determine there is

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			no need for more services within a planning district or region. COPN stakeholders requested this addition.
320-20 Computed Tomography (CT)		Consumer acceptance of services offered	Deleted: philosophical statement, non-measurable or verifiable during the project review process.
320-30	230-90	Location	Section title changed to Travel time. Preference statement moved to 230-60, when competing applications received.
320-40		Financial considerations; ability to pay	Deleted: section duplicative and redundant, combined under single section 230-60, when completing applications received.
320-50	230-100	Need for new service.	Section technically amended for clarity, volume standard increased to 10,000 procedures based on newer, faster technology; exemption added for CTs used exclusively for simulation with radiation therapy treatment services; allows for services in distinct remote areas.
320-60	230-110	Expansion of existing service	Section technically amended; increase of volume standard to 10,000 procedures based on newer, faster technology.
320-70		Replacement of existing equipment	Deleted: replacement of equipment was repealed as a COPN project, section deleted.
320-80		Coordination of service	Deleted: philosophical statement; not measurable or verifiable during the project review process.
320-90		Cost and charges	Deleted: section duplicative and redundant, located under 230-50
	230-120		New section on adding/expanding mobile CT services, utilizing prorated formula from 230-70.
320-100	230-130	Staffing	Section technically amended as requested by advisory committee and public comment.
320-110		Space	Deleted: space requirements are licensure criteria, not COPN.
320-120 Magnetic		Consumer acceptance of	Deleted: philosophical statement; not

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Resonance Imaging (MRI)		services offered.	measurable or verifiable during the project review process.
320-130	230-150	Location	Section title changed to Travel time. Preference standard moved to 230-60, when competing applications received.
320-140		Financial	Deleted: section duplicative and redundant, combined under single section 230-60, when completing applications received.
320-150	230-150	Need for new service	Section technically amended for clarity, volume standard increased to 5,000 procedures based on newer, faster technology; provides allowance for services in distinct remote areas.
320-160		Alternative need for new MRI service	Deleted: combined with preceding section to facilitate use of the SMFP.
320-170	230-160	Expansion of services	Section technically amended for clarity, volume standard increased to 5,000 procedures;
320-180	230-170	Mobile services	New language addition/expansion of mobile MRI services, utilizing prorated formula from 230-70, better defines requirements.
320-190		Replacement of existing equipment	Deleted: Replacement of equipment was repealed as a COPN project, section deleted.
320-200		Coordination of services	Deleted: philosophical statement deleted; not measurable or verifiable during the project review process.
320-210		Cost	Deleted: section duplicative and redundant, located under 230-50
320-220	230-180	Staffing	Section technically amended as requested by advisory committee and public comment.
320-230		Space	Deleted: this is a licensure requirement, not COPN.
320-240 Magnetic Resource Imaging (MSI)	230-190	Policy for the development of MSI services	Statement retained to provide guidance regarding magnetic resource imaging.
320-250		Potential clinical applications of MSI	Deleted: statement of philosophy, not measurable.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		Technology	
320-260		MSI technology described	Deleted: statement of philosophy, not measurable.
320-270 Positron Emission Tomography (PET)		Consumer acceptance of services offered	Deleted: statement of philosophy, not measurable.
320-280	230-200	Service area	Section revised defining a 60 minute travel time for 95% of the planning district population, thus allowing for more PET providers to enter the market in the applicable planning region.
320-290		Hours of operation	Deleted: this is a licensure standard, not enforceable by COPN.
320-300		Location of services	Combine with new section 230-200
320-310		Service capability	Deleted; combined in section on 'need for new services.'
320-320	230-210	Projecting demand for service	Section title changed to "need for new fixed site services; volume standard increased to 6,000 procedures, based on newer, faster technology; provides allowance for services in distinct remote areas; Clarification provided on PET/CT machines taking concurrent images.
320-330		Minimum utilization	Deleted: combined with 230-210; standard lowered to 850 new cases.
320-340	230-230	Additional scanners	Section reassigned to 'expansion of fixed site services; increasing volume standard to 6,000 procedures, based on newer, faster technology.
320-350		Replacement of service	Deleted: replacement of equipment was repealed as a COPN project.
320-360		Coordination of services	Deleted: Section no longer a relative consideration for project review.
320-370		Less costly alternatives	Deleted: section duplicative and redundant, combined under sections 230-50 and 60.
320-380		Financial access	Deleted: section duplicative and redundant, combined under section 230-60.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	230-330	Does not address mobile services	New language addition/expansion of mobile MRI services, utilizing prorated formula from 230-70, better defines requirements.
320-390	230-240	Staffing	Section technically amended as requested by advisory committee and public comment.
320-400 Single Photon Emission Computed Tomography (SPECT)		Consumer acceptance of service offered	Deleted: philosophical statement
320-410	230-250 Non-cardiac Nuclear Imaging	Location	Section title changed to Travel time. Preference standard moved to 230-60, when competing applications received.
320-420		Financial considerations; ability to pay	Deleted: section was duplicative and redundant; combined into 230-60.
320-430	230-260	Introduction of SPECT as a new service	Section title amended; and section format technically amended for clarification
320-440		Additional scanners	Deleted: addressed by section 230-260
320-450		Replacement of existing equipment	Deleted: replacement of equipment repealed as a reviewable project, section deleted.
320-460		Comparability of charges	Deleted: section was duplicative and redundant; sections were combined in 230-50.
320-470		Medical Director	Deleted: this is a licensure standard, not enforceable by COPN.
320-480	230-270	Additional staff	Section title amended; Section technically amended as requested by advisory committee and public comment.
340-20 Radiation Therapy Services		Acceptability; consumer participation	Deleted: philosophical statement; not measurable or verifiable under COPN.
340-30	230-280	Accessibility; time; financial considerations	Section title amended; standard on 'hours of operation,' a licensure standard deleted; standard on ability to pay combined in 230-60; standard on rural services is 1 of 20 COPN determinations specified in law.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
340-40	230-290	Availability; need for new service; expanded; replacement of service	Section title amended to 'need for new service,' volume standard lowered to 5,000 procedures; number of new cancer cases increased to 60% in the need formula.
	230-300		New section on expansion taken from current language; volume standard lowered to 8,000 procedures
340-50	230-310	Continuity; tumor registry; discharge and follow-up care	Section and title amended to reflect the statewide cancer registry as required by law.
340-60		Cost; cost comparability	Deleted: section duplicative and redundant, combined under section 230-50.
340-70	230-320	Quality; staffing; financial considerations; patient care; support; care.	Standard on staffing revised as requested by the advisory committee and public comment; all other standards deleted as duplicative or not enforceable under COPN.
340-80 Gamma Knife Surgery	230-330 Stereotactic Radiosurgery*	Accessibility; travel time; financial considerations	*"Gamma Knife" is a trademark name, therefore, name of subsection change to reflect actual category of equipment, i.e., stereotactic radiosurgery. Section title amended, actual travel time established; other standards deleted as not enforceable under COPN.
340-90	230-340	Availability; need for new service	Section title amended and specific criteria established to clarify standards.
	230-350		Section on expansion of services added.
340-100	230-360	Continuity; coordination of services; tumors registry; discharge and follow-up	Section and title amended to reflect the statewide cancer registry as required by law; other standards deleted as not enforceable under COPN.
340-110		Cost comparability	Deleted: section duplicative and redundant, combined under sections 230-50 and 230-60.
340-120	230-370	Quality; staffing; equipment	Standard on staffing revised as requested by the advisory committee and public comment; all other standards deleted as duplicative or not

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			enforceable under COPN.
260-20 Cardiac Services, i.e. cardiac catheterization and open heart surgery		Acceptability; consumer participation	Deleted: philosophical statement; not measurable during the project review process.
260-30	230-380	Accessibility; financial considerations.	Section title amended, actual travel time established; standard on ability to pay combined in 230-60; standard on rural services is 1 of 20 COPN determinations specified in law.
260-40	230-390	Availability; need for new services; alternatives	Section title amended to 'need for new service;' revised to provide measurable criteria; standards on 'additional services,' 'expansion of services,' 'pediatric services,' and 'non-emergent services' adjusted to individual sections for clarity and identification of specific requirements.
	230-400		Section created from expansion standards in 260-40; technically amended for consistency with proposed draft.
	230-410		Section created from pediatric standards in 260-40; Technically amended for consistency with proposed draft.
	230-420		Section created from non-emergent standards in 260-40; technically amended for consistency with proposed draft.
260-50		Continuity; coordination	Deleted: philosophical statement. Standards not verifiable or enforceable during the project review process; addressed in facility licensure criteria, 12 VAC 5-410.
260-60		Cost; alternatives	Deleted: section duplicative and redundant, combined under sections 230-50 and 230-60.
260-70	230-430	Quality; staffing; patient care and support services	Standard on staffing revised as requested by the advisory committee and public comment; all other

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			standards deleted as duplicative or not enforceable under COPN.
260-80 Open heart surgery		Acceptability; consumer participation	Deleted: Philosophical statement; not measurable or verifiable.
260-90	230-440	Accessibility; travel time; financial considerations	Section title amended to 'travel time;' distance shortened to 60 minutes; 'ability to pay' standard located in 230-60
260-100	230-450	Availability; need for the new service; alternatives	Section technically amended for clarity; volume standard increased to 1,200 procedures; equipment replacement repealed as a COPN category; 'expansion' and 'pediatric' services established as separate sections
	230-460		Section created from existing 'expansion' text of 260-100
	230-470		Section created from existing 'pediatric' standards of 260-100.
260-110		Continuity; coordination	Deleted, 'referral agreements' and 'discharge planning' are licensure concerns, not enforceable under COPN.
260-120		Cost; alternatives	Deleted: section duplicative and redundant, combined under sections 230-50 and 230-60.
260-130	230-480	Quality; staffing patient care and support services	Section revised to address staffing as requested by the advisory committee and public comment; all other criteria deleted as not enforceable under COPN.
270-20 General Surgical Services		Acceptability	Deleted: philosophical statement; not measurable or verifiable under COPN
270-30	230-490	Accessibility; travel time; financial	Section title amended; population increased slightly to 95%; 'ability to pay' located under 230-60.
270-40	230-500	Availability; need	Section title amended; formula for determining need reconfigured; new population data source adopted.
270-50		Cost; charges	Deleted: relocated under 230-50 and 60.
270-60		Quality;	Deleted: philosophical statement, not

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		accreditation/licensure	enforceable under COPN.
	230-510		Staffing section added for consistency in proposed draft at requested of advisory committee.
240-20 General Acute Care Services	230-520	Accessibility	Section titled amended to 'travel time;' preference standards located under 230-60.
240-30	230-530	Availability	Section renamed 'need for service;' 'med/surg,' 'pediatric,' 'intensive care,' and 'expansion' standards established as separate sections.
	230-540		Section on 'med/surg' created from 240-30; new formula developed for consistency with document at request of advisory committee
	230-550		Section on 'pediatric' created from 240-30; new formula developed for consistency with document at request of advisory committee
	230-560		Section on 'intensive care' created from 240-30; new formula developed for consistency with document as request of advisory committee
	230-570		Section on 'expansion' created from 240-30; new formula developed for consistency with document as request of advisory committee
	230-580		New section to address new acute care patient category; developed using federal LTACH standards.
	230-590		Staffing section added for consistency in proposed draft at requested of advisory committee.
240-40		Continuity	Deleted: licensure standards; standards not verifiable or enforceable under COPN.
240-50		Cost	Deleted: located under 230-50 and 230-60
240-60		Quality; accreditation and compliance with chapters.	Deleted: licensure standards; not verifiable or enforceable under COPN.
360-20 Nursing Home		Acceptability	Deleted: licensure standards, not measurable or verifiable under COPN

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Services			
360-30	230-600	Accessibility	Section amended to 'travel time;' revised; distance lowered to 30 minutes of 95% of the population; 'ability to pay' and 'correction of maldistrbution of beds' located under 230-60; standard regarding improved access added;
360-40	230-610	Availability	Section title amended; language ambiguities removed; occupancy level lowered to 93%; bed need forecast table revised; freestanding bed capacity lowered to 90; new population data resource used; 'expansion' standards established as separate section..
	230-620		Section on 'expansion' created from 240-360-40; occupancy level lowered to 93%
	230-630		Section on 'continuing care retirement communities' created from 360-40; language taken from law
	230-640		Section on 'staffing' added at request of advisory committee for documents consistency.
360-50		Continuity	Deleted: licensure standards, not enforceable under COPN.
360-60		Costs	Deleted: section duplicative and redundant, located under sections 230-50 and 230-60.
360-70		Quality	Deleted: licensure standards; not measurable or verifiable under COPN.
330-20 Lithrotripsy Services		Acceptability; waiting time; consumer participation	Deleted: licensure standards; not measurable or verifiable under COPN.
330-30	230-650	Accessibility; financial considerations	Section title amended and travel time reduced to 30 minutes drive time; Financial considerations deleted; located under 230-60.
			New section establishes travel time of 30 minutes for 95% of population.
330-40	230-660	Availability; need for new services; expanded or replaced.	Section title amended; separate standards for renal and orthopedic procedures established; volume standard lowered; replacement standard

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			deleted; new section established for service expansion and mobile services;
	230-670		New expansion section created from existing text; volume standard lowered
	230-680		New mobile section created from existing text using prorated formula in 230-70.
330-50		Continuity; coordination of services	Deleted: licensure standard; not measurable or verifiable under COPN.
330-60		Cost comparability	Deleted: located in 230-
330-70	230-690	Quality; staffing	Section amended as requested by the advisory committee and public comment.
280-20 Organ Transplant Services		Acceptability; consumer participation	Deleted: licensure standard; not measurable or verifiable under COPN.
280-30	230-700	Accessibility; travel time; access to available organs	Section title amended; Deleted: organ recipient policies - licensure standards, not verifiable under COPN.
280-40	230-710	Availability; rationalization of services; conditional approval; HCFA Medicare requirements	Section title amended; expansion standards moved to 230-730; Deleted: compliance with federal standards - licensure criteria;
280-50		Continuity of care; discharge planning procedures and follow-up	Deleted: licensure standards, not measurable or verifiable under COPN.
280-60		Cost and charges	Deleted: located under 230-50
280-70	230-720	Quality; minimum utilization; minimum survival rate; services proficiency; staffing; systems operations; support services	Section title amended; transplant volumes and survival rates revised reflecting national standards; staffing standards moved to 230-740
	230-730		New section created from existing text in 230-720 at request of advisory committee for continuity and consistency
	230-740		New Section created from existing text at request of advisory committee and public comment for document continuity

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
350-10 Miscellaneous Capital Expenses	230-750	Purpose	Technically amended.
350-20	230-760	Project need	Technically amended, reflects HB2546 (2007) increase in capital expenditures from $1 million to $15 million.
350-30	230-770	Facilities expansion	Technically amended
350-40	230-780	Renovation or modernization	Technically amended
350-50	230-790	Equipment	Technically amended
350-60		Assurances	Deleted: invalid
310-20 Medical Rehabilitation Services		Acceptability; channels of consumer participation	Deleted: licensure standard, not measurable or verifiable under COPN.
310-30	230-800	Accessibility; travel time; financial considerations	Section title amended; cost standards located in 230-60; rural access standard deleted; redundant of law (§32.1-102.3, criteria for determining need).
310-40	230-810	Availability; need	Section title amended; population data sources revised; formula technically amended for conformity with other COPN formulas; expansion standard moved to 230-820
310-50		Continuity; integration	Deleted: licensure standard, not measurable or verifiable under COPN
310-60		Cost	Deleted: located under 230-50.
	230-820		New section created from existing text at request of advisory committee and public comment
310-70	230-830	Quality; Staffing and services	Section amended at request of advisory committee and public comment for consistency with documents.
290-20 Psychiatric and Substance Abuse Treatment Services		Acceptability	Deleted: licensure standard, not measurable or verifiable under COPN.
290-30	230-840	Accessibility; travel time; financial considerations	Section title amended; revised as requested by the Department of Mental Health, Mental Retardation and Substance Abuse Services (DMHMRSAS), language was updated

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			and ambiguities removed.
290-50	230-850	Continuity; integration	Section relocated and expanded at request of DMHMRSAS
290-40	230-860	Availability; treatment beds; combined need; intermediate care	Section revised as requested by the DMHMRSAS
290-60		Cost and charges	Deleted: located under 230-60
290-70		Quality; accreditation and compliance with chapters	Deleted: licensure standard.
300-20 Mental Retardation Services		Accessibility; financial considerations	Deleted: located in 230-60.
300-30	230-870	Availability; need	Section title amended; standards revised to reflect 2004 legislative change; revised as requested by the DMHMRSAS.
300-40	230-880	Continuity, integration	New section added at request of DMHMRSAS
300-50	230-890	Quality	Section title amended.
300-60		Acceptability; size, channels for consumer; participation	Deleted: relocated to 230-870.
300-70		Cost and Charges	Deleted: located under 230-50.
250-20 Perinatal Services		Acceptability	Deleted: licensure standard - not verifiable or enforceable under COPN.
250-30	230-900	Accessibility	Section title amended; ability to pay located under 230-60; rural services provision deleted - redundant of law (§32.1-102.3)
250-40	230-910	Availability	Bases need on population and utilization of current services; preference established on consolidation of services' current standards are not measurable under COPN
250-50	230-920	Continuity	Standards amended to reflect measurable standards; transfer agreements are the licensure standard
250-60		Cost	Deleted: located under 230-50 and 230-60
250-70		Quality standards; data collection.	Section deleted, references were archaic and not measurable under COPN; data on mortality/morbidity

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			redundant of law.
	230-930		Staffing section created at request of advisory committee
250-80 Neonatal special Care Services	23-940	Accessibility, travel time; payment	Standards deleted: philosophical statements, not measurable under COPN. New standards establish levels of neonatal services: intermediate and specialty/subspecialty reflective of licensure law
250-90	230-950	Availability; service capacity	Section amended to establish policy for requesting services under COPN; existing standards archaic.
250-100		Neonatal services; continuity; agreement; follow-up care.	Deleted: measurable or enforceable under COPN
250-110		Cost; regionalization; levels of care.	Deleted: located under 230-60.
250-120		Quality	Deleted: not measurable under COPN
	230-960		Establishes intermediate level newborn criteria as reflected by licensure laws and regulations; requested by public comment
	230-970		Establishes specialty level newborn criteria as reflected by licensure laws and regulations; requested by public comment
	230-980		Establishes subspecialty level newborn criteria as reflected by licensure laws and regulations; requested by public comment
	230-990		Requires COPN application to identify hospital to be served by the 3 neonatal level of care
	230-1000		Staffing section requested by advisory committee for continuity with document