Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-230 promulgate 12VAC5-240 through 360 repeal
Regulation title	State Medical Facilities Plan (SMFP)
Action title	Final Promulgation of comprehensive revision document
Date this document prepared	June 25, 2008

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

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

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 goal of the revision project is to update the criteria and standards to reflect industry standards, remove archaic language and ambiguities, and consolidate all portions of the SMFP into one comprehensive document. As a result of the consolidation, 12 VAC 5-240 through 12 VAC 5-360 are being repealed as 12 VAC 5-230 is amended and promulgated.

Because of stakeholder concerns regarding the initial proposed draft, the Board of Health (Board) directed staff to reconvene the work group and consider additional amendments to the draft. Substantive changes were made to the draft, including, but not limited to, a number of sections created from existing text or added to facilitate identification of specific topics. A reproposal comment period was held this February 2008.

Statement of final agency action

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

On July 18, 2008, the State Board of Health (Board) adopted the final comprehensive revision to the State Medical Facilities Plan

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 numbers, if applicable, and (2) promulgating entity, i.e., 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,on behalf of the Board, 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; 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. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The Virginia Medical Care Facilities COPN 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 one of twenty-one criteria used to determine public need in eleven categories of medical care facilities subject to the COPN law. The SMFP is a fundamental tool in the COPN program as it provides the methodologies used in decision making 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 agents with a framework for examining the need for these projects.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

Changes providing clarity and better direction have been made to the draft as a result of the reproposal period. Changes include:

Amended planning region to read *health* planning region.

Part I. Definitions and General Information.

Definitions added or clarified. Sections on guiding principles, and competing applications were technically amended to provide direction and clarify intent. Adopted a new formula and title and added clarifying language to 12VAC5-230-70.

Part II. Diagnostic Imaging.

Article 1. Computed Tomography: Modified the volume standards from 10,000 procedures to 7,400 procedures.

Article 2. Magnetic Resonance Imaging: Technical changes made.

Article 4. Positron Emission Tomography: Technical changes made.

Article 5. Non-cardiac nuclear Imaging: Technical change made.

Part III. Radiation therapy services: Technical changes made.

Part IV. Cardiac Services: Technical changes made.

Part V. General Surgical Services: Technical changes made.

Part VI. Inpatient Bed Requirements: Technical change regarding pediatric age cohort.

Part VII. Nursing Facilities: Clarified the 'presumption of no need' date. Section 630 amended to conform to §32.1-102.3:2 of the Code.

Part VIII. Lithotripsy Services: Technical changes made.

Part IX. Organ Transplant Services. Technical change made.

Part XI. Medical Rehabilitation: Technical change made.

Part XIII. Perinatal Services: 'and Obstetrical' inserted into title to read: Perinatal *and Obstetrical* Services; technical changes made.

No changes or amendments were made to the following subsections: 40, 50, 80, 130, 190, 260, 310, 360, 370, 410 - 430, 480, 510, 530, 540, 570-590, 640, 690, 720, 750-790, 830, 850, 870-890, 920, 930, 990, 1000.

Issues

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

The SMFP is an integral part of the COPN process. Therefore, no discussion of the SMFP can be conducted without mentioning the COPN program. The COPN law states the following 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 controversial. However, lacking a consensus on what might work better, Virginia, like 36 other states, has chosen to maintain its COPN program regarding specified services and equipment. 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 perceptions regarding the COPN program that subsequently affect the SMFP: (i) the COPN program ensures quality health care services, and (ii) the program has become a 'franchise' guarantor, making it difficult for new health care providers, especially stand alone or non-institutional practitioners, to obtain a needed certificate in order to provide service.

Over time, the COPN program has garnered a reputation as a key element in assuring quality health care services to Virginia's citizens. The reality is that the COPN program addresses a small fraction of the burgeoning health care market. Further, only legislatively mandated licensure programs 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 can only be verified once the project has been completed and, subsequently, is outside the realm of COPN oversight. Therefore, such criteria as meeting specific staffing requirements, assurances that the project will comply with applicable licensure regulations, or requiring national accreditation were removed. While we recognize the resultant discomfort of such elimination, the fact remains that the COPN law does not authorize or provide for enforcement of the individual sections of the SMFP once the certificate has been issued. A certificate 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. It is unlikely that revocation of a COPN would be sought pursuant to 'willful or reckless misrepresented intentions' because a

provider fails to obtain national accreditation, for example. The COPN law does not permit inspection after issuing the COPN, which is the only method by which such quality failures can be identified.

Those same 'quality of care' standards 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 legitimate health care providers as well as denying access to needed health care services by Virginia's citizens. As stated above, a goal 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 service volume and utilization criteria, the process is now open to a broader range of providers which will provide greater choices for Virginia's citizens. 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. Therefore, VDH believes many of the difficulties to obtaining a COPN have been removed.

The means by which the SMFP does impact quality is through the service volume or utilization standards within each of the project specific sections. In health care, higher volume or utilization equates to quality service and better patient outcomes. Therefore, as part of the revision project, the service volume and utilization standards were reviewed and adjusted to reflect changes in technology. Since the current SMFP was promulgated, technological changes have been multifold and have contributed to improved patient procedure times, more affordable equipment, increased availability of the equipment across the Commonwealth, and lower costs to patients.

Of particular concern to both institutional and non-institutional providers were volume standards for diagnostic imaging services, especially Computed Tomography (CT) units. Non-institutional practitioners opposed the proposed CT service volume increase from a base of 3000 procedures to 10,000 procedures, feeling that such an increase proved the 'guarantor' perception. Institutional providers expressed concern that volume standards lower than 10,000 procedures jeopardized their ability to maintain utilization rates by increasing availability of such equipment. The department found available data regarding utilization inconclusive as not all diagnostic imaging providers are required to annually report usage to the health data organization under contract to the department. Since consensus could not be reached among stakeholders regarding an appropriate volume standard, the department determined that averaging statewide utilization was an equitable compromise, as such averaging would reflect the rise in usage due to technological improvements. The department determined that a average utilization statewide of 85% would support extant providers currently maximizing technology, but would not adversely affect new providers trying to enter the market.

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, VDH staff were directed to reconvene the work group with the intent of discussing responses to the public comments received. That process was accomplished over the course of eight months and ten meetings. Membership on the work group consisted of representatives from the Virginia Hospital and Healthcare Association, the Medical Society of Virginia, the Virginia Health

Care Association, the Virginia Association of Nonprofit Homes for the Aging, the Regional Health Planning Agenceis, the Board of Health and the VDH Division of COPN. 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.

In the course of this regulatory project, VDH also discovered that there are misperceptions regarding the application of the SMFP in the decision making process. Those discoveries include: applicants consider the SMFP as the 'sole source' decision factor and that 'preferences' were actually mandates upon the State Health Commissioner.

While it is correct that 'any decision to issue or approve the issuance of a certificate shall be consistent with the most recent applicable provisions of the [SMFP],' the SMFP cannot be the sole source for applying for the certificate, as it provides only the 'methodologies for projecting need for medial care facilities beds and services.' There are twenty qualifiers that must also be addressed in each project application in order for a decision to be made and a certificate issued. In addition, the Commissioner has the authority to declare any portion of the SMFP 'not relevant to a rural locality's needs, inaccurate, outdated, inadequate or otherwise inapplicable,' referred to as 'set asides.' If the SMFP was the sole source document for determining need, the process would be disrupted when the Commissioner did set aside a provision of the SMFP. However, that does not happen as there are the additional criteria used allowing decisions to be made and certificates granted.

The department was intrigued to learn that many stakeholders perceive that project specific 'preferences' were a mandate on the Commissioner to grant a certificate. The department was asked to substitute 'consideration' as a alternative. The department does not believe the substitution of 'consideration' to be appropriate to address the actual intent of the preferences. Regardless of topic, when an oversight authority establishes preferences, the authority is providing policy direction for an applicant. In the case of COPN projects, preferences support VDH's public health mission by promoting and protecting the health of Virginia's citizens through the development of new services when and where needed and limiting the unnecessary duplication of expensive technologies and services. However, since all the proposed preferences are permissive in nature, they are non-biding in the decision making process, should a competing application present a more compelling care that its project offers Virginia's citizens a better use of health care dollars. Therefore, preferences should be interpreted as an expression of ideal circumstances, not as an 'all or nothing' situation.

As a result of the overall project objectives and the reconvened work group meetings, the department believes the final amendments to the SMFP fulfills 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 stakeholders for development of services would be affected by the revised document. This would include consultants and attorneys hired to help the applicants through the COPN process.

Changes made since the re-proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the re-proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
Global	'Planning region' used throughout the document.	Amended to read: *health* planning region	Commenters reported confusion of intent, this clarifies intent
10		Clarified definitions: bassinet, beds, inpatient, minimum survival rates, neonatal special care, operating room, outpatient, pediatric, radiation therapy, and stereotactic surgery	Clarified as a result of comments received from the re-proposal period
10		Added definitions: Gamma Knife®, medical rehabilitation, and stereotactic radiotherapy.	Added as a result of comments received from the re-proposal period.
10		Corrected definitions: continuing care retirement community, COPN, intensive care beds, long-term acute care hospital, and procedure	Corrected as a result of comments receive.
		Deleted definition: pediatric cardiac catheterization	Since 'pediatric' and 'cardiac catheterization' are defined, a definition of 'pediatric cardiac catheterization' was determined not necessary.
30	30 A 1 reads: capacity *and* 30 A 2 reads geographical *dispersion*	Change to read capacity or; geographical distribution	Changed as a result of comments received.
40/50		No changes made	
60	Section read: 'consideration will'	Change to read: 'preference may'	Please refer to the discussion of 'preferences' under 'Issues;' language change to assure permissive authority in response to concerns.
70*	Section addresses prorating mobile services; offers formula.	Title and language rewritten; new formula proposed	Section rewrite proposed by comments received.
80		No change	
90		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
100	CT volume set at 10,000 procedures	Added to apply to mobile as well as fixed services; procedure volume reduced to 7,400	The CT volume of 10,000 procedures was deemed to high a

			standard for non-institutional providers; therefore, reduced to 7,400 procedures (refer to CT volumes under Issues). Other edits suggested by comments received.
110*	CT volume set at 10,000 procedures	Procedure volume reduced to 7,400	The CT volume of 10,000 procedures was deemed to high a standard for non-institutional providers; therefore, reduced to 7,400 procedures (refer to CT volumes under Issues).
120		Edits made for consistency with other sections within the document.	Requested by commenters.
130		No changes.	
140		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
150/160/170		Edits made for consistency with other sections within the document.	Requested by commenters.
190		No changes.	
200		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
210/220/230		Edits made for consistency with other sections within the document.	Requested by commenters.
250		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
260		No changes	
270	Requires designated users of isotopes to be licensed	Removes reference to isotopes	Commissioner determined that isotope therapy no longer a COPN project, therefore references to isotopes deleted.
280		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
290/300		Edits made for consistency with other sections within the document.	Requested by commenters.
310		No changes	

320	Requires designated users of isotopes to be licensed	Removes reference to isotopes	Commissioner determined that isotope therapy no longer a COPN project, therefore references to isotopes deleted.
330		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
340	Section reads: 'consideration..'	Change to read: 'preference may' Edits made for consistency with other sections within document	Please refer to the discussion of 'preferences' under 'Issues;' Requested by commenters
360/370		No changes	
380		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
390/400		Added 'per existing and approved laboratory;' Changed 'laboratory' to read 'service'	Requested by commenters.
410/420/430		No changes	
440		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
450	subsection reads: 'consideration..'	Changed to read: 'preference	Please refer to the discussion of 'preferences' under 'Issues;'
450/460/470		Technical edits made	Requested by commenters
480		No changes	
490		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
500		Technical edits made	Requested by commenters
510		No changes	
520		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
530/540		No changes	
550	Reflects pediatric age at less then 19	Changed to properly reflect state law of under 18 years of age	Requested by comment
560	Reflects only adult cohort, but applicable to both adult and pediatric	Added: 'or older for adults or under 18 for pediatric patients'	Requested by comment

	patients		
570/580/590		No changes	
600		Added 'using mapping software as determined by the Commissioner.' 'consideration' changed to read: 'preference'	Suggested by comment, modified for Commissioner discretion. Please refer to the discussion of 'preferences' under 'Issues;'
610	Date of 'presumption of no need' was confusing and subject to interpretation.	Clarifies date of 'presumption of no need' as date of issuance of certificate. 'consideration' changed to read: 'preference'	Requested by commenter Please refer to the discussion of 'preferences' under 'Issues;'
620		Technical edit	Requested by commenter
630	Subsection reflected incorrect statute reference	Edited to reflect COPN law regarding CCRC type nursing facilities	Comment received identified error.
640		No changes	
650		Added 'using mapping software as determined by the Commissioner.' 'consideration' changed to read: 'preference'	Suggested by comment, modified for Commissioner discretion. Please refer to the discussion of 'preferences' under 'Issues;'
670/680		Technical edits	Requested by commenter
690		No changes	
700		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
720		No changes	
730		"consideration' changed to read; 'preference'	Please refer to discussion of 'preferences' under 'Issues.'
740		No changes	
750 – 790		No changes	
800		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
810	Reads 85% bed occupancy	Changed to read: 80% bed occupancy	Requested by commenter
820		"consideration' changed to read;	Please refer to

		'preference'	discussion of 'preferences' under 'Issues.'
830		No changes	
840		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
850		No changes	
860		"consideration' changed to read; 'preference'	Please refer to discussion of 'preferences' under 'Issues.'
870- 890		No changes	
900		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
910		Deleted subsection B; technical edits	Requested by commenters
920/930		No changes	
940		Added 'using mapping software as determined by the Commissioner.'	Suggested by comment, modified for Commissioner discretion.
950		Deleted subsection B	Requested by commenters
960/970/980		Technical edits made	Removes redundant language
990/1000		No changes	

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

To assist in correlating the comments to the corresponding sections of the proposed SMFP, the comments have been transcribed in section order and are in bold to identify where each grouping of comments begins below.

Commenter	Comment	Agency response
These comments were made by more than one respondent. Rather than repeat, they are consolidated here.	Successful implementation of the [SMFP] requires comprehensive and accurate information. A utilization database in which all providers are required to participate is essential. Currently there are several diagnostic centers and outpatient surgery centers that are not required to report separately	This comment has merit, but is beyond the scope of this project as it requires legislative action to implement. We are placing this on the agenda for the newly established SMFP Task Force, as required by HB396 (2008), to consider for further action. The Task Force is slated to hold its first meeting in September 2008.

	and do not. This gap needs to be filled. VHI has the technology and willingness to undertake this and we suggest that this be actively pursued.	
	We note our objection to the substance of the Department of Planning and Budget's Economic Impact Analysis, which far exceeds the appropriate scope of analysis of the reproposed SMFP by instead attempting to assess the effectiveness of the COPN program with an analysis that was not entirely objective.	This comment is beyond the scope of this project.
	There was a discrepancy in the public comment period as published on the Regulatory Townhall that we understand was related to the Townhall's technical procedures. The "Virginia Town Hall Regulatory Action" notice sent to interested parties by e-mail February 22, 2008, incorrectly announced a public comment period of March 3 to May 4; the posting on the Townhall correctly indicated the period to extend from March 3 to April 4. VDH has made every effort to inform stakeholders of procedures and deadlines throughout this process, but the Townhall's action may have misled some stakeholders as to their opportunity to comment.	While this comment is beyond the scope of this project, we assure the commenter that provision was made to allow everyone that wanted to submit comments an opportunity to do so. In fact, specific efforts were made to contact individuals and allow them the opportunity to comment. We are confident that everyone that wanted to comment had an opportunity to do so.
Carol Ann Coryell, RN Chairperson HSA of No. Va. (Coryell) Sally Nan Barber Special Advisor to the Vice President and CEO UVA Medical Center (Barber)	Reference to quality concerns and standards have been eliminated. It is unclear why this was done. Removing quality considerations from the plan reduces its value and utility.	While we recognize the discomfort some involved with COPN feel as a result of proposed revisions, we disagree. From the beginning of this project, we have been providing discussion and stating the reason why current 'quality' references are inappropriate and outmoded. We consider correcting the focus of quality as it pertains *directly* to the SMFP/COPN to be an important feature of this entire regulatory process. Our discussion of 'quality' is located above under "Issues."
Coryell	We support the elimination of references to the use of proprietary data such as Claritas population estimates and projections, in planning and COPN review formula and calculations.	The requirements related to data sources was crafted specifically to provide the Commissioner the discretion to stipulate the use of proprietary data information if doing so achieves 'best outcomes' in decision making. We understand that the chief concern relating

	Giving the Commissioner the flexibility to determine the appropriate demographic factors and standards to be used in planning and COPN regulation is appropriate.	to the use of such programs is the cost, which some consider prohibitive. However, we do not believe that cost should be the sole determining factor for not utilizing such data sources. Because we received support for the use of proprietary data source such as Claritas, we are asking for a determination by the Commissioner. Should it be determined that such data programs are desirable for the decision making process, we are confident that the financial resources will become available.
Geo. Phillips Director Strategic Support Services Riverside health System (Phillips)	This draft ..lacks comprehensiveness and consistency. Specifically [in] population data; preference vs consideration; appears to give blanket approval to institutional need [can contains] many inconsistencies and omissions that need to be addressed. It would be preferable to re-do the draft document and release it for further comment before a final Plan is released.	It is unfortunate that the commenter feels that the project has not succeeded. However, we disagree and believe that substantial effort by all parties concerned has gone into the draft. We recognize that the SMFP will never be perfect in the eyes of everyone that must obtain a COPN. We also believe that the draft, while not perfect, is certainly far better than the current Plan. We believe it is imperative to complete this project in order to implement the positive changes that have been proposed.
	A number of definitions contained in the current SMFP have been deleted in the proposed plan, many of which are important in the effective operation of the COPN program. In addition, there are other definitions that should have been included. The lack of definitions significantly hurts the effectiveness and administration of [COPN].	Without further clarification of what the commenter would like to have defined, it is difficult to respond. Each definition in the draft has been carefully screened for applicability within the document. Those definitions that had no application in the draft 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. In addition, it will not contain terms that are not used within the document.
	Under each category, there are several standards changed or eliminated [i.e., acceptability, accessibility, continuity, quality]	We have explained previously the rationale for eliminating those categories. For the purposes of the current SMFP, we found the criteria listed under acceptability, accessibility, etc., was not verifiable or enforceable during the project review process. Therefore the standards were deleted.
	One particular item missing is the ability of the applicant to successfully implement the	We disagree, but thank the commenter for highlighting a fault with the current system, i.e., that too many applicants rely solely on the

	proposed project [i.e., credentialed staff, adequate support staff and infrastructure, projected costs similar to other providers, projected volumes sufficient to maintain competency and proficiency.]	SMFP for arguing the need for their project. Rather, there are 21 criteria for project review and we remind all applicants that any application for COPN must successfully address each of those criteria in turn.
Susan Ward Vice President and General Counsel Virginia Hospital and Healthcare Association (Ward)	We suggest VDH determine all the [current SMFP set asides] and ensure that the [draft] reflects those actions so that obsolete provisions are not included. We again note our recommendation [that VDH] should use to the extent feasible a template for uniformity of elements (travel time, need determination, staffing) in each service specific section to enhance clarity and consistency. While we do not have a specific position as to how these inconsistencies and ambiguities should be resolved, we emphasize that they may effect the goal of fair and consistent application of the SMFP.	Without further clarification of particular set asides the commenter feels remain in the draft, we cannot respond. Again, without specifics we cannot address and respond. Every effort has been made to assure consistency within the draft. However, it must be recognized that each project type has its own unique identity which will not lend itself to rigid uniformity and consistency without sacrificing flexibility for the applicant. While such rigidity would make the decision making process easier, we do not believe that is the sought after intent of the comment. We agree that fair and consistent application of the SMFP is the goal of all parties involved in the process, not just the applicants.
Phillips	The changes to: 12VAC5-230-140 MRI; 12VAC5-230-190 MSI; 12VAC5-230-250 Noncardiac nuclear imaging; 12VAC5-230-280 Radiation therapy; 12VAC5-230-280 Cardiac catheterization; 12VAC5-230-440 Open Heart Surgery 12VAC5-230-600 Nursing facilities; 12VAC5-230-650 Lithotripsy 12VAC5-230-700 Organ Transplant and 12VAC5-230-750 Misc Capital Expenditures appear to be reasonable.	Thank you.
Coryell	[We suggest] a brief section on the purpose, role and use of the plan could be added to subsection 12VAC50230-30	We do not concur, believing that to do so would place undue weight on the SMFP over the other 20 COPN review criteria. One of the goals of this project has been to properly focus the SMFP as one of 21 factors for project consideration and believe that the definition contained in section 10 is sufficient for describing the SMFP. A better understanding is gained by fully understanding the COPN law.
Coryell	The substitution of 'consideration' for 'preference' is not done consistently.	That oversight has been corrected.

	The same pattern occurs in using 'should' and 'shall," Economic access criteria have been removed. Access is a major concern…[and] should be addressed in the 'guiding principles'	We believe the words have been taken out of context, the use of shall/should is not intended to be consistent, but to convey when flexibility (should) is allowed in decision making and when it is not (shall). We remind the commenter that access to health services is contained in no less than 7 of the 21 criteria for determining project need (§32.1-102.3) and is contained in 12VAC5-230-30 'Guiding principles'.
Lori Pycoir Wright Director, Planning Children's Hospital of the Kings Daughters	It is recommended that a task force be named, consisting of analysts from VDH and Virginia's pediatric and adult hospitals, whose sole purpose will be to research community bed need methodologies for each licensed bed category and propose logical processes that will reduce confusion, etc.	We are not sure whether the commenter is requesting a separate task force than that created by HB396 of the 2008 Session of the General Assembly or whether the commenter is aware of the legislation to created the SMFP Task Force. However, such a task force was created this past legislative session. The purpose of the group is to recommend updates and modifications to the SMFP. We have begun the process of placing COPN applicant comments and concerns, that cannot be addressed in this iteration of the SMFP without causing further delay, on the agenda for the Task Force.
Coryell	**12VAC5-230-10: (definitions)** Each definition should be examined carefully to reduce internal conflict and potential confusion among user…the definitions should be reviewed carefully to ensure clarity, eliminate internal consistency, and ensure parallel construction where possible. The last sentence of the definition of [CCRC] invites questions and is not definitional in character; It is unclear how the last sentence of 'bed' could be applied in practice. There is no definition of 'projects reviewed on a regional basis."	We agree and believe that to be the purpose of the public comment periods, of which there have been 4 during the promulgation of this edition of the SMFP. Without the suggestions and comments from interested parties, it is not possible to determine where there is concern or confusion. The sentence has been stricken. We believe this has now been clarified. We disagree there is a need for such definition as numerous projects have historically been subject to regional review. There are only three bases for planning purposes: statewide, regional or district. As a result of this project, only one project category remains subject to statewide applicability, all other project categories have been identified as reviewable on a health planning region or health district level. Such determination is clearly identified within each project category. This allows greater access to services for Virginia's

		citizens.
	The last phrase of 'COPN' appears redundant.	That may be true, but we believe it provides clarification and distinction of the program.
	'Radiosurgery' is not consistent with technological advancements and service delivery trends.	We believe this has now been clarified.
	There is no definition for regional planning agencies	We do not believe there is a need to define the HPAs as they have been in existence since 1989.
	'Use rate' is self referential, resulting is opaque language	That may be so, but without corrective language offered by the commenter to improve the definition, we chose to leave as proposed.
	The definition of magnetic resonance imaging is not germane or useful for planning or COPN review purposes.	Since no 'corrective' language was proposed, we cannot discern how the definition is 'not germane or useful.' Currently it describes what an MRI does, which is the point of providing definitions.
	"body" probably should be substituted for "bodily" in the definition of computed tomography.	We disagree, 'bodily' is an adjective describing the type of structure.
	"minimum survival rates' appears to be the opposite of what is intended	While we have adjusted the language, we believe the term has been read out of context. The definition accurately describes the intent of the phrase.
Phillips	One area that is missing is a definition of stereotactic radiosurgery. Suggest using the definition from the International Radiosurgery Association.	The terms stereotactic radiosurgery is clearly defined in section 10 of the SMFP. After considering all comments and suggestions to amend the term, we believe the modifications made to be appropriate.
Deb Anderson Senior Planner Sentara Healthcare (Anderson)	'pediatric' should not include 18 year old patients, who are considered adults by law. Historically, hospitals consider pediatric patients to be younger than 15.	Thank you for pointing out an error, we changed the definition to read 'younger than 18.'
	'radiation therapy': delete '*including radioisotope therapy*', add <u>radiation therapy does not include radioisotope therapy</u>.	The Commissioner has determined that it is no longer appropriate to include isotope therapy as a category of radiation therapy. Therefore, we have adjusted the draft accordingly.
Thomas Stallings McGuireWoods HCA Virginia Hospitals (Stallings)	'Operating room': suggest adding: <u>, but does not include cystoscopic and endoscopic operating rooms</u>.	We disagree. While we acknowledge the past ambiguity and confusion regarding operating rooms, a goal of this process has been to clarify what constitutes an OR. The COPN law does not include endoscopic/cystoscopic procedures as a project category, rather it addresses ORs as a project category. It is

		important to know that there is no standard definition of 'operating room' and we were unable to reach consensus of the term with Commissioner's SMFP work group members. However, we are placing discussion of 'operating room' on the SMFP Task Force agenda.
	"bassinet": delete *whether located in a hospital nursery or labor and delivery unit*, add <u>and neonatal special care stations</u>.	We understand the confusion in the definitions of 'bassinets' and 'beds' and are confident the modifications made address all concerns.
	'beds': delete: *bed includes cribs and bassinets used for pediatric patients outside the nursery or labor and delivery setting*, add *bassinets shall not be considered 'beds.*'	We disagree; such a change does not recognize infants and smaller children admitted to hospitals, such children are considered *pediatric* patients, and pediatric beds are subject to COPN review.
	"intensive care beds": suggest changing <u>neonatal intensive care units</u> to read: *neonatal special care units.*	We agree, the proper term is neonatal special care units. The term neonatal *intensive* care unit is applicable only to the subspecialty level of care. Ther requested change has been made.
Barber	"LTACH": delete reference to 'extended care facility." LTACHs are already designated as inpatient hospitals.	We agree and have made the requested change.
	The definition of 'stereotactic radiotherapy is incomplete and inadequate.	We believe the modifications made are appropriate.
	We agree that Gamma Knife® be eliminated as a separate category and that it should be reviewed as a type of stereotactic radiosurgery and that it include specific examples	Thank you, we have made appropriate modifications.
	It is unclear that the [1:3 use ratio] will provide suitable utilization when treatments can take much longer that 45 minutes.	For the purposes of the SMFP, we are modifying the use ratio to mirror that of CMS, which is 1:5. However, we are placing radiation therapy, including stereotactic radiosurgery, on the agenda for the SMFP Task Force to consider for further action.
	Suggest definitions for stereotactic radiation therapy (SRT); stereotactic body radiation therapy (SBRT)	We are placing radiation therapy, including stereotactic radiosurgery and these suggested definitions, on the agenda for the SMFP Task Force to consider for further action.
Ward	We reiterate our request for clarification in the definitions of 'beds,' bassinets,' 'intensive care	With clarification provided by other commenters, we believe the definitions are now clear.

	beds,' and references to 'bassinets, stations or beds' referenced [Part XIII].	
	Suggest 'COPN' means the Medical Care Facilities Certificate of Public Need ~~for a project as required by~~ implementing Article 1.1 (§32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.	We agree and made the requested change.
	"Health system" suggest inserting health before 'planning region for projects'	We agreed and have amended 'planning region' to read 'health planning region' throughout the draft.
	[LTACH suggest deleting second line regarding Board of Health designation]	We agree. The deletion has been made.
	"med/surg' delete, not used in the draft	We agree. The deletion has been made.
	'Operating room" delete 'especially those' as it is an inappropriate regulatory reference that adds no clarification. In addition, we request appropriate clarification and consistency as to what is considered an operating room.	We agree. We acknowledge the past ambiguity and confusion. A goal of this process has been to clarify what constitutes an OR. The COPN law does not include endoscopic/ cystoscopic procedures as a project category, rather it addresses OR as a project category. It is important to know that there is no standard definition of 'operating room' and we were unable to reach consensus of the term with work group members. However, we are placing discussion of 'operating room' on the SMFP Task Force agenda.
	"Population' suggest deleting and inserting new section specifying how population will be determined throughout the SMFP.	Because we received support for the use of proprietary data source such as Claritas, we are asking for a determination by the Commissioner.
	"Radiation therapy" suggest excluding radioisotope therapy from COPN review	The Commissioner has determined that it is no longer appropriate to include isotope therapy as a category of radiation therapy. Therefore, we have adjusted the draft accordingly.
	"relevant reporting period" delete: *demographic entity as determined by the Commissioner*, insert: recognized public or proprietary source of demographic data.	We disagree; the proposed language was crafted specifically to allow the Commissioner the discretion to determine the appropriate data source to be used for decision making, whether public or private.
	'stereotactic radiosurgery' suggest replacing with: treatment with a	We have made appropriate modifications.

	precise delivery of a single, high dose of radiation in a [single] session; focused radiation beams are delivered to a specific area of the brain to treat abnormalities, tumors or functional disorders. *or* stereotactically guided conformal irradiation of a defined target volume in a single session. *or* the precise delivery of a single fraction of high-dose ionizing radiation to an imaging-defined target. (Source - Bruce Pollock in his textbook on SRS)	
Wright	Suggest: 'inpatient' [means] a patient who is admitted to a licensed bed in a medical care facility and who, upon admission, is anticipated to remain in the medical care facility for at least 24 hours to receive continuous health-related services and support services, such as food, laundry, or housekeeping. This definition excludes: (a) any patient, who upon discharge, is not assigned a DRG (per CMS regulations), regardless of whether his hospital stay exceeds 24 hours , and (ii) any patient who, upon discharge, is assigned DRG 391 (normal newborn)."	We believe the modifications made to the definition are appropriate.
	Also suggest that since outpatient surgery is defined, then inpatient surgery should also be defined.	We have modified both definitions to better address our intent.
	Medical/surgical' [means] that part of an inpatient's hospital stay when the patient, regardless of age, occupies a licensed medical/surgical or pediatric bed and generates a DRG, excluding DRG 391. It excludes that part of an inpatient's hospital stay when the patient occupies a newborn bassinet or intensive care, rehabilitation, psychiatric, substance abuse, neonatal special care or LTACH bed.	We disagree, believing the definition as written is clear, suggesting a general term to describe non-specialized beds.
	"obstetric services" means the distinct organized program,	We believe this definition is better suited to a hospital licensing program.

	equipment and care provided in a medical care facility and related to pregnancy and the delivery of newborns. Specifically, this definition includes the services provided in labor and delivery (L&D) rooms; postpartum beds (including labor/delivery/recovery/postpartum or LDRP beds); ante partum beds (medical/surgical or outpatient beds provided for the observation or treatment of in and/or outpatients at risk for premature or complicated delivery); and the operating rooms and associated recovery rooms devotes to Cesarean section deliveries, sterilization procedures, and other ante partum or postpartum surgical procedures. Such operating rooms will not be included in a hospitals' licensed operating room inventory. Only postpartum beds are licensed obstetric beds.	
	"Pediatric" [means] in-or outpatients age 21 years an younger. Normal newborns (DGR 391) are excluded from the definition of pediatric inpatient.	We have conformed the definition to the legal age in Virginia. The definition already includes an exclusion for newborns.
	'Perinatal services' means those resources and capabilities described in 12VAC5-410-443 of Rules and Regulations for the Licensure of Hospitals.	We have modified the definition.
	Suggest defining: medical rehabilitation, intensive care, normal newborn, sick neonate, and postpartum.	We have added a definition of medical rehabilitation, the proposed document already includes a definition of intensive care. We believe the definitions of normal newborn, sick neonate and postpartum are better suited to a licensing program, which oversees the actual care provided.
	Does not include definitions of infant care station, nursery or labor and delivery unit.	We do not believe such definitions are necessary as they are in common usage.
	The definition of 'bed' is not specific enough, suggest adding observation beds, L&D beds, and other [types of excluded beds.]	We believe the modifications made are appropriate.
	Neonatal intensive care is not	We changed the phrase to read 'neonatal

	defined anywhere in the new SMFP, nor does it appear in the Virginia Administrative Code. The definition of neonatal special care makes sense until: 'i.e., a hospital elevates its services from general level newborn to intermediate level newborn services, specialty level newborn, or subspecialty level newborn services.' Without a definition of 'midnight census' the calculated bed need projections will be suspect. Suggest VDH reconsider how best to calculate inpatient bed need by licensed bed type. Suggest referencing the ICD-9 codes in the definition of 'open heart surgery' A better definition of 'operating room' would include the verbiage that references the current AIA guidelines.	special care' to correctly identify intent. We also made appropriate changes to the applicable sections of the SMFP. The sentence has been deleted. We disagree. The term was vetted by the Commissioner's SMFP work group and has received its support. The recommendation regarding calculating bed need has been placed in the agenda for the SMFP Task Force. We disagree, believing such references are better suited to a licensing program. However, we are placing the suggestion of the agenda for the SMFP task force. The AIA definition of operating room is the basis for the proposed definition, with requested modifications by the Commissioner's SMFP work group.
Coryell	**12VAC56-230-30: (Guiding Principles)** "underutilization" is subject to interpretation, suggest referencing excess or surplus capacity and low service volumes. "geographical dispersion' is problematic – presumably the point… is properly located, not dispersed.	We disagree. Merriam Webster's defines 'underutilization as: 'to [use] less than fully or below potential use.' We believe that is an important aspect in determining actual need. We have changed 'dispersion' to 'distribution'.
Ward	Suggest for clarity and consistency that section also include the following: <u>This section is not to be used in review of specific projects.</u>	We disagree. The section is used to review new uses of existing technology that have not yet been added to the SMFP as specific projects, e.g. orthopedic lithrotripsy, CT simulation, iMRI, and the Photon Beam project in Hampton. Without the ability to utilize this section, applicants would be unable to apply to use existing technology in newly expanded capacities. We do not believe that is the intent of the VHHA.

Barber	**12VAC5-230-40 (application criteria):** Not clear what 'actively seek to comply with the conditions' in paragraph C means. How would active compliance be measured or assessed?	The term 'actively seeks' means to be in compliance, or make documented attempts at being in compliance, with the stated terms of a condition as required by law. It is measured by the yearly reports filed with OLC/COPN. The law allows the denial of a COPN based on failure of an applicant to fully comply with agreed upon conditions.
Ward	**12VAC5-230-60 (competing applications):** delete: *will be given to the applicant that*, insert: <u>should be given to the extent to which each applicant</u> Delete references to "operating expenses" because the Department authorizes capital costs, not operating expenses.	We disagree, believing the offered language weakens the intent of the standard, thus opening it to interpretation. We disagree, 'operating expenses' was added at the request of the Commissioner's SMFP work group.
Ward	**12VAC5-230-70 (Prorating of mobile service volume requirements):** Suggest title change to: Calculation of utilization of services provided with mobile equipment. In Section A, ".02" should be "0.2" The wording of [subsection] A is unclear, suggest: <u>The minimum service volume of a mobile unit shall be prorated on a 'site by site' basis to reflect the amount of time that proposed mobile units will be, and existing mobile units have been during the relevant reporting period, at each site using using the following formula:</u> <u>Prorated minimum services volume (not to exceed the required full-time minimum service volume) =</u> <u>Required full-time minimum service Volume X</u> <u>The number of days the services will be on site each week X .2</u> <u>The average annual utilization of existing and approved CT, MRI, PET, lithotripsy and catherization services in a planning district shall be calculated for such services as follows:</u>	While we do not believe a change in section title is necessary, the title was changed as suggested. We agree and have made the requested change. We agree and have made the requested change. We agree and have made the requested change. We agree and made the requested change.

	New formula proposed.	
Wright	There is no argument that such costly services should be COPN reviewable.	We disagree. The COPN law does not provide for an exclusion for mobile services.
Wright	**12VAC5-230-80: (Institutional need): [**this section] allows the approval for the expansion of services to meet a justified institutional need, even if an oversupply of services exists in a given planning district.	The section has been added so that entities that have exceeded their capacity to provide service may expand those services and not be penalized by entities that are not as proficient. It should be noted that the section does not require the expansion, but that expansion may be requested. All such decisions are still based on need and on appropriate demonstration of need by the applicant.
Ward	Suggest creating new section: <u>(12VAC5-230-81) Population determination. Whenever a determination of population is required in this regulation, population shall be determined by using census figures shown in the most current series of projections published by a recognized public or proprietary source of demographic data.</u>	We disagree, believing a new section is not necessary. The Commissioner has the discretion to choose the data source to be used. Because we received support for the use of proprietary data source such as Claritas, we are asking for a determination by the Commissioner.
Ward	Suggest new section: <u>12VAC5-230-95 CT Simulation. The utilization thresholds set forth in the Article shall not apply to any project proposing the acquisition of a CT scanner to be used solely for simulation in connection with the provision of radiation therapy services.</u>	CT scanners used solely for simulation with radiation therapy is addressed in subsection B of 12VAC5-230-100. We do not believe a stand alone new section is necessary.
Patrick Devine, Jr. Williams Mullen Vincent Donlon, Administrator Cardiovascular Associates, LTD Richard Hamrick III, MD, MBA President Medical Society of Virginia Amy Foxx-Orenstein, DO, FACG President Daniel Pambianco, MD, FACG	**12VAC5-230-100 (CT)**: increase the current CT availability standard thresholds for new services from 3,000 scans to 10,000 scans per CT scanner…The public comment documents and other documents that the VDH has provided to us do not show any readily apparent reason why the original 4,500 scan proposal was abandoned for a more stringent 10,000 scan requirement. We are also concerned that the 10,000 scan requirement was adopted without much input from physicians and their association… we ask that the VDH re-consider the 10,000 CT scan requirement and consider a more modest increase in the utilization for CT services that will not restrict the	We have modified the CT volumes to 7,400 procedures, based on the statewide use of CT units as explained in 'Issues' above.

ACG Governor for the State of Virginia American College of Gastroenterology David Kreger, MD President Tidewater Gastroenterology, PLLC. P. Frederick Duckworth, Jr. MD President Virginia Gastroenterology Society Phillips	continued development of better care for patients in Virginia.	
Paul E. Parker Consultant	We suggest [establishing 2-tiered threshold utilization standards]…that are more consistent with a broader range of typical hospital CT use and that provide for a distinction between hospitals and freestanding outpatient CT facilities, [i.e., establishing] two separate threshold utilization standards for consideration [: e.g., 12VAC5-230-100(new): (i)] fixed site hospital-based CT services… performed at average of 4,500 procedure; (ii) fixed site freestanding outpatient CT services performed an average of 3,000 procedures. 12VAC5-230-110 (expansion): (i)] fixed site hospital-based CT services… performed at average of 6,000 procedure; (ii) fixed site freestanding outpatient CT services performed an average of 4,500 procedures.	Please see comments above. We believe the edits made appropriately address the concerns.
Charles L. Baird, MD Director Virginia Heart Institute	I suggest the liberalization of the COPN regulations to allow for expanded use of CT and MR technologies in licensed outpatient and inpatient facilities since computerization in medicine will lower health care costs.	We are placing this suggestion on the agenda for the SMFP Task force.
Ward	Recommend new format of separate sections for new fixed site	To adopt these recommendations now would only serve to further delay the adoption of the

	and mobile site CT; and rewrite of sections for expansion of fixed site services, the acquisition of CT equipment, and conversion of mobile to fixed site.	SMFP. We do not believe that is the intent of VHHA or in the best interest of the project at this time. However, we are placing the recommendations on the agenda for the SMFP Task Force.
Ward	Requiring all existing providers to meet volume thresholds would block approval of new services if some are under the threshold. Suggest volume standard for mobile CT scanners be 8,000 scans per unit per year.	We agree and have made the requested change.
Ward	If recommendations are not adopted, then suggest adding 'or mobile' to section 100. 100 B. suggest adding <u>The standards set forth is subsection A of this section shall not apply to a fixed CT unit proposed to be located at a provider-based off-campus hospital emergency department.</u> 120 B: insert 'by the mobile scanner' to clarify that the threshold of 6000 applies only to the mobile unit and not to all units at the site.	We agree and have made the requested change. While we agree that access to CT units is a valuable tool for proper emergency room care, we do not agree that such units designated for off-site emergency rooms should be exempt from COPN. We agree and have made the requested change..
Ward	**12VAC5-230-150 (Magnetic Resource Imaging):** Recommend new format of separate sections for new fixed site and mobile site CT; and rewrite of sections for expansion of fixed site services, the acquisition of CT equipment, and conversion of mobile to fixed site. We offer our assistance in conforming the [CT format] to this section.	To adopt these recommendations now would only serve to further delay the adoption of the SMFP. We do not believe that is the intent of VHHA or in the best interest of the project at this time. However, we are placing the recommendations on the agenda for the SMFP Task Force.
Ward	If the recommendations are not adopted then: strike the volume standard. Requiring all existing providers to meet volume thresholds would block approval of new services if some are under the threshold. Clarify that volume threshold of 3000 [in subsection B] applies only to mobile units and not to all units at the site.	We agree and have made the requested change. We agree and have made the requested change.
Anderson	**12VAC5-230-210, 220, 230 (PET)**: The *6000* threshold is too high; suggest <u>2500</u> based on a 45-60	We disagree, the Commissioner's SMFP work group agreed to 6000 as the threshold based on available data for each planning district.

	minute procedure Propose: Proposals for mobile PET or PET/CT scanners <u>should</u> demonstrate that, for the relevant reporting period, <u>at least 400 PET or PET/CT appropriate patients were seen</u> …	 We have changed 'shall' to <u>should</u>, but disagree with increasing the number of patients to 400 from 230, which was vetted by the Commissioner's SMFP work group.
Phillips	Michigan uses a complex weighted methodology to project 'data units' rather than procedures. It is suggested that VDH re-visit and modify this section.	We are referring this recommendation to the SMFP Task Force for review and consideration.
Ward	Recommend new format of separate sections for new fixed site and mobile site CT; and rewrite of sections for expansion of fixed site services, the acquisition of CT equipment, and conversion of mobile to fixed site. We offer our assistance in conforming the [CT format] to this section.	To adopt these recommendations now would only serve to further delay the adoption of the SMFP. We do not believe that is the intent of VHHA or in the best interest of the project at this time. However, we are placing the recommendations on the agenda for the SMFP Task Force.
Ward	If the recommendations are not adopted: Delete the volume standards. Requiring all existing providers to meet volume thresholds would block approval of new services if some are under the threshold. Clarify that 1400 procedures standards applies only to mobile scanners	We agree and have made ther equested change. We agree and have made the requested change.
Barber	**12VAC5-230-280, 330: (radiation therapy):** Is it reasonable to require patients with cancer to drive 2 hours a day? [60} minutes might be reasonable on a planning region basis, but the proposed language appears to contemplate and planning district review. What is a 'planning region" as compared to a planning district or a health planning region?	We believe the requirement has been misread, it means that such patients should not have to travel more than 60 minutes to receive needed services and the requirement has been reduced from access statewide to district access, thus allowing greater access to services, not less. 'Planning region' and 'health planning region' are synonymous. However, we have clarified the requirement.
Coryell	The formula used needs refinement, reference to greater than 150,000 persons is not sufficient.	We have made no change to the formula for radiation therapy, which seems to have been working properly. However, we are placing radiation therapy on the agenda for the newly convened SMFP Task Force to consider for further action.
Barber	With the continued specialization and growing sophistication of linear accelerators, the number of treatment visits [proposed] … is not	It must be remembered that the effort to revise the SMFP is now more than 7 years in duration. We believe it is imperative to complete this project, in order to implement the

	appropriate for dedicated machines [with] a highly specialized and dedicated range of use. It would appear that volume standards should be revisited to reflect the significant advances in RT since the early 1990s. There are no proposed standards for review of SRT or SBRT services, although such services are clearly being provided. Standards should be drafted and incorporated into the SMFP	positive changes that have been proposed. We recognize that technology constantly undergoes change and are placing UVA's comments and suggestions regarding radiation therapy, including stereotactic radiosurgery, on the agenda for the newly mandated SMFP Task Force to consider for further action.
Barber	Suggest changing 'providers' to 'equipment' in 12VAC5-230-290 C, 300 . Expansion of services may occur in a [PD] with a specialized linear accelerator that would not possibly perform 8000 scans per year. The proposed does not address that possibility.	That has been corrected for consistency. We believe the section has been misinterpreted. The section is not a presumption for expansion; rather it is intended to provide direction for requesting expansion only when an applicant can provide definitive evidence that there is a need for expansion.
Ward	290: replace *shall* with <u>should</u>, add <u>per existing and approved radiation therapy machine</u> after *treatment visits* Suggest change 5000 *procedures* read 5000 <u>treatment visits</u> Strike *as reported in the most current projections of a demographic entity as determined by the Commissioner*. Not necessary Suggest change *increase* to read <u>expansion</u> 320 Strike *such physicians shall be designated authorized users….* Radiation therapy does not use isotopes.	We agree and have made the requested change. We disagree, 'procedure' was vetted by the Commissioner's SMFP work group. We disagree, since we did not accept the suggestion for a separate section regarding population. We agree and have made the requested change. Commissioner Remley has determined that it is no longer appropriate to include isotope therapy as a category of radiation therapy. Therefore, we have adjusted the draft appropriately.
Stallings	**12VAC5-230-330: (Stereotactic Radiosurgery)** HCA Virginia disagrees with the definition of "SRS" contained in the proposed SMFP and the [VHHA} response. [For example,] SRS is not limited to	We believe the modifications made to the definition of SRS appropriately address concerns.

	'one session' treatments; SRS can be a many as many as five fractionated sessions; it is never stated whether stereotactic radiotherapy requires COPN authorization.	
	Suggest: eliminating references to 'one session' and make clear that multi-session treatments (up to five sessions) constitute SRS.	We agree and have made the requested change.
	Propose: "Stereotactic radiosurgery" or 'SRS" means a therapeutic procedure using external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dos to a tissue volume. Examples of stereotactic radiosurgery instruments are the Varian Trilogy, Accuray CyberKnife, and Elekta Gamma Knife. SRS may be delivered in a single session or in a fractionated course of therapy up to five sessions.	We believe we have modified the definition appropriately.
	Delete: 12VAC5-230-340 B	We disagree, the subsection was vetted by the Commissioner's SMFP work group.
	Amend: 12VAC5-230-340 D1 to read: At least 350 non-Gamma Knife appropriate cases were referred out of the region in the relevant reporting period;	We disagree, the subsection was vetted by the Commissioner's SMFP work group.
Coryell	The formulation for [SRS] reads "the unit is not part of a linear accelerator' conflicts with the introductory sentence.	We believe the subsection has been read out of context. The subsection is necessary to allow for a gamma Knife unit that is not part of a linear accelerator.
Barber	It is not clear how 350 treatments was determined to be a reasonable threshold for SRS services, and a more realistic annual treatment volume should be identified. Suggest using CPT codes to determine the weight of a treatment visit, which is recommended by the American College of Radiology.	The number of treatments was vetted by the Commissioner's SMFP work group. We are referring the recommended use of CPT codes to the SMFP Task Force for review and consideration.
	There are no criteria for how volume and cost of service might be 'justified' also, the section does not appear to contemplate a second SRS adaptable linear accelerator	The section has been vetted by the Commissioner's SMFP work group. In addition, we believe there is some confusion as there is an entire section on expansion of services.

	being added by an existing provider. A single machine could not do SRS and continue to deliver standards radiation therapy at the same time, [resulting] in a decrease in conventional treatments.	
	Section does not address linear accelerators equipped to perform hypo-fractionated radiation therapy. Does this mean anticipate continued acquisition of linear accelerators equipped only for standards radiation therapy?	We are referring the recommendation to the SMFP task Force for review and consideration.
	12VAC5-230-340 C: Should be SRS not just Gamma Knife.	We believe that there is some confusion, subsection 340 D pertains to non-Gamma Knife
	On what basis are the utilization rates proposed? How does the applicant justify cost?	We believe such questions are part of the applicant's process for determining whether to apply for a COPN. Certainly, the applicant should consider all aspects of financial feasibility (costs vs. revenues generated; other management related concerns) when submitting an application. As with all COPN projects, there is an inherent expectation that the applicant will conduct the appropriate feasibility studies regarding the characteristics of the requested project. Otherwise there is no need for submitting an application.
	12VAC5-230-340 D: needs clarification and amplification in light of future technologies, i.e., proton beam therapy.	We disagree, as the subsection was vetted by the Commissioner's SMFP work group. However, we are referring the recommendation to the SMFP Task Force for review and consideration.
	12VAC5-230-350: Planning district may be more appropriate than planning region which is undefined.	We disagree, and believe there may be some confusion. Review of SRS on a district level is not warranted at this time. Currently SRS is reviewed on a statewide level. The work group agreed that review on a regional level is more appropriate. As we have explained: planning region means the health planning region which has common understanding across Virginia; however, we are clarifying to read *health* planning region.
Phillips	The one area in which this [section] is significantly lacking is a quality standard reflecting the abilities of the operators of the SRS equipment.	As we stated previously, we disagree, believing the abilities of the operators to be a professional licensing and credentialing issue consistent with licensure standards. The SMFP and COPN are not licensing programs
Ward	340 A 1 strike sentence, insert:	We believe the modifications made address the

	Existing stereotactic radiosurgery services in the health planning region performed an average of 350 procedures per existing and approved unit in the relevant reporting period. 340 A 2 strike below 350 treatments. 340 B, C, D: Suggest grammatical change to clarify that this is not a preference. 350 suggest edits for consistency 360 insert with stereotactic radiosurgery services	commenters concern. We agree and have made the requested change. We disagree, it is a preference. Please see the discussion regarding 'preference' vs. 'consideration' under Issues above. We agree and have made the requested change. We agree and have made the requested change.
Phillips	**12VAC5-23-380 (Cardiac Catherization)**: These standards appear to be reasonable. However, there are a number of hospitals without open-heart capability that are performing interventional cardiac procedures. No attempt at enforcement appears to be made.	If hospitals are providing unauthorized interventional procedures, it is incumbent upon the commenter or his health system to report those hospitals in violation of the law to OLC.
Wright	The pediatric cardiac catheterization [requirements] do not include DEPs,… it is inconsistent that all pediatric catheterization labs are weighted at 2 DEPs. Pediatric cardiac catheterization should only be performed in facilities that offer pediatric intensive care.	That is correct, the section 410 does not use DEPs, which are applicable to adult, not pediatric, cardiac catheterization services. We believe there is some confusion and that pediatric service projects should not be reviewed based on adult criteria. That is a requirement of the proposed SMFP.
Ward	**12VAC5-230-390 (cardiac catheterization):** suggest services instead of *laboratories* Suggesting inserting: per existing and approved laboratory after *DEPs*. C. suggest inserting to whether proposed before new cardiac catheterization; and substituting services for *laboratories* Section 420 should be deleted, it	We agree. We agree. We disagree as it weakens the intent of the subsection. We refer to the 'preference' discussion above in 'Issues.' That is not correct, the section was not set

	was set aside by the Commissioner	aside by the Commissioner, therefore the proposed section will not be deleted.
Wright	There is no prohibition against performing cardiac catheterization on pediatric patients in adult cardiac cath labs.	There seems to be some confusion regarding the purpose of COPN. As we have stated previously, COPN is not a professional licensing or credentialing program.
Ward	**12VAC5-230-450 (open heart surgery):** suggest services instead of *programs* A. suggest deleting below 400 open and closed heart procedures. B. suggest inserting to whether proposed before new cardiac catheterization; and substituting services for *laboratories* 460 1. correct *of* to if 470 remove references to expanded pediatric open heart surgery addressed in 12VAC5-230-460.	We agree. We agree. We disagree as previously stated. We agree. We agree.
Phillips	**12VAC5-230-490 (Surgical Services)**: DCOPN has vacillated between counting true operating rooms or a combination of OR's and endoscopic/cystoscopic rooms. Another definition [of ORs] is offered in the draft. While the standard of hours per room has not changed, the length of many inpatient surgeries has increased.	We are not sure of the intent of this comment. We acknowledge the past ambiguity and confusion. A goal of this process has been to clarify what constitutes an OR. The COPN law does not include endoscopic/cystoscopic procedures as a project category, rather it addresses OR as a project category. It is important to know that there is no standard definition of 'operating room' and we were unable to reach consensus of the term with Commissioner's SMFP work group members.
Ward	Suggest raising the planning horizon from 3 years to 5 years. C. suggest deleting *general purpose* and *by making services available within 30 minutes driving time one way under normal conditions of 95% of the planning district's population*; insert: *(ii) result in the provision of the same surgical services at a lower cost to surgical patients in the planning district; or (iii) optimize the number of operations in the planning district which are performed on an ambulatory basis.*	We agree. We agree.
Stallings	**Part VI. Inpatient Beds:** HCA Virginia has not had sufficient	We are placing the VHHA recommendations on the agenda for the SMFP Task Force.

	opportunity to evaluate the [VHHA] proposed methodologies to determine whether they are appropriate age-adjusted projection methodologies.	
Phillips	The proposed occupancy levels are an improvement, but do not consider all factors influencing average daily census and current medical practice, such as: daily admission and discharge patterns; weekly cycles in admissions and discharges; seasonal fluctuations ; size of the facility. The computational approach advocated by [VHHA] is preferable to the existing methodology.	We are referring the recommendation to the SMFP Task Force for review and consideration.
Ward	Recommend new format for [Part VI] to include new formulas for determining need.	It was requested during the Commissioner's SMFP work group sessions that pediatric beds and medical/ surgical beds be separated, and we agreed to that request. To adopt these recommendations would only serve to further delay the adoption of the SMFP. We do not believe that is the intent of VHHA or in the best interest of the project at this time. However, we are placing the recommendations on the agenda for the SMFP Task Force.
Ward	Suggest new section: 12VAC5-230-565. Ten year planning horizon in certain circumstances. Notwithstanding the provisions of 12VAC5-230-540 [, 12VAC5-230-550] and 12VAC5-230-560, a ten-year planning horizon may be used to compute the need for medical/surgical [, pediatric] or intensive care beds in those circumstances where the number of additional beds needed in a planning district ten years from the current year exceeds by more than twenty percent (20%) the number of additional beds needed in such planning district five years from the current year, provided that if the number of beds needed in the planning district five years from the current year does not exceed the current inventory of licensed, authorized and approved beds in the planning district, then a five-year planning horizon shall be used.	We disagree. As we have stated previously, we do not believe that a 10 year planning horizon is realistic. However, we are placing the suggestion on the agenda for the SMFP Task force.
Wright	Some hospitals have suggested changing the 5-year planning	As stated above, we do not think a 10 year planning horizon is realistic.

	horizon to a 10-year planning horizon. Given the unpredictability of population shifts, a ten-year planning horizon may be too generous.	
Wright	The calculation of ICU bed need seems to only address 'general intensive care units' [i.e., does not include cardiac care ICUs and specialized ICUs.' Pediatric ICU beds are included in the proposed definition of 'specialized' ICUs, which is not advisable since the population of patients admitted to pediatric ICUs is unique and requires child-size equipment that is commonly not available in general ICUs. Suggest VDH consider establishing separate guidelines for pediatric ICU beds.	There must be some confusion, the definition of ICU refers to CCU and specialized units. Revising the current bed need formulas has been placed in the agenda for the SMFP Task Force. While the suggestion has merit, a requirement that there be child size equipment is a hospital licensing issue. We disagree that a pediatric ICU is not a specialized ICU, when, as the commenter states, the pediatric population is unique. We modified the formula to address the concern.
Barber	**12VAC5-230-580:** There are no standards or criteria for determining the need for LTACH beds in either free standing or 'hospital within a hospital' setting or for the function they serve. None of the provisions contemplated the development of a free-standing LTACH, nor does any provision address expansion of the number of beds in either a free-standing or 'hospital within a hospital LTACH. 12VAC230-580 C: This is inconsistent with paragraph A as drafted and its meaning is also unclear. The meaning of 'original intended purposes' is unclear; does this refer to the original use for such beds approved under the host hospital's	We disagree, the first subsection [A] clearly states that *all* LTACH beds shall be considered *part of the inventory in inpatient hospital beds*. Therefore, there is no need to repeat standards or criteria. However, we do want to be clear regarding the specific use of the federal designation of LTACH, so that applicants can not artificially inflate their inpatient bed capacity. We disagree. LTACH is a federal designation for reimbursement purposes only. An LTACH bed is still an inpatient bed; therefore, the establishment of an LTACH impacts the inpatient bed inventory in a planning district. In other words, new beds are not created, but existing hospital beds must be surrendered in order to establish an LTACH. Because of that stipulation, a hospital would be unnecessarily penalize should the LTACH beds no longer be needed. Therefore a host hospital has an opportunity to regain the surrendered beds, under certain conditions as stated in the subsection. Yes, it does.

	COPN?	
	Also exempting an application from standard review under such circumstances might be anti-competitive and inconsistent with the intent and purpose of the COPN process.	We disagree, returning the beds to their original 'owner' and intended purpose cannot be considered anti-competitive, since the host hospital had the beds to begin with. We have exempted such applications from the standard review process as it is not necessary to re-review a need that has previously been granted.
	Delineation of the service area is required in current applications for inpatient beds. To what does this section refer? A hospital's primary service area? A health planning region? A planning district? Something else?	It means the intended service area for the LTACH, based on the applicant's determined need and location of the facility.
	[Subsection F] is redundant because all LTACHs must be certified by CMS in order to operate as such. And what if a hospital is not 'converting' but is actually a new facility –what happens to the beds then?	We disagree – certainly the only reason to establish an LTACH is for reimbursement, however it is not possible to discern future changes in LTACH requirements. As we have previously stated, no LTACHs beds, regardless of type, can be established *without the surrender of licensed inpatient beds*. The section is intended to be clear regarding the specific use of the LTACH designation, so that applicants can not artificially inflate their inpatient bed capacity.
	[Subsection F1]: what if the facility has already obtained an indefinite extension? This section needs further clarification.	We disagree, the requirement clearly notifies applicants that only a single 6 month extension will be granted. Indefinite extensions will not be granted.
	[Subsection F2]: Does this refer to the extension in F1 or something else.	Yes, it refers to the single 6 month extension that may be granted in F1. In the case of LTACHs extensions will not be allowed to continue indefinitely.
Ward	580 B: replace *shall* with <u>should</u>;	We disagree. It must be remembered that LTACH is a federal designation for reimbursement purposes *only*. Such beds are part of the inpatient bed inventory, not a special carve out option.
	Replace *applicant's* with <u>applicant facility's</u>; conversion requirements should apply only to the single facility and not to an entire health system.	We disagree, as stated above LTACH beds are part of the inpatient bed inventory. Allowing a health system to retain excess beds inflates the bed inventory in a planning district and has the perception of guaranteeing a 'franchise', which VDH cannot support.
	Suggest a separate formula be used for determining need for	We disagree. Since LTACH beds are part of the inpatient bed inventory, the same formula

	LTACH beds so that they may be approved without regard to general bed need.	for determining inpatient beds can be used. However, we are placing the commenter's suggestions on the agenda for the SMFP Task Force.
Mary Lynne Bailey VP, Legal & Government Affairs Virginia Health Care Association (VHCA)	**12VAC5-230-610: (nursing facilities)** [change *or the date on the certificate, whichever is longer, for the unconstructed beds*] to "from the date of issuance of the certificate." This clarifies [to which of 3 possible dates on the certificate] the regulation refers. 12VAC5-230-610.E: insert 'capital' to read: 'When evaluating the capital cost of a project." This clarifies the intent to use the DMAS methodology for capital costs.	We agree and have made the requested change. We agree and have made the requested change.
Dana Parsons Legislative Affairs Legal Counsel Virginia Association of Nonprofit Homes for the Aging (VANHA)	12VAC5-230-630 1: add 'population' to the end of the sentence. 12VAC5-230-630 3a: replace 'qualified resident assistance fund' with 'qualified resident assistance policy. This is consistent with §32.1-102.3:2 G	We have amended the section to comport with the law at § 32.1-102.3:2. We agree and made the change consistent with law.
Ward	**12VAC5-230-660 (Lithotripsy):** Recommend incorporating format here that parallels CT sections. We offer assistance in conforming the CT format to this [Part.]	To adopt the recommendation now would only serve to further delay the adoption of the SMFP. We do not believe that is the intent of VHHA or in the best interest of the project at this time. However, we are placing the recommendations on the agenda for the SMFP Task Force.
Ward	If new recommendation is not adopted, then suggest 660: insert whether proposed after *given to*; will be after *lithotripsy services*; strike *provided* insert and 670: strike *increase*, insert expand	We agree.
Anderson	**12VAC5-230-720: (organ transplant)** Suggest making reference to standards put forward by UNOS in place of specific %.	We disagree with the suggestion to incorporate by reference. UNOS data and standards were accessed in determining of this Part of the SMFP.
Ward	730: replace *increase* with expand Insert: *the extent to which the applicant seeks to expand* to clarify that this is not a preference.	We agree. We disagree, the suggestion incorrectly changes the intent of the requirement. We refer to the 'preference' discussion above in 'Issues.'
Thomas Cook	**12VAC5-230-800 – 830: (medical**	Agreed – definition added to 12VAC5-230-10

Chief Executive Officer UVA-HEALTHSOUTH Rehabilitation Hospital	**rehabilitation)** Lack of a definition for [medical rehabilitation] introduces an element of ambiguity that does not recognize the levels of rehabilitation services that are appropriate in different settings. We [suggest] the SMFP should contain a definition of medical rehabilitation services linked to the CMS definition… contained in 42 CFR Part 412.23(b)(2).	
	230-810: We are concerned that the methodology appears to be based on historic utilization …to the exclusion of any other method of demonstrating need for services. For example: if there are no medical rehabilitation services in a planning district, there can be no demonstrated need for such services. Also, [such planning district methodology fails to recognize that these types of services have been provided on a regional basis, and would result in small inefficient facilities that will find it difficult, if not impossible, to provide the range of comprehensive medical rehabilitation services as those terms are commonly understood in the industry. Therefore, we recommend:	There seems to be some misunderstanding. The proposed criteria does not mandate a service in each planning district, rather it provides for such contingency if there is a proven need. It is up to the applicant to demonstrate that a need exists for the service and to declare their intended service area, which may include more than one planning district.
	1. That the SMFP not include a prescribed bed need methodology, rather as in Florida, allow the applicant to present their own bed need methodology as part of their application. This would permit the applicant to designate the services area for a project which might include more than one planning district;	This suggestion will be placed on the agenda for the SMFP Task Force.
	2. A minimum size requirement of 20 beds for comprehensive and specialized rehabilitation units;	This suggestion will be placed on the agenda for the SMFP Task Force.
	3. An 80% bed occupancy, the same as medical-surgical beds; and	We agree ans have made the requested change.
	4. Use of data from established and recognized demographic sources, such as Claritas.	Because we received support for the use of proprietary data source such as Claritas, we are asking for a determination by the

		Commissioner.
	Lastly, 12VAC5-230-620 unfairly rewards skilled nursing facilities treating patients appropriate for a comprehensive and specialized rehabilitation facility, and is contrary to the notion of equitable treatment for each health services category. The exception creates 2 classes of skilled nursing facilities: those that provide rehab services and those that do not. Those that do are granted a reimbursement advantage, access to more Medicare revenue, and the privilege of gaining additional skilled nursing beds. We request that the SMFP not include a hybrid creation granting an unfair advantage to one service class at the expense of another.	We have modified the language in 12VAC5-230-620 to address this concern.
Stallings	**12VAC5-230-940 – 1000 (Neonatal Special Care Services):** The SMFP does not clearly state that the places where neonatal special care services are provided are not hospital beds for the purposes of COPN. It was agreed the SMFP would make explicit that neonatal special care stations are 'bassinets' and not 'beds.'	We believe the amended definitions appropriately address this concern. In addition, we had modified the criteria where necessary.
Stallings	12VAC5-230-960 B, C; 970 B, C; 980 B, C: delete *stations or beds.* 12VAC5-230-960 C; 970 C; 980 B: delete <u>with a bassinet or station counting as the equivalent of one bed</u>.	We agree, the correct term to use is bassinets, which by definition includes stations, but not beds. We agree, reference to bed equivalency is not correct.
Ward	910, 970, 980: Insert <u>significantly</u> before *reducing the* delete subsection B, new OB services in small, especially rural hospitals may be appropriate; it is unclear what 'improve' means as used here. 960 C, 970 C, 980 C. What is the evidentiary basis for threshold of 1000 live births?	We agree and have made the requested change. We agree and have made the requested change. Birth statistics are generally reported per1,000 live births.
Phillips	The proficiency and competency issue is not clarified in this section	Proficiency and competency are professional licensing and credentialing issues consistent with licensure standards. The SMFP and

		COPN are not licensing programs.
Wright	Suggest [renaming] Part XII: "Perinatal and Obstetrical Services"	We agree.
	The current and proposed SMFP [are] confusing [regarding] differentiating beds and bassinets. Within recognized nursery categories, the SMFP is even more confusing. Therefore, CHKD strongly recommends defining all designations above level 1as licensed beds subject to COPN review.	We believe the modifications made are appropriate. However, we also acknowledge the input and concerns of CHKD. We believe we have made every effort to address those needs correctly within the scope of this current project. We are placing additional concerns on the agenda for the Inpatient Hospital Regulation work group to consider.
	CHKD recommends the neonatal intensive care be defined as a subset of licensable intensive care beds.	We are aware of CHKD's concerns regarding the licensure of perinatal services. However, a policy review of licensing perinatal beds is beyond the scope of this project. We have placed the issue on the agenda for the Inpatient Hospital Regulation work group to consider.
	The current nomenclature for [perinatal services] is somewhat burdensome. It is suggested that VDH adopt language similar to that of other states definitions.	We believe this suggestion is better suited to a hospital licensing program. VDH has plans to discuss the levels of care with the Inpatient Hospital Regulation work group. At that time, VDH will recommend the adoption of the levels of care as described by ACOG in the 6th edition of their 'Guidelines for Perinatal Care.'
	The proposed requirement that intermediate level II services be within 30 minutes of level 1 services may result in a proliferation of level II services throughout Virginia since there are numerous level I nurseries located more than a 30 minute drive from any higher level nurseries. Meeting the new requirements will conflict with another proposed requirement that no more than [4 bassinets] per 1,000 live births be established in each planning district.	We believe the travel time is taken out of context. We remind the commenter that the decision to grant a COPN is not made on a single criteria alone, but on the documented evidence the applicant provides addressing all 21 criteria for determining need.
	Suggest qualifying travel time to include source [such as] Mapquest.	We agree and have modified the language leaving the 'source' decision to the discretion of the Commissioner.
	It has been observed repeatedly that many hospitals do not seek COPN approval to increase the level of nursery services – they simply start providing the higher	Since the commenter did not identify whether these repeated observations have ever been reported to the State Health Commissioner or to VDH/OLC, we cannot address the overall concern. However, when such specific

	levels of care.	violations of law have been brought to our attention, the department has taken appropriate action as allowed by law.
	[Consideration] will be given to the expansion of existing services… is confusing. Does this mean a hospital that wants to add more bassinets at any level must seek COPN approval? The COPN regulations do not specify that the addition of [higher] level bassinets is reviewable.	No, applicants wanting to add bassinets to their current level of perinatal care may do so without seeking a COPN; however, applicants seeking to upgrade from a lower level of service to a higher level must seek a COPN prior to offering the higher level of service.
	CHKD recommends that level II, III, and IV accommodations be reclassified as licensable beds, rather than bassinets, and that the addition of such beds be subject to COPN-review.	We are aware of CHKD's concerns regarding the licensure of perinatal services. However, a policy review of licensing perinatal beds is beyond the scope of this project. Therefore, we have placed the issue on the agenda for the Inpatient Hospital Regulation work group to consider.
	CHKD recommends that the 30-minute travel requirements be re-evaluated and revised upward to 60 minutes.	In light of the documented need for obstetrical services in Virginia, we disagree.

All changes made in this regulatory action

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	Global	"planning region' used throughout document	Amended to read *health* planning regions. Clarifies intent. Result of re-proposal period comments.
	60, 340, 450, 600, 610, 650, 730, 820, 860,	'Preferences' changed to 'considerations'	See discussion of preferences above under 'Issues.' Result of re-proposal period comments.
	90, 140, 200, 250, 280, 330, 380, 440, 490, 520, 600, 650, 700, 800, 840, 900, 940		Added 'using mapping software as determined by the commissioner.' Suggested by comment, modified for Commissioner discretion.

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," "Continuing care retirement community," "COPN," "Health planning regions," "Hospital," "Indigent," "Inpatient beds," "Intensive care beds," "Lithotripsy," "Long term acute care hospital," "Neonatal special care," "Open heart surgery," "Operating room," "Operating room use," "operating room visit," "Outpatient surgery," "Pediatric," "Perinatal services," "Population," "Positron emission tomography," "Procedure," "Radiation therapy," "Relevant reporting period," "State medical facilities plan/SMFP," and "Stereotactic radiosurgery." Definitions added: "Bassinets," "Beds," "COPN," "Diagnostic equivalent procedures," "Gamma Knife®," "Health system," "ICF/MR," "Medical rehabilitation," "Medical/surgical," "Pediatric," "PET/CT," "Primary service area," "Qualified," "Stereotactic radiosurgery," and "VHI." 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," "Pediatric cardiac catheterization," "Physician," "Quality of care," "Study," and "The center" were deleted.	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. New definitions added to aid clarification. These definitions were determined unnecessary, other definitions were eliminated pursuant to the initial draft.
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	Amendments made at request of Board of

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		made	Health member. 30A1 and 30A2 read capacity or and geographical distribution – requested by commenter
	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. Title and language rewritten; new formula proposed. Section rewrite proposed by comments received during re-proposal period.
	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 no

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			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. Added to apply to mobile as well as fixed services; procedure volume reduced to 7,400. the CT volume of 10,000 procedures was deemed to high a standard for non-institutional providers; therefore, reduced to 7,400 procedures (refer to CT volumes under 'Issues.' Other edits suggested by comments received during re-proposal period.
320-60	230-110	Expansion of existing service	Section technically amended; increase of volume standard to 10,000 procedures based on newer, faster technology. Procedure volume reduced to 7,400. the CT volume of 10,000 procedures was deemed to high a standard for non-institutional providers; therefore, reduced to 7,400 procedures (refer to CT volumes under 'Issues.' Other edits suggested by comments received during re-proposal period.
320-70		Replacement of existing	Deleted: replacement of equipment was

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		equipment	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. Edits made for consistency with other sections within the document. Requested by commenters during the re-proposal period.
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 Resonance Imaging (MRI)		Consumer acceptance of services offered.	Deleted: philosophical statement; not 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. Edits made for consistency with other sections within the document. Requested by commenters during the re-proposal period.
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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			procedures. Edits made for consistency with other sections within the document. Requested by commenters during the re-proposal period.
320-180	230-170	Mobile services	New language addition/expansion of mobile MRI services, utilizing prorated formula from 230-70, better defines requirements. Edits made for consistency with other sections within the document. Requested by commenters during the re-proposal period.
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 Technology	Deleted: statement of philosophy, not measurable.
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.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
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. Edits made for consistency with other sections within the document. Requested by commenters during the re-proposal period.
320-330		Minimum utilization	Deleted: combined with 230-210; standard lowered to 850 new cases.
	230-220		Edits made for consistency with other sections within the document. Requested by commenters during the re-proposal period.
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. Edits made for consistency with other sections within the document. Requested by commenters during the re-proposal period.
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.
	230-230	Does not address mobile	New language addition/expansion of mobile

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		services	PET 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. Removes references to isotopes. Commissioner determined that isotope therapy no a COPN project, therefore references to isotopes deleted.
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.
340-40	230-290	Availability; need for new	Section title amended to 'need for new

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		service; expanded; replacement of service	service,' volume standard lowered to 5,000 procedures; number of new cancer cases increased to 60% in the need formula. Edits made for consistency with other sections within the document. Requested by commenters during the re-proposal period.
	230-300		New section on expansion taken from current language; volume standard lowered to 8,000 procedures. Edits made for consistency with other sections within the document. Requested by commenters during the re-proposal period.
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. Removes references to isotopes. Commissioner determined that isotope therapy no a COPN project, therefore references to isotopes deleted.
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. Edits made for consistency with other

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			sections within the document. Requested by commenters during the re-proposal period.
	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 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. Added per 'per existing and approved laboratory;' changed 'laboratory' to read 'service.' Requested by commenters during re-proposal period.
	230-400		Section created from expansion standards in 260-40; technically amended for consistency with proposed draft. Added per 'per existing and approved

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			laboratory;' changed 'laboratory' to read 'service.' Requested by commenters during re-proposal period.
	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 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. Technical edits made resulting from re-proposal period.
	230-460		Section created from existing 'expansion' text of 260-100 Technical edits made resulting from re-proposal period.
	230-470		Section created from existing 'pediatric' standards of 260-100.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			Technical edits made resulting from re-proposal period.
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. Technical edits made resulting from re-proposal period.
270-50		Cost; charges	Deleted: relocated under 230-50 and 60.
270-60		Quality; accreditation/licensure	Deleted: philosophical statement, not 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;

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			new formula developed for consistency with document at request of advisory committee. Changed to properly reflect law of under 18 years of age, resulting from re-proposal period.
	230-560		Section on 'intensive care' created from 240-30; new formula developed for consistency with document as request of advisory committee. Added: 'or older for adults or under 18 for pediatric patients' resulting from re-proposal period.
	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 Services		Acceptability	Deleted: licensure standards, not measurable or verifiable under COPN
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;

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			'expansion' standards established as separate section. Clarifies date of 'presumption of no need' as date of issuance of certificate to clarify requirement resulting from re-proposal period.
	230-620		Section on 'expansion' created from 240-360-40; occupancy level lowered to 93%. Technical edits made resulting from re-proposal period.
	230-630		Section on 'continuing care retirement communities' created from 360-40; language taken from law. Edited to reflect COPN law regarding CCRC type of nursing facility resulting from re-proposal period.
	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 deleted; new section established for service expansion and mobile services;

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	230-670		New expansion section created from existing text; volume standard lowered. Technical edits made resulting from re-proposal period.
	230-680		New mobile section created from existing text using prorated formula in 230-70. Technical edits made resulting from re-proposal period.
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
350-10 Miscellaneous	230-750	Purpose	Technically amended.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Capital Expenses			
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. 85% bed occupancy changed to read 80% bed occupancy, technical error corrected as result of re-proposal period.
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 and

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			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. Deleted subsection B result of re-proposal comment received
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 redundant of law.
	230-930		Staffing section created at request of

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			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. Deleted subsection B requested by commenters during re-proposal period.
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. Technical edits made resulting from re-proposal period.
	230-970		Establishes specialty level newborn criteria as reflected by licensure laws and regulations; requested by public comment. Technical edits made resulting from re-proposal period.
	230-980		Establishes subspecialty level newborn criteria as reflected by licensure laws and regulations; requested by public comment. Technical edits made resulting from re-proposal period.
	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

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-one 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.

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.