Virginia Department of Health

Center for Quality Health Care Services and Consumer Protection

Comments Received on the Proposed State Medical Facilities Plan

Service specific – October 11, 2006 - DRAFT

Item No.	Section	Comment	VDH Analysis	Discussion Points	Outcome
A	10	"hospital-based" is too broad, suggest deleting "legally associated with" "hospital-based" should include: whether located on the hospital's campus or at a site not on the hospital's campus.	The definition has been amended.	Definition is no longer necessary; the term is only referenced in DMH part, and is clearly understood, therefore suggest deleting Suggestion to include as concept to allow as a hospital preference in diagnostic imaging section	Consensus to delete "hospital based" definition
B		Include a definition of operating room. "Operating room" means a room located in a fully controlled sterile environment specifically designed for the performance of surgical procedures and involving the administration of anesthesia. This would include open-heart surgery and trauma rooms, but not include endoscopy, cystoscopy, C-section and procedure rooms.	A definition was included in the draft; as a result of comments received it has been amended for clarification. We have chosen to use the definition found in the AIA Guidelines for Design and Construction of Hospitals and Healthcare Facilities, an impartial resource mandated by the passage of HB2366 and SB1024 (2005), which also	Applicability to surgery performed in physician offices Deferred to discussion of section May need to add set of criteria for evaluating 'endo/cysto' procedure rooms.	Consensus to delete reference to endo-systo

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			responds to other comments received regarding consistency.	Suggestion to delete endo/cysto from the definition, but Geo. Barker stated that would create ASC's overnight. Whether some ORs currently excluded would be counted under the new definition or vice versa	
		"Operating rooms" There are many interpretations of operating rooms. Recommend: "a room, located in a fully controlled sterile environment, specifically designed for the performance of surgical procedures, meeting the minimum requirements and conditions of the Virginia Code, and involving the administration of anesthesia." The definition should explicitly exclude minor procedure rooms such as gastrointestinal and endoscopy suites.			
C		"Stereotactic radiosurgery" as radiotherapy meaning more than one session of fractionalization. Radiosurgery is a one-session process. "Stereotactic radiosurgery:" delete "non-invasive" as it is considered an invasive procedures. Also a cyber-knife" does not use an external frame. Also suggest additional review needed as recent technology has made terms less meaningful and	The definition was amended for clarification.	Consistent definition should be based on how the equipment is used (similar to DEP provided for cardiac services), not on the number of sessions performed What to do with radiotherapy when it is being	Consensus on proposed amended language with further clarifying language

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		confusing when applying standards and criteria.		administered by a machine that has stereotactic surgery components and it is not being administered in a single session? Don't want to limit deployment of stereotactic surgery	
D		"Stereotactic radiosurgery" insert: one session after "means a"	The definition has been amended for clarification.		Consensus
E		230-10: "Hospital-based" should also include any entity, facility or location that qualifies under Medicare to bill under the Medicare provider number of the hospital to which such entity, facility or location is "hospital-based.	We disagree – Medicare is a federal reimbursement program. The intent of the standard is to address the proximity of hospital services, not reimbursement.	Issues relates to remote sites that are part of hospital ERs.	Definition no longer necessary; the term is only referenced in DMH part, and is clearly understood. Consensus to delete "hospital based" definition
F		"Open heart surgery" should be modified to cover those procedures requiring the use of heart-lung bypass machines and those that require the bypass to be immediately available.	We disagree. Such a requirement is not part of a definition, but of the applicable standards. It stands to reason that providers offering open-heart surgery will have the needed and necessary equipment available to conduct	Some closed heart surgery may nee to be performed in Open Heart Surgery (OHS) rooms. Geo. Barker stated to leave definition alone , but change	Consensus with current definition. Further consensus to add definition of 'adult equivalent procedure' to

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			the surgery, including bypass pumps.	volume standards for OHS rooms	section 10.
g		"Open-heart surgery:" suggest also referred to as advanced cardiac surgery, means operations on the valve and septa of the heart, coronary artery bypass procedures, implantation of heart and circulatory assist systems, or any other procedures that would require availability of the heart-lung bypass machine or pump.	We disagree, The proposed definition came from the current SMFP and we believe it is sufficient for the purposes of the proposed SMFP.		Consensus with current definition
1	PART II	Question the necessity to specify a particular class of providers that can apply for PET imaging services	The proposed standard references the same providers as the current SMFP.	Suggestions include: 1. Standardized format for all service specific sections, especially the diagnostic imaging sections 2. Exempt from regulation CTs purchased for sole simulation use 3. Seek more reliable tool for determining travel time so	Consensus

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				that effects of driving conditions can be considered; 4. 'Accessibility'' sections should address more than just travel time; 5. Since technology is better/faster, volume standards should so reflect by being increased; 6. Incentives should be created to get newer equipment 7. Use of suggested language proposed by VHHA/HSA ad hoc committee (Dec.14); 8. Objective formula needed for determining need; 9. New service	Consensus to use 'procedures' rather than 'scans,' appropriate definition will be sought

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				needs to be used to service existing population. Discussion of 'procedures' vs 'scans' G. Barker asked to provide revised CT/MRI/PET language at next meeting. This will standardize formatting of sections	Consensus on amended service volumes
2		Suggest allowing the incorporation of integral imaging technologies [i.e., CT & PET] in comprehensive cancer centers.	The applicable standards have been amended for clarification.		Consensus that use of integral technologies is not exclusive to comprehensive cancer centers
3		Suggest defining supervision as CT/MRI & PET: suggest Unless the imaging unit is located in a hospital, the unit should be under the	The SMFP is not the correct tool for establishing such criteria. Such criteria can only be established through licensing	Amend the standard to read, "under the direction or supervision of a	Consensus with the amendment

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		supervision of a board certified radiologist. Direct and on-site supervision by a physician shall be required during examinations utilizing parental contrast administration.	programs. However, we have addressed staffing as appropriate within the scope of the SMFP.	physician qualified to provide that service.“	
4		Many analysts believe that the increased utilization of CT/MRI and PET is driven by non-radiologist physicians, with an ownership interest in imaging equipment who can refer their own patients for imaging examinations.	That is a prohibited practice, see Chapter 24.1 (§ 54.1-2410 et seq.) of Title 54.1 of the Code of Virginia, and should be reported to the Board of Medicine of the Department of Health Professions.		Consensus
5		Suggest that imaging facilities be accredited by the American College of Radiology or an equivalent agency.	We do not believe the SMFP is the correct tool for establishing such criteria.		Consensus
6		Suggest that the SMFP actually reflect appropriate volume changes in the use of technology for CT, MRI, lithrotripsy and other equipment types.	The applicable standards have been amended as needed.	Suggested increase form 3500/4500 CT volume to 10,000 is too large an increase Suggest a specific section addressing about volumes for mobile MRI 64 scan cardiac CTs should not depress	Consensus on CT volume of 10,000 procedures volume; Consensus on MRI volume of 5,000 procedures Mobile volumes are determined using the proposed pro-rating formula section

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				the CT need calculation	
7		Increase the volume to reflect changes in technology, suggest 4,500 for CT and 4,000 MRI scans	The section has been amended to increase the volume standard.		Consensus on CT volume of 10,000 procedures volume; Consensus on MRI volume of 5,000 procedures
8		[120] [and 170]: Suggest physicians with documented formal training in the production and interpretation of cross-sectional CT [MRI] images rather than" broad certified diagnostic radiologists"	We disagree and believe we have addressed staffing as appropriate within the scope of the SMFP.	Amend the standard to read, "under the direction or supervision of a physician qualified to provide that service."	Consensus with the amendment
9		Articles 1 thru 5: Suggest leaving the MRI threshold at 4,000 or increase to 5,00 and raise the CT volume to 6,000.	The sections have been amended.	Suggest that CT volume standard be tiered between 8,000 (rural) and 12,000 (urban) procedures. Suggestion that MRI volume standard be tiered between 4,000 (rural) and 5,000 (urban).	Consensus on proposed volume standards
10		Suggest the CT and MRI are not a purely diagnostic modality, recommend CT simulation be excluded from the COPN application	Currently the Code of Virginia does not make exceptions for CT simulation. To exclude CT simulation from the COPN	Suggestion allowing CT for simulation become an exempted category under §	Consensus

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		process.	application process would require legislative action.	32.1-102.2	
11		Please clarify whether PET/CT machines are embedded in the PET criteria.	The definition has been amended for clarification.		Consensus with amended language
12		Concerned about the lack of accessibility standards and the low numerical volume standards for services such as CT, MRI and Lithotripsy. Suggest inserting per machine	The "deletion" of the accessibility sections for CT and MRI were unintended errors; the error has been corrected. The volume standards for CT, MRI and Lithotripsy have been amended to include the suggested "per machine."	Proposed Litho and MRI volume standards OK	Consensus on proposed volume standards
13		[100].A.2: suggest deleting	The subsection was deleted.		Consensus
14		Diagnostic imaging: Raise the CT standard to 6,000 scans/year. Raise the MRI standard to 4,500 scans/ year, with exceptions for rural areas. Changing the [PET] standard is not necessary.	The diagnostic imaging section was amended as appropriate.		Consensus on new volume standards
15		[190]: suggest moving under [emerging technologies] as no FDA approval has been granted, nor have CMS codes for MSI been approved.	We disagree. The proposed section on emerging technologies has been deleted.	Suggest that 'academic medical center' read 'tertiary center'	Consensus with amendment
16		Staffing for all diagnostic imaging: Suggest reinserting the current standards; the proposal eliminates the requirement of sub-specialization that could result in the proliferation of resources.	We disagree for the reasons previously stated.	Amend the standard to read, "under the direction or supervision of a physician qualified to provide that	Consensus with amendment

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				service."	
17		[220]: a) Request clarification of how standard applies to mobile PET. b) Will there be specific criteria applied to PET/CT or continue to be embedded in the PET criteria? C) Suggest CT procedures performed during PET/CT downtime be reflected as part of the CT utilization, not the PET/CT utilization.	a) The applicant of either fixed or mobile services must demonstrate that additional scanners (either fixed or mobile) do not reduce utilization of fixed machines. b) PET/CT has been clarified in 12 VAC 5-230-10. c) We agree.	Suggest section cross reference 230-60 prorating mobile services	Consensus with cross reference
18	PART III	Radiation therapy: Formula should reflect regional patterns, which vary considerably.	We disagree, believing the formula does recognize and allow for regional differences.		Consensus
19		[280]C: Suggest removing the special allowance for general hospitals, i.e., do not specify a required setting for radiation services. In addition, the 60-minute drive time one way is somewhat arbitrary and may be difficult for patients needing repeated access to services.	The subsection appears to have been taken out of context, resulting in some confusion. It is not intended that patients should have to travel 60 minutes for treatment, but that treatment services should be *no more* than 60 minutes away. Such a standard serves to ensure opportunities for more than one radiation therapy service within a planning district.	Suggest the travel times be determined using another method than MapQuest, which does not take into account traffic patterns Suggest establishment of a separate preference for 'essential community provider'	There are no suitable replacements currently available.
20		[280]: Lowering the volume standard is a constructive change from the existing plan.	Thank you		Consensus

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		The volume decrease from 9,000 to 8,000 is appropriate; this [section] should be reviewed carefully in view of the emergence IMRT and IGRT.			
21		[270]: Suggest amending to include 95% of rural and and be available within 30 minutes driving time one way, under normal conditions, for 95% of the urban and suburban population of the planning district.	We disagree, geographic areas are considered as required by § 32.1-102.3 of the Code of Virginia.		Consensus
22		Recommend the state convene a panel of experts to develop consensus recommendations for [radiation therapy]	We disagree. The SMFP's advisory committee was comprised of experienced individuals with access to expert consensus. Expert consensus was also obtainable through the exposure draft process, in addition to the 60-day comment period. VDH is confident that ample and sufficient opportunity has been provide for expert consensus.		Consensus
23		290.B: the reduction in population from 150,000 to 75,000 is inappropriate and could result in the proliferation of low usage, poorly staffed facilities. Additionally, the current statement regarding	The subsection was amended to reflect a population of 150,000, as suggested.		Consensus

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		decommissioning of replaced units should be retained.			
24		Stereotactic radiosurgery: suggest that additional review and consideration is needed in the definition and use of these terms	We disagree. However, the definition has been amended to provide clarification.	Deb Anderson offered documents from NC and SG2 stereotatic radiologic practices. Discussion deferred to next meeting. Amended language proposed	Consensus on amended language with clarification
25		The definitions of radiosurgery and radiotherapy determines whether an applicant requests fall in this section or radiation therapy.	This was clarified in the definition.		Consensus on proposed amended language with clarification
26		[280] C: Suggest removing the special allowance for general hospitals, i.e., do not specify a required setting for radiation services. In addition, the 60-minute drive time one way is somewhat arbitrary and may be difficult for patients needing repeated access to services.	The subsection appears to have been taken out of context, resulting in some confusion. It is not intended that patients should have to travel 60 minutes for treatment, but that treatment services should be *no more* than 60 minutes away. Such a standard serves to ensure opportunities for more than one radiation therapy service within a planning district.	Suggest a preference for general hospitals 60 min. travel time still presents concern	Consensus on proposed amended language with clarification
27		Change the formula for projecting	The formula already *is* based on		Consensus

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		radiation therapy use on rates per population.	use rate per population.		
28	PART IV.	[350] : Suggest inserting subject to the provision of 12 VAC 5-230-80 at the beginning of the section. Also suggest: A.1: Delete A.2: Delete after "500 diagnostic equivalent procedures" B: Delete after "350 diagnostic equivalent procedures" C: Delete after "400 diagnostic equivalent procedures" D: Delete after "400 diagnostic equivalent procedures"	We agree to include the reference to 12 VAC 5-230-80, but disagree with the remaining suggestions. An important part of the process is to assure that new services do not negatively impact existing services. As part of the process, applicants must prove that their new service is responding to an increased need within a community or locality. To do otherwise would simply be a sanction to lure patients away from established providers. VDH cannot support such a principle.	Suggestion include: 1. Standardization of section; 2. Use average of DEPs. Rationale for higher volume standard in expansion than for establishing new services, Need to ensure facilities perform sufficient numbers of procedures to become proficient. M. Jenkins presented draft language to standardize 'new service' sections	Consensus with suggested amendments Consensus on Jenkins proposed draft language. This will be inserted where appropriate within the document for consistency.
29		[350]:include a formula for calculating diagnostic equivalent procedures (DEP), e.g., diagnostic is 1DEP, therapeutic is 2 DEPs, same session is 3 DEPs, pediatric is 2 DEPs	We agree and have included the suggestion as a definition in section 12 VAC 5-230-10.		Consensus

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30		[350] E & G: The intent of these is apparent, but the language is confusing, need to clarify Emergency availability of open-heart surgery has been eliminated and needs to be retained. It is considered a significant safety issue.	The intent of the subsections has been clarified. The section has been amended to include emergency availability.	Issue raised of intent when COPN has already authorized services in facilities without surgical back-up	No consensus
31		[340]: suggest amending to include rural and and be available within 30 minutes driving time one way, under normal conditions, for 95% of the urban and suburban populations of the planning district	We disagree, geographic areas are considered as required by § 32.1-102.3 of the Code of Virginia.		Consensus
32		[350]D: suggest amending as follows: Proposals for the expansion of an existing cardiac catheterization service shall not be approved unless all of the existing cardiac catheretization laboratories operated by that service have performed…	The subsection has been amended for clarification.	How will VDH apply these provisions, i.e., network vs. applicant? Need to standardize formatting where possible Amend the standard to include "applicant's medical care facility where proposed expansion is to occurred' and "an average of"	Standard will be clarified Consensus Consensus

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33		Add subsection [G]: Non-emergent interventional cardiology services should only be provided at hospitals having open heart surgery services available.	The suggested language has been added.	Extent to which this provision is necessary given current standards of practice	Consensus
34		Cardiac Services: Recommend convening an expert panel to develop consensus recommendations on cardiac catheterization services.	We disagree. The SMFP advisory committee was comprised of experienced individuals with access to expert consensus. Expert consensus was also obtainable through the exposure draft process, in addition to the 60-day comment period. VDH is confident that ample and sufficient opportunity has been provide for expert consensus.		Consensus, dispensed – no discussion.
35		[350]: Recommend defining "diagnostic equivalent catheterization procedures"	A definition has been provided in 12 VAC 5-230-10.		Consensus
36		[350]D: For consistency, recommend: Proposals for the expansion of cardiac catheterization services by existing providers shall not be approved unless…	The subsection has been amended as suggested.	Amend the standard to include "applicant's medical care facility where proposed expansion is to occurred' and "an average of"	Consensus on amended language
37		[350]F.2: Suggest adding without	The subsection has been		Consensus

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		reducing the utilization of existing pediatric cardiac catheterization laboratories in the Commonwealth below 100 pediatric catheterization procedures.	amended accordingly.		
38		Cardiac qualifications are not specific regarding interventional cardiology or participants in interventional procedures.	The sections have been amended as appropriate.		Consensus
39		Cardiac Catheterization: Need to develop plans/exceptions protocols for both primary and elective angioplasty. A number of successful state models are available as examples, i.e., NJ, NY, MD. Need to include practitioner minimum volume standards.	Without further explanation of the expressed need for the suggested protocols here in Virginia, we cannot respond to the comment. The section does include minimum volume standards.	Relationship between this 350.D and 350.F, section F should be deleted in recognition of advances in cardiology and given that COPNs have already been issued for such cardiac cath services	Consensus; the SMFP deals with *service* volumes, not practitioner volumes, that is an individual facility credentialing criteria and responsibility.
40		[370]: Appears to allow at least one open-heart surgery program in each planning district. This would be an unwise policy as some planning districts can be served by programs in nearby planning districts.	The proposed standard appears to have been read out of context.	Suggestion to specify that individuals can be served by programs inside of or outside the planning district, but would need to do so for all services. Address	Consensus on language as currently drafted.

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				within context of overall approach to travel time.	
41		[370]: Suggest striking the reference to planning district. Given that the number of open- heart surgeries is declining [in Virginia], the [SMFP] should not be relaxed.	The logic of the comment appears flawed. There are any number of reasons why open-heart surgeries may be declining. However, none to our knowledge are a result of decisions resulting from the COPN process. Accessibility is a core quality value of the COPN program; therefore, we think it prudent to allow for availability of these surgeries as proposed, should there be a need.		Consensus
42		[380] B: suggest moving "to less than 400 procedures per room" to after " service location" C.1 and C.2: Suggest drive time be 1 hour, not 2	The subsection was amended as suggested. The subsection was amended.		Consensus
43		[380]A.3: Suggest adding per room after "400 open heart procedures" making this subsection consistent with subsections A.2 and B.	The subsection has been amended as suggested.	Comment was discussed with resultant further amendment to use 'per program' rather than 'per room'; may also	Consensus on further amendment

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				need to establish tiered criteria addressing 'closed heart procedures' vs 'open heart procedures.'	
44		Surgical back-up needed for facilities performing interventions without in-house cardiac surgery. Recent articles in JAMA noted an increased risk to patients undergoing interventions in such facilities.	The section has been amended as appropriate.		No consensus
45	PART V.	410: Radically reducing surgical occupancy from 85% to 70 % would result in an immediate increase of more than 20% in the number of beds needed	The occupancy rate was not reduced to 70%, but 80%. We disagree that this reduction will cause the dramatic increase projected by the comment.		Moved to Item 50A
46		[410]: Suggest adding However, existing surgical services may be expanded when all of the applicant's existing general purpose operating rooms have experienced an average of at least 1,600 service hours per operating room for the relevant reporting period.	Such expansion needs can be requested under the new section 12 VAC 5-230-70 [Institutional need].	VHI collection of OR use time data – 1600 hours has been verified by VHI Best way to address this issue is to have VHI revise its data collection dorm. Appropriate service hour threshold for expansion	No consensus, discussion dispensed

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				Inclusion of prep time in definition of 'operating room use.'	
47		[410]: Clarify the formula so that only general purpose operating rooms visits and hours are used, i.e., exclude open heart surgery	The formula description has been amended, where applicable.		Consensus
48		[410]: Since operating rooms for trauma services, open-heart procedures, and caesarian sections have been deleted from the inventory; statistics will have to be revised. Open heart and trauma s/be recognized only in facilities that have approved and designated open heart and trauma programs.	The section has been amended for clarification.		Consensus
49		Consider extending the need threshold to 10 years in line with the recent decision by the Commissioner.	We disagree; the Commissioner's decision is pertinent to a particular project only and should not be considered a "set aside," but assurance that the proposed project, should it succeed, appropriately meets its projected goals. After four years, that project is still in litigation making the decision to require a 10-year planning		Consensus

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			horizon prudent. However, that case cannot be considered routine and should not be taken as precedence for future proposals. We believe a 5-year planning horizon is more realistic for determining actual need.		
50		In light of 230-[70], is this section applicable if the applicant can show institutional need?	Yes, as the applicant would be using this section to show a need.		Consensus
50 A		410: Radically reducing surgical occupancy from 85% to 70 % would result in an immediate increase of more than 20% in the number of beds needed	The occupancy rate was not reduced to 70%, but 80%. We disagree that this reduction will cause the dramatic increase projected by the comment.	E. Bodin will chart tiered occupancy standards	Consensus
51	PART VI.	[430]: Seek to extend the 5-year planning horizon to 10 years, which would require meeting a threshold that justifies expansion and allow the size of expansion to be based on longer-term projected use.	We disagree; believing a 5-year planning horizon more realistic for determining actual need.	Merits of a 5 yr vs 10 yr planning horizon. Suggest inclusion of 'use' spikes i.e., flu season, to allow additional flexibility based on demonstrated trends	Consensus that the 5 yr horizon was sufficient
52		Skewed computation of need for inpatient beds because of overbroad definition that includes categories of	We disagree. We did update the terminology of the bed types listed in the definition, but the	Observation beds can be for < or > 24 hours hrs. If	Consensus to remove 'laundry' list of bed

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		beds nor previously considered inpatient beds for purposes of determining future need.	definition was not broadened as a result.	>24 hours, pts may be occupying unauthorized inpatient beds, as they occupy observation beds and may end up staying for more than 24 hours, but remaining in an COPN unauthorized bed.	types,
53		[430]: Suggest adding except in cases where (i) such relocation can be shown to be a public benefit based on particular conduct or practices of the existing hospital provider, or (ii) it can be clearly demonstrated that the proposed relocation will not materially harm the existing hospital provider, or (iii) the new location is within a thirty minute drive of the existing beds proposed to be relocated.	We disagree. The purpose of COPN is not to guarantee the "franchise" of any one provider group as appears to be suggested.		Consensus
54		[430]B: Add the relocation results in improved distribution of existing resources to meet community needs. Suggest lengthening the planning horizon to 10 years.	We agree and have amended the subsection accordingly. We disagree; believing a 5-year planning horizon more realistic		Consensus Consensus

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		G: delete	for determining actual need. We disagree, but have clarified the intent of the subsection	Sections B & G should be together as they relate to relocation, however the 2 sections may conflict in intent. Suggest G be written as a positive statement rather than negative Hospitals should not be prevented from moving within its service area or market.	No consensus on specific language change Consensus Consensus
55		[430]The calculation of inpatient days and discharges should include observation patients, when such patients occupy licensed beds.	The calculation does not exclude observation beds when calculating inpatient bed need.		Consensus
56		Acute Care Beds: Recommend minimum planning district occupancy level of 80% to add beds	The Commissioner set aside the current occupancy criterion; reducing the rate to 70% addresses the "set aside" as instructed by that decision and required by law, § 32.1-102.3.	The set aside was made in reference to a different section of the SMFP	Consensus on 80% occupancy and 65% occupancy for intensive care
57		Long term acute care hospital: No need to reduce regional occupancy levels, 85% is readily achievable in	The occupancy rate in the section is not exclusive to LTAC beds, nor is it related to LTAC	Should reference stand alone LTACH facilities	LTACH section added

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		LTAC beds. Current occupancy levels have worked well. No basis for reduced occupancy levels presented. Would permit unwarranted excess capacity and facilities to be develop, especially in urban areas. Recommend keeping 85% occupancy standard.	beds. Rather, it is a recommendation of the advisory committee reflecting the inconsistencies in taking patient census for the purpose of applying for needed beds. To address the overall issue of census taking, the committee determined that taking a census at midnight appropriate for obtaining a true measure, the rate was lowered as an adjustment to, and in recognition of, the busier daytime census experienced by an inpatient facility.	CE provided LTAC standards to members	
58		[430] : There is no provision for retention of beds due to surge capacity requirements on homeland security G: is inconsistent with other parts of the draft. Conversion of beds within the medical-surgical category should be addressed, i.e., if less that the threshold cost ($5 million), no COPN is required to convert acute care beds to categories.	Surge capacity is addressed through the hospital licensure standards. The subsection was amended for clarity. Such a standard in the SMFP is not necessary as hospitals can	SMFP should not be used for crisis management, that is a community planning issue	Consensus Sections B and G will be relocated into an expansion of services' section. 'G' will be written in positive tense rather than negative.

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			designate beds as needed to suit the needs of their patients.		Consensus
59		[430]A and B: Recommend combining general medical/ surgical, pediatric, "step-down" or " intermediate care," and intensive care beds and a single occupancy standard of 80% as the threshold for adding new inpatient beds. E & F: Recommend 80% threshold for adding new beds. Since VEC data shows lower population than actual experience, suggest allowing substitution of local data, if it results in substantially larger need calculation.	The definition of "inpatient beds" includes the bed categories listed. The occupancy rate standard has been set aside by Commissioner decision. We disagree and lowered the occupancy to 70%. The Commissioner has designated use of VEC data. If VEC data is not accurate, the commenter should contact VEC.	Request use of a more definitive data source, e.g., Claritas, Weldon Cooper, Cacki than VEC and to allow flexibility in decision-making. VEC does not provide currant population projections. Applicants are provider an incentive to find the data source that projects the greatest population growth. Preferable that a specific source of data should not be listed in the SMFP.	Consensus to use another population data source than VEC
60		[430]D.1: Suggest adding: However, the medical/surgical and pediatric bed capacity of a hospital or the ICU bed capacity of a hospital, may be allowed to increase when existing	The section has been amended.	Suggest conforming ICU bed "99% probability" for consistency.	Consensus

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		beds in those categories have experienced respectively and average of 80% and 65% occupancy for the relevant reporting period and when no beds exist at the hospital or at any other hospital within the same hospital system in the planning district which can be converted to, or relocated to, the hospital that is in need of such expansion. [430]G: Suggest deleting or change to read "less than 80% average annual occupancy" so it is consistent with 12 VAC 5-20-450.E.2.b	The subsection has been amended.		Consensus reached at 80%
61		[430]: Appears to be an inconsistency in subsection A2 and 3 and E2b.	The inconsistency has been addressed.		Consensus
62	PART VII.	Section [450] A is absolutely unworkable. Suggest removing (iii) from A and reestablish section B as it was in the previous draft.	Subsection A and B have been amended as suggested.	Suggestion to re-format section to increase opportunities to issue or reissue an RFA: 1. Automatic re-issue of RFAs for beds that are relinquished; 2. Allow 93% of existing in any 1 of the 1st 3 years	Consensus on amended language. Note: Amendment 1 would need to be addressed through amendment to the COPN rules and regs.

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				3. Include authorized beds in the 93% occupancy determination; 4. Split 'A' into 2 subsections;	
63		Suggest amending [450] B to include: This presumption of no need for additional beds will extend for no longer than three years from the date of issuance of the certificate of public need for the unconstructed beds.	The section has been amended as authorized by law, which does allow extension of the standard 3-year period for construction.		Consensus on amended language
64		Nursing homes and nursing home beds: The CCRC bed ratio limitation is needed. Calculation of bed need under the RFA process should be based in regional use rates trends rather than the current fixed-point historical use rate.	The bed ratio for CCRCs is prescribed in law and the sections were amended accordingly. Changes can only be made legislatively. The RFA bed need calculation is beyond the scope of this project.		Consensus
65		Eliminate the 2-year delay following opening of nursing home beds when the occupancy rate, including approved beds, was 93 percent for the most recent 2 years.	We disagree, believing there is sufficient flexibility in the RFA process to address bed needs that arise.	Amended language, see item #62	Consensus on amended language
66		[450]C and E: If this applies to CCRC's, it could significantly diminish the ability of rapidly developing CCRC's to meet the life-care obligation to their residents.	There seems to be some confusion by the CCRC community regarding the applicability of these subsections. These standards		Consensus

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		Suggest adding: Only [subsection] F in 12VAC5-230-470 applies to development of new nursing facilities or the expansion of existing facilities at [CCRCs].	address freestanding facilities, not the nursing facility component of CCRC's.		
67		[450]F1: Oppose as it's in direct conflict with § 32.1-102.3:2 D and E to reduce nursing facilities bed capacity from 20% to 10%. This prevents CCRCs from meeting their contractual obligations resulting in unmet resident nursing care needs.	The text of the standard has been amended to conform to the law.		Consensus
68		[450]F.4: Incorrectly implies that a CCRC would require a resident to leave a facility based the resident's financial status. Suggest deleting "and that, in the event such resident becomes a Medicaid recipient and is eligible for nursing facility placement, the resident will not be eligible for placement in the CCRC's nursing facility unit."	The entire subsection has been amended to conform to the law.	Suggestion to omit 'standard' in reference to contract since most contracts in [450] F.5 are no longer standardized.	Consensus
69		[450]G: the current capital cost reimbursement methodology utilized by [DMAS] should apply to CCRCs that are precluded from Medicaid. Since CCRCs do not participate in Medicaid, there is no public interest in limiting the amount of capital	We disagree – to do so would in general lower the area wide nursing facility occupancy of most PDs and make it even harder to qualify a PD for an RFA to develop additional beds.	Question the calculation of fair rental value by DMAS	Consensus to leave standard as proposed.

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		invested in their nursing facilities. Suggest solution as proposed above.			
70		[450]B: This restriction will prevent state planners from addressing a fast-growing area's nursing bed need. Suggest the prohibition last for only 3 years after approval of new beds and that the occupancy of a newly licensed facility not count for the first full year of operation in computing the NF bed occupancy.	We disagree – the COPN law allows for extensions beyond the initial 3-year "construction" or "start-up" period. We also believe the RFA process is sufficiently flexible to address "fast growing" needs.	Amended language offered, see item 62	Consensus on amended language
71	PART VIII.	Part VIII: Suggest distinguishing between renal and orthopedic lithrotripsy. It is unclear if approved provider of renal lithrotripsy will be permitted to add orthopedic lithrotripsy without COPN.	While we believe the proposed definition does distinguish between renal and orthopedic, the definition has been clarified.	Does renal and orthopedic litho use the same equipment?	Consensus, but suggest formatting for consistency
72		Lithotripsy services: the standards should distinguish between renal and orthopedic lithotripsy.	While we believe the standards are clear, further clarification has been provided.	Suggestion that renal and ortho litho be separate sections in SMFP	Consensus
73		Use the lithotripsy section previously proposed.	To adopt this comment would disregard other comments received during the public comment periods. We do agree with that.		Consensus
74		[470]: suggest adding subsection <u>E. Proposed orthopaedic lithrotripsy services may be located at the offices of physicians and podiatrists,</u>	Subsection E has been added.	470 A: Does this mean there is an expectation that 100 cases will be	Consensus

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		and a new service may be approved of the applicant can demonstrate that it can reasonably be expected that the proposed new service would have a volume of at least 100 orthopaedic lithrotripsy patients annually.		given away?	
75	PART IX.	Organ Transplant program: Support as proposed, except change the pancreas transplant standard to require that the procedures occur in a program that meets the kidney transplant standard of 30 cases per year (based on Medicare program policy).	The subsection has been amended.		Consensus
76		[500]A: Suggest changing transplant services to reflect Medicare and national trends, i.e.: Heart s/be 12, not 17 Heart/lung no minimum, but require an active heart program Lung s/be 10, not 12 Liver s/be 12, not 21 Pancreas or pancreas/kidney no minimum, but an active kidney program	We disagree; the proposed standards meet the recommendations of UNOS. Medicare is a federal reimbursement program. The intent of the standard is to address service proficiency and patient survival rates, not reimbursement. However, we have amended the section to reference the federal "Organ Procurement and Transplantation Network" or OPTN.		Consensus

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		Pt survival for heart/lung s/be increased to 70%			
77		[500]A: Suggest 12 pancreas or kidney/pancreas transplants be deleted and add: Any proposed pancreas transplant program must be part of a kidney transplant program that has achieved at least the SMFP's minimum volume standard for kidney transplants as well as the minimum transplant survival rates stated in 12 VAC 5-230-520.C	The subsection has been amended as suggested.		Consensus
78	PART XI.	[560]: Change "planning region" to planning district.	The section has been amended.		No consensus on 'region' or 'district'
79		Section 570: There is no utilization for rehab beds - .90 has been crossed out	The "deletion" was in error and has been corrected.		Consensus
80		570: Change the occupancy rate for metropolitan areas from 90% to 85%	Without further explanation as to why a further reduction to 85% is requested, we cannot respond. We have recognized a lower percentage for rural areas.	Occupancy rates are changing due to reimbursement issues. Data on rehab beds in HPR V provided by DA was distributed to	Consensus reached on 85%

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				members.	
81	PART XII.	[600]: Suggest some clarification under “needs” section should be included to facilitate in-state placement of children and adolescents.	Response from DMHMRSAS: Although state agencies have complained that there is a shortage of children and adolescent (C&A) beds, we have no information to substantiate the complaint. To address this issue the 2002 General Assembly passed legislation requesting that the DMHMRSAS track and report on the number of available beds and staffed beds in the system to serve children. The Legislation required that all Community Policy and Management Teams (CPMTs) and each operating community services board (CSB), administrative policy board, local government departments with a policy-advisory board, or behavioral health authority report to the Department instances of a child or adolescent for whom admission to an acute care psychiatric hospital or residential treatment facility was sought but was	Question about crisis stabilization units (CSU)	The CSUs are part of the Governor's initiative to address community mental health issues. They do not fall within the purview of the SMFP or COPN. Continuing questions regarding the CSU should be referred to the appropriate area CSB. Part coordinated with DMHMRSAS

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			unable to be obtained by the reporting entities as well as the reasons these admissions were denied. The legislation also requested the Department to identify and track requests for acute psychiatric beds and acute residential treatment facilities on a quarterly bases. We have no data to support that there is a shortage of C& A beds based on the data that we have been collecting.		
82		Suggest thought be given to separating geriatric psychiatric services from general psychiatric services. Geriatric involves significantly different patient care parameters.	Response from DMHMRSAS: We agree that the geriatric population may require specialized care that is not provided in general acute psychiatric facilities. We have provided language to give special consideration to projects that involve the addition of dedicated beds for geriatric patients.	Suggestion that occupancy rate be consistent at 80%, not split between 75% and 80% as currently proposed	Consensus Part coordinated with DMHMRSAS
83		Psychiatric Facilities: No need to reduce regional occupancy levels substantially. The purpose of the change is unclear. Perhaps it is assumed that a lower occupancy	The changes to Part XII- Mental Health Services were requested by the Department of Mental Health, Mental Retardation, and Substance Abuse Services.		Consensus Part coordinated with DMHMRSAS

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		standard will make it more likely that needed psychiatric beds will be developed. Occupancy levels of determining need should be no lower than 80%			
84	PART XIII.	[670]: Oppose the deletion of the requirements of current 12 VAC 5-250-80.B and 90.B through D relating to specialty and subspecialty neonatal special care. Specialty level or subspecialty level nurseries should be within 90 minutes drive time one way; limit the 45 minute drive time to intermediate level service [670]A: Average annual occupancy should be 85% for specialty and subspecialty level nurseries. [670]B: Specialty and subspecialty beds should contain a minimum of 15 [infant] stations. In addition, there should be no more than 4 bassinets per 1,000 live births for specialty or subspecialty services in each planning region, and current services should not be negatively	Part XIII has been amended as suggested.	If a provider is already a neonatal special care provider, it is necessary to obtain COPN approval to migrate to a higher level? Outstanding issues: 1. Definition of neonatal special care 2. Treatment of bassinets, i.e., OB/newborn vs inpatient usage 3. Movement to higher levels of care; 4. OB volumes: rural vs urban	No consensus

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		impacted by any new services.			
85		670:A drive time of 30 /45 minutes may be appropriate for intermediate level perinatal services, but not for specialty or subspecialty levels	We agree and have changed the standard accordingly.		No consensus
86		670: does not distinguish between intermediate level newborn services and specialty and subspecialty levels, this presents a significant problem.	We agree and have changed the section as suggested.		No consensus
87		Suggest reducing the minimum volume of deliveries for new services	The subsection was set aside by Commissioner decision.	Members feel strongly that some language should be proposed to replace the standard removed by the set aside.	Consensus
88		There is no discussion of high-risk patients and transfer agreements with regional NICU units. Safety and quality have apparently been disregarded in terms of plans and protocols.	We can assure the commenter that safety and quality of services are paramount to VDH. However, transfer agreements are addressed in the hospital licensure regulations, which is the proper venue.		Discussion dispensed
89		Part XIII: there is no occupancy standard to guide projection of needed obstetrical beds.	The sections in Part XIII related to neonatal services have been amended.	Suggest there should be an occupancy level	Consensus
90		Recommend getting expert consensus on minimum standard of	We disagree, the SMFP's advisory committee, was		Discussion dispensed

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		deliveries from a quality and efficiency perspective.	comprised of experienced individuals with access to expert consensus. Expert consensus was also obtainable through the exposure draft process, in addition to the 60-day comment period required by the APA. VDH is confident ample and sufficient opportunity has been provided for expert consensus.		
91		[640]: Suggest driving time be 60 minutes for rural areas	We disagree. Given that there is a shortage of obstetric services and beds in Virginia as stated in the Governor's Task Force Report, and that obstetric services are closing, our goal is to facilitate access to needed services. We believe the proposed standards assist in that goal.		No consensus
92		Perinatal services: Suggest the addition of occupancy standards for obstetrical beds [650]: Suggest the driving time be consistent with neonatal services at 45 minutes.	We agree and have made appropriate amendments. We disagree. Given that there is a shortage of obstetric services and beds in Virginia as stated in the Governor's Task Force Report, and that obstetric services are closing, our goal is		See item 89

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		Neonatal services: Suggest retaining the current neonatal sections including the definition of "regional neonatal services." Refer to the State Perinatal Plan, which is consistent with the perinatal regionalization scheme of the AAP and ACOG. The regional plan is critical for maintaining quality and should be preserved.	to facilitate access to needed services. We believe the proposed standards assist in that goal. Developed in 1988, the State Perinatal Plan was never adopted by the Board of Health. Therefore, to utilize that plan as part of this project is not appropriate.		Dispensed – no discussion
93		NICU definitions should be consistent with AAP definitions outlining the appropriate level of care provided at the NICU level.	Such change must be accomplished through the hospital licensure regulation since the SMFP references that regulation.	Suggest VDH needs to define neonatal special care in regulation is it is an under defined in statute.	Consensus
94		Suggest the inclusion of requirements regarding high-risk patients and transfer agreements with regional NICU units.	We disagree, these are hospital licensure issues.		Cosensus
95		Suggest the standards be reviewed with the recommendations of the Governor's Working Group on rural Obstetrical Care to ensure	The suggestion is duly noted and has been accommodated.		Discussion dispensed

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		consistency.			
96		Neonatal Special Care Services: Neonatal special care services are volume sensitive of quality and financial viability. The perinatal services subcommittee recommended keeping the 85% occupant standard. There is no reference to travel times in rural areas.	The subsection on neonatal services has been amended.	See item 89	Discussion dispensed
97		Obstetrical Services/Beds: No need to change regional standard. Recommend retaining existing planning standards. A bed standard [for rural areas] is needed and should be based on occupancy levels.	Given that there is a shortage of obstetric services and beds in Virginia, as stated in the Governor's Task Force Report, the intent of this statement is unclear. As stated previously, a goal of the revision project has been to provide access to needed services. Holding to previous regional standards when facilities are closing is counterproductive. Geographic areas are considered as required by § 32.1-102.3 of the Code of Virginia.		Discussion dispensed
98		The occupancy calculation for obstetric beds should be based on probability of demand exceeding supply, but have the calculation apply to each facility rather than	We disagree, believing the proposed section is a better response to the results of the Governor's Task Force on Obstetric Care. In addition, this		Discussion dispensed

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		planning district.	decision also addresses a separate comment regarding the Governor's Task Force.		
99		Consider minimum size of obstetric units in metropolitan areas but apply to levels of use reached or maintained by affected units rather than indicating there could be no negative effect.	We disagree believing the proposed section is a better response to the results of the Governor's Task Force on Obstetric Care.		Discussion dispensed