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November 16, 2006

Chapter 230.
State Medical Facilities Plan.

PART I.
Definitions and General Information.

12 VAC 5-230-10. Definitions.

The following words and terms when used in ~~Chapters 230 (12 VAC 5-230) through 360 (12 VAC 5-360)~~ this chapter shall have the following meanings, unless the context clearly indicates otherwise:

~~"Acceptability" means to the level of satisfaction expressed by consumers with the availability, accessibility, cost, quality, continuity and degree of courtesy and consideration afforded them by the health care system.~~

~~["Accessibility" means the ability of a population or segment of the population to obtain appropriate, available services. This ability is determined by economic, temporal, locational, architectural, cultural, psychological, organizational and informational factors which may by barriers or facilitators to obtaining services.~~]

"Acute psychiatric services" means hospital-based inpatient psychiatric services provided in distinct inpatient units in general hospitals or freestanding psychiatric hospitals.

"Acute substance abuse disorder treatment services" means short term hospital-based inpatient treatment services with access to the resources of (i) a general hospital, (ii) a psychiatric unit in a general hospital, (iii) an acute care addiction treatment unit in a general hospital licensed by the Department of Health, or (iv) a chemical dependency specialty hospital with acute care medical and nursing staff and life support equipment licensed by the Department of Mental Health, Mental Retardation and Substance Abuse Services.

~~["Applicant" means any individual, corporation, partnership, association, trust, or other legal entity, whether governmental or private, submitting an application for a Certificate of Public Need.~~]

[~~"Availability" means the quantity and types of health services that can be produced in a certain area given the supply of resources to produce those services.~~]

["Bassinet" means an infant care station, including warming stations and isolates, whether located in a hospital nursery, labor and delivery unit, or pediatric care unit.]

["Bed" means that unit, within the complement of a medical care facility, subject to COPN review as required by 32.1-102.1 of the Code of Virginia and designated for use by patients of the facility or service. For the purposes of this chapter, beds includes cribs and bassinets used for pediatric patients outside the nursery or labor and delivery setting.]

"Cardiac catheterization" means a procedure where a flexible tube is inserted into the patient through an extremity blood vessel and advanced under fluoroscopic guidance into the heart chambers [~~to perform (i) a hemodynamic, electrophysiologic or angiographic examination of the left or right heart chamber or the coronary arteries; (ii) aortic root injections to examine the degree of aortic root regurgitation or deformity of the aortic valve, or (iii) angiographic procedures to evaluate the coronary arteries~~ . ~~Therapeutic intervention in a coronary artery may also be performed using cardiac catheterization.~~] Cardiac catheterization [may include therapeutic intervention, but] does not include a simple right heart catheterization for monitoring purposes as might be performed in an electrophysiology laboratory, pulmonary angiography as an isolated procedure, or cardiac pacing through a right electrode catheter.

[~~"Certificate of Public Need" or "COPN" means the orderly administrative process used to make medical care facilities and services needs decisions~~].

~~[~~"Charges" means all expenses incurred by the provider in the production and delivery of health services.]

"Commissioner" means the State Health Commissioner.

"Competing applications" means applications for the same or similar services and facilities that are proposed for the same planning district [, or planning region for projects reviewed on a regional basis,] and are in the same batch review cycle.

"Computed tomography" or "CT" means a noninvasive diagnostic technology that uses computer analysis of a series of cross-sectional scans made along a single axis of a bodily structure or tissue to construct [~~a three-dimensional~~ an] image of that structure.

[~~"Condition" means the agreed upon qualifications placed on a project by the commissioner when grating a Certificate of Public Need. Such conditions shall direct an applicant to provide a level of care to indigents, accept patients requiring specialized needs, or facilitate the development and operation of primary care services in designated medically underserved areas of the applicant's service area.~~]

"Continuing care retirement community" or "CCRC" means a retirement community consistent with the requirements of Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia. CCRCs can have nursing home services available on-site or at licensed facilities off-site.

~~"Continuity of care" means the extent of effective coordination of services provided to individuals and the community over time, within and among health care settings.~~

~~"Costs" means all expenses incurred in the production and delivery of health services.~~

[~~"Department" means the Virginia Department of Health.~~]

["Diagnostic equivalent procedures" or "DEP" means a method for weighing the relative value of various cardiac catheterization procedures as follows: a diagnostic procedure equals 1 DEP, a therapeutic procedure equals 2 DEPS, a same session procedure (diagnostic and therapeutic) equals 3 DEPs, and a pediatric procedure equals 2 DEPs.]

"[~~General inpatient hospital beds " means beds located in the following units or categories:~~

~~1. Medical/surgical units available for the care and treatment of adults not requiring specialized services; and~~

~~2. Pediatric units that are maintained and operated as a distinct unit for use by patients younger than 21. Newborn cribs and bassinets used in newborn nurseries] are excluded from this definition.~~]

"Health planning region" means a contiguous geographic area of the Commonwealth as designated by the [~~department~~ Board of Health] with a population base of at least 500,000 persons, characterized by the availability of multiple levels of medical care services, reasonable travel time for tertiary care, and congruence with planning districts.

"Hospital" means a medical care facility licensed as [~~a general, community, or special hospital licensed~~ an inpatient hospital or outpatient surgical center] by the Department of Health or [as] a psychiatric hospital [~~licensed~~] by the Department of Mental Health, Mental Retardation, and Substance Abuse Services.

[~~"Hospital-based" means a service operating physically within, connected to, or on the campus, and legally associated with a hospital.~~]

"Indigent [~~or uninsured~~]" means [~~persons eligible to receive reduced rate or uncompensated care at or below Income Level E as defined in 12 VAC 5-200-10 of the Virginia Administrative Code~~ any person whose gross family income is equal to or less than 200 percent of the Federal Non-Farm Poverty Level or income levels A through E of 12 VAC 5-200-10 and who is uninsured].

"Inpatient [~~beds~~]" means accommodations in a medical care facility with continuous support services, such as food, laundry, housekeeping, and staff to provide health or health-related services to patients who generally remain in the facility [~~in excess of~~] 24 hours [or longer]. [~~Such accommodations are known by various nomenclatures including but not limited to: nursing facility, intensive care, minimal or self care, isolation, hospice, observation beds equipped and staffed for overnight use, obstetric, medical/surgical, psychiatric, substance abuse disorder,~~

~~medical rehabilitation, and pediatric. Bassinets and , incubators and beds in labor and birthing delivery rooms, neonatal special care units, emergency rooms, preparation or anesthesia induction rooms, diagnostic or treatment procedure rooms, or on-call staff rooms are excluded from this definition.~~]

"Intensive care beds" or "ICU" means [~~acute care~~ inpatient] beds located in the following units or categories:

1. General intensive care units are those units where patients are concentrated by reason of serious illness or injury regardless of diagnosis. Special lifesaving techniques and equipment are immediately available and patients are under continuous observation by nursing staff;

2. Cardiac care units[, also known as Coronary Care Units or CCUs,] are units staffed and equipped solely for the intensive care of cardiac patients; and

3. Specialized intensive care units are any units with specialized staff and equipment for the purpose of providing care to seriously ill or injured patients [~~for~~ based on age] or selected categories of diagnoses, including units established for burn care, trauma care, neurological care, pediatric care, and cardiac surgery recovery. This category of beds does not include neonatal intensive care units.

[~~"Intermediate care substance abuse disorder treatment services" means long term hospital-based inpatient treatment services that provide structured programs of assessment, counseling, vocational rehabilitation, and social rehabilitation.~~]

"Lithotripsy" means a noninvasive therapeutic procedure [~~of crushing kidney,~~ to (i) crush] renal and biliary stones using shock waves [~~Lithotripsy can also be used to fragment matter such as calcifications or bone~~ , i.e., renal lithotripsy or (ii) to treat certain musculoskeletal conditions] and to relieve the pain associated with tendonitis [, i.e., orthopedic lithotripsy].

["Long term acute care hospital" or "LTACH" means an inpatient hospital that provides care for patients who require a length of stay greater than 25 days and is, or proposes to be, certified by the Centers for Medicare and Medicaid Services as a long term inpatient hospital pursuant to 42 CFR Part 412. An LTACH may be either a free standing facility, or located within an existing or host hospital.]

"Magnetic resonance imaging" or "MRI" means a non-invasive diagnostic technology using a nuclear spectrometer to produce electronic images of specific atoms and molecular structures in solids, especially human cells, tissues and organs**.**

["Medical/surgical" or "med/surge" means those services available for the care and treatment of patient not requiring specialized services.]

"Minimum survival rates" means the lowest percentage of those receiving organ transplants who survive at least one year or for such other period of time as specified by the United Network for Organ Sharing.

[~~"MRI relevant patients" means the sum of: 0.55 times the number of patients with a principal diagnosis involving neoplasms (ICD-9-CM codes 140-239); 0.70 times the number of patients with a principal diagnosis involving diseases of the central nervous system (ICD-9-CM codes 320-349); 0.40 times the number of patients with a principal diagnosis involving cerebrovascular disease (ICD-9-CM codes 430-438); 0.40 times the number of patients with a principal diagnosis involving chronic renal failure (ICD-9-CM code 585); 0.19 times the number of patients with a principal diagnosis involving dorsopathies (ICD-9-CM codes 720-724); 0.40 times the number of patients with a principal diagnosis involving diseases of the prostate (ICD-9-CM codes 600-602); and 0.40 times the number of patients with a principal diagnosis involving inflammatory disease of the ovary, fallopian tube, pelvic cellular tissue or peritoneum (ICD-9-CM code 614). The applicant shall have discharged all patients in these categories during the most recent 12-month reporting period.~~]

"Neonatal special care" means care for infants in one or more of the [~~three~~ higher] service levels designated in [~~12 VAC 5-410-440 D 2~~ 12 VAC 5-410-443] of the "Rules and Regulations for the Licensure of Hospitals, i.e., [a hospital elevates its service level from general level normal newborn to] intermediate level newborn services, specialty level newborn services, or subspecialty level newborn services.

[~~"Network" means a group of medical care facilities, including hospitals, or health care systems, legally or operationally associated with one or more hospitals in a planning region~~].

"Nursing facility" means those facilities or components thereof licensed to provide long-term nursing care.

[~~"Nursing facility beds" means inpatient beds which are located in distinct units of general hospitals that are licensed as long-term care units by the department. Beds in these long-term units are not included in the calculations of inpatient bed need.~~]

"Obstetrical services" means the distinct organized program, equipment and care related to pregnancy and the delivery of newborns in inpatient facilities.

"Off-site replacement" means the relocation of existing beds or services from an existing medical care facility site to another location within the same planning district.

"Open heart surgery" means [~~a set of surgical procedures using a heart-lung bypass machine or pump to perform extracorporeal circulation and oxygenation during surgery. This technique is used when the heart must be slowed down to correct congenital and acquired cardiac and coronary artery disease~~ a surgical procedure requiring the use or immediate availability of a heart-lung bypass machine or 'pump'.] The use of the pump during the procedure distinguishes "open heart" from "closed heart" surgery.

["Operating room" means a room [~~, meeting the requirements of 12 VAC 5-410-820, in a licensed general or outpatient surgical hospital and~~] used solely or principally for the provision of surgical procedures [~~, excluding endoscopic and systscopic procedures~~, especially those involving the administration of anesthesia, multiple personnel, recovery room access, and a fully controlled environment. This does not include rooms designated as procedure rooms or rooms dedicated exclusively for the performance of cesarean sections.]

"Operating room use" means the amount of time a patient occupies an operating room[~~, plus the estimated or actual~~ and includes] room preparation and cleanup time.

"Operating room visit" means one session in one operating room in [~~a licensed general~~ an inpatient] hospital or outpatient surgical [~~hospital~~ center], which may involve several procedures. Operating room visit may be used interchangeably with "operation" or “case.”

“Outpatient [surgery]" means [~~services~~ those surgical procedures] provided to individuals who are not expected to require overnight hospitalization but who require treatment in a medical care facility exceeding the normal capability found in a physician's office. For the purposes of this chapter, outpatient [~~services~~ surgery] refers only to surgical services provided in operating rooms in [~~licensed general~~ inpatient] hospitals or [~~licensed~~] outpatient surgical [~~hospitals~~ centers], and does not include [~~surgical~~] services provided in outpatient departments, emergency rooms, or [~~treatment~~ procedure] rooms of hospitals, or physicians' offices.

[“Pediatric” means those services provided in a distinct unit for patients 18 years of age and younger. Newborns in nurseries are excluded from this definition.]

"Pediatric cardiac catheterization" means the cardiac catheterization of patients [~~less than 21 years of age~~ 18 years of age and younger].

"Perinatal services" means those resources and capabilities that all hospitals offering general level newborn services as described in [~~12 VAC 5-410-440.D.2.a (1)~~ 12 VAC 5-410-443] of the “Rules and Regulations for the Licensure of Hospitals” must provide routinely to newborns.

[“PET/CT scanner” means a single machine capable of producing a PET image with a concurrently produced CT image overlay to provide anatomic definition to the PET image. For the purpose of granting a COPN, a PET/CT scanner shall be reviewed under the PET criteria as an enhanced PET scanner, unless the CT unit will be used independently. In such cases, a PET/CT scanner that will be used to take independent PET and CT images will be reviewed under the applicable PET and CT service criteria.]

[~~"Physician" means a person licensed to practice in Virginia by the Board of Medicine to practice medicine or osteopathy in Virginia~~.]

"Planning district" means a contiguous area within the boundaries established by the Virginia

Department of Housing and Community Development or its successor.

"Planning horizon year" means the particular year for which bed [or service] needs are projected.

"Population" means the U.S. census figures shown in the most current series of projections published by [~~the Virginia Employment Commission~~ Claritas® or a similar demographic entity as determined by the Commissioner].

"Positron emission tomography" or "PET" means a non-invasive diagnostic [or imaging modality] using the computer-generated image of local metabolic and physiological functions in tissues produced through the detection of gamma rays emitted when introduced radio-nuclides decay and release positrons. [~~A PET system includes two major elements: (i) a cyclotron that produces radio-pharmaceuticals and (ii) a scanner that includes a data acquisition system and a computer~~ A PET device or scanner may include an integrated CT to provide anatomic structure definition.]

["Procedure" means a study or treatment or a combination of studies and treatments identified by a distinct ICD9 or CPT code performed in a single session on a single patient.]

~~"Quality of care" means to the degree to which services provided are properly matched to the needs of the population, are technically correct, and achieve beneficial impact. Quality of care can include consideration of the appropriateness of physical resources, the process of producing and delivering services, and the outcomes of services on health status, the environment, and/or behavior.~~

["Qualified" means meeting current legal requirements of licensure, registration or certification in Virginia or having appropriate training, including competency testing, and experience commensurate with assigned responsibilities.]

"Radiation therapy" means [~~the treatment of disease with radiation, especially by selective irradiation with x-rays or other ionizing radiation and by ingestion of radioisotopes~~ a clinical specialty, including radioisotope therapy, in which ionizing radiation is used for treatment of cancer or other diseases, often in conjunction with surgery or chemotherapy or both. The predominant form of radiation therapy involves an external source of radiation whose energy is focused on the diseased area. Radioisotope therapy is a process involving the direct application of a radioactive substance to the diseased tissue and usually requires surgical implantation.]

"Relevant reporting period" means the most recent 12-month period, prior to the beginning of the applicable batch review cycle, for which data is available from [~~the Virginia Employment Commission, Virginia Health Information, or other source identified by the department~~ VHI, Claritas, Inc. ® or a similar demographic entity as determined by the Commissioner].

"Rural" means territory, population, and housing units that are classified as "rural" by the Bureau of the Census of the United States Department of Commerce, Economic and Statistics Administration.

[~~"State medical facilities plan" or "SMFP" means the planning document adopted by the Board of Health that includes, but is not limited to (i) methodologies for projecting need for medical facility beds and services; (ii) statistical information on the availability of medical facility beds and services; and (iii) procedures, criteria and standards for the review of applications for projects for medical care facilities and services.~~]

"Stereotactic radiosurgery" [or "SRS"] means a [~~noninvasive~~ one session] therapeutic procedure for precisely locating [diseased] points within the body using [~~an external,~~ a] 3-diminsional frame of reference. [~~A stereotactic instrument is attached to the body and used to localize precisely an area in the body by means of coordinates related to anatomical structures.~~] An example of a stereotactic radiosurgery instrument is a Gamma Knife® unit. [Stereotactic radiotherapy means more than one session is required. One SRS procedure equals three standard radiation therapy procedures.]

[~~"Study" or "scan" means the gathering of data [using a single piece of equipment] during a single patient visit from which one or more images may be constructed for the purpose of reaching a definitive clinical diagnosis.~~]

"Substance abuse disorder treatment services" means services provided to individuals for the prevention, diagnosis, treatment, or palliation of chemical dependency, which may include attendant medical and psychiatric complications of chemical dependency. [Substance abuse disorder treatment services are licensed by the Department of Mental, Mental Retardation and Substance Abuse Services.]

[~~"The center" means the center for quality health care services and consumer protection~~].

"Use rate" means the rate at which an age cohort or the population uses medical facilities and services. The rates are determined from periodic patient origin surveys conducted for the department by the regional health planning agencies, or other health statistical reports authorized by Chapter 7.2 (§ 32.1-276.2 et seq.) of Title 32.1 of the Code of Virginia.

["VHI" means the health data organization defined in § 32.1-276.4 of the Code of Virginia and under contract with the Virginia Department of Health.]

12 VAC 5-230-20.[~~Preface. Responsibility of the department.~~ Repealed.]

~~Virginia's Certificate of Public Need law defines the State Medical Facilities Plan as the "planning document adopted by the Board of Health which shall include, but not be limited to, (i) methodologies for projecting need for medical facility beds and services; (ii) statistical~~

~~information on the availability of medical facility beds and services; and (iii) procedures, criteria and standards for the review of applications for projects for medical care facilities and services." (§ 32.1-102.1 of the Code of Virginia.)~~

~~Section 32.1-102.3 of the Code of Virginia states that, "Any decision to issue or approve the issuance of a certificate (of public need) shall be consistent with the most recent applicable provisions of the State Health Plan and the State Medical Facilities Plan; provided, however, if the commissioner finds, upon presentation of appropriate evidence, that the provisions of either such plan are not relevant to a rural locality's needs, inaccurate, outdated, inadequate or otherwise inapplicable, the commissioner, consistent with such finding, may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to such plan."~~

~~Subsection B of § 32.1-102.3 of the Code of Virginia requires the commissioner to consider "the relationship" of a project "to the applicable health plans of the board" in "determining whether a public need for a project has been demonstrated."~~

~~This State Medical Facilities Plan is a comprehensive revision of the criteria and standards for COPN reviewable medical care facilities and services contained in the Virginia State Health Plan established from 1982 through 1987, and the Virginia State Medical Facilities Plan, last updated in July, 1988. This Plan supersedes the State Health Plan 1980 - 1984 and all subsequent amendments thereto save those governing facilities or services not presently addressed in this Plan.~~

~~A. Virginia's Certificate of Public Need law defines the State Medical Facilities Plan as the "planning document adopted by the Board of Health which shall include, but not be limited to, (i) methodologies for projecting need for medical facility beds and services; (ii) statistical information on the availability of medical facility beds and services; and (iii) procedures, criteria and standards for the review of applications for projects for medical care facilities and services." (§ 32.1-102.1 of the Code of Virginia.)~~

~~[A. Sections 32.1-102.1 and 32.1-102.3 of the Code of Virginia requires the Board of Health to adopt a planning document for review of COPN applications and that decisions to issue a COPN shall be consistent with the most recent provisions of the State Medical Facilities Plan.~~

~~B. The commissioner is the designated decision maker in the process of determining public need.~~

~~C. The center is a unit of the department responsible for administering the COPN program under the direction of the commissioner.~~

~~[D. The regional health planning agencies assist the department in determining whether a~~

~~certificate should be granted.]~~

~~[E D]. The center's COPN staff is available to answer questions and provide technical assistance throughout the application process.~~

~~[F E]. In developing or revising standards for the COPN program, the board adheres to the requirements of the Administrative Process Act and the public participation process. The department, acting for the board, solicits input from applicants, applicant representatives, industry associations, and the general public in the development or revision of these criteria through informal and formal comment periods and may hold public hearings, as appropriate.~~

~~[G F]. If, upon presentation of appropriate evidence, the commissioner finds that the provisions of this chapter are not relevant to a rural locality's needs, or are inaccurate, outdated, inadequate or otherwise inapplicable, he may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to this chapter.~~]

12 VAC 5-230-30. Guiding principles in certificate of public need.

[A.] The following general principles ~~will be used in guiding the implementation of Virginia's Medical Care Facilities Certificate of Public Need (COPN) Program and have served~~ *serve* as *the* basis for the development of the review criteria and standards for specific medical care facilities and services contained in this document:

1. The COPN program [~~will give preference to~~ requests that encourage ~~medical~~ care facility and service ~~development approaches which can document improvement in~~ that improve ~~the cost-effectiveness of health care delivery. Providers should strive to develop new facilities and equipment and use already available facilities and equipment to deliver needed services at the same or higher levels of quality and effectiveness, as demonstrated in patient outcomes, at lower costs~~ is based on the understanding that excess capacity and underutilization of medical facilities is detrimental to both cost effectiveness and quality of medical services in Virginia].

2. The COPN program ~~will seek~~ seeks [~~to achieve a balance between appropriate~~ the ~~levels of availability and access to medical care facilities and services for all the citizens of Virginia~~ of Virginia's citizens ~~and the need to constrain excessive facility and service capacity~~ the geographical dispersion of medical facilities and to promote the availability and accessibility of proven technologies].

3. The COPN program ~~will seek~~ [~~seeks to achieve economies of scale in development and operation, and optimal quality of care, through establishing limits on the development of specialized medical care facilities and services, on a statewide, regional, or planning district basis~~ promotes the development and maintenance of services and access to those services by every person who needs them without respect to their ability to pay].

4. The COPN program ~~will give preference to~~ [~~seeks to promote the development and maintenance of needed services which are accessible to every person who can benefit from the services regardless of their ability to pay~~ encourages the conversion of facilities to new and efficient uses and the reallocation of resources to meet evolving community needs].

5. ~~The COPN program promotes the elimination of excessive facility and service capacity.~~ The COPN program ~~will promote the~~ [~~promotes the elimination and~~ ~~conversion of excess facility and service capacity to meet identified needs~~ discourages the proliferation of services that would undermine the ability of sole community providers to maintain their financial viability]. ~~The COPN program will not facilitate the survival of medical care facilities and services that are rendered superfluous by changes in health care delivery and financing~~.

[B. Any conflict between the meaning and application of a service-specific requirement and the general principles shall be interpreted in favor of the service-specific requirement, unless a general principle indicates that it supercedes any and all service-specific requirements.]

12 VAC 5-230-40. General application filing criteria.

A. In addition to meeting the [applicable] requirements of [~~the State Medical Facilities Plan~~ this chapter], applicants for a Certificate of Public Need shall [~~provide~~ include] documentation [in their application] that their [~~proposal also~~ project] addresses the applicable [~~20 considerations~~ requirements] listed in §32.1-102.3 of the Code of Virginia.

B.[~~Facilities and services shall be provided in locations that meet established zoning regulations, as applicable~~ The burden of proof shall be on the applicant to produce information and evidence that the project is consistent with the applicable requirements and review policies as required under Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.]

C. [~~The department shall consider an application complete when all information and the application fee have been received by the department. If the department finds the application incomplete, the applicant will be notified in writing and the application may be held for possible review in the next available applicable batch review cycle~~ The Commissioner may condition the approval of a COPN by requiring an applicant to provide care to Virginia's indigent population, to patients requiring specialized care, and to the medically underserved. The applicant must actively seek to provide opportunities to offer a conditioned service directly to indigent or uninsured persons at a reduced rate or free of charge to patients with specialized needs, or by the facilitation of primary care services in designated medically underserved areas.]

12 VAC 5-230-50. Project costs.

[~~The capital development and operating costs for providing services should be comparable to similar services the health planning region~~ The capital development costs of a facility and the operating expenses of providing the authorized services should be comparable to the costs and expenses of similar facilities within the health planning region].

12 VAC 5-230-60. [~~Preferences~~ When competing applications received.]

In [~~the review of~~ reviewing] competing applications, preference will be given to [~~applicants~~ the

applicant that]:

1. [~~Who have~~ Has] an established performance record in completing projects on time and within the authorized [operating expenses and] capital costs;

2. [~~Whose proposals have~~ Has both] lower [~~direct construction and equipment~~ capital] costs and [~~cost of equipment~~ operating expenses] than their competitors and can demonstrate that their [~~cost~~] estimates are credible;

3. [~~Who can demonstrate a commitment to facilitate the transport of patients residing in rural areas or medically underserved areas of urban localities to needed services, directly or through coordinated efforts with other organizations~~;

~~4. Who can~~ Can] demonstrate a consistent compliance with state licensure and federal certification regulations and a consistent history of few documented complaints, where applicable; or

[~~5 .Who can~~ 4. Can] demonstrate a commitment to [~~enhancing financial accessibility to services through the provision of documented charity care, exclusive of bad debts and disallowances from payers, and services to Medicaid beneficiaries~~ serving their community or service area as evidenced by un-reimbursed services to the indigent and providing needed but unprofitable services, taking into account the demands of the particular service area].

12 VAC 5-230-70. [~~Emerging technologies~~ Prorating of mobile service volume requirements.]

[~~Inasmuch as the SMFP cannot contemplate all possible future applications and advances in the regulated technologies, these future applications and technological advances will be evaluated based on emerging national trends and evidence in the peer review literature. Until such time as the SMFP can be updated to reflect changes, emerging technologies should be registered with the Center following 12 VAC 5-220-110 of the Virginia Administrative Code.~~

A. The required minimum service volumes for the establishment of services and the addition of capacity for mobile services shall be prorated on a “site by site” basis based on the amount of time the mobile services will be operational at each site using the following formula:

Prorated annual mobile volume (not to exceed the required full time volume)	=	Required full time annual volume	*	Number of days the service will be on site each week	* 0.2]

B. This section does not prohibit an applicant from seeking to obtain a COPN for a fixed site service provided capacity for the service has been achieved as described in the applicable service section.]

12 VAC 5-230-80. [~~Institutional need~~ When intuitional expansion needed].

[A.] Notwithstanding any other provisions of this chapter, [~~consideration will be given to~~ the

Commissioner may grant approval] for the expansion of services at [an] existing medical care [~~facilities~~ facility] in [a] planning [~~districts~~ district] with an excess supply of such services when the proposed expansion can be justified on the basis of [~~facility-specific utilization~~ a facility's need having exceeded its current service capacity to provide such service] or [on the] geographic remoteness [of the facility].

[B.] If a facility with an institutional need [to expand] is part of a [~~network~~ health system], the under-utilized services at other facilities within [~~the network should be relocated to the facility within the planning district with the institutional need when possible~~ the health system should be reallocated, when appropriate, to the facility with the institutional need to expand before additional services are approved for the applicant. However, under-utilized services located at a health system's geographically remote facility may be disregarded when determining institutional need for the proposed project.]

[C. This section is not applicable to nursing facilities pursuant to §32.1-102.3:2 of the Code of Virginia.]

[D. Applicants shall not use this section to justify a need to establish new services.]

[~~12 VAC 5-230-90 . Compliance with the terms of a condition.~~

~~A. The commissioner may condition the approval of a COPN to provide care to Virginia's indigent population, patients with specialized needs , or the medically underserved.~~

~~B. The applicant shall actively seek to provide opportunities to offer the conditioned service directly to indigent or uninsured persons at a reduced rate or free of charge to patients with specialized needs, or by the facilitation of primary care services in designated medically underserved areas.~~

~~C. If the direct provision of the conditioned services does not fulfill the terms of the condition, the Center may determine the applicant to be in compliance with the terms of the condition when:~~

~~1. The applicant is part of a facility or provider network and the facility or provider network has provided reduced rate or uncompensated care at or above the regional standard; or~~

~~2. The applicant provides direct financial support for community based health care services at a value equal to or greater than the difference between the terms of the condition and the amount of direct care provided.~~

~~Such direct financial support shall be in addition to, and not a substitute for, other charitable giving chosen by the applicant.~~

~~D. Acceptable proof for direct financial support is a signed receipt indicating the number or amount of services or other support provided and dollar value of that service or support.~~

~~Applicants providing direct financial support for community based health care services should render that support through one of the following organizations:~~

~~1. The Virginia Association of Free Clinics;~~
~~2. The Virginia Health Care Foundation; or~~
~~3. The Virginia Primary Care Association.~~

~~E. Applicants shall demonstrate compliance with the terms of a condition for the previous 12 month period. The written condition report shall be [filed on the form certified or affirmed by the applicants and filed with the center. Such report shall include, but is not limited to, the:~~

~~1. Facility or service name and address;~~
~~2. Certificate number;~~
~~3. Facility or service gross patient revenues;~~
~~4. Dollar value of the charity care provided, excluding bad debts and disallowances from payers; and~~
~~5. Number of individuals served by the direct provision of care or a receipt from one of the allowable organizations listed in subsection D of the section.~~]

PART II.
DIAGNOSTIC IMAGING SERVICES.

Article 1.
Criteria and Standards for Computed Tomography.

[~~12 VAC 5-230-100~~ 12 VAC 5-230-90]. [~~Accessibility~~ Travel time.].

CT services should be within 30 minutes driving time one way, under normal conditions, of 95% of the population of the planning district.

[~~12 VAC 5-230-110~~ 12 VAC 5-230-100]. Need for new service.

[~~A. No CT service should be approved at a location that is within 30 minutes driving time one way of :~~
~~1. A service that is not yet operational ; or~~
~~[2. An existing CT unit has performed fewer than 3,000 scans during the relevant reporting period.~~]

[~~B~~ A]. No new CT service [~~or network~~] shall be approved unless all existing CT services [~~or networks~~] in the planning district performed an average of [~~4,500 CT scans per machine during the relevant reporting period~~ 10,000 CT procedures per existing and approved CT scanner were performed during the relevant reporting period and the proposed new service would not reduce

the utilization of existing providers in the planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of CT scanners in such planning district.]

[~~C. Consideration may be given to new CT services proposed for sites located beyond 30 minutes driving time one way of existing facilities that do not meet the 4,500 scans per machine criterion if the proposed sites are in rural areas~~ B. CT scanners to be used solely for simulation with radiation therapy treatment shall be exempt from this article.]

[C. No new CT capacity shall be added within 30 minutes driving time one way under normal driving conditions of any CT services that is not yet operational in the planning district.]

[~~12 VAC 5-230-120~~ 12 VAC 5-230-120]. Expansion of [~~existing~~] service.

[A.] Proposals to increase the number of CT scanners in an existing CT service [~~or network~~] may be approved only [~~if~~ when] the existing [~~service or network~~ services] performed an average of [~~3,000~~ 10,000] CT [~~scans~~ procedures per scanner] for the relevant reporting period [and the proposed expansion would not reduce the utilization of existing scanners in the planning district. The utilization of scanners operated by a hospital and serving an area distinct from the proposed expansion site may be disregarded in computing the average utilization of CT scanners in such planning district].

[B. No additional CT capacity shall be added within 30 minutes driving time one way under normal driving conditions of any CT scanner service that is not yet operational.]

[12 VAC 5-230-130. Adding or expanding mobile CT services.

A. Proposals for mobile CT scanners shall demonstrate that, for the relevant reporting period, at least 4,800 procedures prorated according to 12 VAC 5-230-70 were performed and that the proposed mobile unit will not reduce the utilization of existing providers in the planning district.

B. Proposals to convert mobile CT scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, at least 6,000 procedures prorated according to 12 VAC 5-230-70 were performed and that the proposed conversion will not reduce the utilization of existing providers in the planning district.

C. No additional mobile CT capacity shall be added within 30 minutes driving time one way under normal driving conditions of any CT scanner service, whether mobile or fixed site, that is not yet operational in the planning district.]

[~~12 VAC 5-230-130~~ 12 VAC 5-230-140]. Staffing.

[~~Providers of~~]CT services should be under the [~~direct supervision of one or more board certified~~

~~diagnostic radiologists~~ direction or supervision of one or more physicians qualified to provide such services].

[~~12 VAC 5-230-140. Space.~~

~~Applicants shall provide documentation that:~~

~~1. A suitable environment will be provided for the proposed CT services, including protection against known hazards; and~~

~~2. Space will be provided for patient waiting, patient preparation, staff and patient bathrooms, staff activities, storage of records and supplies, [and other space necessary to accommodate the needs of handicapped persons.~~]

Article 2.
Criteria and Standards for Magnetic Resonance Imaging.

[~~12 VAC 5-230-150~~ 12 VAC 5-230-150]. [~~Accessibility~~ Travel time].

MRI services should be within 30 minutes driving time one way, under normal conditions, of 95% of the population of the planning district.

[~~12 VAC 5-230-160~~ 12 VAC 5-230-160]. Need for new service.

A. No new MRI services shall be approved unless all existing [MRI] services in the planning district performed an average of [~~4,000 scans per machine during the relevant reporting period~~ 5,000 MRI procedures per existing and approved MRI scanner during the relevant reporting period and the proposed new service would not reduce the utilization of existing providers in the planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of MRI scanners in such planning district.]

B. [~~Consideration may be given to new MRI services proposed for sites located beyond 30 minutes driving time one way of existing facilities that do not meet the 4,000 scans per machine criterion if the proposed sites are in rural areas.~~ No new MRI capacity shall be added within 30 minutes driving time one way under normal driving conditions of any MRI service that is not yet operational in the planning district.]

[~~12 VAC 5-230-170~~ 12 VAC 5-230-170]. Expansion of [~~services~~ service].

[A.] Proposals to [~~expand existing MRI services~~ increase the number of MRI scanners] in an [existing] MRI [~~services through the addition of a new scanning unit may~~ service shall] be approved] [~~if~~ only when] the existing service performed [~~at least 4,000 scans~~ an average of 5,000 MRI procedures] per [~~existing unit during~~ scanner for] the relevant reporting period [and the proposed expansion would not reduce the utilization of existing providers in the planning district.

The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed expansion site may be disregarded in computing the average utilization of MRI scanners in such planning district].

[B. No additional MRI capacity shall be added within 30 minutes driving time one way under normal driving conditions of any MRI service that is not yet operational in the planning district.]

[12 VAC 5-230-180. Adding or expanding mobile MRI services.

A. Proposals for mobile MRI scanners shall demonstrate that, for the relevant reporting period, at least 2,400 procedures prorated according to 12 VAC 5-230-70 were performed and that the proposed mobile unit will not reduce the utilization of existing providers in the planning district.

B. Proposals to convert mobile MRI scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, 3,000 procedures prorated according to 12 VAC 5-230-70 were performed and that the proposed conversion will not reduce the utilization of existing providers in the planning district.

C. No additional mobile MRI capacity shall be added within 30 minutes driving time one way under normal driving conditions of any MRI service, whether mobile or fixed site, that is not yet operational in the planning district.]

[~~12 VAC 5-230-180~~ 12 VAC 5-230-190]. Staffing.

MRI [~~machines~~ services] should be under the [~~direct, on-site supervision of one or more board certified diagnostic radiologists~~ direct supervision of one or more physicians qualified to provide such services].

[~~12 VAC 5-230-190. Space.~~

~~Applicants should provide documentation that:~~

~~1. A suitable environment will be provided for the proposed MRI services, including shielding and protection against known hazards; and~~

~~2. Space will be provided for patient waiting, patient preparation, staff and patient bathrooms, staff activities, storage of records and supplies, and other space necessary to accommodate the needs of handicapped persons.~~]

Article 3.
Magnetic Source Imaging.

[~~12 VAC 5-230-200~~ 12 VAC 5-230-200]. Policy for the development of MSI services.

Because Magnetic Source Imaging (MSI) scanning systems are still in the clinical research stage

of development with no third party payment available for clinical applications, and because it is uncertain as to how rapidly this technology will reach a point where it is shown to be clinically suitable for widespread use and distribution on a cost-effective basis [, it is preferred that] the entry and development of this technology in Virginia should initially occur at, or in affiliation with, the academic medical centers in the state.

Article 4.
Positron Emission Tomography.

[~~12 VAC 5-230-210~~ 12 VAC 5-230-210]. [~~Accessibility~~ Travel time].

[~~The service area for each proposed PET service shall be an entire planning district.~~ PET services should be within 60 minutes driving time one way, under normal conditions, of 95% of the planning district.]

[~~12 VAC 5-230-220~~ 12 VAC 5-230-220]. Need for [new] service.

A. [~~Whether the applicant is a consortium of hospitals, a hospital network, or a single general hospital, at least 850 new PET appropriate cases should have been diagnosed in the planning district~~ If the applicant is a hospital, whether free-standing or within a hospital system, 850 new PET appropriate cases shall have been diagnosed and the hospital shall provide radiation therapy services with specific ancillary services suitable for the equipment before a new PET service will be approved for the planning district.]

B. [~~If the applicant is a general hospital , consortium of hospitals, or a hospital within a health system, the facility shall provide radiation therapy services and specific ancillary services suitable for the equipment, and have reported at least 500 new courses of treatment or at least 8,000 treatment visits in the most recent reporting period~~ No new PET services shall be approved unless an average of 6,000 PET procedures per existing and approved PET scanner were performed in the planning district during the relevant reporting period and the proposed new service would not reduce the utilization of existing providers in the planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of PET units in such planning district.

Note: For the purposes of tracking volume utilization, an image taken with a PET/CT scanner that takes concurrent PET/CT images shall be counted as 1 PET procedure. Images made with PET/CT scanners that can take PET or CT images independently shall be counted as individual PET procedures and CT procedures respectively, unless those images made concurrently

C. [~~If the applicant is a consortium of general hospitals or a hospital network, at least one of the consortium or network members shall provide radiation therapy services and specific ancillary~~

~~services suitable for the equipment, and have reported [at least] 500 new PET appropriate patients.~~ No additional PET or PET/CT capacity shall be added within 60 minutes driving time one way under normal driving conditions of any PET or PET/CT service that is not yet operational in the planning district.]

[~~D. Future applications of PET equipment shall be evaluated based on review of national literature~~.]

[~~12 VAC 5-230-230~~ 12 VAC 5-230-230]. [~~Additional scanners~~ Expansion of services].

[A.] ~~No additional PET scanners shall be added in a planning district unless the applicant can demonstrate that the utilization of the existing PET service was 1,200 PET scans for a fixed site unit and that the proposed new or expanded service would not reduce the utilization of existing services below 850 PET scans for a fixed site unit. The applicant shall also provide documentation that the project complies with 12 VAC 5-230-240~~ . Proposals to increase the number of PET scanners in an existing PET service shall be approved only when the existing scanners performed 1,200 PET procedures for the relevant reporting period and the proposed expansion would not reduce the utilization of existing providers in the planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new site may be disregarded in computing the average utilization of PET scanners in such planning district].

[B. No additional PET or PET/CT capacity shall be added within 60 minutes driving time one way under normal driving conditions of any PET or PET/CT service that is not yet operational in the planning district.]

[12 VAC 5-230-240. Adding or expanding mobile PET or PET/CT services.

A. Proposals for mobile PET or PET/CT scanners shall demonstrate that, for the relevant reporting period, at least 230 procedures prorated according to 12 VAC 5-230-70 were performed and that the proposed mobile unit will not reduce the utilization of existing providers in the planning district.

B. Proposals convert mobile PET or PET/CT scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, at least 1,400 procedures prorated according to 12 VAC 5-230-70 were performed and that the proposed conversion will not reduce the utilization of existing providers in the planning district.

C. No additional PET or PET/CT capacity shall be added within 60 minutes driving time one way under normal driving conditions of any PET or PET/CT service, whether fixed or mobile, that is not yet operational in the planning district.]

[~~12 VAC 5-230-240~~ 12 VAC 5-230-250]. Staffing.

PET services should be under the [~~direction of a physician who is a board certified radiologist~~ direct supervision of one or more physicians qualified to provide such services]. Such [~~physician~~ physicians] shall be [~~a~~] designated authorized [~~user~~ users] of isotopes used for PET by the Nuclear Regulatory Commission or licensed by the [~~Office~~ Division] of Radiologic Health of the Virginia Department of Health, as applicable.

Article 5.
Noncardiac Nuclear Imaging Criteria and Standards.

[~~12 VAC 5-230-250~~ 12 VAC 5-230-260]. [~~Accessibility~~ Travel time].

Noncardiac nuclear imaging services should be available within 30 minutes driving time one way, under normal driving conditions, of 95% of the population of the planning district.

[~~12 VAC 5-230-260~~ 12 VAC 5-230-270]. [~~Introduction of a service~~ Need for new service].

[~~Any applicant proposing to establish a medical care facility for the provision of non-cardiac nuclear imaging, or introducing nuclear imaging as a new service at an existing medical care facility, shall provide documentation that~~ A. No new noncardiac imaging services shall be approved unless] the service can achieve a minimum utilization level of [:]

[~~(i) 650scans~~ 1. 650 procedures] in the first 12 months of service[~~,~~ ;]

[~~(ii) 1,000 scans~~ 2. 1,000 procedures] in the second 12 months of [~~services , and (iii) 1,250 scans in the 12 months of operation~~ service; and

3. The proposed new service would not reduce the utilization of existing providers in the planning district.

Note: The utilization of an existing service operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of non-cardiac nuclear imaging services in such planning district.]

[B. No new noncardiac nuclear imaging services shall be added within 30 minutes driving time one way under normal driving conditions of any non-cardiac nuclear imaging service that is not yet operational in the planning district.]

[~~12 VAC 5-230-270~~ 12 VAC 5-230-280]. Staffing.

The proposed new or expanded [noncardiac] nuclear imaging service [~~shall~~ should] be under the [~~direction of a board certified physician~~ direct supervision of one or more physicians qualified to provide such service]. Such physicians shall be [~~a~~] designated authorized [~~user~~ users] of isotopes licensed by the Nuclear Regulatory Commission or the [~~Office~~ Division] of Radiologic Health of the Virginia Department of Health, as applicable.

PART. III.
RADIATION THERAPY SERVICES.

Article 1.
Radiation Therapy Services.

[~~12 VAC 5-230-280~~ 12 VAC 5-230-290]. [~~Accessibility~~ Travel time].

Radiation therapy services should be available within 60 minutes driving time one way, under normal conditions, [~~for~~ of] 95% of the population of the planning district.

[~~12 VAC 5-230-290~~ 12 VAC 5-230-300]. [~~Availability~~ Need for new service].

A. No new radiation therapy service shall be approved unless:

[~~(i) existing~~ 1. Existing] radiation therapy machines located in the planning district were used for at least 320 cancer cases and at least 8,000 treatment visits [~~for~~ in] the relevant reporting period; and

[~~(ii) it can be reasonably projected that the~~ 2. The] new service will perform at least [~~6,000~~ 5,000] procedures by the [~~third~~ second] year of operation without reducing the utilization [~~of existing radiation therapy machines within 60 minutes drive time one way, under normal conditions, such that less than 8,000 procedures will be performed by an existing machine~~ of existing providers in the planning district].

B. The number of radiation therapy machines needed in a [~~primary service area~~ planning district] will be determined as follows:

$$\frac{\text{Population} \times \text{Cancer Incidence Rate} \times 60\%}{320}$$

where:

1. The population is projected to be at least [~~75,000~~ 150,000] people three years from the current year as reported in the most current projections of [~~the Virginia Employment Commission~~ Claritas® or a similar demographic entity as determined by the Commissioner];

2. The [~~"~~]cancer incidence rate [~~" is based on~~ as determined by] data from the Statewide Cancer Registry;

3. 60% is the estimated number of new cancer cases in a planning district that are treatable with radiation therapy; and

4. 320 is 100% utilization of a radiation therapy machine based upon an anticipated average of 25 treatment visits per case.

C. [~~Consideration will be given to the approval of~~ Proposals for] new radiation therapy services located [~~at a general hospital at least~~ less than] 60 minutes driving time one way, under normal

conditions, from any site that radiation therapy services are available [~~if the applicant can~~ shall] demonstrate that the proposed new services will perform at least 4,500 treatment procedures annually by the second year of operation, without reducing the utilization [~~of existing machines located within 60 minutes driving time one way, under normal conditions, from the proposed new service location~~ of existing providers in the planning region].

D. [~~Proposals for the expansion of radiation therapy services should not be approved unless all existing radiation therapy machines operated by the applicant in the planning district have performed at least 8,000 procedures for the relevant reporting period.~~ No new radiation therapy services shall be added within 60 minutes driving time one way under normal driving conditions of any radiation therapy services that is not yet operational in the planning district.]

[12 VAC 5-230-310. Expansion of service.

A. Proposals to increase radiation therapy services shall be approved only when] all existing radiation therapy machines operated by the applicant in the planning district have performed at least 8,000 procedures for the relevant reporting period and the proposed expansion would not reduce the utilization of existing providers.

B. No additional radiation therapy services shall be added within 60 minutes driving time one way under normal driving conditions of any radiation therapy service that is not yet operational in the planning district.]

[~~12 VAC 5-230-300~~ 12 VAC 5-230-320]. Statewide Cancer Registry.

Facilities with radiation therapy services [~~shall~~ should] participate in the Statewide Cancer Registry as required by Article 9 (32.1-70 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia.

[~~12 VAC 5-230-310~~ 12 VAC 5-230-340]. Staffing.

Radiation therapy services [~~shall~~ should] be under the [~~direction of a physician board certified in radiation oncology~~ direct supervision of one or more physicians qualified to provide such services. Such physicians shall be [~~a~~] designated authorized [~~user~~ users] of isotopes licensed by the Nuclear Regulatory Commission or the [~~Office~~ Division] of Radiologic Health of the Virginia Department of Health, as applicable.].

[~~12 VAC 5-230-320. Equipment, patient care; support services~~].

[~~In addition to the radiation therapy machine, the service should have direct access to:~~
~~1. Simulation equipment capable of precisely producing the geometric relations of the equipment to be used for treatment of the patient;~~
~~2. A computerized treatment planning system;~~

~~3. A custom block design and cutting system; and~~

~~4. Diagnostic, laboratory oncology services.~~]

Article 2.
Criteria and Standards for Stereotactic Radiosurgery.

[12 VAC 5-230-350. Travel time.

Stereotactic radiosurgery services should be available within 60 minutes driving time one way, under normal conditions, of 95% of the population of a planning region.]

[~~12 VAC 5-230-330~~ 12 VAC 5-230-360]. [~~Availability; need~~ Need] for new service.

[A.] No new [stereotactic radiosurgery] services [~~should~~ shall] be approved unless [:]

[~~(i) the~~ 1. The] number of procedures performed with existing units in the planning region [~~average~~ averaged] more than 350 per year; and

[~~(ii) it can be reasonably projected that the~~ 2. The] proposed new service will perform at least 250 procedures in the second year of operation without reducing [~~patient volumes to~~ the utilization of] existing providers [in the planning region below 350 treatments per year].

[B. Consideration may be given to a stereotactic radiosurgery service incorporated within an existing standard radiation therapy service using a linear accelerator when at least 8,000 treatments during the relevant reporting period were performed and the applicant can demonstrate that the volume and cost of the service is justified.

C. Consideration may be given a dedicated Gamma Knife® incorporated within an existing radiation therapy service when:

1. At least 350 Gamma Knife appropriate cases were referred out of the region in the relevant reporting period; and

2. The applicant can demonstrate that:

a. At least 250 procedures will be performed in the second year of operation;
b. Utilization of existing services in the planning region will not be reduced below 350 treatments per year; and
c. The cost is justified.

D. Consideration may be given to non-Gamma Knife® technology incorporated within an existing radiation therapy service when:

1. The unit is not part of a linear accelerator; or

2. At least 8,000 radiation treatments per year were performed by the existing radiation therapy service;

3. At least 250 procedures will be performed within the second year of operation, and

3. Utilization of existing services in the planning region will not be reduced below 350 treatments per year.

E. No new stereotactic radiosurgery services shall be added within 60 minutes driving time one way under normal driving conditions of any SRS that is not yet operational in a planning region.]

[12 VAC 5-230-370. Expansion of service.

A. Proposals to increase the number of stereotactic radiosurgery services shall be approved only when all existing stereotactic radiosurgery machines in the planning region have performed 350 procedures for the relevant reporting period and the proposed expansion would not reduce the utilization of existing providers in the planning region.

B. No additional SRS shall be added within 60 minutes one way under normal driving conditions of any SRS that is not yet operational or that performed fewer than 250 procedures in the relevant reporting year in the planning region.]

[~~12 VAC 5-230-340~~ 12 VAC 5-230-380]. Statewide Cancer Registry.

Facilities [~~shall~~ should] participate in the Statewide Cancer Registry as required by Article 9 (32.1-70 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia.

[~~12 VAC 5-230-350~~ 12 VAC 5-230-390]. Staffing.

[~~The proposed new or expanded stereotactic~~ Stereotactic] radiosurgery services [~~shall~~ should] be under the [~~direction of a physician who is board-certified in neurosurgery and a Radiation Oncologist with training in stereotactic radiosurgery~~ direct supervision of one or more physicians qualified to provide such services].

PART IV.
CARDIAC SERVICES.

Article 1.
Criteria and Standards for Cardiac Catheterization Services.

[~~12 VAC 5-230-360~~ 12 VAC 5-230-400]. [~~Accessibility~~ Travel time].

[~~Adult cardiac~~ Cardiac] catheterization services should be [~~accessible~~] within 60 minutes driving time one way, under normal conditions, [~~for~~ of] 95% of the population of the planning district.

[~~12 VAC 5-230-370~~ 12 VAC 5-230-410]. [~~Availability~~ Need for new service].

A. No new fixed site cardiac catheterization laboratory [~~should~~ shall] be approved for a planning district unless:

1. All existing fixed site cardiac catheterization laboratories located in the planning

district [~~were used for at least~~ performed at least] 960 diagnostic-equivalent cardiac catheterization procedures for the relevant reporting period; and

2. [~~It can be reasonably projected that the~~ The] proposed new service will perform at least 200 diagnostic equivalent procedures in the first year of operation[~~,~~ and] 500 diagnostic equivalent procedures in the second year of operation [~~without reducing the utilization of existing laboratories in the planning district to less than 960 diagnostic equivalent procedures at any of those existing laboratories~~; and

3. The utilization of existing services in the planning district will not be reduced.]

B. Proposals for [~~the use of freestanding or~~] mobile cardiac catheterization laboratories shall be approved only if such laboratories will be provided at a site located on the campus of [~~a general or community~~ an inpatient] hospital. Additionally, applicants for proposed mobile cardiac catheterization laboratories shall be able to project that they will perform 200 diagnostic equivalent procedures in the first year of operation, [and] 350 diagnostic equivalent procedures in the second year of operation without reducing the utilization of existing laboratories in the planning district [~~to less than 960 diagnostic equivalent procedures at any of those existing laboratories~~].

C. Consideration may be given for [~~the approval of~~] new cardiac catheterization services located at [~~a general~~ an inpatient] hospital [~~located~~ that is] 60 minutes or more driving time one way, under normal conditions, from existing laboratories, if [~~it can be projected~~ the applicant can demonstrate] that the proposed new laboratory will perform at least 200 diagnostic-equivalent procedures in the first year of operation, [and] 400 diagnostic-equivalent procedures in the second year of operation without reducing the utilization of existing laboratories [~~located within 60 minutes driving time one way, under normal conditions, of the proposed new service location~~ in the planning district].

D. [~~Proposals for the addition of cardiac catheterization laboratories shall not be approved unless all existing cardiac catheterization laboratories in the planning district operated by the applicant have performed at least 1,200 diagnostic-equivalent procedures for the relevant reporting period, and the applicant can demonstrate that he expended service will achieve a minimum of 200 diagnostic equivalent procedures per laboratory in the first 12 months of operation, 400 diagnostic equivalent procedures in the second 12 months of operation without reducing the utilization of existing cardiac catheterization laboratories in the planning district below 960 diagnostic equivalent procedures~~ No new cardiac catheterization service shall be added within 60 minutes driving time one way under normal driving conditions of any cardiac catheterization laboratory that is not yet operational in the planning district.]

[~~E. Emergency cardiac catheterization services shall be available within 30 minutes of admission to the facility.~~]

[12 VAC 5-230-420. Expansion of services.

[A. Proposals to increase cardiac catheterization services shall be approved only when:

1. All existing cardiac catheterization laboratories operated by the applicant's facilities where the proposed expansion is to occur have performed an average of 1,200 diagnostic-equivalent procedures for the relevant reporting period; and

2. The applicant can demonstrate that the expanded service will achieve an average of 200 diagnostic equivalent procedures per laboratory in the first 12 months of operation and] 400 diagnostic equivalent procedures in the second 12 months of operation without reducing the utilization of existing cardiac catheterization laboratories in the planning district.]

B. No additional cardiac catheterization service shall be added within 60 minutes driving time one way under normal driving conditions of any cardiac catheterization laboratory that is not yet operational in the planning district.]

[12 VAC 5-230-430. Pediatric cardiac catheterization.]

[~~F.~~ A.] No new or expanded pediatric cardiac catheterization services [~~should~~ shall] be approved unless [~~the proposed service will be provided at a hospital that~~]:

1. [~~Provides~~ The proposed service will be provide at an inpatient hospital with open heart surgery services, [~~provides~~] pediatric tertiary care services, [~~has a pediatric intensive care unit and~~] or [~~provides~~ specialty or subspecialty level] neonatal special care [~~or has a cardiac intensive care unit and provides pediatric open heart surgery services~~];[~~and~~]

2. The applicant can demonstrate that [~~each~~ the] proposed laboratory will perform at least 100 pediatric cardiac catheterization procedures in the first year of operation and 200 pediatric cardiac catheterization procedures in the second year of operation [; and

3. The utilization of existing pediatric cardiac catheterization laboratories in the planning district will not be reduced below 100 procedures per year].

[~~G. Applications for new or expanded cardiac catheterization services that include non-emergent interventional cardiology services should not be approved unless emergency open heart surgery services are available within 15 minutes drive time in the hospital where the proposed cardiac catheterization service will be located.~~ B. No new or additional pediatric cardiac catheterization service shall be added within 60 minutes driving time one way under normal driving conditions of any pediatric cardiac catheterization service that is not yet operational in the planning district].

[12 VAC 5-230-440. Non-emergent cardiac catheterization.

A. Proposals to provide elective interventional cardiac procedures such as PTCA, transseptal puncture, transthoracic left ventricle puncture, myocardial biopsy or any valvuloplasty procedure, diagnostic pericardiocentesis or therapeutic procedure shall be approved only when open heart surgery services are available on-site in the same hospital in which the proposed non-emergent cardiac service will be located.

B. No non-emergent cardiac catheterization services shall be added within 60 minutes driving

time one way under normal driving conditions of any non-emergent cardiac catheterization service that is not yet operational in the planning district.]

[~~12 VAC 5-230-380~~ 12 VAC 5-230-450]. Staffing.

A. Cardiac catheterization services should have a medical director who is board certified in cardiology and [has] clinical experience in performing physiologic and angiographic procedures.

In the case of pediatric cardiac catheterization services, the medical director should be board-certified in pediatric cardiology and have clinical experience in performing physiologic and angiographic procedures.

B. [~~All physicians who will be performing cardiac catheterization procedures should be board-certified or board-eligible in cardiology and~~ Cardiac catheterization services should be under the direct supervision of one or more physicians qualified to provide such services. Such physicians should] have clinical experience in performing physiologic and angiographic procedures.

[~~In the case of pediatric~~ Pediatric] catheterization services [~~, each physician performing pediatric procedures should be board-certified or board-eligible in~~ should be under the direct supervision of one or more physicians qualified to provide[pediatric] cardiology [services.] [~~, and have~~ Such physicians should have] clinical experience in performing [pediatric] physiologic and angiographic procedures.

[~~C. All anesthesia services should be provided by, or supervised by, a board-certified anesthesiologist.~~

~~In the case of pediatric catheterization services, the anesthesiologist should be experienced and trained in pediatric anesthesiology.~~]

Article 2.
Criteria and Standards for Open Heart Surgery.

[~~12 VAC 5-230-390~~ 12 VAC 5-230-460]. [~~Accessibility~~ Travel time.]

[A.] Open heart surgery services should be [~~available 24 hours a day 7 days a week and accessible~~] within [~~a~~] 60 minutes driving time one way, under normal conditions, for 95% of the population of the planning district.

[B. Such service shall be available 24 hours a day 7days a week.]

[~~12 VAC 5-230-400~~ 12 VAC 5-230-470]. [~~Availability~~ Need for new service].

A. No new open heart services [~~should~~ shall] be approved unless:

1. The service will be [~~made~~] available in [~~a general~~ an inpatient] hospital with [an] established cardiac catheterization [~~services~~ service] that [~~have been used for at least~~ has performed] 960 diagnostic equivalent procedures for the relevant reporting period and [~~have~~ that has] been in operation for at least 30 months;

2. [~~All existing open~~ Open] heart surgery [~~rooms~~ programs] located in the planning district [~~have been used for at least~~ performed at least] 400 open [and closed] heart surgical procedures for the relevant reporting period; and

3. [~~It can be reasonably projected that the~~ The] proposed new service will perform at least 150 procedures per room in the first year of operation and 250 procedures per room in the second year of operation without reducing the utilization of existing open heart surgery programs in the planning district to less than 400 open [and closed] heart procedures performed at those existing services.

B. [~~Notwithstanding subsection A of this subsection section, consideration will~~ Consideration may] be given to [~~the approval of~~] new open heart surgery services located at [~~a general~~ an inpatient] hospital more than 60 minutes driving time one way, under normal conditions, from any site in which open heart surgery services are currently available [~~if it can be projected that the~~ when;

1. The] proposed new service will perform at least 150 open heart procedures in the first year of operation; and 200 procedures in the second year of operation without reducing the utilization of existing open heart surgery rooms [~~to less than 400 procedures per room~~] within 2 hours driving time one way, under normal conditions, from the proposed new service location [~~.~~ to less than 400 procedures per room; and]

[~~Such hospitals should also have~~ 2. The hospital] provided at least 960 diagnostic equivalent cardiac catheterization procedures during the relevant reporting period [~~on equipment~~ in a service] that has been in operation at least 30 months.

[C. No new open heart services shall be approved within 60 minutes driving time one way under normal driving conditions of any open heart service that is not yet operational in the planning district].

[12 VAC 5-230-480. Expansion of service.]

[~~C~~ A]. Proposals [~~for the expansion of~~ to increase] open heart surgery services shall [~~not be approved unless all~~ demonstrate that] existing open heart surgery rooms operated by the applicant have performed at least:

1. 400 adult-equivalent open heart surgery procedures in the relevant reporting period if the proposed increase is within [~~two hours~~ one hour] driving time one way, under normal conditions, of an existing open heart surgery service, or

2. 300 adult-equivalent open heart surgery procedures in the relevant reporting period if the proposed services is in excess of [~~two hours~~ one hour] driving time, under normal conditions, of an existing open heart surgery service in the planning district.

[B. No additional open heart surgery service shall be added within 60 minutes driving time one way under normal driving conditions of any open heart surgery service that is not yet operational in the planning district.]

[12 VAC 5-230-490. Pediatric open heart surgery services.]

[~~D~~ A]. No new or expanded pediatric open heart surgery services [~~should~~ shall] be approved unless the proposed new or expanded service is provided at [~~a~~ an inpatient] hospital that:

1. Has pediatric cardiac catheterization services that have been in operation for 30 months and have performed at least 200 pediatric cardiac catheterization procedures for the relevant reporting period; and

2. Has pediatric intensive care services and provides [specialty or subspecialty] neonatal special care.

[C. No new or additional pediatric open heart surgery service shall be added within 60 minutes driving time one way under normal driving conditions of any open heart surgery service that is not yet operational.]

[~~12 VAC 5-230-410~~ 12 VAC 5-230-500]. Staffing.

A. Open heart surgery services should have a medical director [who is board] certified [~~by the American Board of Thoracic Surgery~~] in cardiovascular [or cardiothoracic] surgery [~~with special qualifications and experience in cardiac surgery~~ by the appropriate board of the American Board of Medical Specialties].

In the case of pediatric [~~open heart~~ cardiac] surgery, the medical director [~~shall~~ should] be [board] certified [~~by the American Board of Thoracic Surgery~~] in cardiovascular [or cardiothoracic] surgery [~~and experience~~ , with special qualifications and experience] in pediatric [~~cardiovascular~~ cardiac] surgery and congenital heart disease [, by the appropriate board of the American Board of Medical Specialists].

B. [~~All physicians performing open heart surgery procedures should be board certified or board eligible in cardiovascular surgery , with experience in cardiac surgery. In addition to the cardiovascular surgeon who performs the procedure, there should be a suitably trained board-certified or board-eligible cardiovascular surgeon acting as an assistant during the open heart surgical procedure. There should also be present at least one board-certified or board-eligible anesthesiologist with experience in open heart surgery.~~ Cardiac surgery should be under the direct supervision of one or more physicians qualified to provide such services.]

[~~In the case of pediatric open heart~~ Pediatric cardiac] surgery services [~~, each physician performing and assisting with pediatric procedures should be board-certified or board-eligible in cardiovascular surgery with experience in pediatric surgery~~ should be under the direct

supervision of one or more physicians qualified to provide such services.] [~~In addition to the cardiovascular surgeon who performs the procedure, there should be a suitably trained board-certified or board-eligible cardiovascular surgeon acting as an assistant during the open heart surgical procedure. All pediatric procedures should include a board-certified anesthesiologist with experience in pediatric anesthesiology and pediatric open heart surgery.~~]

PART V.
GENERAL SURGICAL SERVICES.

[~~12 VAC 5-230-420~~ 12 VAC 5-230-510]. [~~Accessibility~~ Travel time].

Surgical services should be available within 30 minutes driving time one way, under normal conditions, for 95% of the population of the planning district.

[~~12 VAC 5-230-430~~ 12 VAC 5-230-520]. [~~Availability~~ Need for new service].

A. The combined number of inpatient and outpatient general purpose [~~surgical~~] operating rooms needed in a planning district, exclusive of [~~Level I and Level II Trauma Centers dedicated to the needs of the trauma service~~,] dedicated cesarean section rooms, operating rooms designated exclusively for [~~open heart~~ cardiac] surgery [, procedure rooms] or VDH designated trauma services], will be determined as follows:

$$FOR = \frac{((ORV/POP) \times (PROPOP)) \times AHORV}{1600}$$

ORV = the sum of total [inpatient and outpatient general purpose] operating room visits [~~(inpatient and outpatient)~~] in the planning district in the most recent five years for which [general purpose] operating room utilization data has been reported by [~~Virginia Health Information~~ VHI]; and

POP = the sum of total population in the planning district [~~in the most recent five years for which operating room utilization data has been reported by Virginia Health Information, as found in the most current projections of the Virginia Employment Commission~~, as reported by Claritas® or similar entity as determined by the Commissioner, for the same five year period as used in determining ORV].

PROPOP = the projected population of the planning district five years from the current year as reported [~~in the most current projections of the Virginia Employment Commission~~ by Claritas® or a similar demographic entity as determined by the commissioner].

AHORV = the average hours per general [purpose] operating room visit in the planning district for the most recent year for which average hours per general [purpose] operating room [~~visit has~~

visits have] been calculated [~~from information collected by Virginia Health Information~~ as reported by VHI.]

FOR = future general purpose operating rooms needed in the planning district five years from the current year.

1600 = available service hours per operating room per year based on 80% utilization of an operating room [~~that is~~] available 40 hours per week, 50 weeks per year.

B. Projects involving the relocation of existing general purpose operating rooms within a planning district may be authorized when it can be reasonably documented that such relocation will improve the distribution of surgical services within a planning district by making services available within 30 minutes driving time one way, under normal conditions, of 95% of the planning district's population.

[C. No new or additional surgical services shall be added within 60 minutes driving time one way under normal driving conditions of any surgery service that is not yet operational.]

[12 VAC 5-230-530. Staffing.

Surgical services should be under the direction or supervision of one or more physicians qualified to provide such services.]

PART VI.
[~~GENERAL~~] INPATIENT [~~SERVICES~~ BED REQUIREMENTS].

[~~12 VAC 5-230-440~~ 12 VAC 5-230-540]. [~~Accessibility~~ Travel time].

[~~Acute care inpatient facility~~ Inpatient] beds should be within 30 minutes driving time one way, under normal conditions, of 95% of the population of a planning district.

[~~12 VAC 5-230-450~~ 12 VAC 5-230-550]. [~~Availability~~ Need for new service].

A. [~~Subject to the provisions of 12 VAC 5-230-80, no~~ No] new inpatient beds [~~should~~ shall] be approved in any planning district unless:

1. The resulting number of beds [for each bed category contained in this article] does not exceed the number of beds projected to be needed [~~, for each inpatient bed category,~~] for that planning district for the fifth planning horizon year; and

2. The average annual occupancy, based on the number of beds ~~[, is at least 70 % (midnight census)~~ in the planning district] for the relevant reporting period [~~; or~~

~~The intensive care bed capacity has an average annual occupancy of [at least] 65% [(midnight census)] for the relevant reporting period, based on the number of beds~~ is:

a. 80% at midnight census for medical/surgical or pediatric beds;
b. 65% at midnight census for intensive care beds.]

[~~B. No proposal to replace or relocate inpatient beds to a location not contiguous to the existing site should be approved unless:~~

~~1. Off-site replacement is necessary to correct life safety or building code deficiencies;~~

~~2. The population currently served by the beds to be moved will have reasonable access to the beds at the new site, or to neighboring inpatient facilities;~~

~~3. The beds to be replaced experienced an average annual utilization of 70% (midnight census) for general inpatient beds and 65% for intensive care beds in the relevant reporting period;~~

~~4. The number of beds to be moved off-site is taken out of service at the existing facility; and~~

~~5. The off-site replacement of beds results in: (i) a decrease in the licensed bed capacity, (ii) a substantial cost savings, cost avoidance, or consolidation of underutilized facilities, or (iii) generally improved operating efficiency in the applicant's facility or facilities .~~]

[~~C~~ B]. For proposals [~~involving~~ to convert under-utilized beds that are] a capital expenditure of $ 5 million or more, [~~and involving the conversion of under-utilized beds to medical/surgical, pediatric or intensive care services,~~] consideration [~~will~~ may] be given to [~~a~~ such] proposal if:

[~~(i) there~~ 1.There] is a projected need in the [applicable] category of inpatient beds [~~that would result from the conversion~~]; and

[~~(ii) it can be demonstrated~~ 2. The applicant can demonstrate] that the average annual occupancy of the [converted] beds [~~to be converted would reach~~ would meet] the [utilization] standard [~~in subdivisions B 1, 2 and 3~~] for the [applicable] bed category [~~that would result from the conversion,~~] by the first year of operation.

[For the purposes of this Part, 'underutilized' means less than 70% average annual occupancy for medical/surgical [~~and~~ or] pediatric beds, when the relocation involves such beds[~~;~~] and less than 65% average annual occupancy for intensive care beds when relocation involves such beds.]

[~~D . In addition to the terms of 12 VAC 5-230-80, a need for additional general inpatient in a given category may be demonstrated if the total number of beds in a given category in the planning district is less than the number of such beds projected as necessary to meet demand in the fifth planning horizon year for which the application is submitted.~~]

[C. No new inpatient beds shall be added within 30 minutes driving time one way under normal driving conditions of any inpatient beds that are not yet operational in the planning district.]

[12 VAC 5-230-560. Need for medical/surgical beds.]

[~~E~~]. The number of medical/surgical beds projected to be needed in a planning district shall be computed as follows:

1. [~~Determine the projected total number of medical/surgical and pediatric inpatient days for the fifth planning horizon year as follows:~~

~~a. Add the medical/surgical and pediatric inpatient days for the past three years for all acute care inpatient facilities in the planning district as reported in the Annual Survey of Hospitals;~~

~~b. Add the projected planning district population for the same three year period as reported by the Virginia Employment Commission];~~

~~c. Divide the total of the medical/surgical and pediatric inpatient days by the total of the population and express the resulting rate in days per 1,000 population;~~

~~d. Multiply the days per 1,000 population rate by the projected population for the planning district (expressed in thousands) for the fifth planning horizon year.~~

Determine the use rate for medical/surgical beds for the planning district using the formula;

$$BUR = (IPD / Pop) X 1,000$$

Where:

BUR = the bed use rate for the planning district.

IPD = the sum of total inpatient days in the planning district for the most recent three years for which inpatient day data has been reported by VHI; and

Pop = the sum of total population in the planning district for the same three years used to determine IPD as reported by Claritas® or a similar demographic entity as determined by the Commissioner].

2. [~~Determine the projected number of medical/surgical and pediatric beds that may be needed in the planning district for the planning horizon year as follows:~~

~~a. Divide the result in subdivision E 1 d by 365;~~

~~b. Divide the quotient obtained by 0.80 in planning districts in which 50% or more of the population resides in non-rural areas or 0.75 in planning districts in which less than 50% of the population resides in non-rural areas.~~

Determine the total number of medical/surgical beds needed for the planning district in five years from the current year using the formula;

$$ProBed = ((BUR X ProPop) / 365) / 0.70$$

Where:

ProBed = the projected number of medical/surgical beds needed in the planning district for five years from the current year.

BUR = the bed use rate for the planning district determined in 12 VAC 5-230-530.1.

ProPop = the projected population of the planning district five years from the current year as reported by Claritas® or a similar demographic entity as determined by the Commissioner.]

3. [~~Determine the projected number of medical/surgical and pediatric beds that may be established or relocated within the planning district for the fifth planning horizon year as follows:~~

~~a. Determine the number of medical/surgical and pediatric beds as reported in the inventory;~~

~~b. Subtract the number of beds identified in subdivision E1 from the number of beds needed as determined in subdivision E 2 b. If the difference indicated is positive, then a need may exist for additional medical/surgical or pediatric beds. If the difference is negative, then no need for additional beds exists.~~

Determine the number of medical/surgical beds that may be established or relocated within the planning district for the fifth planning horizon year as follows:

NewB = ProBed – CurrentBed

Where:

NewBed = the number of new medical/surgical beds that can be established in a planning district, if the number is positive. If NewBed is a negative number, no additional medical/surgical beds may be authorized for the planning district.

ProBed = the projected number of medical/surgical beds needed in the planning district for five years from the current year determined in 12 VAC 5-230-530.2.

CurrentBed = the current inventory of licensed and authorized medical/surgical beds in the planning district.]

[12 VAC 5-230-570. Need for pediatric beds.

The number of pediatric beds projected to be needed in a planning district shall be computed as follows:

1. Determine the use rate for pediatric beds for the planning district using the formula;

PBUR = (PIPD / PedPop) X 1,000

Where:

PBUR = the pediatric bed use rate for the planning district.

PIPD = the sum of total pediatric inpatient days in the planning district for the most recent three years for which inpatient day data has been reported by VHI; and

PedPop = the sum of population under 19 years of age in the planning district for the same three years used to determine PIPD as reported by Claritas® or a similar demographic entity as determined by the Commissioner.

2. Determine the total number of pediatric beds needed for the planning district in five years from the current year using the formula;

ProPedBed = ((PBUR X ProPedPop) / 365) / 0.70

Where:

ProPedBed = the projected number of pediatric beds needed in the planning district for five years from the current year

PBUR = the pediatric bed use rate for the planning district determined in 12 VAC 5-230-540.1.

ProPedPop = the projected population under 19 years of age of the planning district five years from the current year as reported by Claritas® or a similar demographic entity as determined by the Commissioner.

3. Determine the number of pediatric beds that may be established or relocated within the planning district for the fifth planning horizon year as follows:

NewPedB = ProPedBed – CurrentPedBed

Where:

NewPedBed = the number of new pediatric beds that can be established in a planning district, if the number is positive. If NewPedBed is a negative number, no additional pediatric beds may be authorized for the planning district.

ProPedBed = the projected number of pediatric beds needed in the planning district for five years from the current year determined in 12 VAC 5-230-540.2.

CurrentPedBed = the current inventory of licensed and authorized pediatric beds in the planning district.

[12 VAC 5-230-580. Need for intensive care beds.]

[~~F.~~] The projected need for intensive care beds [in a planning district] shall be computed as

follows:

1. [~~Determine the projected total number of intensive care inpatient days for the fifth planning horizon year as follows:~~

~~a. Add the intensive care inpatient days for the past three years for all inpatient facilities in the planning district as reported in the annual survey of hospitals;~~

~~b. Add the planning district's projected population for the same three-year period as reported by the Virginia Employment Commission;~~

~~c. Divide the total of the intensive care days by the total of the population to obtain the rate in days per 1,000 population;~~

~~d. Multiply the days per 1,000 population rate by the projected population for the planning district (expressed in thousands) for the fifth planning horizon year to yield the expected intensive care patient days~~

1. Determine the use rate for ICU beds for the planning district using the formula;

ICUBUR = (ICUPD / Pop) X 1,000

Where:

ICUBUR = the ICU bed use rate for the planning district

ICUPD = the sum of total ICU inpatient days in the planning district for the most recent three years for which inpatient day data has been reported by VHI; and

Pop = the sum of population in the planning district for the same three years used to determine ICUPD as reported by Claritas® or a similar demographic entity as determined by the Commissioner.]

2. [~~Determine the projected number of intensive care beds that may be needed including bed availability for unscheduled admissions] for the planning horizon year as follows:~~

~~a. Divide the number of days projected in subdivision F 1d of this subsection by 365 to yield the projected average daily census;~~

~~b. Calculate the beds needed to assure with 99% probability that an intensive care bed will be available for unscheduled admissions;~~

Determine the total number of ICU beds needed for the planning district, including bed availability for unscheduled admissions, in five years from the current year using the formula;

ProICUBed = ((ICUBUR X ProPop) / 365) / 0.65

Where:

ProICUBed = the projected number of ICU beds needed in the planning district for five years

from the current year

ICUBUR = the ICU bed use rate for the planning district determined in 12 VAC 5-230-550.1.

ProPop = the projected population of the planning district five years from the current year as reported by Claritas® or a similar demographic entity as determined by the Commissioner

3. [~~Determine the projected number of intensive care beds that may be established or relocated within the planning district for the fifth planning horizon year as follows:~~

~~a. Determine the number of intensive care beds as reported in the inventory.~~

~~b. Subtract the number of beds identified in subdivision F 3 a of this subsection from the number of beds needed as determined in subdivision F 2 b of this subsection . If the difference is positive, then a need may exist for additional intensive care beds. If the difference is negative, then no need for additional beds exists~~

Determine the number of ICU beds that may be established or relocated within the planning district for the fifth planning horizon year as follows:

NewICUB = ProICUBed – CurrentICUBed

Where:

NewICUBed = the number of new ICU beds that can be established in a planning district, if the number is a positive. If NewICUBed is a negative number, no additional ICU beds may be authorized for the planning district.

ProICUBed = the projected number of ICU beds needed in the planning district for five years from the current year determined in 12 VAC 5-230-550.2.

CurrentICUBed = the current inventory of licensed and authorized ICU beds in the planning district

[12 VAC 5-230-590. Expansion or relocation of services.

A. Proposals to relocate beds to a location not contiguous to the existing site shall be approved only when:

1. Off-site replacement is necessary to correct life safety or building code deficiencies;

2. The population currently served by the beds to be moved will have reasonable access to the beds at the new site, or to neighboring inpatient facilities;

1. The number of beds to be moved off-site is taken out of service at the existing facility;

2. The off-site replacement of beds results in:

a. A decrease in the licensed bed capacity,

b. A substantial cost savings, cost avoidance, or consolidation of underutilized facilities, or

c. Generally improved operating efficiency in the applicant's facility or facilities; and

5. The relocation results in improved distribution of existing resources to meet community needs.

B. Proposals to relocate beds within a planning district where underutilized beds are within 30 minutes driving time one way under normal conditions of the site of the proposed relocation shall be approved only when the applicant can demonstrate that the proposed relocation will not materially harm existing hospital providers.

C. No additional inpatient beds shall be added within 30 minutes driving time one way under normal driving conditions of any inpatient beds that are not yet operational in the planning district.]

[12 VAC 5-230-600. Long-term acute care hospitals.

A. Long term care hospital beds will not be considered as a separate category for planning or licensing purposes. All LTACH beds remain part of the inventory of inpatient hospital beds.

B. An LTACH shall only be approved if an existing hospital converts existing medical/surgical beds to LTACH beds or if there is an identified need for LTACH beds within a planning district. New LTACH beds that would result in an increase in total licensed beds above 165% of the average daily census for the planning district will not be approved. Excess inpatient beds within existing acute care facilities must be converted to fill any unmet need for additional LTACH beds.

C. If an existing or host hospital converts existing beds for use as LTACH beds, those beds must be de-licensed from the bed inventory of the existing hospital. If the LTACH ceases to exist, terminates its services, or does not offer services for a period of 12 months within its first year of operation, the beds de-licensed by the host hospital to establish the LTACH shall revert back to that host hospital.

If the LTACH ceases operation in subsequent years of operation, the host hospital may reacquire the LTACH beds by obtaining a COPN provided the beds are to be used exclusively for general medical/surgical purposes and the application meets all other applicable project delivery requirements. Such an application shall not be subject to comparative review and shall be processed under Part VI (§12 VAC 5-220-280 et seq.) of the Certificate of Public Need Rules and Regulations.

D. The application shall delineate the service area for the LTAC by documenting the expected areas from which it is expected to draw patients.

E. A LTACH shall be established for 10 or more beds.

F. All LTACHs shall become certified by CMS as a long term acute care hospital and shall not convert to a hospital for patients needing a length of stay of less than 25 days without obtaining a certificate of need.

1. If the LTACH fails to meet the CMS requirements as a LTACH within 12 months after beginning operation, it may apply for a 6-month extension of its COPN.

2. If the LTACH fails to meet the CMS requirements as a LTACH within the extension period, then the COPN granted pursuant to this section shall expire automatically.

G. No new or additional LTACH beds shall be added within 30 minutes driving time one way under normal driving conditions of any LTACH beds that are not yet operational in the planning district.]

[12 VAC 5-230-610. Staffing.

Inpatient services should be under the direction or supervision of one or more physicians qualified to provide such services.]

PART VII.
NURSING FACILITIES.

[~~12 VAC 5-230-460~~ 12 VAC 5-230-620.]. [~~Accessibility~~ Travel time].

A. Nursing facility beds should be [~~accessible~~] within [~~60~~ 30] minutes driving time one way, under normal conditions, to 95% of the population in a planning [~~region~~ district].

B. Nursing facilities should be accessible by public transportation when such systems exist in an area.

C. Preference will be given to proposals that improve geographic access and reduce travel time to nursing facilities within a planning district.

[~~12 VAC 5-230-470~~ 12 VAC 5-230-630]. [~~Availability~~ Need for new service].

A. [~~No~~ A] planning district shall be considered to have a need for additional nursing facility beds [~~unless (i) the~~ when:

1. The] bed need forecast [~~in that planning district (see subdivision D of this section)~~] exceeds the current inventory of beds [~~in that~~ for the] planning district[;] and

[~~(ii)the~~ 2.] The [~~estimated~~] average annual occupancy of all existing [and authorized] Medicaid-certified nursing facility beds in the planning district was at least 93% [~~for the most~~

~~recent two years following the first year of operation of new beds~~], excluding the bed inventory and utilization of the Virginia Veterans Care [~~Center~~ Centers].

[Exception: When there are facilities that have been in operation less than three years in the planning district, their occupancy can be excluded from the calculation of average occupancy if the facilities had an annual occupancy of at least 93% in one of its first three years of operation.]

B. No planning district shall be considered to have a need for additional beds if there are unconstructed beds designated as Medicaid-certified. [This presumption of 'no need' for additional beds extends for three years or the date on the certificate; whichever is longer, for the unconstructed beds.]

~~[C. Proposals for expanding existing nursing facilities should not be approved unless the facility has operated for at least two years and the average annual occupancy of the facility's existing beds was at least 93% in the most recent year for which bed utilization has been reported to the department.~~

~~Exceptions will be considered for facilities that operated at less than 93% average annual occupancy in the most recent year for which bed utilization has been reported when the facility has a rehabilitative or other specialized care focus that results in a relatively short average length of stay , causingin an average annual occupancy lower than 93% for the facility.]~~

[~~D~~ C]. The bed need forecast will be computed as follows:

PDBN = (UR64 x PP64) + (UR69 x PP69) + (UR74 x PP74) + (UR79 x PP79) + (UR84 x PP84) + (UR85 x PP85) where:

PDBN = Planning district bed need.

UR64 = The nursing home bed use rate of the population aged 0 to 64 in the planning district as determined in the most recent nursing home patient origin study authorized by [~~the department~~ VHI].

PP64 = The population aged 0 to 64 projected for the planning district three years from the current year as most recently published by [~~the Virginia Employment Commission~~ Claritas® or a similar demographic entity as determined by the Commissioner].

UR69 = The nursing home bed use rate of the population aged 65 to 69 in the planning district as determined in the most recent nursing home patient origin study authorized by [~~the department~~ VHI].

PP69 = The population aged 65 to 69 projected for the planning district three years from the

current year as most recently published by [~~the Virginia Employment Commission~~ Claritas® or a similar demographic entity as determined by the Commissioner].

UR74 = The nursing home bed use rate of the population aged 70 to 74 in the planning district as determined in the most recent nursing home patient origin study authorized by [~~the department~~ VHI].

PP74 = The population aged 70 to 74 projected for the planning district three years from the current year as most recently published by [~~the Virginia Employment Commission~~ Claritas® or a similar demographic entity as determined by the Commissioner].

UR79 = The nursing home bed use rate of the population aged 75 to 79 in the planning district as determined in the most recent nursing home patient origin study authorized by [~~the department~~ VHI].

PP79 = The population aged 75 to 79 projected for the planning district three years from the current year as most recently published by [~~the Virginia Employment Commission~~ Claritas® or a similar demographic entity as determined by the Commissioner].

UR84 = The nursing home bed use rate of the population aged 80 to 84 in the planning district as determined in the most recent nursing home patient origin study authorized by [~~the department~~ VHI].

PP84 = The population aged 80 to 84 projected for the planning district three years from the current year as most recently published by [~~the Virginia Employment Commission~~ Claritas® or a similar demographic entity as determined by the Commissioner].

UR85+ = The nursing home bed use rate of the population aged 85 and older in the planning district as determined in the most recent nursing home patient origin study authorized by [~~the department~~ VHI].

PP85+ = The population aged 85 and older projected for the planning district three years from the current year as most recently published by [~~the Virginia Employment Commission~~ Claritas® or a similar demographic entity as determined by the Commissioner].

Planning district bed need forecasts will be rounded as follows:

Planning District Bed Need	Rounded Bed Need
1 – 29	0
30 – 44	30
45 – 84	60
85 – 104	90

105 – 134	120
135 – 164	150
165 – 194	180
195 – 224	210
225+	240

[~~The above applies, except in the case of~~ Exception: When] a planning district [~~that~~] has [~~two~~ :

1. Two or more nursing facilities[~~, has had~~ ;

2. Had] an average annual occupancy rate in excess of 93% for the most recent two years for which bed utilization has been reported to [~~the department,~~ VHI ;] and

[~~has~~ 3. Has] a forecasted bed need of 15 to 29 beds[~~. In such a case~~], [then] the bed need for this planning district will be rounded to 30.

[~~E~~ D]. No new freestanding nursing facilities of less than 90 beds [~~should~~ shall] be authorized. [~~Consideration will~~ However, consideration may] be given to [a] new freestanding [~~facilities~~ facility] with fewer than 90 nursing facility beds when [the applicant can demonstrate that] such [~~facilities can be~~ a facility is] justified [~~on the basis of a lack of local demand for a larger~~ based on a locality's preference for such smaller] facility and [~~a maldistribution of~~ there is a proven poor distribution of] nursing facility beds within [~~a~~ the] planning district.

[~~F . Proposals for the development of new nursing facilities or the expansion of existing facilities by continuing care retirement communities will be considered when:~~

~~1. The total number of new or additional beds plus any existing nursing facility beds operated by the continuing care provider does not exceed [10 20] % of the continuing care provider's total existing or planned independent living and adult care residence;~~

~~2. The proposed beds are necessary to meet existing or reasonably anticipated obligations to provide care to present or prospective residents of the continuing care facility;~~

~~3. The applicant agrees in writing not to seek certification for the use of such new or additional beds by persons eligible to receive Medicaid;~~

~~4. The applicant agrees in writing to obtain the resident's written acknowledgement, prior to admission, that the applicant does not serve Medicaid recipients 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;~~

~~5. The applicant agrees in writingthat only continuing care contract holders who have resided in the CCRC as independent living residents or adult care residents will be admitted to the nursing facility unit after the first three years of operation.]~~

[~~G . The construction cost of proposed nursing facilities should be comparable to the most recent cost for similar facilities in the same health planning region. Consideration should be given to the current capital cost reimbursement methodology utilized by the Department of Medical Assistance Services~~ E. When evaluating the cost of a project, consideration may be given to projects that use the current methodology as determined by the Department of Medical

Assistance Services].

[~~H~~ F]. Consideration [~~should~~ may] be given to [~~applicants proposing~~ proposals] to replace outdated and functionally obsolete facilities with modern [~~nursing~~] facilities that [~~will~~] result in the more cost efficient [~~delivery of health care services to residents~~ resident services]in a more aesthetically pleasing and comfortable environment. [~~Proponents of the replacement and relocation of nursing facility beds should demonstrate that the replacement and relocation are reasonable and could result in savings in other cost centers, such as realized operational economies of scale and lower maintenance costs.~~]

[G. No new or additional nursing facility beds shall be added within 30 minutes driving time one way under normal driving conditions of any nursing facility that is not yet operational in the planning district.]

[12 VAC 5-230-640. Expansion of services.

Proposals to increase existing nursing facility bed capacity shall not be approved unless the facility has operated for at least two years and the average annual occupancy of the facility's existing beds was at least 93% in the relevant reporting period as reported to VHI.

Note: Exceptions will be considered for facilities that operated at less than 93% average annual occupancy in the most recent year for which bed utilization has been reported when the facility has a rehabilitative or other specialized care program causing a short average length of stay resulting in an average annual occupancy lower than 93% for the facility.]

[12 VAC 5-230-650. Continuing care retirement communities.

Proposals for the development of new nursing facilities or the expansion of existing facilities by continuing care retirement communities will be considered when:

1. The total number of new or additional beds plus any existing nursing facility beds operated by the continuing care provider does not exceed 20 % of the continuing care provider's total existing or planned independent living and adult care residence;

2. The proposed beds are necessary to meet existing or reasonably anticipated obligations to provide care to present or prospective residents of the continuing care facility; and

3. The applicant certifies that:

a. The CCRC has, or will have, a qualified resident assistance fund and that the facility will not rely on federal and state public assistance funds for reimbursement of the proposed beds;

b. The continuing care contract or disclosure statement, as required by § 38.2 4902 of the Code, has been filed with the State Corporation Commission and that the Commission has deemed the contract or disclosure statement in compliance with applicable law; and

c. Only continuing care contract holders residing in the CCRC as independent living residents or adult care residents or who is a family member of a contract holder residing in a non-nursing facility portion of the CCRC will be admitted to the nursing facility unit after the first three years of operation.]

[12 VAC 5-230-660. Staffing.

Nursing facilities shall be staffed by a licensed administrator and by nursing professionals qualified to provide such services as required by law.]

PART VIII.
Lithotripsy Services.

[~~12 VAC 5-230-480~~ 12 VAC 5-230-670]. [~~Accessibility~~ Travel time].

[~~A. The waiting time for lithotripsy services should be no more than one week.~~

~~B~~ ~~A~~]. Lithotripsy services should be available within 30 minutes driving time [~~in urban areas and 45 minutes driving time~~] one way, under normal conditions, for 95% of the population of the health planning region].

[12 VAC 5-230- ~~490~~ 12 VAC 5-230-680]. [~~Availability~~ Need for new service].

A. Consideration [~~will~~ may] be given to new [renal or orthopedic] lithotripsy services established at a [~~general hospital~~ new facility] through contract with, or by lease of equipment from, an existing service provider authorized to operate in Virginia, provided the [~~hospital~~ facility] has referred at least two [appropriate] patients per week, or 100 [appropriate] patients annually, for the relevant reporting period to other facilities for [either renal or orthopedic] lithotripsy services.

B. A new [renal lithotripsy] service may be approved [~~at the site of any general hospital or hospital-based clinic or licensed outpatient surgical hospital provided the service is provided by:~~

~~1. A vendor currently providing services in Virginia;~~

~~2. A vendor not currently providing services can demonstrate that the proposed unit can provide at least 750 procedures annually at all sites served; or~~

~~3. The~~ if the] applicant can demonstrate that the proposed [~~unit~~ service] can provide at least 750 [renal lithotripsy] procedures annually [~~at all sites to be served~~].

C. [~~Proposals for the expansion of services by existing vendors or providers of such services may be approved if it can be demonstrated that each existing unit owned or operated by that vendor or provider has provided a minimum of 750 procedures annually at all sites served by the vendor or provider~~ A new orthopedic lithotripsy service may be approved if the applicant can demonstrate that the proposed service can provide at least 500 orthopedic lithotripsy procedures

annually.]

D. [~~A new or expanded lithotripsy service may be approved when the applicant is a consortium of hospitals or a hospital network, when a majority of procedures will be provided at sites or facilities owned or operated by the hospital consortium or by the hospital network.~~ No new lithotripsy service shall be added within 30 minutes driving time one way under normal driving conditions of any lithotripsy service that is not yet operational in the planning region.]

[12 VAC 5-230-690. Expansion of services.

A. Proposals to increase renal lithotripsy services shall demonstrate that each existing unit owned or operated by that vendor or provider has provided at least 750 procedures annually at all sites served by the vendor or provider.

B. Proposals to increase orthopedic lithotripsy services shall demonstrate that each existing unit owned or operated by that vendor or provider has provided at least 500 procedures annually at all sites served by the vendor or provider.

C. No new lithotripsy service shall be added within 30 minutes driving time one way under normal driving conditions of any mobile or fixed lithotripsy service that is not yet operational in the planning region.]

[12 VAC 5-230-700. Adding or expanding mobile lithotripsy services.

A. Proposals for mobile lithotripsy services shall demonstrate that, for the relevant reporting period at least 125 procedures, as prorated according to 12 VAC 5-230-70, were performed and that the proposed mobile unit will not reduce the utilization of existing machines in the planning region.

B. Proposals to convert a mobile lithotripsy service to a fixed site lithotripsy service shall demonstrate that, for the relevant reporting period at least 430 procedures, as prorated according to 12 VAC 5-230-60, were performed and the proposed conversion will not reduce the utilization of existing providers in the planning district.

C. No additional mobile lithotripsy service shall be added within 30 minutes driving time one way under normal driving conditions of any mobile or fixed lithotripsy service that is not yet operational in the planning region.]

[12 VAC 5-230-710. Staffing.

Lithotripsy services should be under the direction or supervision of one or more physicians qualified to provide such services.]

PART IX.
ORGAN TRANSPLANT.

[~~12 VAC 5-230-500~~ 12 VAC 5-230-720]. [~~Accessibility~~ Travel time].

A. Organ transplantation services should be [~~accessible~~] within two hours driving time one way, under normal conditions, of 95% of Virginia's population.

B. Providers of organ transplantation services should facilitate access to pre- and post-transplantation services needed by patients residing in rural locations by establishing part-time satellite clinics.

[~~12 VAC 5-230-510~~ 12 VAC 5-230-730]. [~~Availability~~ Need for new service].

A. There [~~should~~ shall] be no more than one program for each transplantable organ in a health planning region.

[B. ~~Proposals to expand existing transplantation programs shall demonstrate that existing organ transplantation services comply with all applicable Medicare program coverage criteria.~~ Performance of minimum transplantation volumes as cited in 12 VAC 5-230-*** does not indicate a need for additional transplantation capacity or programs.

C. No new organ transplant program shall be added within two hours driving time one way under normal driving conditions of a similar organ transplant service that is not yet operational.]

[~~12 VAC 5-230-520~~ 12 VAC 5-230-740]. [~~Minimum utilization; minimum survival rate~~; Transplant volumes; survival rates];service proficiency; systems operations.

A. Proposals to establish [~~or expand~~] organ transplantation services [~~should~~ shall] demonstrate that the minimum number of transplants would be performed annually. The minimum number transplants of required by organ system is:

Kidney	30
Pancreas or kidney/pancreas	12
Heart	17
Heart/Lung	12
Lung	12
Liver	21
Intestine	2

[~~Performance of minimum transplantation volumes does not indicate a need for additional transplantation capacity or programs~~ Note: Any proposed pancreas transplant program must be a

part of a kidney transplant program that has achieved a minimum volume standard of 30 cases per year for kidney transplants as well as the minimum transplant survival rates stated in subsection B.]

B. [~~Preference will be given to expansion of successful existing services, either by enabling necessary increases in the number of organ systems being transplanted or by adding transplantation capability for additional organ systems, rather than developing additional programs that could reduce average program volume.~~

~~C. Facilities should~~ Applicants shall] demonstrate that they will achieve and maintain at least the minimum transplant patient survival rates. Minimum one-year survival rates, listed by organ system, are:

Kidney	95%
Pancreas or kidney/pancreas	90%
Heart	85%
Heart/Lung	[~~60%~~ 70%]
Lung	77%
Liver	86%
Intestine	77%

[12 VAC 5-230-750. Expansion of transplant services.]

[~~D~~ A]. Proposals to [~~add additional~~ increase] organ transplantation services [~~should~~ shall] demonstrate at least two years successful experience with all existing organ transplantation systems [at the hospital].

[B. Preference will be given to expanding successful existing services through increases in the number of organ systems being transplanted rather than developing new programs that could reduce existing program volumes.

C. No additional organ transplant service shall be added within two hours driving time one way under normal driving conditions of a similar organ transplant service that is not yet operational.]

12 VAC 5-230-760. Staffing.]

[~~E. All physicians that perform transplants should be board certified by the appropriate professional examining board, and should have a minimum of one year of formal training and two years of experience in transplant surgery and post-operative care~~ Organ transplant services should be under the direct supervision of one or more physicians qualified to provide such services].

PART X.
MISCELLANEOUS CAPITAL EXPENDITURES.

[~~12 VAC 5-230-530~~ 12 VAC 5-230-770]. Purpose.

This part of the SMFP is intended to provide general guidance in the review of projects that require COPN authorization by virtue of their expense but do not involve changes in the bed or service capacity of a medical care facility addressed elsewhere in this chapter. This part may be used in coordination with other [services specific] parts of the SMFP [~~addressing changes in bed or service capacity used in the COPN review process~~].

[~~12 VAC 5-230-540~~ 12 VAC 5-230-780]. Project need.

All applications involving the expenditure of $5 million dollars or more by a medical care facility should include documentation that the expenditure is necessary in order for the facility to meet the identified medical care needs of the public it serves. Such documentation should clearly identify that the expenditure:

1. Represents the most cost-effective approach to meeting the identified need; and
2. The ongoing operational costs will not result in unreasonable increases in the cost of delivering the services provided.

[~~12 VAC 5-230-550~~ 12 VAC 5-230-790]. Facilities expansion.

Applications for the expansion of medical care facilities should document that the current space provided in the facility for the areas or departments proposed for expansion are inadequate. Such documentation should include:

1. An analysis of the historical volume of work activity or other activity performed in the area or department;
2. The projected volume of work activity or other activity to be performed in the area or department; and
3. Evidence that contemporary design guidelines for space in the relevant areas or departments, based on levels of work activity or other activity, are consistent with the proposal.

[~~12 VAC 5-230-560~~ 12 VAC 5-230-800]. Renovation or modernization.

A. Applications for the renovation or modernization of medical care facilities should provide documentation that:

1. The timing of the renovation or modernization expenditure is appropriate within the life cycle of the affected building or buildings; and
2. The benefits of the proposed renovation or modernization will exceed the costs of the renovation or modernization over the life cycle of the affected building or buildings to be renovated or modernized.

B. Such documentation should include a history of the affected building or buildings, including a chronology of major renovation and modernization expenses.

C. Applications for the general renovation or modernization of medical care facilities should include downsizing of beds or other service capacity when such capacity has not operated at a reasonable level of efficiency as identified in the relevant sections of this chapter during the most recent [~~three~~ five] year period.

[~~12 VAC 5-230-570~~ 12 VAC 5-230-810]. Equipment.

Applications for the purchase and installation of equipment by medical care facilities that are not addressed elsewhere in this chapter should document that the equipment is needed. Such documentation should clearly indicate that the (i) proposed equipment is needed to maintain the current level of service provided, or (ii) benefits of the change in service resulting from the new equipment exceed the costs of purchasing or leasing and operating the equipment over its useful life.

PART XI.
MEDICAL REHABILITATION.

[~~12 VAC 5-230-580~~ 12 VAC 5-230-820]. [~~Accessibility~~ Travel time].

[~~Comprehensive inpatient~~ Medical] rehabilitation services should be available within 60 minutes driving time one way, under normal conditions, of 95% of the population of the planning [~~region~~ district].

[~~12 VAC 5-230-590~~ 12 VAC 5-230-830]. [~~Availability~~ Need for new service].

A. The number of comprehensive and specialized rehabilitation beds [~~needed in a health planning region will~~ shall] be [~~projected~~ determined] as follows:

[~~((UR x PROJ. POP.)/365)/.90~~ ((UR x PROPOP)/365)/.85]

Where UR = the use rate expressed as rehabilitation patient days per population in the health planning [~~region~~ district] as reported [~~in the most recent "Industry Report for Virginia Hospitals and Nursing Facilities" published by Virginia Health Information~~ by VHI]; and

[~~PROJ.POP.~~ PROPOP] = the most recent projected population of the health planning region three years from the current year as published by [~~the Virginia Employment Commission~~ Claritas® or a similar demographic entity as determined by the Commissioner].

[B. Proposals for new medical rehabilitation beds shall be considered] when [the applicant can

demonstrate that:

1. The rehabilitation specialty proposed is not currently offered in the health planning region; and

2. There is a documented need for the service or beds in the planning district].

[C. No new medical rehabilitation beds shall be added within 60 minutes driving time one way under normal driving conditions of medical rehabilitation services that are not yet operational in the planning district.]

[12 VAC5-230-840. Expansion of services.

[~~B~~ A]. No additional rehabilitation beds [~~should~~ shall] be authorized for a health planning region in which existing rehabilitation beds were utilized [~~at~~] an average annual occupancy of less than 90% in the most recently reported year.]

[~~Preference will~~ Exception: Consideration may] be given to [~~the development of needed~~ expanding] rehabilitation beds through the conversion of underutilized medical/surgical beds.

[~~C. Notwithstanding subsection A of this section, the need for proposed inpatient rehabilitation beds will be given consideration when:~~

~~1. The rehabilitation specialty proposed is not currently offered in the health planning region; and~~

~~2. A documented basis for recognizing a need for the service or beds is provided by the applicant.~~ B. No additional medical rehabilitation beds shall be added within 60 minutes driving time one way under normal conditions of any medical rehabilitation service that is not yet operational in the planning district.]

[~~12 VAC 5-230-600~~ 12 VAC 5-230-850]. Staffing.

Medical rehabilitation facilities should [~~have full-time medical direction by a physiatrist or other physician with a minimum of two years experience in the proposed specialized inpatient medical rehabilitation program~~ be under the direction or supervision of one or more physicians qualified to provide such services].

PART XII.
MENTAL HEALTH SERVICES.

Article 1.
[Acute] Psychiatric and [Acute] Substance Abuse Disorder Treatment Services

[~~12 VAC 5-230-610~~ 12 VAC 5-230-860]. [~~Accessibility~~ Travel time].

A. Acute psychiatric [, and] acute substance abuse disorder treatment services ~~[, and intermediate~~

~~care substance abuse disorder treatment services~~] should be available within 60 minutes driving time one way, under normal conditions, of 95% of the population.

[12 VAC 5-230-870. Continuity; integration.]

[~~B~~ A]. Existing and proposed acute psychiatric [~~,~~ and] acute substance abuse disorder treatment [~~, and intermediate care substance abuse disorder treatment service~~] providers shall have established plans for the provision of services to indigent patients [~~which include , at a minimum~~ that includes]:

[~~(i) the~~ 1. The] minimum number of unreimbursed patient days to be provided to indigent patients who are not Medicaid recipients;

[~~(ii) the~~ 2. The] minimum number of Medicaid-reimbursed patient days to be provided, unless the existing or proposed facility is ineligible for Medicaid participation;

[~~(iii) the~~ 3. The] minimum number of unreimbursed patient days to be provided to local community services boards; and

[~~(iv) a~~ 4.A] description of the methods to be utilized in implementing the indigent patient service plan and assuring the provision of the projected levels of unreimbursed and Medicaid-reimbursed patient days.

[~~C~~ B]. Proposed acute psychiatric [~~,~~ and] acute substance abuse disorder treatment ~~[, and intermediate care substance abuse disorder treatment service~~] providers shall have formal agreements with [~~their identified~~ the appropriate local] community services boards [or behavioral health authority] that:

[~~(i) specify~~ 1. Specify] the number of [~~charity care~~] patient days [~~which~~ that] will be provided to the community service board;

[~~(ii) describe~~ 2. Describe] the mechanisms to monitor compliance with charity care provisions;

[~~(iii) provide~~ 3. Provide] for effective discharge planning for all patients, including return to the patients place of origin or home state if not Virginia; and

[~~(iv) consider~~ 4. Consider] admission priorities based on relative medical necessity.

[~~D~~ C]. Providers of acute psychiatric [~~,~~ and] acute substance abuse disorder treatment ~~[, and intermediate care substance abuse disorder treatment services~~] serving large geographic areas should establish satellite outpatient facilities to improve patient access, where appropriate and feasible.

[~~12 VAC 5-230-620~~ 12 VAC 5-230-880]. [~~Availability~~ Need for new service].

A. The combined number of acute psychiatric and acute substance abuse disorder treatment beds needed in a planning district with existing acute psychiatric or acute substance abuse disorder treatment beds or both will be determined as follows:

[~~((UR x PROJ.POP.)/365)/.75~~ ((UR x PROPOP)/365)/.75]

Where UR = the use rate of the planning district expressed as the average acute psychiatric and acute substance abuse disorder treatment patient days per population reported for the most recent five-year period; and

[~~PROJ.POP.~~ PROPOP] = the projected population of the planning district five years from the current year as reported in the most recent published projections [~~of the Virginia Employment Commission~~ by a demographic entity as determined by the Commissioner of the Department of Mental Health, Mental Retardation and Substance Abuse Services].

For purposes of this methodology, no beds shall be included in the inventory of psychiatric or substance abuse disorder beds when these beds (i) are in facilities operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services; (ii) have been converted to other uses; (iii) have been vacant for six months or more; or (iv) are not currently staffed and cannot be staffed for acute psychiatric or substance abuse disorder patient admissions within 24 hours.

B. Subject to the provisions of [~~12 VAC 5-230-80~~ 12 VAC 5-230-70], no additional acute psychiatric or acute substance abuse disorder treatment beds should be authorized for a planning district with existing acute psychiatric or acute substance abuse disorder treatment beds or both if the existing inventory of such beds is greater than the need identified using the above methodology.

[~~However, consideration will be given to the addition of acute psychiatric or acute substance abuse disorder beds by existing medical care facilities in planning districts with an excess supply of beds when such additions can be justified on the basis of facility-specific utilization or geographic remoteness, i.e., driving time of 60 minutes or more, one way under normal conditions, to alternate acute care facilities. If the facility with the institutional need for beds is part of a hospital network, underutilized beds at the other facilities within the network should be relocated to the facility with the institutional need if possible.~~]

[Consideration may also be given to the addition of acute psychiatric or acute substance abuse beds dedicated for the treatment of geriatric patients in planning districts with an excess supply of beds when such additions are justified on the basis of the specialized treatment needs of geriatric patients.]

C. No existing acute psychiatric or acute substance disorder abuse treatment beds should be relocated unless it can be reasonably projected that the relocation will not have a negative impact on the ability of existing acute psychiatric or substance abuse disorder treatment providers or both to continue to provide historic levels of service to Medicaid or other indigent patients.

D. The combined number of acute psychiatric and acute substance abuse disorder treatment beds needed in a planning district without existing acute psychiatric or acute substance abuse disorder

treatment beds will be determined as follows:

[~~((UR x PROJ.POP.)/365)/.80~~ ((UR x PROPOP)/365)/.75]

Where UR = the use rate of the health planning region in which the planning district is located expressed as the average acute psychiatric and acute substance abuse disorder treatment patient days per population reported for the most recent five-year period;

[~~PROJ.POP.~~ PROPOP] = the projected population of the planning district five years from the current year as reported in the most recent published projections [~~of the Virginia Employment Commission~~ by a demographic entity as determined by the Commissioner of the Department of Mental Health, Mental Retardation and Substance Abuse Services].

E. Preference will be given to the development of needed acute psychiatric [~~and intermediate substance abuse disorder treatment~~] beds through the conversion of unused general hospital beds. Preference will also be given to proposals for acute psychiatric and substance abuse beds demonstrating a willingness to accept persons under temporary detention orders (TDO) and that have contractual agreements to serve populations served by [~~Community Services Boards~~ community services boards], whether through conversion of underutilized general hospital beds or development of new beds.

[~~F. The number of intermediate care substance disorder abuse treatment beds needed in a planning district with existing intermediate care substance abuse disorder treatment beds will be determined as follows:~~

~~((UR x PROJ.POP.)/365)/.75~~

~~Where UR = the use rate of the planning district expressed as the average intermediate care substance abuse disorder treatment patient days per population reported for the most recent three year period; and~~

~~PROJ.POP. = the projected population of the planning district three years from the current year as reported in the most recent published projections of the Virginia Employment Commission].~~

~~G. Subject to the provisions of 12 VAC 5-230-80, no additional intermediate care substance abuse disorder treatment beds should be authorized for a planning district with existing intermediate care substance abuse disorder treatment beds if the existing inventory of such beds is greater than the need identified. No beds in facilities operated by DMHMRSAS will be included in the inventory of intermediate care substance abuse disorder beds.~~

~~However, consideration will be given to the addition of intermediate care substance abuse disorder treatment beds by existing medical care facilities in planning districts with an excess supply of beds when such addition can be justified on the basis of facility-specific utilization or~~

~~geographic remoteness, i.e., driving time of 60 minutes or more one way under normal conditions, to alternate acute care facilities. If the facility with the institutional need for beds is part of a hospital network, underutilized beds at the other facilities within the network should be relocated to the facility with the institutional need if possible.~~

~~H. No existing intermediate care substance abuse disorder treatment beds should be relocated from one site to another unless it can be reasonably projected that the relocation will not have a negative impact on the ability of existing intermediate care substance abuse disorder treatment providers to continue to provide historic levels of service to indigent patients.~~

~~I. The number of intermediate care substance abuse disorder treatment beds needed in a planning district without existing intermediate care substance abuse disorder treatment beds will be determined as follows:~~

~~((UR x PROJ.POP.)/365)/.75~~

~~Where UR = the use rate of the health planning region in which the planning district is located expressed as the average intermediate care substance abuse disorder treatment patient days per population reported for the most recent three-year period;~~

~~[PROJ.POP. PROPOP] = the projected population of the planning district three years from the current year as reported in the most recent published projections of the Virginia Employment Commission~~.

~~J. Preference will be given to the development of needed intermediate care substance abuse disorder treatment beds through the conversion of underutilized general hospital beds.~~]

Article 2.
Mental Retardation.

[~~12 VAC 5-230-630~~ 12 VAC 5-230-890]. [~~Availability~~ Need for new service].

The establishment of new ICF/MR facilities [~~should~~ with more than 12 beds shall] not be authorized unless the following conditions are met:

1. Alternatives to the proposed service are not available in the area to be served by the new facility;
2. There is a documented source of referrals for the proposed new facility;
3. The manner in which the proposed new facility fits into the continuum of care for the mentally retarded is identified;
4. There are distinct and unique geographic, socioeconomic, cultural, transportation, or other factors affecting access to care that require development of a new ICF/MR;
5. Alternatives to the development of a new ICF/MR consistent with the Medicaid waiver

program have been considered and can be reasonably discounted in evaluating the need for the new facility.

6. The proposed new facility [will have a maximum of 20 beds and] is consistent with [~~the current~~ any plan of the] DMHMRSAS [~~Comprehensive Plan~~] and the mental retardation service priorities for the catchment area identified in the plan;

7. Ancillary and supportive services needed for the new facility are available; and

8. Service alternatives for residents of the proposed new facility who are ready for discharge from the ICF/MR setting are available.

[~~12 VAC 5-230-640~~ 12 VAC 5-230-900]. Continuity; integration.

Each facility should have a written transfer agreement with one or more hospitals for the transfer of emergency cases if such hospitalization becomes necessary.

[~~12 VAC 5-230-650~~ 12 VAC 5-230-910]. [~~Acceptability~~ Compliance with licensure standards.]

Mental retardation facilities should meet all applicable licensure standards as specified in 12 VAC 35-105, Rules and Regulations of the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services.

PART XIII.
PERINATAL SERVICES.

Article 1.
Criteria and Standards for Obstetrical Services.

[~~12 VAC 5-230-660~~ 12 VAC 5-230-920]. [~~Accessibility~~ Travel time].

Obstetrical services should be located within 30 minutes driving time one way, under normal conditions of 95% of the population [~~in rural areas and within 30 minutes driving time one way, under normal conditions, in urban and suburban areas~~ of the planning district].

[~~12 VAC 5-230-670~~ 12 VAC 5-230-930]. [~~Availability~~ Need for new service].

A. ~~Proposals to establish new obstetrical services in rural areas should demonstrate that obstetrical volumes within the travel times listed in 12 VAC 5-230-660 will not be negatively affected~~ No new obstetrical services shall be approved unless the applicant can demonstrate that, based on the population and utilization of current services, there is a need for such services in the planning district without reducing the utilization of existing providers in the planning district.

[~~B . Proposals to establish new obstetrical services in urban and suburban areas should demonstrate that a minimum of 2,500 deliveries will be performed annually by the second year of operation and that obstetrical volumes of existing providers located within the travel times~~

~~listed in 12 VAC 5-230-660 will not be negatively affected~~].

[~~C~~ B]. Applications to improve existing obstetrical services, and to reduce costs through consolidation of two obstetrical services into a larger, more efficient service [~~will~~ shall] be given preference over [~~the addition of~~ establishing] new services or [~~the expansion of~~ expanding] single service providers.

[C. No new obstetrical services shall be added within 30 minutes drive time one way under normal conditions of any obstetrical service that is not yet operational.]

[~~12 VAC 5-230-680~~ 12 VAC 5-230-940]. Continuity.

A. Perinatal service capacity[, including service availability for unscheduled admissions,] should be developed [~~and sized~~] to provide routine newborn care to infants delivered in the associated obstetrics service, and shall have the capability to stabilize and prepare for transport those infants requiring the care of a neonatal special care services unit.

B. The [~~application should~~ proposal shall] identify the primary and secondary neonatal special care center nearest the proposed service [~~and~~ ; shall] provide travel time one-way, under normal conditions, to those centers[, and shall document the [~~provider's~~ applicant's] participation in community activities within their designated perinatal region].

[12 VAC 5-230-950. Staffing.

Obstetric services should be under the direction or supervision of one or more physicians qualified to provide such services.]

Article 2.
Neonatal Special Care Services.

[~~12 VAC 5-230-690~~ 12 VAC 5-230-960]. [~~Accessibility~~ Travel time].

[A. Intermediate level neonatal special care services shall be located within an average of 30 minutes driving time one way, under normal conditions, of hospitals providing general level new born services.]

[~~Neonatal~~ B. Specialty and subspecialty neonatal] special care services [~~should~~ shall] be located within an average of [~~45~~ 90] minutes driving time one way, under normal conditions[~~, in urban and suburban areas~~] of hospitals providing general [or intermediate] level newborn services.

[~~12 VAC 5-230-700~~ 12 VAC 5-230-970]. [~~Availability~~ Need for new service].

[A. No new level of neonatal service shall be offered by a hospital unless that hospital has first obtained a COPN granting approval to provide each such level of service.

B. Preference will be given to the expansion of existing services, rather than the creation of new services[, and to existing services that fully participate in perinatal activities in their region.]

C. No new neonatal special care services shall be added within the driving times listed in 12 VAC 5-230-920 of any like neonatal special care service that is not yet operational in the planning region].

[12 VAC 5-230-980. Intermediate level newborn services.]

A. Existing neonatal special care units [~~located within the travel times listed in 12 VAC 5-230-670 should achieve 65% average annual occupancy before new services can be added to the planning region~~ providing intermediate level newborn services as designated in 12 VAC 5-410-443, located within [~~the travel times listed in 12 VAC 5-230-670~~ 30 minutes driving time one way under normal conditions] should achieve 85% average annual occupancy before new [intermediate level newborn services] can be added to the planning region. [~~Existing neonatal special care units providing specialty or subspecialty level newborn services as designated in 12 VAC 5-410-443, located within the travel times listed in 12 VAC 5-230-670 should each achieve 85% average annual occupancy before respective new specialty or subspecialty level newborn services can be added to the health planning region~~.]

[B. Neonatal special care units providing intermediate level newborn services as designated in 12 VAC 5-410-443 should contain a minimum of six bassinets, stations or beds.

C. No more than four bassinets, stations and beds for intermediate level newborn services as designated in 12 VAC 5-410-443 per 1,000 live births shall be established in each planning region, with a bassinet or station counting as the equivalent of one bed.]

[12 VAC 5-230-990. Specialty level newborn services.

A. Neonatal special care units providing specialty level newborn services as designated in 12 VAC 5-410-443 shall contain a minimum of 18 bassinets, stations or beds. A station shall equal one bed.

B. No more than four bassinets, stations and beds for specialty level newborn services as designated in 12 VAC 5-410-443 per 1,000 live births shall be established in each planning region, with a bassinet or station counting as the equivalent of one bed.

C. Proposals to establish specialty level neonatal special care services as designated in 12 VAC 5-410-443 shall demonstrate that service volumes of existing specialty level neonatal special care providers located within the travel times listed in 12 VAC 5-230-920 will not be reduced.]

[12 VAC 5-230-1000. Subspecialty level newborn services.

A. Neonatal special care units providing subspecialty level newborn services as designated in 12 VAC 5-410-443 shall contain a minimum of 18 bassinets, stations or beds. A station shall equal one bed.

B. No more than four bassinets, stations and beds for subspecialty level newborn services as designated in 12 VAC 5-410-443 per 1,000 live births shall be established in each planning region, with a bassinet or station counting as the equivalent of one bed.

C. Proposals to establish subspecialty level neonatal special care services as designated in 12 VAC 5-410-443 shall demonstrate that service volumes of existing subspecialty level neonatal special care providers located within the travel times listed in 12 VAC 5-230-920 will not be reduced.]

[~~12 VAC 5-230-710~~ 12 VAC 5-230-1001]. Neonatal services.

The application [~~should~~ shall] identify the service area [~~,~~ and the] levels of service [~~, and capacity~~] of [all] the [~~current general level newborn service~~] hospitals to be served [~~within the identified area~~ by the proposed service, as well as the applicant's participation in community. activities within their designated perinatal region].

[12 VAC 5-230-1002. Staffing.

All levels of neonatal special care services should be under the direction or supervision of one or more physicians qualified to provides such services as described in 12 VAC 5-410- 443.]