

**State Board of Health**

**12 VAC 5-230**

**Virginia Medical Care facilities Certificate of Public Need  
State Medical Facilities Plan**



Office of Licensure and Certification  
Virginia Department of Health  
9960 Mayland Drive, Ste. 401  
Richmond, VA 23233

Derived from VR 355-30-100 § 1, effective July 1, 1993.

Amended.....February 3, 2003

Amended .....February 15, 2009

Amended.....April 1, 2009

The SMFP is available on the web at:

[www.vdh.virginia.gov/olc](http://www.vdh.virginia.gov/olc)

Office of Licensure and Certification

Virginia Department of Health

9960 Mayland Drive, Ste. 401

Richmond, VA 23233

Phone: (804) 367-2126

FAX:(804)527-4501

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**Project 523 - Final**

**DEPARTMENT OF HEALTH  
Comprehensive SMFP Revision**

Part I  
Definitions and General Information

**12VAC5-230-10. Definitions.**

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"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.

"Bassinets" means an infant care station, including warming stations and isolettes.

"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, bed does include cribs and bassinets used for pediatric patients, but does not include cribs and bassinets in the newborn nursery or neonatal special care 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. 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.

"Commissioner" means the State Health Commissioner.

"Competing applications" means applications for the same or similar services and facilities that are proposed for the same health planning district, or same health 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 an image of that structure.

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"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.

"COPN" means a Medical Care Facilities Certificate of Public Need for a project as required in Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia .

"COPN program" means the Medical Care Facilities Certificate of Public Need Program implementing Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.

"DEP" means diagnostic equivalent procedure, 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.

"Direction" means guidance, supervision or management of a function or activity.

"Gamma knife®" means the name of a specific instrument used in stereotactic radiosurgery.

"Health planning district" means the same contiguous areas designated as planning districts by the Virginia Department of Housing and Community Development or its successor.

"Health planning region" means a contiguous geographic area of the Commonwealth as designated by the 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.

"Health system" means an organization of two or more medical care facilities, including but not limited to hospitals, that are under common ownership or control and are located within the same health planning district, or health planning region for projects reviewed on a regional basis.

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

"ICF/MR" means an intermediate care facility for the mentally retarded.

"Indigent" means any person whose gross family income is equal to or less than 200% of the federal Nonfarm Poverty Level or income levels A through E of 12VAC5-200-10 and who is uninsured.

"Inpatient" means a patient who is hospitalized longer than 24 hours for health or health related services.

"Intensive care beds" or "ICU" means 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

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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 based on age selected categories of diagnoses, including units established for burn care, trauma care, neurological care, pediatric care, and cardiac surgery recovery, but does not include bassinets in neonatal special care units.

"Lithotripsy" means a noninvasive therapeutic procedure to (i) crush renal and biliary stones using shock waves, i.e., renal lithotripsy or (ii) 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 care 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 noninvasive 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 rehabilitation" means those services provided consistent with 42 CFR 412.23 and 412.24.

"Medical/surgical" means those services available for the care and treatment of patients not requiring specialized services.

"Minimum survival rates" means the base percentage of transplant recipients who survive at least one year or for such other period of time as specified by the United Network for Organ Sharing (UNOS).

"Neonatal special care" means care for infants in one or more of the higher service levels designated in 12VAC5-410-443 of the Rules and Regulations for the Licensure of Hospitals.

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

"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 health planning district.

"Open heart surgery" means 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 used solely or principally for the provision of surgical procedures involving the administration of anesthesia, multiple personnel, recovery room access, and a fully controlled environment.

"Operating room use" means the amount of time a patient occupies an operating room and includes room preparation and cleanup time.

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"Operating room visit" means one session in one operating room in an inpatient hospital or outpatient surgical center, which may involve several procedures. Operating room visit may be used interchangeably with "operation" or "case."

"Outpatient" means a patient who visits a hospital, clinic, or associated medical care facility for diagnosis or treatment, but is not hospitalized 24 hours or longer.

"Pediatric" means patients younger than 18 years of age. Newborns in nurseries are excluded from this definition.

"Perinatal services" means those resources and capabilities that all hospitals offering general level newborn services as described in 12VAC5-410-443 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, the Board of Health pursuant to § 32.1-102.2 A 6 of the Code of Virginia has designated PET/CT as a specialty clinical service. 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 services criteria.

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

"Population" means the census figures shown in the most current series of projections published by a demographic entity as determined by the commissioner.

"Positron emission tomography" or "PET" means a noninvasive 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-nuclids decay and release positrons. A PET device or scanner may include an integrated CT to provide anatomic structure definition.

"Primary service area" means the geographic territory from which 75% of the patients of an existing medical care facility originate with respect to a particular service being sought in an application.

"Procedure" means a study or treatment or a combination of studies and treatments identified by a distinct ICD-9 or CPT code performed in a single session on a single patient.

"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 treatment using ionizing radiation to destroy diseased cells and for the relief of symptoms. Radiation therapy may be used alone or in combination with surgery or chemotherapy.

"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 VHI or a demographic entity as determined by the commissioner.

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"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.

"SMFP" means the state medical facilities plan as contained in Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia used to make medical care facilities and services needs decisions.

"Stereotactic radiosurgery" or "SRS" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume. SRS may be delivered in a single session or in a fractionated course of treatment up to five sessions.

"Stereotactic radiotherapy" or "SRT" means more than one session of stereotactic radiosurgery.

"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 Health, Mental Retardation and Substance Abuse Services.

"Supervision" means to direct and watch over the work and performance of others.

"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.

12VAC5-230-20. (Repealed.)

**12VAC5-230-30. Guiding principles in the development of project review criteria and standards.**

The following general principles 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 is based on the understanding that excess capacity or underutilization of medical facilities are detrimental to both cost effectiveness and quality of medical services in Virginia.
2. The COPN program seeks the geographical distribution of medical facilities and to promote the availability and accessibility of proven technologies.
3. The COPN program seeks to promote the development and maintenance of services and access to those services by every person who needs them without respect to their ability to pay.

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4. The COPN program seeks to encourage the conversion of facilities to new and efficient uses and the reallocation of resources to meet evolving community needs.
5. The COPN program discourages the proliferation of services that would undermine the ability of essential community providers to maintain their financial viability.

**12VAC5-230-40. General application filing criteria.**

A. In addition to meeting the applicable requirements of this chapter, applicants for a Certificate of Public Need shall include documentation in their application that their project addresses the applicable requirements listed in § 32.1-102.3 of the Code of Virginia.

B. 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 commissioner may condition the approval of a COPN by requiring an applicant to: (i) provide a level of care at a reduced rate to indigents, (ii) accept patients requiring specialized care, or (iii) facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area. The applicant must actively seek to comply with the conditions placed on any granted COPN.

**12VAC5-230-50. Project costs.**

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 with the health planning region.

**12VAC5-230-60. When competing applications received.**

In reviewing competing applications, preference may be given to an applicant who:

1. Has an established performance record in completing projects on time and within the authorized operating expenses and capital costs;
2. Has both lower capital costs and operating expenses than his competitors and can demonstrate that his estimates are credible;
3. Can demonstrate a consistent compliance with state licensure and federal certification regulations and a consistent history of few documented complaints, where applicable; or
4. Can demonstrate a commitment to serving his community or service area as evidenced by unreimbursed services to the indigent and providing needed but unprofitable services, taking into account the demands of the particular service area.

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**12VAC5-230-70. Calculation of utilization of services provided with mobile equipment.**

A. The minimum service volume of a mobile unit shall be prorated on a site-by-site basis reflecting the amount of time that proposed mobile units will be used, and existing mobile units have been used, during the relevant reporting period, at each site using the following formula:

$$\begin{array}{l} \text{Required full-time} \\ \text{minimum service} \\ \text{volume} \end{array} \quad \times \quad \begin{array}{l} \text{Number of days the} \\ \text{service will be on site} \\ \text{each week} \end{array} \quad \times 0.2 = \begin{array}{l} \text{Prorated minimum} \\ \text{services volume (not to} \\ \text{exceed the required} \\ \text{full-time minimum} \\ \text{service volume)} \end{array}$$

B. The average annual utilization of existing and approved CT, MRI, PET, lithotripsy, and catheterization services in a health planning district shall be calculated for such services as follows:

$$\frac{\text{Total volume of all units of the relevant service in the reporting period}}{\left( \begin{array}{l} \# \text{ of} \\ \text{existing} \\ \text{or} \\ \text{approved} \\ \text{fixed} \\ \text{units} \end{array} \times \begin{array}{l} \text{Fixed} \\ \text{unit} \\ \text{minimum} \\ \text{service} \\ \text{volume} \end{array} \right) + \begin{array}{l} Y \\ \text{Utilization} \end{array}} \times 100 = \begin{array}{l} \% \\ \text{Average} \\ \text{Utilization} \end{array}$$

Y = the sum of the minimum service volume of each mobile site in the health planning district with the minimum services volume for each such site prorated according to subsection A of this section.

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

**12VAC5-230-80. When institutional expansion needed.**

A. Notwithstanding any other provisions of this chapter, the commissioner may grant approval for the expansion of services at an existing medical care facility in a health planning district with an excess supply of such services when the proposed expansion can be justified on the basis of 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 health system, the underutilized services at other facilities within the health system should be reallocated, when appropriate, to

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the facility with the institutional need to expand before additional services are approved for the applicant. However, underutilized 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.

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Part II  
Diagnostic Imaging Services  
Article 1  
Criteria and Standards for Computed Tomography

**12VAC5-230-90. Travel time.**

CT services should be within 30 minutes driving time one way under normal conditions of 95% of the population of the health planning district using a mapping software as determined by the commissioner.

**12VAC5-230-100. Need for new fixed site or mobile service.**

A. No new fixed site or mobile CT service should be approved unless fixed site CT services in the health planning district performed an average of 7,400 procedures per existing and approved CT scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing providers in the health 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 health planning district.

B. Existing CT scanners used solely for simulation with radiation therapy treatment shall be exempt from the utilization criteria of this article when applying for a COPN. In addition, existing CT scanners used solely for simulation with radiation therapy treatment may be disregarded in computing the average utilization of CT scanners in such health planning district.

**12VAC5-230-110. Expansion of fixed site service.**

Proposals to expand an existing medical care facility's CT service through the addition of a CT scanner should be approved when the existing services performed an average of 7,400 procedures per scanner for the relevant reporting period. The commissioner may authorize placement of a new unit at the applicant's existing medical care facility or at a separate location within the applicant's primary service area for CT services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health planning district.

**12VAC5-230-120. 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 were performed and that the proposed mobile unit will not significantly reduce the utilization of existing CT providers in the health planning district.

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B. Proposals to convert authorized mobile CT scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, at least 6,000 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing CT providers in the health planning district.

**12VAC5-230-130. Staffing.**

CT services should be under the direction or supervision of one or more qualified physicians.

Article 2  
Criteria and Standards for Magnetic Resonance Imaging

**12VAC5-230-140. Travel time.**

MRI services should be within 30 minutes driving time one way under normal conditions of 95% of the population of the health planning district using a mapping software as determined by the commissioner.

**12VAC5-230-150. Need for new fixed site service.**

No new fixed site MRI services should be approved unless fixed site MRI services in the health planning district performed an average of 5,000 procedures per existing and approved fixed site MRI scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site MRI providers in the health 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 health planning district.

**12VAC5-230-160. Expansion of fixed site service.**

Proposals to expand an existing medical care facility's MRI services through the addition of an MRI scanner may be approved when the existing service performed an average of 5,000 MRI procedures per scanner during the relevant reporting period. The commissioner may authorize placement of the new unit at the applicant's existing medical care facility, or at a separate location within the applicant's primary service area for MRI services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health planning district.

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**12VAC5-230-170. 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 were performed and that the proposed mobile unit will not significantly reduce the utilization of existing MRI providers in the health planning district.

B. Proposals to convert authorized mobile MRI scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, 3,000 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing MRI providers in the health planning district.

**12VAC5-230-180. Staffing.**

MRI services should be under the direct supervision of one or more qualified physicians.

Article 3  
Magnetic Source Imaging

**12VAC5-230-190. 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

**12VAC5-230-200. Travel time.**

PET services should be within 60 minutes driving time one way under normal conditions of 95% of the health planning district using a mapping software as determined by the commissioner.

**12VAC5-230-210. Need for new fixed site service.**

A. 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 have provided

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radiation therapy services with specific ancillary services suitable for the equipment before a new fixed site PET service should be approved for the health planning district.

B. No new fixed site PET services should be approved unless an average of 6,000 procedures per existing and approved fixed site PET scanner were performed in the health planning district during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site PET providers in the health 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 health 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 one 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 are made concurrently.

**12VAC5-230-220. Expansion of fixed site services.**

Proposals to increase the number of PET scanners in an existing PET service should be approved only when the existing scanners performed an average of 6,000 procedures for the relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing fixed site providers in the health planning district.

**12VAC5-230-230. Adding or expanding mobile PET or PET/CT services.**

A. Proposals for mobile PET or PET/CT scanners should demonstrate that, for the relevant reporting period, at least 230 PET or PET/CT appropriate patients were seen and that the proposed mobile unit will not significantly reduce the utilization of existing providers in the health planning district.

B. Proposals to convert authorized mobile PET or PET/CT scanners to fixed site scanners should demonstrate that, for the relevant reporting period, at least 1,400 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing providers in the health planning district.

**12VAC5-230-240. Staffing.**

PET services should be under the direction or supervision of one or more qualified physicians. Such physicians shall be designated or authorized by the Nuclear Regulatory Commission or licensed by the Division of Radiologic Health of the Virginia Department of Health, as applicable.

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Article 5  
Noncardiac Nuclear Imaging Criteria and Standards

**12VAC5-230-250. 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 health planning district using a mapping software as determined by the commissioner.

**12VAC5-230-260. Need for new service.**

No new noncardiac imaging services should be approved unless the service can achieve a minimum utilization level of:

1. 650 procedures in the first 12 months of operation;
2. 1,000 procedures in the second 12 months of service; and
3. The proposed new service would not significantly reduce the utilization of existing providers in the health 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 noncardiac nuclear imaging services in such health planning district.

**12VAC5-230-270. Staffing.**

The proposed new or expanded noncardiac nuclear imaging service should be under the direction or supervision of one or more qualified physicians designated or authorized by the Nuclear Regulatory Commission or the Division of Radiologic Health of the Virginia Department of Health, as applicable.

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Part III  
Radiation Therapy Services  
Article 1  
Radiation Therapy Services

**12VAC5-230-280. Travel time.**

Radiation therapy services should be available within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using a mapping software as determined by the commissioner.

**12VAC5-230-290. Need for new service.**

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

1. Existing radiation therapy machines located in the health planning district performed an average of 8,000 procedures per existing and approved radiation therapy machine in the relevant reporting period; and
2. The new service will perform at least 5,000 procedures by the second year of operation without significantly reducing the utilization of existing providers in the health planning district.

B. The number of radiation therapy machines needed in a health planning district will be determined as follows:

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

320

where:

1. The population is projected to be at least 150,000 people three years from the current year as reported in the most current projections of a demographic entity as determined by the commissioner;
2. The cancer incidence rate as determined by data from the Statewide Cancer Registry;
3. 60% is the estimated number of new cancer cases in a health 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 procedures per case.

C. Proposals for new radiation therapy services located less than 60 minutes driving time one way, under normal conditions, from any site that radiation therapy services are available

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shall demonstrate that the proposed new services will perform an average of 4,500 procedures annually by the second year of operation, without significantly reducing the utilization of existing services in the health planning district.

**12VAC5-230-300. Expansion of service.**

Proposals to expand radiation therapy services should be approved only when all existing radiation therapy services operated by the applicant in the health planning district have performed an average of 8,000 procedures for the relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing providers.

**12VAC5-230-310. Statewide Cancer Registry.**

Facilities with radiation therapy services shall 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.

**12VAC5-230-320. Staffing.**

Radiation therapy services should be under the direction or supervision of one or more qualified physicians designated or authorized by the Nuclear Regulatory Commission or the Division of Radiologic Health of the Virginia Department of Health, as applicable.

Article 2  
Criteria and Standards for Stereotactic Radiosurgery

**12VAC5-230-330. 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 health planning region using a mapping software as determined by the commissioner.

**12VAC5-230-340. Need for new service.**

- A. No new stereotactic radiosurgery services should be approved unless:
1. The number of procedures performed with existing units in the health planning region averaged more than 350 per year in the relevant reporting period; and
  2. The proposed new service will perform at least 250 procedures in the second year of operation without significantly reducing the utilization of existing providers in the health planning region.

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B. Preference may be given to a project that incorporates stereotactic radiosurgery service incorporated within an existing standard radiation therapy service using a linear accelerator when an average of 8,000 procedures during the relevant reporting period and utilization of existing services in the health planning region will not be significantly reduced.

C. Preference may be given to a project that incorporates a dedicated Gamma Knife® 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. An average of 250 procedures will be preformed in the second year of operation; and
  - b. Utilization of existing services in the health planning region will not be significantly reduced.

D. Preference may be given to a project that incorporates non-Gamma Knife® SRS technology within an existing radiation therapy service when:

1. The unit is not part of a linear accelerator;
2. An average of 8,000 radiation procedures per year were performed by the existing radiation therapy services;
3. At least 250 procedures will be performed within the second year of operation; and
4. Utilization of existing services in the health planning region will not be significantly reduced.

**12VAC5-230-350. Expansion of service.**

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

**12VAC5-230-360. Statewide Cancer Registry.**

Facilities with stereotactic radiosurgery services shall 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.

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**12VAC5-230-370. Staffing.**

Stereotactic radiosurgery services should be under the direction or supervision of one or more qualified physicians.

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Part IV  
Cardiac Services  
Article 1  
Criteria and Standards for Cardiac Catheterization Services

**12VAC5-230-380. Travel time.**

Cardiac catheterization services should be within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

**12VAC5-230-390. Need for new service.**

A. No new fixed site cardiac catheterization service should be approved for a health planning district unless:

1. Existing fixed site cardiac catheterization services located in the health planning district performed an average of 1,200 cardiac catheterization DEPs per existing and approved laboratory for the relevant reporting period;
2. The proposed new service will perform an average of 200 DEPs in the first year of operation and 500 DEPs in the second year of operation; and
3. The utilization of existing services in the health planning district will not be significantly reduced.

B. Proposals for mobile cardiac catheterization laboratories should be approved only if such laboratories will be provided at a site located on the campus of an inpatient hospital. Additionally, applicants for proposed mobile cardiac catheterization laboratories shall be able to project that they will perform an average of 200 DEPs in the first year of operation and 350 DEPs in the second year of operation without significantly reducing the utilization of existing laboratories in the health planning district below 1,200 procedures.

C. Preference may be given to a project that locates new cardiac catheterization services at an inpatient hospital that is 60 minutes or more driving time one way under normal conditions from existing services if the applicant can demonstrate that the proposed new laboratory will perform an average of 200 DEPs in the first year of operation and 400 DEPs in the second year of operation without significantly reducing the utilization of existing laboratories in the health planning district.

**12VAC5-230-400. Expansion of services.**

Proposals to increase cardiac catheterization services should be approved only when:

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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 DEPs per existing and approved laboratory for the relevant reporting period; and
2. The applicant can demonstrate that the expanded service will achieve an average of 200 DEPs per laboratory in the first 12 months of operation and 400 DEPs in the second 12 months of operation without significantly reducing the utilization of existing cardiac catheterization laboratories in the health planning district.

**12VAC5-230-410. Pediatric cardiac catheterization.**

No new or expanded pediatric cardiac catheterization services should be approved unless:

1. The proposed service will be provided at an inpatient hospital with open heart surgery services, pediatric tertiary care services or specialty or subspecialty level neonatal special care;
2. The applicant can demonstrate that 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 health planning district will not be reduced below 100 procedures per year.

**12VAC5-230-420. Nonemergent cardiac catheterization.**

Proposals to provide elective interventional cardiac procedures such as PTCA, transseptal puncture, transthoracic left ventricle puncture, myocardial biopsy or any valvuloplasty procedures, diagnostic pericardiocentesis or therapeutic procedures should 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.

**12VAC5-230-430. 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. Cardiac catheterization services should be under the direct supervision or one or more qualified physicians. Such physicians should have clinical experience in performing physiologic and angiographic procedures.

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Pediatric catheterization services should be under the direct supervision of one or more qualified physicians. Such physicians should have clinical experience in performing pediatric physiologic and angiographic procedures.

Article 2  
Criteria and Standards for Open Heart Surgery

**12VAC5-230-440. Travel time.**

A. Open heart surgery services should be within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

B. Such services shall be available 24 hours a day, seven days a week.

**12VAC5-230-450. Need for new service.**

A. No new open heart services should be approved unless:

1. The service will be available in an inpatient hospital with an established cardiac catheterization service that has performed an average of 1,200 DEPs for the relevant reporting period and has been in operation for at least 30 months;
2. Open heart surgery services located in the health planning district performed an average of 400 open heart and closed heart surgical procedures for the relevant reporting period; and
3. 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 significantly reducing the utilization of existing open heart surgery services in the health planning district.

B. Preference may be given to a project that locates new open heart surgery services at an inpatient hospital more than 60 minutes driving time one way under normal condition from any site in which open heart surgery services are currently available and:

1. The proposed new service will perform an average of 150 open heart procedures in the first year of operation and 200 procedures in the second year of operation without significantly reducing the utilization of existing open heart surgery rooms within two hours driving time one way under normal conditions from the proposed new service location below 400 procedures per room; and
2. The hospital provided an average of 1,200 cardiac catheterization DEPs during the relevant reporting period in a service that has been in operation at least 30 months.

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**12VAC5-230-460. Expansion of service.**

Proposals to expand open heart surgery services shall demonstrate that existing open heart surgery rooms operated by the applicant have performed an average of:

1. 400 adult equivalent open heart surgery procedures in the relevant reporting period if the proposed increase is within 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 service is in excess of one hour driving time one way under normal conditions of an existing open heart surgery service in the health planning district.

**12VAC5-230-470. Pediatric open heart surgery services.**

No new pediatric open heart surgery service should be approved unless the proposed new service is provided at an inpatient hospital that:

1. Has pediatric cardiac catheterization services that have been in operation for 30 months and have performed an average of 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.

**12VAC5-230-480. Staffing.**

A. Open heart surgery services should have a medical director who is board certified in cardiovascular or cardiothoracic surgery by the appropriate board of the American Board of Medical Specialists.

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

B. Cardiac surgery should be under the direct supervision of one or more qualified physicians.

Pediatric cardiac surgery services should be under the direct supervision of one or more qualified physicians.

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Part V  
General Surgical Services

**12VAC5-230-490. Travel time.**

Surgical services should be available within 30 minutes driving time one way under normal conditions for 95% of the population of the health planning district using mapping software as determined by the commissioner.

**12VAC5-230-500. Need for new service.**

A. The combined number of inpatient and outpatient general purpose surgical operating rooms needed in a health planning district, exclusive of procedure rooms, dedicated cesarean section rooms, operating rooms designated exclusively for cardiac surgery, procedures rooms or VDH-designated trauma services, shall be determined as follows:

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

Where:

ORV = the sum of total inpatient and outpatient general purpose operating room visits in the health planning district in the most recent five years for which general purpose operating room utilization data has been reported by VHI; and

POP = the sum of total population in the health planning district as reported by a demographic entity as determined by the commissioner, for the same five-year period as used in determining ORV.

PROPOP = the projected population of the health planning district five years from the current year as reported by a demographic program as determined by the commissioner.

AHORV = the average hours per general purpose operating room visit in the health planning district for the most recent year for which average hours per general purpose operating room visits have been calculated as reported by VHI.

FOR = future general purpose operating rooms needed in the health 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 available 40 hours per week, 50 weeks per year.

B. Projects involving the relocation of existing operating rooms within a health planning district may be authorized when it can be reasonably documented that such relocation will: (i) improve the distribution of surgical services within a health planning district ; (ii) result in the

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provision of the same surgical services at a lower cost to surgical patients in the health planning district; or (iii) optimize the number of operations in the health planning district that are performed on an outpatient basis.

**12VAC5-230-510. Staffing.**

Surgical services should be under the direction or supervision of one or more qualified physicians.

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Part VI  
Inpatient Bed Requirements

**12VAC5-230-520. Travel time.**

Inpatient beds should be within 30 minutes driving time one way under normal conditions of 95% of the population of a health planning district using a mapping software as determined by the commissioner.

**12VAC5-230-530. Need for new service.**

A. No new inpatient beds should be approved in any health 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 that health planning district for the fifth planning horizon year; and
2. The average annual occupancy based on the number of beds in the health planning district for the relevant reporting period is:
  - a. 80% at midnight census for medical/surgical or pediatric beds;
  - b. 65% at midnight census for intensive care beds.

B. For proposals to convert under-utilized beds that require a capital expenditure of \$15 million or more, consideration may be given to such proposal if:

1. There is a projected need in the applicable category of inpatient beds; and
2. The applicant can demonstrate that the average annual occupancy of the converted beds would meet the utilization standard for the applicable bed category by the first year of operation.

For the purposes of this part, "underutilized" means less than 80% average annual occupancy for medical/surgical 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.

**12VAC5-230-540. Need for medical/surgical beds.** Revised 4/09

The number of medical/surgical beds projected to be needed in a health planning district shall be computed as follows:

1. Determine the use rate for the medical/surgical beds for the health planning district using the formula:

$$\text{BUR} = (\text{IPD}/\text{PoP})$$

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Where:

BUR = the bed use rate for the health planning district.

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

PoP = the sum of total population 18 years of age and older in the health planning district for the same five years used to determine IPD as reported by a demographic program as determined by the commissioner.

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

$$\text{ProBed} = ((\text{BUR} \times \text{ProPop})/365)/0.80$$

Where:

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

BUR = the bed use rate for the health planning district determined in subdivision 1 of this section.

ProPop = the projected population 18 years of age and older of the health planning district five years from the current year as reported by a demographic program as determined by the commissioner.

3. Determine the number of medical/surgical beds that are needed in the health planning district for the five planning horizon years as follows:

$$\text{NewBed} = \text{ProBed} - \text{CurrentBed}$$

Where:

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

ProBed = the projected number of medical/surgical beds needed in the health planning district for five years from the current year determined in subdivision 2 of this section.

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

**12VAC5-230-550. Need for pediatric beds.** Revised 4/09

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

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

$$PBUR = (PIPD/PedPop)$$

Where:

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

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

PedPop = The sum of population under 18 years of age in the health planning district for the same five years used to determine PIPD as reported by a demographic program as determined by the commissioner.

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

$$ProPedBed = ((PBUR \times ProPedPop)/365)/0.80$$

Where:

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

PBUR = The pediatric bed use rate for the health planning district determined in subdivision 1 of this section.

ProPedPop = The projected population under 18 years of age of the health planning district five years from the current year as reported by a demographic program as determined by the commissioner.

3. Determine the number of pediatric beds needed within the health planning district for the fifth planning horizon year as follows:

$$NewPedBed = ProPedBed - CurrentPedBed$$

Where:

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

ProPedBed = the projected number of pediatric beds needed in the health planning district for five years from the current year determined in subdivision 2 of this section.

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

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**12VAC5-230-560. Need for intensive care beds.** Revised 4/09

The projected need for intensive care beds in a health planning district shall be computed as follows:

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

$$\text{ICUBUR} = (\text{ICUPD}/\text{Pop})$$

Where:

ICUBUR = The ICU bed use rate for the health planning district.

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

Pop = The sum of population 18 years of age or older for adults or under 18 for pediatric patients in the health planning district for the same five years used to determine ICUPD as reported by a demographic program as determined by the commissioner.

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

$$\text{ProICUBed} = ((\text{ICUBUR} \times \text{ProPop})/365)/0.65$$

Where:

ProICUBed = The projected number of ICU beds needed in the health planning district for five years from the current year;

ICUBUR = The ICU bed use rate for the health planning district as determine in subdivision 1 of this section;

ProPop = The projected population 18 years of age or older for adults or under 18 for pediatric patients of the health planning district five years from the current year as reported by a demographic program as determined by the commissioner.

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

$$\text{NewICUB} = \text{ProICUBed} - \text{CurrentICUBed}$$

Where:

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

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ProjICUBed = The projected number of ICU beds needed in the health planning district for five years from the current year as determined in subdivision 2 of this section.

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

**12VAC5-230-570. Expansion or relocation of services.**

A. Proposals to relocate beds to a location not contiguous to the existing site should 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;
3. The number of beds to be moved off-site is taken out of service at the existing facility;
4. 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 health planning district where underutilized beds are within 30 minutes driving time one way under normal conditions of the site of the proposed relocation should be approved only when the applicant can demonstrate that the proposed relocation will not materially harm existing providers.

**12VAC5-230-580. Long-term acute care hospitals (LTACHs).**

A. LTACHs 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. A 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 health planning district. New LTACH beds that would result in an increase in total licensed beds above 165% of the average daily census for the health planning district will not be approved. Excess inpatient beds within an applicant's 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 delicensed 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

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operation, the beds delicensed 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 their original intended purpose and the application meets all other applicable project delivery requirements. Such an application shall not be subject to the standard batch review cycle and shall be processed as allowed under Part VI (12VAC5-220-280 et seq.) of the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations.

D. The application shall delineate the service area for the LTACH 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. A LTACH shall become certified by the Centers for Medicare and Medicaid Services (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 public 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 six-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.

**12VAC5-230-590. Staffing.**

Inpatient services should be under the direction or supervision of one or more qualified physicians.

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Part VII  
Nursing Facilities

**12VAC5-230-600. Travel time.**

A. Nursing facility beds should be accessible within 30 minutes driving time one way under normal conditions to 95% of the population in a health planning district using mapping software as determined by the commissioner.

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

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

**12VAC5-230-610. Need for new service.**

A. A health planning district should be considered to have a need for additional nursing facility beds when:

1. The bed need forecast exceeds the current inventory of beds for the health planning district; and
2. The average annual occupancy of all existing and authorized Medicaid-certified nursing facility beds in the health planning district was at least 93%, excluding the bed inventory and utilization of the Virginia Veterans Care Centers.

Exception: When there are facilities that have been in operation less than three years in the health 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 health planning district should be considered in need of additional beds if there are unconstructed beds designated as Medicaid-certified. This presumption of 'no need' for additional beds extends for three years from the issuance date of the certificate.

C. The bed need forecast will be computed as follows:

$$\text{PDBN} = (\text{UR64} \times \text{PP64}) + (\text{UR69} \times \text{PP69}) + (\text{UR74} \times \text{PP74}) + (\text{UR79} \times \text{PP79}) + (\text{UR84} \times \text{PP84}) + (\text{UR85} \times \text{PP85})$$

Where:

PDBN = Planning district bed need.

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

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PP64 = The population aged 0 to 64 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.

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

PP69 = The population aged 65 to 69 projected for the health planning district three years from the current year as most recently published by the a demographic program as determined by the commissioner.

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

PP74 = The population aged 70 to 74 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.

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

PP79 = The population aged 75 to 79 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.

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

PP84 = The population aged 80 to 84 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.

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

PP85+ = The population aged 85 and older projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.

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Health planning district bed need forecasts will be rounded as follows:

Health 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

Exception: When a health planning district has:

1. Two or more nursing facilities;
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 VHI; and
3. Has a forecasted bed need of 15 to 29 beds, then the bed need for this health planning district will be rounded to 30.

D. No new freestanding nursing facilities of less than 90 beds should be authorized. However, consideration may be given to a new freestanding facility with fewer than 90 nursing facility beds when the applicant can demonstrate that such a facility is justified based on a locality's preference for such smaller facility and there is a documented poor distribution of nursing facility beds within the health planning district.

E. When evaluating the capital cost of a project, consideration may be given to projects that use the current methodology as determined by the Department of Medical Assistance Services.

F. Preference may be given to projects that replace outdated and functionally obsolete facilities with modern facilities that result in the more cost-efficient resident services in a more aesthetically pleasing and comfortable environment.

**12VAC5-230-620. Expansion of services.**

Proposals to increase existing nursing facility bed capacity 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 relevant reporting period as reported to VHI.

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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 offers short stay services causing an average annual occupancy lower than 93% for the facility.

**12VAC5-230-630. Continuing care retirement communities.**

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

1. The facility is registered with the State Corporation Commission as a continuing care provider pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia;
2. The number of nursing facility beds requested in the initial application does not exceed the lesser of 20% of the continuing care retirement community's total number of beds that are not nursing home beds or 60 beds;
3. The number of new nursing facility beds requested in any subsequent application does not cause the continuing care retirement community's total number of nursing home beds to exceed 20% of its total number of beds that are not nursing facility beds; and
4. The continuing care retirement community has established a qualified resident assistance policy.

**12VAC5-230-640. Staffing.**

Nursing facilities shall be under the direction or supervision of a licensed nursing home administrator and staffed by licensed and certified nursing personnel qualified as required by law.

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Part VIII  
Lithotripsy Service

**12VAC5-230-650. Travel time.**

Lithotripsy services should be available within 30 minutes driving time one way under normal conditions for 95% of the population of the health planning region using mapping software as determined by the commissioner.

**12VAC5-230-660. Need for new service.**

A. Preference may be given to a project that establishes new renal or orthopedic lithotripsy services at a new facility through contract with, or by lease of equipment from, an existing service provider authorized to operate in Virginia, and the 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 if the applicant can demonstrate that the proposed service can provide at least 750 renal lithotripsy procedures annually.

C. 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.

**12VAC5-230-670. Expansion of services.**

A. Proposals to expand renal lithotripsy services should 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 expand orthopedic lithotripsy services should 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.

**12VAC5-230-680. Adding or expanding mobile lithotripsy services.**

A. Proposals for mobile lithotripsy services should demonstrate that, for the relevant reporting period, at least 125 procedures were performed and that the proposed mobile unit will not reduce the utilization of existing machines in the health planning region.

B. Proposals to convert a mobile lithotripsy service to a fixed site lithotripsy service should demonstrate that, for the relevant reporting period, at least 430 procedures were performed and the proposed conversion will not reduce the utilization of existing providers in the health planning district.

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**12VAC5-230-690. Staffing.**

Lithotripsy services should be under the direction or supervision of one or more qualified physicians.

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Part IX  
Organ Transplant

**12VAC5-230-700. 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 using mapping software as determined by the commissioner.

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.

**12VAC5-230-710. Need for new service.**

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

B. Performance of minimum transplantation volumes as cited in 12VAC5-230-720 does not indicate a need for additional transplantation capacity or programs.

**12VAC5-230-720. Transplant volumes; survival rates; service proficiency; systems operations.**

A. Proposals to establish organ transplantation services should 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

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

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transplants as well as the minimum transplant survival rates stated in subsection B of this section.

B. 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	70%
Lung	77%
Liver	86%
Intestine	77%

**12VAC5-230-730. Expansion of transplant services.**

A. Proposals to expand organ transplantation services shall demonstrate at least two years successful experience with all existing organ transplantation systems at the hospital.

B. Preference may be given to a project expanding the number of organ systems being transplanted at a successful existing service rather than developing new programs that could reduce existing program volumes.

**12VAC5-230-740. Staffing.**

Organ transplant services should be under the direct supervision of one or more qualified physicians.

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Part X  
Miscellaneous Capital Expenditures

**12VAC5-230-750. 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 service specific parts addressed elsewhere in this chapter.

**12VAC5-230-760. Project need.**

All applications involving the expenditure of \$15 million 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.

**12VAC5-230-770. 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 is 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.

**12VAC5-230-780. 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

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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 five-year period.

**12VAC5-230-790. 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.

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Part XI  
Medical Rehabilitation

**12VAC5-230-800. Travel time.**

Medical rehabilitation services should be available within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

**12VAC5-230-810. Need for new service.**

A. The number of comprehensive and specialized rehabilitation beds shall be determined as follows:

$$((UR \times PROPOP)/365)/.80$$

Where:

UR = the use rate expressed as rehabilitation patient days per population in the health planning district as reported by VHI; and

PROPOP = the most recent projected population of the health planning district five years from the current year as published by a demographic entity as determined by the commissioner.

B. Proposals for new medical rehabilitation beds should be considered when the applicant can demonstrate that:

1. The rehabilitation specialty proposed is not currently offered in the health planning district; and
2. There is a documented need for the service or beds in the health planning district.

**12VAC5-230-820. Expansion of services.**

No additional rehabilitation beds should be authorized for a health planning district in which existing rehabilitation beds were utilized with an average annual occupancy of less than 80% in the most recently reported year.

Preference may be given to a project to expand rehabilitation beds by converting underutilized medical/surgical beds.

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**12VAC5-230-830. Staffing.**

Medical rehabilitation facilities should be under the direction or supervision of one or more qualified physicians.

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Part XII  
Mental Health Services  
Article 1  
Acute Psychiatric and Acute Substance Abuse Disorder Treatment Services

**12VAC5-230-840. Travel time.**

Acute psychiatric and acute substance abuse disorder treatment services should be available within 60 minutes driving time one way under normal conditions of 95% of the population using mapping software as determined by the commissioner.

**12VAC5-230-850. Continuity; integration.**

A. Existing and proposed acute psychiatric and acute substance abuse disorder treatment providers shall have established plans for the provision of services to indigent patients that include:

1. The minimum number of unreimbursed patient days to be provided to indigent patients who are not Medicaid recipients;
2. The minimum number of Medicaid-reimbursed patient days to be provided, unless the existing or proposed facility is ineligible for Medicaid participation;
3. The minimum number of unreimbursed patient days to be provided to local community services boards; and
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.

B. Proposed acute psychiatric and acute substance abuse disorder treatment providers shall have formal agreements with the appropriate local community services boards or behavioral health authority that:

1. Specify the number of patient days that will be provided to the community service board;
2. Describe the mechanisms to monitor compliance with charity care provisions;
3. Provide for effective discharge planning for all patients, including return to the patient's place of origin or home state if not Virginia; and
4. Consider admission priorities based on relative medical necessity.

C. Providers of acute psychiatric and acute substance abuse disorder treatment serving large geographic areas should establish satellite outpatient facilities to improve patient access where appropriate and feasible.

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**12VAC5-230-860. Need for new service.**

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

$$((UR \times PROPOP)/365)/.75$$

Where:

UR = the use rate of the health 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

PROPOP = the projected population of the health planning district five years from the current year as reported in the most recent published projections 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 12VAC5-230-70, no additional acute psychiatric or acute substance abuse disorder treatment beds should be authorized for a health 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.

Preference may also be given to the addition of acute psychiatric or acute substance abuse beds dedicated for the treatment of geriatric patients in health 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 abuse disorder 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 health planning district without existing acute psychiatric or acute substance abuse disorder treatment beds will be determined as follows:

$$((UR \times PROPOP)/365)/.75$$

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Where:

UR = the use rate of the health planning region in which the health 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;

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

E. Preference may be given to the development of needed acute psychiatric 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, whether through conversion of underutilized general hospital beds or development of new beds.

Article 2  
Mental Retardation

**12VAC5-230-870. Need for new service.**

The establishment of new ICF/MR facilities 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 any plan of the Department of Mental Health, Mental Retardation and Substance Abuse Services 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.

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**12VAC5-230-880. 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.

**12VAC5-230-890. Compliance with licensure standards.**

Mental retardation facilities should meet all applicable licensure standards as specified in 12VAC35-105, Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services.

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Part XIII  
Perinatal and Obstetrical Services  
Article 1  
Criteria and Standards for Obstetrical Services

**12VAC5-230-900. Travel time.**

Obstetrical services should be located within 30 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

**12VAC5-230-910. Need for new service.**

No new obstetrical services should 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 health planning district without significantly reducing the utilization of existing providers in the health planning district.

**12VAC5-230-920. Continuity.**

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

B. The proposal shall identify the primary and secondary neonatal special care center nearest the proposed service shall provide transport one-way to those centers.

**12VAC5-230-930. Staffing.**

Obstetric services should be under the direction or supervision of one or more qualified physicians.

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Article 2  
Neonatal Special Care Services

**12VAC5-230-940. Travel time.**

A. Intermediate level neonatal special care services should be located within 30 minutes driving time one way under normal conditions of hospitals providing general level newborn services using mapping software as determined by the commissioner.

B. Specialty and subspecialty neonatal special care services should be located within 90 minutes driving time one way under normal conditions of hospitals providing general or intermediate level newborn services using mapping software as determined by the commissioner.

**12VAC5-230-950. Need for new service.**

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.

**12VAC5-230-960. Intermediate level newborn services.**

A. Existing intermediate level newborn services as designated in 12VAC5-410-443 should achieve 85% average annual occupancy before new intermediate level newborn services can be added to the health planning region.

B. Intermediate level newborn services as designated in 12VAC5-410-443 should contain a minimum of six bassinets.

C. No more than four bassinets for intermediate level newborn services as designated in 12VAC5-410-443 per 1,000 live births should be established in each health planning region.

**12VAC5-230-970. Specialty level newborn services.**

A. Existing specialty level newborn services as designated in 12VAC5-410-443 should achieve 85% average annual occupancy before new specialty level newborn services can be added to the health planning region.

B. Specialty level newborn services as designated in 12VAC5-410-443 should contain a minimum of 18 bassinets .

C. No more than four bassinets for specialty level newborn services as designated in 12VAC5-410-443 per 1,000 live births should be established in each health planning region.

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D. Proposals to establish specialty level services as designated in 12VAC5-410-443 shall demonstrate that service volumes of existing specialty level newborn service providers located within the travel time listed in 12VAC5-230-940 will not be significantly reduced.

**12VAC5-230-980. Subspecialty level newborn services.**

A. Existing subspecialty level newborn services as designated in 12VAC5-410-443 should achieve 85% average annual occupancy before new subspecialty level newborn services can be added to the health planning region.

B. Subspecialty level newborn services as designated in 12VAC5-410-443 should contain a minimum of 18 bassinets .

C. No more than four bassinets for subspecialty level newborn services as designated in 12VAC5-410-443 per 1,000 live births should be established in each health planning region.

D. Proposals to establish subspecialty level newborn services as designated in 12VAC5-410-443 shall demonstrate that service volumes of existing subspecialty level newborn providers located within the travel time listed in 12VAC5-230-940 will not be significantly reduced.

**12VAC5-230-990. Neonatal services.**

The application shall identify the service area and the levels of service of all the hospitals to be served by the proposed service.

**12VAC5-230-1000. Staffing.**

All levels of neonatal special care services should be under the direction or supervision of one or more qualified physicians as described in 12VAC5-410-443.