

State Board of Health

12 VAC 5-230 through 12 VAC 5-360

State Medical Facilities Plan



Center for Quality Health Care Services and Consumer Protection
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VIRGINIA DEPARTMENT OF HEALTH

VIRGINIA MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED
STATE MEDICAL FACILITIES PLAN

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**State Medical Facilities Plan
12 VAC 5-230-10 through 30**

12 VAC 5-230-10. Definitions.

The following words and terms, when used in Chapters 230 (12 VAC 5-230-10 et seq.) through 360 (12 VAC 5-360-10 et seq.) shall have the following meanings, unless the context clearly indicated 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 be barriers or facilitators to obtaining services.

"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.

"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.

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

"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.

"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.

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12 VAC 5-230-20. Preface.

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 Medical Facilities Plan; provided, however, if the commissioner finds, upon presentation of appropriate evidence, that the provisions of 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.

12VAC5-230-30. Guiding principles in certificate of public need.

The following general principles will be used in guiding the implementation of the Virginia Medical Care Facilities Certificate of Public Need (COPN) Program and have served as 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 medical facility and service development approaches which can document improvement in 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.

2. The COPN program will seek to achieve a balance between appropriate levels of

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availability and access to medical care facilities and services for all the citizens of Virginia and the need to constrain excess facility and service capacity.

3. The COPN program will seek 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.

4. The COPN program will give preference to the development and maintenance of needed services which are accessible to every person who can benefit from the services regardless of ability to pay.

5. The COPN program will promote the elimination of excess facility and service capacity. The COPN program will promote the conversion of excess facility and service capacity to meet identified needs. The COPN program will not facilitate the survival of medical care facilities and services which have rendered superfluous by changes in health care delivery and financing.

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General Acute Care Services
12 VAC 5-240-10 through 120.

PART I.
Definitions.

12 VAC 5-240-10. Definitions.

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

"Acute inpatient facility beds" means any beds included in the definitions of "general medical/surgical beds" and "intensive care beds."

"Acute care inpatient facility" means any hospital, ambulatory surgical center providing overnight accommodations, or other medical care facility which provides medical care and distinct housing of patients whose length of stay averages at most 30 days.

"Department" means the Virginia Department of Health.

"General medical/surgical beds" means acute care inpatient beds located in the following units or categories:

1. General medical/surgical units that are organized facilities and services (excluding those for newborns) available for the care and treatment of patients, not requiring specialized services; and

2. Pediatric units that are organized facilities and services maintained and operated as a distinct unit for regular use by inpatients below the age of 15. Newborn cribs and bassinets are excluded from this definition.

"Inpatient beds" means accommodations within 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 medical care facility in excess of 24 hours. Such accommodations are known by various nomenclatures including but not limited to; nursing facility beds, intensive care beds, minimal or self care beds, insolation beds, hospice beds, observation beds equipped and staffed for overnight use, and obstetric, medical surgical, psychiatric, substance abuse, medical rehabilitation and pediatric beds including pediatric bassinets and incubators. Bassinets and incubators in the maternity department and beds located in labor and birthing rooms, emergency rooms, preparation or anesthesia inductor rooms, diagnostic or treatment procedure rooms, or on-call staff rooms are excluded from this definition.

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"Intensive care beds" means acute inpatient beds that are located in the following units or categories:

1. General intensive care units (ICU) means those units in which patients are concentrated, by reason of serious illness or injury, without regard to diagnosis. Special lifesaving techniques and equipment are immediately available, and patients are under continuous observation by nursing staff specially trained and selected for the care of this class of patient;

2. Cardiac care units (CCU) means special units staffed and equipped solely for the intensive care of cardiac patients;

3. Specialized intensive care units (SICU) means any units with specialized staff and equipment for the purpose of providing care to seriously ill or injured patients for selected categories of diagnoses. Examples include 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; and

4. Progressive care units (PCU) means any units which have been established to care for seriously ill or injured patients who do not require the continuous level of care available in an intensive care unit but whose conditions require monitoring at a level which is generally not available in a general medical/surgical bed.

"Licensed bed" means those inpatient care beds licensed by the department's Office of Health Facilities Regulation.

"Nursing facility beds" means inpatient beds which are located in distinct units of acute inpatient facilities which are licensed as long-term care units by the department. Beds in these long-term units are not included in the calculations of acute inpatient bed need.

"Off-site replacement" means the movement of existing beds off of the existing site of an acute care inpatient facility.

"Planning horizon year" means the particular year for which beds are projected to be needed.

"Relevant reporting period" means the most recent 12 month period, prior to the beginning of the Certificate of Public Need application's review cycle, for which data is available and acceptable to the department.

"Skilled nursing units (SNF)" means those units which provide patient care at a level of care below that normally required in an acute care setting and greater than that of an intermediate care nursing facility. Although such units often have lengths of stays of less than 30 days, they are considered nursing facility beds and are excluded in calculations of acute care inpatient bed need.

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"Staffed beds" means that portion of the licensed or approved beds that are immediately available to be occupied. Beds which are not available due to lack of staffing or renovation are excluded from this category.

PART II.
Criteria and Standards.

12 VAC 5-240-20. Accessibility.

Acute care inpatient facility beds should be within 30 minutes driving time, under normal conditions, of 90% of the population of a planning district.

Providers of acute care inpatient facility services serving rural areas should facilitate the transport of patients residing in rural areas to needed medical care facilities and services, directly or through coordinated efforts with other organizations. Preference will be given in the review of competing applications to applicants who can document a commitment to development of transportation resources for rural populations.

12 VAC 5-240-30. Availability.

A. Need for new service.

1. No new acute inpatient care beds should be approved in any planning district unless the resulting number of licensed and approved beds in a planning district does not exceed the number of beds projected to be needed, for each acute inpatient bed category, for that planning district for the fifth planning horizon year.

2. Notwithstanding the need for new acute inpatient care beds above, no proposals to increase the general medical/surgical and pediatric bed capacity in a planning district should be approved unless the average annual occupancy, based on the number of licensed beds in the planning district where the project is proposed, is at least 85% for the relevant reporting period.

3. Notwithstanding the need for new acute inpatient beds above, no proposals to increase the intensive care bed capacity in a non-rural area should be approved unless: (i) the average annual occupancy rate, based on the number of licensed beds in the non-rural area where the project is proposed, is at least 65% for the relevant reporting period; or (ii) for hospitals in rural areas, the number of beds projected to be needed to provide 99% probability that adequate bed capacity will exist for all unscheduled admissions, exceeds the number of licensed beds projected for the fifth planning horizon year.

B. Off-site replacement of existing services.

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1. No proposal to replace acute care inpatient beds off-site, to a location not contiguous to the existing site, should be approved unless: (i) off-site replacement is necessary to correct life safety or building code deficiencies; (ii) the population served by the beds to be moved will have reasonable access to the acute care beds at the new site, or the population served by the facility to be moved will generally have comparable access to neighboring acute care facilities; and (iii) the beds to be replaced experienced an average annual utilization of 85% for general medical/surgical beds and 65% for intensive care beds in the relevant reporting period.

2. The number of beds to be moved off-site must be taken out of service at the existing facility.

3. The off-site replacement of beds should result in a decrease in the licensed bed capacity of the applicant facility(ies) or substantial cost savings, cost avoidance, consolidation of underutilized facilities, or in other ways improve operation efficiency, or improvements in the quality of care delivered over that experienced by the applicant facility(ies).

C. Alternative need for the conversion of underutilized licensed bed capacity. For proposals involving a capital expenditure of \$1 million or more, and involving the conversion of underutilized licensed bed capacity to either medical/surgical, pediatric or intensive care, consideration will be given to the approval of the project if: (i) there is a projected need for the category of acute inpatient care beds that would result from the conversion; and (ii) it can be reasonably demonstrated that the average annual occupancy of the beds to be converted would reach the standard in subdivision B 1 of this section for the bed category that would result from the conversion, by the first year of operation.

D. Computation of the need for general medical/surgical and pediatric beds.

1. A need for additional acute care inpatient beds may be demonstrated if the total number of licensed and approved beds in a given category in the planning district where the proposed project will be located is less than the number of such beds that are projected as potentially necessary to meet demand in the fifth planning horizon year from the year in which the application is submitted.

2. The number of licensed and approved general medical/surgical beds will be based on the inventory presented in the most recent edition of the State Medical Facilities Plan or amendment thereof, and may also include subsequent reductions in or additions to such beds for which documentation is available and acceptable to the department. The number of general medical/surgical beds projected to be needed in the planning district shall be computed using the following method:

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

(1) Sum the medical/surgical and pediatric unit 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;

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(2) Sum the planning district projected population for the same three year period as reported by the Virginia Employment Commission;

(3) Divide the sum of the general medical/surgical and pediatric unit inpatient days by the sum of the population and express the resulting rate in days per 1,000 population;

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

b. Determine the projected number of general medical/surgical and pediatric unit beds which may be needed in the planning district for the planning horizon year as follows:

(1) Divide the result in subdivisions D 2 a (4) (number of days projected to be needed) by 365;

(2) Divide the quotient obtained by .85 in planning districts in which 50% or more of the population resides in non-rural areas and .75 in planning districts in which less than 50% of the population resides in non-rural areas.

c. Determine the projected number of general medical/surgical and pediatric beds which may be established or relocated within the planning district for the fifth planning horizon year as follows:

(1) Determine the number of licensed and approved medical/surgical and pediatric beds as reported in the inventory of the most recent edition of the State Medical Facilities Plan, available data acceptable to the department;

(2) Subtract the number of beds identified in subdivision 2 a of this subsection from the number of beds needed as determined in subdivision 2 b (2) of this subsection. If the difference indicated is positive, then a need may be determined to exist for additional general medical/surgical or pediatric beds. If the difference is negative, then no need shall be determined to exist for additional beds.

E. Computation of need for distinct pediatric units.

1. Beds used to form pediatric units must be taken from the inventory of general medical/surgical beds of a facility if need for additional such beds cannot be demonstrated.

2. Should a hospital desire to establish or expand a distinct pediatric unit within its licensed bed capacity, the following methodology shall be used to determine the appropriate size:

a. Determine the utilization of the individual hospital's inpatient days by persons under 15 years of age:

(1) Sum the general medical/surgical (including pediatric unit) inpatient days for the past three years for all patients under 15 years of age from hospital discharge abstracts;

(2) Sum the planning district projected population for the 0 to 14 age group for the same three year period as reported by the Virginia Employment Commission;

(3) Divide the sum of the general medical/surgical days by the sum of the population and express the resulting rate in days per 1,000 population;

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(4) Multiply the days per 1,000 population rate by the projected population age 0 to 14 for the planning district (expressed in 1,000s) for the fifth planning horizon year to yield the projected pediatric patient days;

(5) Divide the patient days by 365 to yield the projected average daily census (PADC);

(6) Calculate the number of beds needed to assure that adequate bed capacity will exist with a 99% probability for an unscheduled pediatric admission using the following formula:

$$\text{Number of pediatric beds allowable} = \text{PADC} + 2.33\sqrt{\text{PADC}}$$

F. Computation of need for intensive care beds.

1. The number of licensed and approved intensive care beds will be based on the inventory presented in the most recent edition of the State Medical Facilities Plan or amendment thereof, and may also include subsequent reductions in or additions to such beds for which documentation is available and acceptable to the department.

2. The number of intensive care beds projected to be needed in the planning district shall be computed using the following method:

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

(1) Sum the intensive care 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;

(2) Sum the planning district projected population for the same three year period as reported by the Virginia Employment Commission;

(3) Divide the sum of the intensive care days by the sum of the population and express the resulting rate in days per 1,000 population;

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

b. Determine the projected number of intensive care beds which may be needed in the planning district for the planning horizon year as follows:

(1) Divide the number of days projected in subdivision 2a (4) of this subsection by 365 to yield the projected average daily census (PADC);

(2) Calculate the beds needed to assure with 99% probability that an intensive care bed will be available for the unscheduled admission:

$$\text{Number of intensive care beds needed} = \text{PADC} + 2.33\sqrt{\text{PADC}}$$

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

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(1) Determine the number of licensed and approved intensive care beds as reported in the inventory of the most recent edition of the State Medical Facilities Plan, an amendment thereof, or the inventory after subsequent documented reductions or additions have been determined by the department.

(2) Subtract the number of licensed and approved beds identified in subdivision 2 c (1) of this subsection from the number of beds needed as determined in subdivision 2 b (2) of this subsection. If the difference indicated is positive, then a need may be determined to exist for additional intensive care beds. If the difference is negative, then no need shall be determined to exist for additional beds.

12 VAC 5-240-40. Continuity; system coordination for intensive care beds.

A. All proposals to establish or expand general intensive care beds or cardiac care beds should provide written policies and agreements providing for transfer of patients to specialized units outside of their facility.

B. All proposals to establish or expand specialized intensive care units should provide agreements with all hospitals in their primary and secondary service areas for the transfer of only those patients requiring specialized care to their units.

12 VAC 5-240-50. Cost.

A. Use of underutilized beds.

1. For proposals that have a capital cost of \$1 million or more, preference shall be given to applications which propose to expand intensive care or pediatric units through the conversion of existing underutilized general medical/surgical beds, or to the expansion of general medical/surgical beds through the conversion of underutilized specialty beds.

2. No hospital should relocate beds to a new location if underutilized beds (less than 85% average annual occupancy for medical/surgical and pediatric beds and less than 65% average annual occupancy for intensive care beds) are available within ten miles of the proposed site of the applicant hospital.

B. Reasonable construction cost.

1. The cost per square foot of new construction as well as renovation to the existing facility should be consistent with state and regional costs for similar facilities and patient units.

2. Preference will be given to those proposals which identify the major source of capital as accumulated reserves.

C. Operating cost and charges.

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1. The applicant should demonstrate that projected operating costs and charge structure will be comparable or less than similar facilities operating in the same planning district.

2. For projects involving an off-site replacement of beds, the applicant should, in addition to the above standard, demonstrate that the operating costs and charge structure of the proposed facility shall be comparable to, or less than continued operations at the existing facility.

3. Preference should be given to those facilities which have consistently demonstrated the highest levels of charity care as a percent of total patient revenues as reported to the Virginia Health Services Cost Review Council.

12 VAC 5-240-60. Quality; accreditation and compliance with chapters.

A. The applicant should provide assurances that the proposed facility or units will be designed, staffed, and operated in compliance with applicable state licensure chapters.

B. The applicant should agree to apply for accreditation with the Joint Commission on Accreditation of Healthcare Organizations or other appropriate accreditation organization.

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Perinatal Services
12 VAC 5-250 10 through 120

PART I.
Definitions.

12 VAC 5-250-10. Definitions.

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

"Basic obstetrical services" means the distinct, organized inpatient facilities, equipment and care related to pregnancy and the delivery of newborns.

"Basic perinatal services" means those minimal resources and capabilities that all hospitals offering obstetrical services must provide routinely to newborns. The basic services are defined, in Appendix J, specifically by the Virginia Perinatal Services Advisory Board in its "Guidelines for Neonatal Special Care."

"Department" means the Virginia Department of Health.

"Neonatal special care" means care for infants in one or more of the eight patient categories identified by the Perinatal Services Advisory Board in its "Guidelines for Neonatal Special Care."

"Regional neonatal services" (often referred to as Level III neonatal intensive care) means those minimal resources and capabilities available to provide care for all (with the exception of providing invasive cardiac evaluation) of the eight neonatal categories specified in the "Guidelines for Neonatal Special Care" developed by the Perinatal Services Advisory Board. A regional neonatal services provider has accepted at least 10 neonatal transfers from less comprehensive settings within the past twelve months and is certified by Medicaid as rendering extensive neonatal care under Item 6 of Attachment 4.19-A to the State Plan for Medical Assistance.

For the purposes of defining extensive neonatal care, a recognized intensive care unit is defined as a unit which meets the following criteria:

1. It qualifies for reimbursements as an "intensive care unit" under the Medicare principles of reimbursement (see HIM-15, Section 2202.7);
2. It is designated or eligible as a regional perinatal center pursuant to Amendment

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Number 5 to the Virginia State Health Plan 1980-1984 on perinatal care adopted September 19, 1984, by the Statewide Health Coordinating Council, effective November 15, 1984;

3. It is operating in a manner consistent with the Statewide Perinatal Services Plan, developed by the Statewide Perinatal Services Advisory Council of the Commonwealth of Virginia, dated May 1983 (revised 1984); and

4. It is in conformance with all guidelines for Level III facilities identified in Guidelines for Perinatal Care issued by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists (1992).

"Regional obstetric services" means those minimal resources and capabilities to handle the different complications identified in "Guidelines Concerning Maternal Transfer" adopted by the Perinatal Services Advisory Board. A regional obstetric services provider has accepted at least 10 maternal transfers from less comprehensive settings within the past 12 months.

"Regional perinatal center" ("RPC") means a comprehensive obstetric, perinatal and neonatal program serving the Perinatal Service Area as defined by the Department and the Perinatal Services Advisory Board and recognized unofficially as the referral center. The RPC has (i) the capability to handle the different complications identified in "Guidelines Concerning Maternal Transfer" adopted by the Perinatal Services Advisory Board; (ii) the capability to provide care for all (with the possible exception of providing invasive cardiac evaluation when other arrangements are made) of the eight neonatal categories, and applicable standards of special requirements for capabilities, personnel, and equipment, specified in the "Guidelines for Neonatal Special Care" developed by the Perinatal Services Advisory Board; and (iii) accepted at least 10 maternal or neonatal transfers from less comprehensive settings within the past 12 months. Two hospitals within a region may serve as the "regional perinatal center" for that region where one provides the "regional obstetric services" and the other provides the "regional neonatal services."

Regional perinatal centers have not been officially designated in Virginia. The department and the Perinatal Board have divided the Commonwealth into seven perinatal services areas and recognize, unofficially, the following hospitals as regional perinatal centers:

Region I (Southwest)	None designated
Region II (Western)	Community Hospital of Roanoke Valley
Region III (Southside).....	Virginia Baptist Hospital
Region IV (Piedmont).....	University of Virginia
Region V (Northern).....	Fairfax Hospital
Region VI (Central)	Medical College of Virginia
Region VII (Eastern).....	Children's Hospital of the King's Daughters/ Sentara Norfolk General Hospital.

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"Transfer agreement" means a formal agreement between a hospital's obstetrics and neonatal services and a regional perinatal center specifying (i) which categories of maternal and neonatal patients may be served at the local hospital; (ii) the categories, circumstances and protocols for transferring maternal and neonatal patients to the regional perinatal center; and (iii) the reciprocal circumstances and procedures under which such patients may be transferred back to the referring hospital.

PART II.
Criteria and Standards for Obstetrical Services.

12 VAC 5-250-20. Acceptability; patient education.

Obstetrical service providers should offer an array of family planning and related maternal and child health education programs that are readily accessible to current and prospective patients.

12 VAC 5-250-30. Accessibility; travel time; financial considerations.

A. Consistent with minimum size and use standards delineated below, basic obstetrical services should be available within one hour average travel time of 95% of the population in rural areas and within 30 minutes average travel time in urban and suburban areas.

B. Obstetrical and related services should be open to all without regard to ability to pay or payment source.

C. Providers of obstetrical facility services serving rural areas should facilitate transport of patients residing in rural areas to needed obstetrical facility services, directly or through coordinated efforts with other organizations. Preference will be given in the review of competing applications to applicants who can demonstrate a commitment to the development of transportation resources for rural populations.

12 VAC 5-250-40. Availability; service capacity; occupancy; consolidation of services.

A. Obstetrical services should be located and sized to ensure that there is 95% probability of there being an empty obstetrics bed in the planning district at any given time.

B. Proposals to establish new obstetrical services or expand existing obstetrical services in rural areas should demonstrate that they will perform a minimum of 1,000 deliveries by the second year of operation or expansion and that obstetrical patient volumes of existing providers will not be negatively affected.

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C. Proposals to establish new obstetrical services or expand existing obstetrical services in urban and suburban areas should demonstrate that they will perform a minimum of 3,000 deliveries annually by the second year of operation or expansion and that obstetrical program volumes of existing providers will not be negatively affected.

D. Average annual occupancy of licensed obstetric beds in a planning district should be at the highest attainable level consistent with the above service capacity standard.

E. Applications to improve existing obstetrical services, and to reduce costs through consolidation of two obstetrical services into a larger, more efficient service will be given preference over the addition of new services or the expansion of single service providers.

12 VAC 5-250-50. Continuity.

A. Regional Perinatal Center affiliation.

Facilities seeking to expand existing obstetrical services should affiliate and coordinate their service program with the Regional Perinatal Center.

B. Transfer agreements for high-risk patients.

1. Obstetrical services providers should maintain written transfer agreements with a regional perinatal center specifying the circumstances and procedures under which high-risk maternal patients and newborn infants will be transported to the regional perinatal center and returned to the referring hospital.

2. Written plans and protocols should demonstrate that more than 95% of extremely low birth-weight infants (less than 1,500 grams) and more than 80% of low birth-weight infants (less than 2,000 grams) will be delivered at the regional perinatal center.

12 VAC 5-250-60. Cost.

A. The total cost of providing necessary obstetrical services to a community is a function of the number, size, location and relative efficiency of the programs providing care. Preference will be given to proposals which reduce or minimize the aggregate costs of providing obstetrical services to a community.

B. Obstetrical unit costs (cost per delivery or per patient day of care) tend to be a function of program size and efficiency.

Preference will be given to proposals which demonstrate the ability to provide care at a

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unit cost below the median and mean unit cost in their perinatal service area.

12 VAC 5-250-70. Quality standards; data collection.

A. The standards and requirements established by the Virginia Perinatal Services Advisory Council and the Virginia Department of Health will be utilized as guidance in the evaluation of the ability of proposed and existing providers of regional neonatal services (neonatal intensive care) to provide quality care.

B. Proposals to expand existing services or to add new obstetrical services must demonstrate that they will provide infant and maternal mortality and morbidity data, and program and unit cost and charge data, as requested by the Department of Health.

PART III.

Criteria and Standards for Neonatal Special Care Services.

12 VAC 5-250-80. Accessibility; travel time; payment.

A. Basic perinatal services should be available as an intrinsic element of inpatient obstetrics programs. Neonatal special care services should be located within an average driving time of 45 minutes in urban and suburban areas.

B. Perinatal service areas identified by the Virginia Perinatal Services Advisory Council and the Virginia Department of Health should have one designated or recognized regional neonatal service (often referred to as a Level III neonatal intensive care unit). These services should be located within one and one-half hours driving time of 95% of the population to be served.

C. Neonatal service and related services should be open to all without regard to ability to pay or payment source.

12 VAC 5-250-90. Availability; service capacity.

A. Basic perinatal services capacity should be developed and sized to provide routine newborn care to infants delivered in the associated obstetrics service, and should have the capability to stabilize and prepare for transport those infants requiring the specialized care available in a regional perinatal center.

B. Regional perinatal centers should have regional neonatal services (intensive care units) containing a minimum of 15 stations or beds.

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C. No more than four neonatal special care bassinets and regional neonatal service beds per 1,000 live births should be established in each perinatal service area.

D. Neonatal special care units should achieve 85% average annual occupancy.

E. Preference will be given to the expansion of existing regional perinatal centers, rather than the creation of new programs, unless extraordinary circumstances require consideration of the development of a second regional perinatal center.

12 VAC 5-250-100. Neonatal services; continuity; agreements; follow-up care.

A. Regional neonatal service programs should develop and maintain formal agreements with the obstetrics programs in the region governing the transport, admission and return transport of patients to those hospitals.

B. Regional neonatal service programs should develop and maintain educational programs designed to encourage the delivery of high risk births in the regional perinatal centers, as well as the transport and back transport of newborns requiring neonatal special care.

C. Regional neonatal service providers should provide appropriate outpatient neonatal follow-up care for patients at risk for problems related to prematurity or intensive care nursery stays, such as developmental delays.

12 VAC 5-250-110. Cost; regionalization; levels of care.

A. Each perinatal region should have only one regional perinatal center unless responsibilities are shared by a hospital providing regional obstetrical services and a hospital providing regional neonatal services.

The regional perinatal center should have responsibility for establishing transfer agreements that provide for quality care of maternal and neonatal patients.

More than one hospital should be authorized to operate as a regional perinatal center only if the existing perinatal center does not meet its responsibility to provide care to most categories of patients, to accept transfers and referrals, and comply with the requirements to be certified by Medicaid as a neonatal intensive care unit.

B. Hospitals should be authorized to provide additional levels of care only when it has been demonstrated that regional system costs would not increase and that the quality of care would not be reduced or jeopardized.

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12 VAC 5-250-120. Quality.

A. The standards and requirements established by the Virginia Perinatal Services Advisory Council and the Virginia Department of Health will be utilized as guidance in the evaluation of the ability of proposed and existing providers of regional neonatal services (neonatal intensive care) to provide quality care.

B. All referral regional neonatal services should be provided in the recognized regional perinatal center.

DOCUMENTS INCORPORATED BY REFERENCE

Guidelines for Perinatal Care, Third Edition, American Academy of Pediatrics and American College of Obstetricians and Gynecologists, 1992.

Guidelines Concerning Maternal Transfer, Statewide Perinatal Services Plan, May, 1988.

Guidelines for Neonatal Special Care, Statewide Perinatal Services Plan, May, 1988.

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Cardiac Services
12 VAC 5-260-10 through 130

PART I.
Definitions.

12 VAC 5-260-10. Definitions.

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

"Adult catheterization" means the cardiac catheterization of patients 15 years of age or older.

"Adult open heart surgical procedure" means the performance of an open heart surgical procedure on a patient 15 years of age or older.

"Capacity, cardiac catheterization laboratory or room" means that 1,200 diagnostic equivalent procedures have been performed in the dedicated (not shared with other services) cardiac catheterization laboratory or room on an annual basis. One PTCA or other therapeutic procedure is valued at two diagnostic equivalent procedures; one pediatric catheterization procedure is valued at two diagnostic equivalent procedures; and all other procedures are valued at one diagnostic equivalent procedure.

"Capacity, open heart surgery room or suite" means that 500 adult-equivalent procedures have been performed in the open heart surgery room or suite on an annual basis. One pediatric open heart surgery procedure is valued at two adult procedures.

"Cardiac catheterization" means a procedure performed in a cardiac catheterization room or laboratory whereby a flexible tube is inserted into the patient's body, usually through an extremity blood vessel, and advanced under fluoroscopic guidance into the heart chambers to perform a hemodynamic, electrophysiologic or angiographic examination of the left or right heart chamber, or coronary arteries. Therapeutic intervention in a coronary artery may also be performed using cardiac catheterization. By this definition, a cardiac catheterization does not include a simple right heart catheterization for monitoring purposes as might be done in an electrophysiology laboratory, pulmonary angiography as an isolated procedure, or cardiac pacing through a right electrode catheter. This definition does include angiographic procedures to evaluate the coronary arteries, and aortic root injections to examine the degree of aortic root regurgitation or deformity of the aortic valve.

"Cardiac catheterization procedure" means a single episode of cardiac catheterization.

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"Cardiac" or "cardiovascular surgeon" means a surgeon who is eligible or certified in cardiovascular surgery by the American Board of Thoracic Surgery.

"Cardiac surgery room or suite" means a physically identifiable room or suite adequately staffed and equipped for the performance of open heart and closed heart surgery and extracorporeal bypass.

"Cardiac surgery intensive care unit" means a specially designated unit where cardiac vascular surgical patients are held for post-operative care which is not a part of an existing intensive care unit.

"Cardiac surgery team" means the designated specialists, including cardiovascular surgeons and support personnel, who consistently work together in the performance of open heart surgery.

"Cardiovascular surgical procedure" means any surgical procedure dealing with the heart, coronary arteries, and great vessels.

"Cardiovascular surgical service" means the programs, equipment, and staff dealing with the surgery of the heart, coronary arteries, and great vessels.

"Closed heart surgery" means any cardiovascular surgical procedure(s) which does not include the use of a heart-lung bypass machine.

"Comprehensive cardiac services program" means a cardiac services program which provides a full range of clinical services associated with the treatment of cardiovascular disease including community outreach, emergency treatment of cardiovascular illnesses, noninvasive diagnostic imaging modalities, diagnostic and interventional cardiac catheterization, open heart surgery, and cardiac rehabilitation services. Community outreach and cardiac rehabilitation services may be provided through arrangements with other agencies and facilities located within the same jurisdiction or planning district. All other components of a comprehensive cardiac catheterization services program must be provided within a single facility.

"Dedicated cardiac catheterization laboratory or room" means a laboratory or room which is staffed and operated solely for the provision of cardiac catheterization and which has the equipment required to perform angiographic and physiologic catheterization procedures.

"Department" means the Virginia Department of Health.

"Diagnostic cardiac catheterization procedure" means a cardiac catheterization procedure performed for the purpose of detecting and identifying defects in the great arteries or veins or the heart structure or abnormalities in the heart structure.

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"Expanded cardiac catheterization service" means the addition or conversion of a laboratory or room to be dedicated to cardiac catheterization procedures and the purchase of additional equipment specially designed to perform cardiac catheterizations.

"Expanded open heart surgery service" means the addition, through new construction, conversion or renovation of space, of a operating room or suite to be used solely for open heart surgery.

"Extracorporeal circulation bypass" means the circulation of blood outside the body as through a heart-lung machine for carbon dioxide-oxygen exchange.

"Open heart surgery" means a highly specialized set of surgical procedures which utilize 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 perform necessary surgery to correct congenital and acquired cardiac and coronary artery disease. The use of the "pump" during the procedure distinguishes "open heart" from "closed heart" surgery.

"Pediatric catheterization" means the cardiac catheterization of patients under 15 years of age with congenital heart disease.

"Pediatric open heart surgery" means the performance of an open heart surgical procedure on a patient younger than 15 years of age.

"Percutaneous transluminal coronary angioplasty (PTCA)" means an interventional cardiac catheterization procedure that is therapeutic in nature and used to treat coronary artery disease. In PTCA, a balloon-tipped catheter is placed in a disease artery and the balloon is inflated to compress the plaque blocking the artery. This definition shall also include, for computational purposes, the use of laser-tipped catheters, rather than balloon-tipped catheters, to eliminate or reduce the plaque blocking arteries.

"Pump procedures" means the use in surgery of a heart-lung bypass machine to perform the work of the heart and lungs. Included in these procedures are myocardial revascularization, aortic and mitral valve replacement, ventricular aneurysm repairs, pulmonary valvuloplasty, and other procedures utilizing a cardiac pump.

"Relevant reporting period" means the most recent 12 month period, prior to the beginning of the Certificate of Public Need Application's review cycle, for which data are available and acceptable to the department.

"Special procedures laboratory" or "room with a cardiac catheterization service" means a

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laboratory or room which is not dedicated exclusively to performing cardiac catheterization but is also utilized for other procedures not directly related to cardiac catheterization, yet which has the equipment, staff and support services required to provide cardiac catheterization and in which such cardiac catheterizations are routinely performed. A room or laboratory defined in this section is to be counted in the inventory of cardiac catheterization rooms.

PART II.

Criteria and Standards for Cardiac Catheterization Services.

12 VAC 5-260-20. Acceptability; consumer participation.

A. The waiting time for elective procedures should be less than two weeks. Emergency cardiac catheterization services should be available 24 hours a day, seven days a week.

B. Providers with cardiac catheterization services will provide a program of patient and family education regarding the nature of the patient's heart/circulatory disease and available methods of diagnosis and treatment of the patient and family in the management of the problem.

12 VAC 5-260-30. Accessibility; financial considerations.

A. Adult cardiac catheterization services should be accessible within a one hour driving time, under normal conditions, for 90% of Virginia's population.

B. Cardiac catheterization services should be accessible to all patients in need of services without regard to their ability to pay or the payment source.

C. Providers of cardiac catheterization services serving rural areas should facilitate the transport of patients residing in rural areas to needed cardiac catheterization services, directly or through coordinated efforts with other organizations. Preference will be given in the review of competing applications to applicants who can demonstrate a commitment to the development of transportation resources for rural populations.

12 VAC 5-260-40. Availability; need for new services; alternatives.

A. Need for new service. No new cardiac catheterization service should be approved unless (i) all existing cardiac catheterization laboratories located in the planning district in which the proposed new service will be located where used for at least 960 diagnostic-equivalent cardiac catheterization procedures for the relevant reporting period; and (ii) it can be reasonably projected that the proposed new service will perform at least 200 diagnostic equivalent procedures in the first year of operation, 500 diagnostic equivalent procedures in the second year of operation, and 800 diagnostic equivalent procedures in the third year of operation without

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reducing the utilization of existing laboratories in the planning district such that less than 960 diagnostic equivalent procedures are performed at any of those existing laboratories.

B. Mobile cardiac catheterization service. Proposals for the use of freestanding or mobile cardiac catheterization services should only be approved if such services will be provided at a site located on the campus of a general/community hospital and complies with all applicable sections of the state medical facilities plan as determined by the department.

C. Alternative need for new services in rural areas. Notwithstanding the standards for approval of new cardiac catheterization services outlined above, consideration will be given to the approval of new cardiac catheterization services which will be located at a general hospital located 60 minutes or more driving time, under normal conditions, from any site at which cardiac catheterization services are available if it can be reasonably projected that the proposed new services will perform at least 200 diagnostic-equivalent procedures in the first year of operation, 400 diagnostic-equivalent procedures in the second year of operation, and 600 diagnostic-equivalent procedures in the third year of operation without reducing the utilization of existing laboratories located within 60 to 70 minutes driving time, under normal conditions, from the proposed new service location.

D. Need for expanded service. Proposals for the expansion of cardiac catheterization services should not be approved unless all existing cardiac catheterization laboratories operated by the applicant have performed at least 1,200 diagnostic-equivalent cardiac catheterization procedures for the relevant reporting period, and it can be reasonably demonstrated that the expanded cardiac catheterization service will achieve a minimum of 200 diagnostic equivalent procedures per laboratory to be added in the first 12 months of operation, 400 diagnostic equivalent procedures in the second 12 months of operation, and 600 procedures per laboratory in the third year of operation, without reducing the utilization of existing cardiac catheterization laboratories in the planning district below 960 diagnostic equivalent procedures.

E. Replacement.

1. Proposals for the replacement of existing cardiac catheterization services should not be approved unless the equipment to be replaced has been in service for at least five years and; (i) in the case of providers located within 60 minutes driving time, under normal conditions, of alternative cardiac catheterization services, the equipment to be replaced has been used in the performance of at least 960 diagnostic-equivalent cardiac catheterization procedures in the relevant reporting period; or (ii) in the case of providers located beyond 60 minutes driving time, under normal conditions, of alternative cardiac catheterization services, the equipment to be replaced has been used in the performance of at least 600 diagnostic-equivalent cardiac catheterization procedures in the relevant reporting period.

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2. Additionally, all proposals for replacement of cardiac catheterization services should comply with all applicable sections of this state medical facilities plan component, as determined by the department.

F. Emergency availability. Cardiac catheterization services should be available for emergency cardiac catheterization within 30 minutes or less at all times.

G. Pediatric services. No new or expanded pediatric cardiac catheterization services should be approved unless the proposed new or expanded service will be provided at: (i) a hospital that also provides open heart surgery services, provides pediatric tertiary care services, has a pediatric intensive care unit and provides neonatal special care; or (ii) a hospital that is a regional perinatal center, has a cardiac intensive care unit and provides open heart surgery services; and it can be reasonably demonstrated that each proposed laboratory will perform at least 100 pediatric cardiac catheterization procedures in the first year of operation, 200 pediatric cardiac catheterization procedures in the second year of operation and 400 pediatric cardiac catheterization procedures in the third year of operation.

H. Emergency availability of open heart surgery. No application for new, expanded, or replacement cardiac catheterization services which includes the provision or potential provision of PTCA, transeptal puncture, transthoracic left ventricular puncture, or myocardial biopsy services should be approved unless emergency open heart surgery services are, or will be available on-site at all times at the same hospital at which the proposed new, expanded, or replacement cardiac catheterization service will be located.

12 VAC 5-260-50. Continuity; coordination.

A. Coordination of services. Any application for new or expanded cardiac catheterization services should provide written assurances that the applicant presently has, or will have, a signed coordination agreement (including transportation), with a hospital providing open heart surgery services, such that continuity of patient care will be maintained when transfer is necessary, and that the procedures done at the applicant's laboratory will not be routinely repeated at the surgical facility.

B. Discharge planning procedures and follow-up care.

1. All cardiac catheterization services should have written procedures and policies for discharge planning and follow-up care for the patient and family which are part of the institution's overall discharge planning program.

2. All cardiac catheterization services should presently have, or will have, established protocols for referring physicians and the cardiac surgical service to assure adequate post-operative diagnostic evaluation for cardiac surgical patients.

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12 VAC 5-260-60. Cost; alternatives.

A. Less costly alternatives. Existing or proposed providers of cardiac catheterization services should document to the satisfaction of the department access to a full range of less serious, noninvasive, cardiac diagnostic procedures at the facility where cardiac catheterization services are or will be provided. At a minimum, these shall include the following:

1. Nuclear medicine.
2. Echocardiography.
3. Pulmonary function testing.
4. Stress testing.
5. Electrocardiography.
6. Cardiac chest X-ray.

B. Cost and charges.

1. The usual and customary charge to the patient for cardiac catheterization services should be commensurate with cost.

2. The average charge to the patient for cardiac catheterization services should be comparable to the average charges of other cardiac catheterization providers in the planning district and/or health planning region.

12 VAC 5-260-70. Quality; staffing; patient care and support services.

A. Staffing.

1. Cardiac catheterization services should have a medical director who is board certified in cardiology with subspecialty training in cardiovascular radiology, and experienced in the performance of physiologic and angiographic procedures. In the case of pediatric cardiac catheterization services, the medical director should be board certified in pediatric cardiology.

2. All physicians on staff who will be performing cardiac catheterization procedures should be board certified or board eligible in cardiology, and experienced in the performance of physiologic and angiographic procedures. In addition to the cardiologist who performs the procedure, there should be another suitably trained board eligible cardiologist immediately available on-site to provide assistance. In the case of pediatric catheterization services, each physician performing pediatric procedures should be board certified or board eligible in pediatric cardiology, and have clinical experience in performing physiologic and angiographic procedures.

3. All anesthesia services should be provided by, or supervised by, a board certified anesthesiologist, and in the case of pediatric catheterization services, the anesthesiologist should also be experienced and trained in pediatric anesthesiology.

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4. If cardiac catheterization services include PTCA services, each physician who performs PTCA procedures should perform the equivalent of one PTCA procedure per week or 52 per year. The minimum training standard for such physician should be performance of at least 125 PTCA procedures, of which 75 were as the primary operator with satisfactory outcomes. Continued performance of PTCA shall be dependent upon the demonstration of success and complication rates which meet expected standards.

5. The staffing pattern for each team performing cardiac catheterizations should be composed of the following nonphysical personnel:

a. One RN nurse with special training and current experience in critical care of cardiac patients, cardiovascular medication and catheterization equipment.

b. At least three technicians with current specialized training in cardiac care who are capable of performing the duties of a radiologic technologist, cardiopulmonary technician, monitoring and recording technician, and darkroom technician.

6. In addition to the team physician, at least two members of the team should be trained in cardiopulmonary resuscitation.

7. Each team should have the capability to treat immediately the possible complications of cardiac catheterization, such as anaphylaxis and cardiac arrhythmias.

8. All cardiac catheterization laboratories should have access to a medical social worker to counsel those patients and families who need assistance with financial and emotional problems prior to and following catheterization.

B. Patient care and support services.

1. Facilities providing cardiac catheterization services should have the following services:

- a. Intensive care unit;
- b. Laboratory and pathology services (hematology, pulmonary function, blood gasses and blood bank);
- c. Anesthesiology, including inhalation therapy;
- d. Radiology;
- e. Cardiac arrest and surgical team (rapid mobilization should be possible at all times);
- f. Maintenance and monitoring equipment;
- g. Electrocardiography and testing services to include stress testing and continuous cardiogram monitoring;
- h. Echocardiography services; and
- i. Microbiology laboratory.

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2. Cardiac catheterization laboratories should be competent to provide a range of both angiographic (angiocardiography, coronary arteriography) and hemodynamic and physiologic (measurement of cardiac output, intracardiac pressure) studies.

3. Facilities providing cardiac catheterization services should have the capability to diagnose and treat vascular occlusions and serious hemorrhages which may result from cardiac catheterization.

C. Clinical proficiency. All physicians with cardiac catheterization laboratory privileges should demonstrate the maintenance of proficiency in this procedure by the successful performance of an adequate number and type of cardiac catheterization procedures within a laboratory-specified time period that is equivalent to 150 adult-equivalent procedures per year.

D. Team clinical proficiency - mobile services. Each team (see 12VAC5-260-70) providing cardiac catheterization services in a mobile unit should perform at least 150 diagnostic-equivalent procedures per year, as a team, on the site of the mobile unit.

E. Accreditation and compliance with chapters. Cardiac catheterization services should meet the accreditation standards of the Joint Commission on the Accreditation of Healthcare Organizations, and comply with the applicable chapters of the Virginia Department of Health's Bureau of Radiological Health.

PART III.

Criteria and Standards for Open Heart Surgery.

12 VAC 5-260-80. Acceptability; consumer participation.

A. The waiting time for elective open heart surgery procedures should be less than one month.

B. Providers of open heart surgery should provide a program of patient and family education regarding the nature of the patient's heart disease, and which attempts to assure the family and the patient's joint compliance in the post-operative management of the patient.

The patient and his family should be fully informed and involved in the decision-making regarding the open heart surgery.

C. Providers of open heart surgery services should have in place a mechanism for identifying travel and housing problems for patients and their families, particularly in rural areas, and provide assistance in making arrangements for these services for those patients and their families who may need them during the period of surgery and post-operative management.

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12 VAC 5-260-90. Accessibility; travel time; financial considerations.

A. Open heart surgery services should be accessible within a two hour driving time, under normal conditions, for 90% of Virginia's population.

B. Open heart surgery services should be accessible to all patients in need of the services without regard to their ability to pay.

C. Open heart surgery service should be available for operation at least eight hours a day for five days a week. Emergency open heart surgery and cardiac catheterization capability should be available 24 hours a day, seven days a week.

12 VAC 5-260-100. Availability; need for the new service; alternatives.

A. Need for the new service. No new open heart services should be approved unless: (i) the service is to be made available in a general hospital which has established cardiac catheterization services that have been used for the performance of at least 960 diagnostic-equivalent procedures for the relevant reporting period and has been in operation for at least 30 months; (ii) all existing open heart surgery rooms located in the planning district in which the proposed new service will be located have been used for at least 400 adult-equivalent open heart surgical procedures for the relevant reporting period; and (iii) it can be reasonably projected that the proposed new service will perform at least 150 adult-equivalent procedures in the first year of operation, 250 adult-equivalent procedures in the second year of operation, and 400 adult-equivalent procedures in the third year of operation without reducing the utilization of existing open heart surgery programs in the planning district such that less than 400 adult-equivalent open heart procedures are performed at those existing laboratories.

B. Alternative need for new services in rural areas. Notwithstanding the standards for approval of new open heart services outlined above, consideration will be given to the approval of new open heart surgery services which will be located at a general hospital located more than two hours driving time, under normal conditions, from any site at which open heart surgery services are available if it can be reasonably projected that the proposed new service will perform at least 150 adult-equivalent open heart procedures in the first year of operation, 225 adult-equivalent procedures in the second year of operation, and 300 adult-equivalent procedures in the third year of operation without reducing the utilization of existing open heart surgery rooms within a 120-150 minute driving time, under normal conditions, from the proposed new service location below 400 adult-equivalent open heart surgical procedures per room. Such hospitals should also have provided at least 760 diagnostic-equivalent cardiac catheterization procedures during the relevant reporting period on equipment which has been in operation at least 30 months.

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C. Need for expanded service. Proposals for the expansion of open heart surgery services should not be approved unless all existing open heart surgery rooms operated by the applicant have performed at least 400 adult-equivalent open heart surgery procedures in the relevant reporting period if the facility is within two hours driving time, under normal conditions, of an existing open heart surgery service, or at least 300 adult-equivalent open heart surgery procedures in the relevant reporting period if the facility that proposes expanded services is in excess of two hours driving time, under normal conditions, of an existing open heart surgery service.

Additionally, all proposals for the expansion of open heart surgery services should comply with all applicable sections of this State Medical Facilities Plan component, as determined by the department.

D. Replacement. Proposals for the replacement of existing open heart surgery services should not be approved unless the equipment to be replaced has been in operation for at least 30 months; and (i) in case of providers located within two hour's driving time, under normal conditions, of alternative open heart surgery services, the open heart surgery equipment to be replaced has been used in the performance of at least 400 adult-equivalent procedures in the relevant reporting period; or (ii) in the case of providers located beyond two hour's driving time, under normal conditions, of alternative open heart surgery services, the open heart surgery room to be replaced has been used in the performance of at least 300 adult-equivalent procedures in the relevant reporting period.

Additionally, all proposals for the replacement of open heart surgery services should comply with all the applicable sections of the State Medical Facilities Plan component, as determined by the department.

E. Pediatric services. No new, expanded or replacement pediatric open heart surgery service should be approved unless the proposed new, expanded or replacement service is provided at a hospital that: (i) has cardiac catheterization services which have been in operation for 30 months and that have been used in the performance of at least 200 pediatric cardiac catheterization procedures for the relevant reporting period, provides pediatric tertiary care services, has pediatric intensive care services and provides neonatal special care; or (ii) is a regional perinatal center and has a cardiac intensive care unit.

12 VAC 5-260-110. Continuity; coordination.

A. Coordination of services. Any application for new, expanded or replacement open heart surgery services should provide written assurances satisfactory to the department that the applicant presently has, or will have, a signed referral agreement with other community hospitals and physicians to receive referrals for open heart surgery.

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B. Discharge planning procedures and follow-up care. All open heart surgery services should have written protocols for discharge planning and follow-up care for the patient and family which are part of the institution's overall discharge planning program.

12 VAC 5-260-120. Cost; alternatives.

A. Less costly alternatives. The applicant should provide documentation satisfactory to the department that shared services and consolidation arrangements for open heart surgery have been investigated and found less advantageous in terms of cost, quality, accessibility, availability, and continuity of care.

B. Cost and charge.

1. The usual and customary charge to the patient for open heart surgery services should be commensurate with cost.

2. The average charge to the patient for the proposed open heart surgery service will be comparable to or less than the average charges of other open heart surgery providers in the planning district and the health planning region.

12 VAC 5-260-130. Quality; staffing; patient care and support services.

A. Staffing.

1. Open heart surgery services should have a medical director who is certified by the American Board of Thoracic Surgery in cardiovascular surgery with special qualification and experience in cardiac surgery. In the case of pediatric open heart surgery, the medical director shall be certified by the American Board of Thoracic Surgery in cardiovascular surgery, and experienced in pediatric cardiovascular surgery and congenital heart disease.

2. All physicians on staff who will be 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 suitable trained board certified or board eligible cardiovascular surgeon acting as an assistant during the open heart surgical procedure. There should also be at least one board certified or board eligible anesthesiologist with experience in open heart surgery. In the case of pediatric open heart surgery services, each physician performing and assisting with pediatric procedures should be board certified or board eligible in cardiovascular surgery with experience in pediatric cardiovascular surgery. All pediatric procedures should include a board certified anesthesiologist with experience in pediatric anesthesiology and pediatric open heart surgery.

3. The staffing pattern for each team performing open heart surgical procedures should be composed of at least the following nonphysician personnel:

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- a. One certified registered nurse anesthetist;
 - b. One or more circulating nurses or scrub nurses trained cardiac surgical procedures; and
 - c. At least three technicians with current specialized training in cardiac care, two of which are certified pump technicians, and the third capable of performing the duties of operating room technician;
4. Post-operatively, the cardiac surgical intensive care unit should provide 24-hour nursing coverage with at least one registered nurse per patient during the first 24 hours and one for every two patients for the second 24 hours for adult and pediatric cases.
5. There should be at least two cardiovascular surgeons, at least one of whom is board certified and the other at least board eligible, on the staff of a hospital with a cardiac surgical program, and one of whom should be immediately available at all times; pediatric open heart surgery programs should have two similarly qualified surgeons experienced and trained in pediatric cardiovascular surgery, one of which should be immediately available at all times.
6. A clinical board certified or eligible cardiologist should be on staff as a member of the surgical team responsible for the medical management of patients, and the selection, assisted by the cardiovascular surgeon, of suitable candidates for surgery.
7. Optimally, on a rotating basis, physician members (a thoracic or cardiovascular surgeon or trainee or a surgical residents with experience in cardiovascular surgery) of the surgical team should be physically present at all times that the patient is in the hospital.
8. Back-up personnel in cardiology, anesthesiology, pathology thoracic surgery and radiology should be immediately available.
9. A medical social worker should be available to all cardiovascular surgery programs.
10. Twenty-four hour a day coverage should be arranged for the operation of the extra-corporeal pump oxygenator.
11. All members of the physician and nurse team involved in the care of cardiovascular surgical patients should be proficient in cardiopulmonary resuscitation.

B. Patient care support services.

1. Facilities providing open heart surgery services should have the following:
 - a. Non-invasive cardiographics lab, (including electrocardiography, stress testing services, phonocardiography, and echocardiography);
 - b. Laboratory and pathology services (hematology, pulmonary function, blood gasses and blood bank);
 - c. Medicine (cardiology, hematology, nephrology, and infectious disease);
 - d. Anesthesiology including inhalation therapy;
 - e. Radiology (including a diagnostic nuclear medicine laboratory);
 - f. Neurology;
 - g. Microbiology laboratory;

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- h. Cardiac catheterization services including diagnostic and interventional/therapeutic cardiac catheterization capabilities;
- i. Cardiac surgical intensive care unit with at least four beds;
- j. Social services;
- k. Cardiac rehabilitation services and community outreach and education programs available through the facility on-site or at locations off-site but in reasonable proximity to the patient population;
- l. Emergency room staffed 24-hours a day for cardiac emergencies; and
- m. Maintenance and equipment services.

C. Clinical proficiency. All physicians with open heart surgery privileges should demonstrate the maintenance of proficiency in this procedure by the successful performance of an adequate number and type of open heart surgical procedures within a specified time period in accordance with acceptable professional standards.

D. Team clinical proficiency. Each open heart surgical team (same individuals) should work together regularly and frequently (preferably four to five times a week) and maintain an adequate caseload to assure clinical proficiency, equivalent to at least 150 open heart surgical procedures per year.

E. Accreditation and compliance with chapters. Open heart surgery services should meet the accreditation standards of the Joint Commission on the Accreditation of Healthcare Organizations.

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General Surgical Services
12 VAC 5-270-10 through 60

PART I.
Definitions.

12 VAC 5-270-10. Definitions.

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

"Ambulatory (outpatient) surgical services" are surgical services provided to individuals who are not expected to require inpatient (overnight) hospitalization but who require treatment in a medical environment exceeding the normal capability found in a physician's office. For the purposes of these chapters, ambulatory surgical services refers only to surgical services provided in operating rooms in licensed general hospitals or licensed outpatient surgical hospitals, and does not include surgical services safely and appropriately provided in outpatient departments, emergency rooms, or treatment rooms of hospitals, or in physicians' offices.

"Ambulatory surgical operating room" means an operating room in a licensed general or outpatient surgical hospital, which is intended to be used solely or principally for the provision of ambulatory surgical services.

"Inpatient surgical operating room" means an operating room in a licensed general hospital, which is intended to be used solely or principally for the provision of surgery to individuals requiring inpatient (overnight) hospitalization.

"Inpatient surgical services" are surgical services provided to individuals who are expected to require inpatient (overnight) hospitalization.

"Licensed facilities" are surgical facilities licensed as general hospitals or outpatient surgical hospitals in accordance with the Rules and Regulations for the Licensure of Hospitals in Virginia (12VAC5-410-10) of the Virginia Department of Health.

"Operating room capacity" means 1,600 available service hours per operating room per year. This is based on 80% utilization of an operating room that is available 40 hours per week, 50 weeks per year.

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

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"Operating room visit" means one session in one operating room in a licensed general hospital or outpatient surgical hospital, which may involve several procedures. Operating room visit may be used interchangeably with "operation."

"Population" means population figures shown in the most current series of population projections published by the Virginia Employment Commission.

"Surgical services" means the provision of surgery to inpatients or outpatients (ambulatory) patients in licensed general or outpatient (ambulatory) surgical hospitals (centers).

**PART II.
Criteria and Standards.**

12 VAC 5-270-20. Acceptability.

Self-referral - Surgical services providers should comply with all applicable federal and state statutes governing the ability of physicians to refer patients to facilities in which they have an ownership interest.

12 VAC 5-270-30. Accessibility; travel time; financial.

Surgical services should be available within a maximum driving time, under normal conditions, of 30 minutes for 90% of the population of a planning district.

Surgical services should be accessible to all patients in need of services without regard to their ability to pay or the payment source.

Providers of surgical services serving rural areas should facilitate the transport of patients residing in rural areas to needed surgical services, directly or through coordinated efforts with other organizations. Preference will be given in the review of competing applications to applicants who can demonstrate a commitment to the development of transportation resources for rural populations.

12 VAC 5-270-40. Availability; need.

A. Need.

The combined number of inpatient and ambulatory surgical operating rooms needed in a planning district will be determined as follows:

1. CSUR = ORV/POP

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Where CSUR is the current surgical use rate in a planning district as calculated in the above formula;

ORV is the sum of total operating room visits (inpatient and outpatient) in the planning district in the most recent three consecutive years for which operating room utilization data has been reported by the Virginia Center for Health Statistics; and

POP is the sum of total population in the planning district in the most recent three consecutive years for which operating room utilization data has been reported by the Virginia Center for Health Statistics, as found in the most recent published projections of the Virginia Employment Commission.

$$2. \text{PORV} = \text{CSUR} * \text{PROPOP}$$

Where PORV is the projected number of operating room visits in the planning district three years from the current year; and

PROPOP is 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.

$$3. \text{FORH} = \text{PORV} * \text{AHORV}$$

Where FORH is future operating room hours needed in the planning district three years from the current year; and

AHORV is the average hours per operating room visit in the planning district for the most recent year for which average hours per operating room visit as been calculated from information collected by the Virginia Department of Health.

$$4. \text{FOR} = \text{FORH}/1600$$

Where FOR is future operating rooms needed in the planning district three years from the current year.

No additional operating rooms should be authorized for a planning district if the number of existing or authorized operating rooms in the planning district is greater than the need for operating rooms identified using the above methodology. New operating rooms may be authorized for a planning district up to the net need identified by subtracting the number of existing or authorized operating rooms in the planning district from the future operating rooms needed in the planning district, as identified using the above methodology.

Consideration will be given to the addition of operating rooms by existing medical care facilities in planning districts with an excess supply of operating rooms, based on the

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methodology outlined above, when such addition can be justified on the basis of facility-specific utilization and/or geographic remoteness (driving time of 45 minutes or more, under normal conditions, to alternative surgical facilities).

B. Relocation. Projects involving the relocation of existing operating rooms within a planning district may be authorized when it can be reasonably documented that such relocation will: (i) improve the distribution of surgical services within a planning district; or (ii) result in the provision of the same surgical services at a lower cost to surgical patients in the planning district; or (iii) optimize the number of operations in the planning district which are performed on an ambulatory basis.

C. Ambulatory surgical facilities. Preference will be given to the development of needed operating rooms in dedicated ambulatory surgical facilities developed within general hospitals or as freestanding centers owned and operated by general hospitals.

12 VAC 5-270-50. Cost; charges.

Preference among competing applications to provide surgical services identified as needed in a planning district will be given to applicants who can reasonably document that the costs of providing services and the charges for these services will be less than the average costs and charges for comparable services provided in the planning district or health planning region in which the project is to be located, consistent with the other standards of this plan component.

12 VAC 5-270-60. Quality; accreditation/licensure.

A. Surgical services providers should meet all applicable accreditation standards of the Joint Commission on the Accreditation of Healthcare Organizations or the Association for Accreditation of Ambulatory Health Centers and licensure standards of the Department of Health.

B. Existing and proposed providers of surgical services should document the availability of physicians who are board-certified or board-eligible in appropriate surgical specialties.

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Organ Transplant Services
12 VAC 5-280-10 through 70

PART I.
Definitions.

12 VAC 5-280-10. Definitions.

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

“Department” means Virginia Department of Health.

"Donor organ/organ system" means an organ/organ system retrieved from a cadaver or living donor, and processed under appropriate rules and protocols, for the purpose of surgical transplantation into a recipient selected in accordance with established guidelines and protocols.

"Medicare requirements" means those clinical, certification and administrative requirements and standards set by the Centers for Medicare and Medicaid Services (CMS) of the United State Department of Health and Human Services to establish eligibility for Medicare program reimbursement.

"Minimum survival rates" means the lowest percentage of those receiving transplants who survive at least one year or for such other periods of times as specified by the department. Minimum survival rates not specified in these standards shall be established by the department as experience permits.

"Minimum utilization" means the number of transplants expected to be performed annually. Minimum utilization requirements not specified in these standards shall be established by the department as experience permits.

"Organ/organ system" means any of the number of clinically distinct components of the human body containing tissues performing a function for which it is especially adapted. Distinct organ/organ systems include, but are not limited to, kidney, heart, heart/lung, liver, and pancreas.

"Organ transplantation" means a set of medical procedures performed to remove surgically a defined diseased or nonfunctioning organ/organ system from a patient and replace it with a healthier functioning donor organ/organ system.

"Satellite clinic" means a scheduled program of outpatient services for pre- ~~or~~and] post-transplant patients conducted at a site remote from the facility in which the organ transplant

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surgical services are provided that allows patients to obtain outpatient services associated with organ transplantation closer to their city or county of residence.

PART II.
Criteria and Standards.

12 VAC 5-280-20. Acceptability; consumer participation.

Providers of organ transplantation services should provide a program of patient and family education regarding the nature of the patient's organ disease and the treatment of the patient and family in the management of the organ pre- and post-transplantation.

12 VAC 5-280-30. Accessibility; travel time; access to available organs.

A. Organ transplantation services, of any type, should be accessible within two hours driving time, under normal conditions, of 95% of Virginia's population.

B. Providers of organ transplantation services should demonstrate to the satisfaction of the department that they have clearly defined patient/organ recipient policies based solely on medical criteria.

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

12 VAC 5-280-40. Availability; regionalization of services; conditional approval; HCFA Medicare requirements.

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

B. Approval of organ transplantation programs shall be conditioned upon a facility's meeting both minimum volume and survival standards. Failure to meet these standards within two years of initiation of the service may be cause for revocation of the certificate of public need.

C. 1. Proposals to establish new transplantation services should demonstrate compliance with all Medicare program coverage criteria within two years of the initiation of the program.

2. Proposals to expand existing transplantation programs should demonstrate that existing organ transplantation services comply with all applicable federal Health Care Financing Administration criteria for Medicare program coverage.

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12 VAC 5-280-50. Continuity of care; discharge planning procedures and follow-up care.

A. Providers of organ transplantation services should have written procedures and policies for discharge planning and follow-up care for the patient and family which are part of the institution's overall discharge planning program.

B. Providers of organ transplantation services should have established protocols for referring physicians and the organ transplantation service to assure adequate post-operative diagnostic evaluation for transplant patients.

12 VAC 5-280-60. Cost and charges.

The total cost (direct and indirect) for providing all organ transplantation services should be comparable to other similar service providers in the health planning region and the state.

12 VAC 5-280-70. Quality; minimum utilization; minimum survival rate; service proficiency; staffing; systems operations; support services.

A. 1. Proposals to establish, expand or replace organ transplantation services should demonstrate that a minimum number of transplants will be performed annually. The minimum number required by organ system is

Kidney.....	25
Heart.....	12
Heart/Lung	12
Liver.....	20
Pancreas	12

2. Successful transplantation programs are expected to perform substantially larger numbers of transplants annually. Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs.

3. 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 other programs that could reduce average program volume.

B. 1. Facilities should demonstrate that they will achieve and maintain minimum transplant patient survival rates. Minimum one year survival rates, listed by organ system, are:

Kidney.....	90-95%
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Heart..... 70-80%
Heart/Lung(none set)
Liver..... 50-60%
Pancreas 80-90%

2. Survival rates beyond one year should be consistent with the Medicare program requirements, or with applicable professional society recommended standards acceptable to the department where there are no Medicare criteria.

C. Proposals to add additional organ transplantation services should demonstrate at least two years successful experience with all existing organ transplantation systems.

D. 1. 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.

2. Organ transplantation services should have a complete team of surgical, medical and other specialists, with at least two years experience in the proposed organ transplantation system.

E. 1. Providers of organ transplantation services should document that they participate in a regional and national organ donor network. The facility should have written policies and procedures governing organ and tissue procurement.

2. Providers of organ transplantation services should have an ongoing approved medical education program.

3. Providers of organ transplantation services should collect and submit to the department transplantation program operating statistics, including patient and procedure volumes, mortality data and program cost and charges.

F. Providers of organ transplantation services should demonstrate that they have direct and immediate access to a histocompatibility testing laboratory that meets the American Society for Histocompatibility and Immunogenetic (ASHI) standards.

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Psychiatric and Substance Abuse Treatment Services
12 VAC 5-290-10 through 70

PART I.
Definitions.

12 VAC 5-290-10. 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" are inpatient psychiatric services provided at the hospital level of care that have a reported inpatient average length of stay of 90 days or less.

"Acute substance abuse treatment services" are inpatient substance abuse treatment services provided at the hospital level of care, exemplified by medical detoxification, treatment of the medical and psychiatric complications of chemical dependency, and continuous nursing services.

"Inpatient psychiatric services" are acute psychiatric services provided through distinct inpatient units of medical care facilities or through free-standing psychiatric hospitals. Inpatient psychiatric beds are licensed by the Department of Mental Health, Mental Retardation, and Substance Abuse Services (DMHMRSAS). "Psychiatric services" are services provided to individuals for the prevention, diagnosis, treatment, and/or palliation of psychiatric disorders.

"Inpatient substance abuse treatment services" are substance abuse treatment services provided through distinct inpatient units of medical care facilities or through free-standing inpatient substance abuse treatment facilities. Inpatient substance abuse treatment beds are licensed by the Department of Mental Health, Mental Retardation, and Substance Abuse Services (DMHMRSAS).

"Intermediate care substance abuse treatment services" are inpatient substance abuse treatment services provided at the residential level of care, exemplified by sub-acute (nonhospital) detoxification services and structured programs of assessment, counseling, vocational rehabilitation, and social rehabilitation.

"Long term psychiatric services" are inpatient psychiatric services provided at the hospital level of care which have a reported inpatient average length of stay in excess of 90 days. These services have traditionally been provided in facilities operated by the DMHMRSAS and, in that case, have not been subject to certificate of public need requirements.

"Satellite clinic" means a scheduled program of outpatient services for patients requiring

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psychiatric or substance abuse treatment following discharge from an inpatient program conducted at a site remote from the facility in which the inpatient services are provided that allows patients to obtain needed outpatient services for their psychiatric illness substance abuse or both closer to their city or county of residence.

"Substance abuse treatment services" are services provided to individuals for the prevention, diagnosis, treatment,] palliation of chemical dependency, that may include attendant medical and psychiatric complications of chemical dependency.

PART II.
Criteria and Standards.

12 VAC 5-290-20. Acceptability; channels for consumer participation.

Psychiatric and substance abuse providers should have programs of patient and family education regarding the nature of the patient's illness and ongoing needs and the patient and family's role in achieving treatment and rehabilitation objectives.

12 VAC 5-290-30. Accessibility; travel time; financial considerations.

A. Acute psychiatric, acute substance abuse treatment, and intermediate care substance abuse treatment services should be available within a maximum driving time, under normal conditions, of 60 minutes one-way for 95% of the population.

B. 1. Acute psychiatric, acute substance abuse treatment, and intermediate care substance abuse treatment services should be accessible to all patients in need of services without regard to their ability to pay or the payment source.

2. Existing and proposed acute psychiatric, acute substance abuse treatment, and intermediate care substance abuse treatment service providers should have established plans for the provision of services to indigent patients which include, at a minimum: (i) the number of unreimbursed patient days to be provided to indigent patients who are not Medicaid recipients; (ii) the number of Medicaid-reimbursed patient days to be provided (unless the existing or proposed facility is ineligible for Medicaid participation); (iii) the number of unreimbursed patient days to be provided to local community services boards; and (iv) 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. The definition of indigent person used in the indigent patient service plan should be consistent with the definition of charity care used by Virginia's Indigent Care Trust Fund.

3. Proposed acute psychiatric, acute substance abuse treatment, and intermediate care substance abuse treatment service providers should have formal agreements with community services boards in their identified service area which: (i) specify the number of charity care

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patient days which will be provided to the community service board; (ii) provide adequate mechanisms for the community services board to monitor compliance with charity care provisions; and (iii) provide for effective discharge planning for all patients (to include the return of patients to their place of origin/home state if other than Virginia).

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

12 VAC 5-290-40. Availability; treatment beds; combined need; intermediate care.

A. 1. The combined number of acute psychiatric and substance abuse treatment beds needed in a planning district with existing acute psychiatric or acute substance abuse treatment beds or both will be determined as follows:

$$[(UR * PROJ.POP.)/365]/.90$$

Where UR = the use rate of the planning district expressed as the average acute psychiatric and acute substance abuse 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.

2. No additional acute psychiatric or acute substance abuse treatment beds should be authorized for a planning district with existing acute psychiatric or acute substance abuse treatment beds or both if the existing inventory of such beds is greater than the need identified using the above methodology. For purposes of this methodology, no beds in facilities operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services shall be included in the inventory of psychiatric or substance abuse beds.

3. No additional acute psychiatric or acute substance abuse treatment beds should be authorized for a planning district in which the combined inventory of existing acute psychiatric and acute substance abuse treatment beds, exclusive of beds located in medical care facilities or medical care facility units of 20 or fewer beds, were utilized at an average annual occupancy of less than 85% in the most recently reported year.

4. No additional acute psychiatric or acute substance abuse treatment beds should be authorized as additions to existing facilities with more than 20 acute psychiatric or acute substance abuse treatment beds or both unless the average annual occupancy of those existing beds was 90% or higher in the most recently reported year.

5. No existing acute psychiatric or acute substance abuse treatment beds should be authorized to relocate 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 acute psychiatric or

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substance abuse treatment providers or both to continue to provide historic levels of service to Medicaid or other indigent patients.

6. The combined number of acute psychiatric and acute substance abuse treatment beds needed in a planning district without existing acute psychiatric or acute substance abuse treatment beds will be determined as follows:

$$[(UR * PROJ.POP.)/365]/OE$$

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

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; and

OE = an occupancy expectation of .90 if the projected average daily census for the planning district is greater than 20 and an occupancy expectation of .80 if the projected average daily census for the planning district is 20 or less.

7. Preference will be given to the development of needed acute psychiatric and substance abuse treatment beds through the conversion of unutilized general hospital beds. Preference will also be given to the development of needed acute psychiatric and substance abuse beds which demonstrate a willingness to accept persons under temporary detention orders (TDO) and those with specific contractual agreements for public/private partnerships to serve populations served by Community Services Boards.

B. 1. The number of intermediate care substance abuse treatment beds needed in a planning district with existing intermediate care substance abuse treatment beds will be determined as follows:

$$[(UR * PROJ.POP.)/365]/.90$$

Where UR = the use rate of the planning district expressed as the average intermediate care substance abuse 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.

2. No additional intermediate care substance abuse treatment beds should be authorized for a planning district with existing intermediate care substance abuse treatment beds if the existing inventory of such beds is greater than the need identified using the above methodology. For purposes of this methodology, no beds in facilities operated by DMHMRSAS will be included in the inventory of intermediate care substance abuse beds.

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3. No additional intermediate care substance abuse treatment beds should be authorized for a planning district in which the combined inventory of existing intermediate care substance abuse treatment beds, exclusive of beds located in medical care facility units of 20 or fewer beds, were utilized at an average annual occupancy of less than 85% in the most recently reported year.

4. No additional intermediate care substance abuse treatment beds should be authorized as additions to existing facilities with more than 20 intermediate care substance abuse treatment beds unless the average annual occupancy of those existing beds was 90% or higher in the most recently reported year.

5. No existing intermediate care substance abuse treatment beds should be authorized to relocate 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 treatment providers to continue to provide historic levels of service to indigent patients.

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

$$[(UR * PROJ.POP.)/365]/OE$$

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 treatment patient days per population reported for the most recent three year period;

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; and

OE = an occupancy expectation of .90 if the projected average daily census for the planning district is greater than 20 and an occupancy expectation of .80 if the projected average daily census for the planning district is 20 or less.

7. Preference will be given to the development of needed intermediate care substance abuse treatment beds through the conversion of unutilized general hospital beds.

12 VAC 5-290-50. Continuity; integration.

Psychiatric and substance abuse treatment services should be coordinated to insure linkages among all available levels and settings of service.

12 VAC 5-290-60. Cost and charges.

Preference will be given to applicants who can reasonably document that the costs of providing services and the charges for these services will be less than the average costs and

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charges for comparable services provided in the planning district or health planning region or both in which the project is to be located, consistent with the other standards of these chapters.

12 VAC 5-290-70. Quality; accreditation and compliance with chapters.

Psychiatric and substance abuse treatment providers should meet all applicable accreditation standards of the Joint Commission on the Accreditation of Healthcare Organizations and licensure standards of the Department of Mental Health, Mental Retardation, and Substance Abuse Services.

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Mental Retardation Services
12 VAC 5-300-10 through 70

PART I.
Definitions.

12 VAC 5-300-10. Definitions.

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

"Intermediate care facility/mental retardation (IFC/MR)" is a facility, licensed by the Department of Mental Health, Mental Retardation, and Substance Abuse Services (DMHMRSAS) in which care is provided to mentally retarded individuals who are not in need of skilled nursing care, but who need more intensive training and supervision than would be available in a rooming, boarding home, or group home; such facilities must comply with Title XIX standards, provide health or rehabilitative services, and provide active treatment to clients toward the achievement of a more independent level of functioning.

"Mental retardation facilities" are facilities which provide services to mentally retarded individuals. The only classification of mental retardation facility subject to certificate of public need (COPN) requirements is the intermediate care facility/mental retardation (ICF/MR).

PART II.
Criteria and Standards.

12 VAC 5-300-20. Accessibility; financial considerations.

Mental retardation facilities and services should be accessible to all patients in need of services without regard to their ability to pay or payment source.

12 VAC 5-300-30. Availability; need.

The establishment of new ICF/MR facilities should not be authorized unless the following conditions are met:

1. Alternatives to the service proposed to be provided by the new ICF/MR are not available in the area to be served by the new facility;
2. There is a documented source of resident referrals for the proposed new facility;
3. The applicant can identify the manner in which the proposed new facility fits into the continuum of care for the mentally retarded;

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4. There are distinct and unique geographic, socioeconomic, cultural, transportation, or other factors affecting access to care which 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 is consistent with the current 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 5-300-40. Continuity; integration.

A. Mental retardation facilities should be coordinated to insure linkages among all available levels and settings of service.

B. Each facility should have a written plan for cooperation with other public and private organizations, such as schools, social service agencies, and community service boards, to ensure that each resident under its care will receive comprehensive care.

C. 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 5-300-50. Quality.

Mental retardation facilities should meet all applicable licensure standards of the Department of Mental Health, Mental Retardation, and Substance Abuse Services.

12 VAC 5-300-60. Acceptability; size, channels for consumer; participation.

A. The maximum size of a proposed new ICF/MR should be four beds.

B. Mental retardation facilities should have programs of resident and family education regarding the nature of the resident's disability and ongoing needs and the resident's and family's role in achieving treatment plan objectives.

12 VAC 5-300-70. Cost and charges.

A. The total costs for providing mental retardation facility services should not significantly exceed the total costs of other similar service providers in the Commonwealth. In no case should the cost for Medicaid funded ICF/MRs exceed the cost of state operated

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ICF/MRs.

B. The charges established for the provision of mental retardation facility services should be commensurate with costs and should not significantly exceed the charges established by other similar service providers in the Commonwealth.

C. Preference will be given to applicants who can reasonably document that the costs of providing services and the charges for these services will be less than the average costs and charges for comparable services provided in the planning district or health planning region or both in which the project is to be located, consistent with the other standards of these chapters.

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Medical Rehabilitation Services
12 VAC 5-310-10 through 70

PART I.
Definitions.

12 VAC 5-310-10. Definitions.

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

"Comprehensive inpatient medical rehabilitation services" means medical rehabilitation services provided through inpatient departments of general acute care hospitals or through free-standing medical rehabilitation hospitals which are organized on an interdisciplinary basis to provide both inpatient and outpatient services for a range of physical disabilities. Only medical care facilities which are dedicated to comprehensive inpatient medical rehabilitation and are excluded, in their entirety, under the Medicare prospective payment system or medical care facilities which have distinct comprehensive inpatient medical rehabilitation units which are excluded under the Medicare prospective payment system are considered to provide comprehensive inpatient medical rehabilitation.

"Medical rehabilitation services" means services provided to individuals who are primarily physically disabled for the restoration of normal form and function after injury or illness. The objective of these restorative services is self-sufficiency and a return to suitable gainful employment in the shortest possible time or both. Medical rehabilitation services do not include services provided to individuals whose primary disability is psychiatric illness or substance abuse. However, medical rehabilitation services includes mental health services needed by individuals whose disability is primarily physical in nature. The medical rehabilitation services subject to certificate of public need review are comprehensive inpatient medical rehabilitation services and specialized inpatient medical rehabilitation.

"Specialized inpatient medical rehabilitation services" means medical rehabilitation services provided through inpatient departments of general acute care hospitals or through free-standing medical rehabilitation hospitals which are organized on an interdisciplinary basis to: (i) provide both inpatient and outpatient services to a specific category of physically disabled patients, such as spinal cord injured or brain injured patients, or (ii) provide a specialized category of inpatient and outpatient rehabilitation services, such as chronic pain management. Only medical care facilities which are dedicated to specialized inpatient medical rehabilitation and are excluded, in their entirety, under the Medicare prospective payment system or medical care facilities which have distinct specialized inpatient medical rehabilitation units which are excluded under the Medicare prospective payment system are considered to provide specialized inpatient

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medical rehabilitation.

PART II.
Criteria and Standards.

12 VAC 5-310-20. Acceptability; channels of consumer participation.

Medical rehabilitation services should have programs of patient and family education regarding the nature of the patient's rehabilitation prognosis and ongoing needs and the patient and family's role in achieving rehabilitation objectives.

12 VAC 5-310-30. Accessibility; travel time; financial considerations.

A. Comprehensive inpatient rehabilitation services should be available within a maximum driving time, under normal conditions, of 60 minutes for 95% of the population.

B. Medical rehabilitation services should be accessible to all patients in need of services without regard to their ability to pay.

C. Providers of comprehensive medical rehabilitation services should facilitate access to outpatient medical rehabilitation services for discharged patients residing in remote or rural areas, directly or through the establishment of referral links with general hospitals or other appropriate organizations.

12 VAC 5-310-40. Availability; need.

The number of comprehensive and specialized rehabilitation beds needed in a health planning region will be projected as follows:

$$[(UR * PROJ. POP.)/365]/.85$$

Where UR = the use rate expressed as rehabilitation patient days per population in the health planning region as reported in the most recent published Beds and Utilization annual report of the Virginia Center for Health Statistics; and

PROJ.POP. = the most recent projected population of the health planning region three years from the current year as published by the Virginia Employment Commission.

No additional rehabilitation beds should 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 recent reported year.

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Preference will be given to the development of needed rehabilitation beds through the conversion of unutilized hospital beds.

The need for proposed specialized inpatient rehabilitation services will be given consideration beyond the formulated need standard when: (i) the rehabilitation specialty proposed is not currently offered in the health planning region; and (ii) a reasonably documented basis for recognizing a need for the service is provided by the applicant.

12 VAC 5-310-50. Continuity; integration.

Medical rehabilitation services should be coordinated to insure linkages among all available levels and settings of rehabilitation service.

12 VAC 5-310-60. Cost.

The total costs for providing medical rehabilitation services should not significantly exceed the total costs of other comparable service providers in the Commonwealth.

12 VAC 5-310-70. Quality; staffing and services.

A. Medical rehabilitation facilities should provide the following staff categories:

1. Full-time medical direction by a physiatrist or other physician with a minimum of two years of experience in a comprehensive or specialized inpatient medical rehabilitation program;
2. Intensive skilled rehabilitation nursing care with nursing supervision provided by a nurse with a minimum of two years of experience in a comprehensive or specialized inpatient medical rehabilitation program;
3. Physical therapy;
4. Occupational therapy;
5. Speech/language pathology;
6. Psychology;
7. Social services counseling; and
8. Discharge planning.

B. Medical rehabilitation facilities shall provide or make formal arrangements for the provision of the following services, as appropriate:

1. Audiology;
2. Drivers education;
3. Orthotics;
4. Prosthetics;

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5. Rehabilitation engineering;
6. Respiratory therapy;
7. Therapeutic recreation; and
8. Vocational rehabilitation.

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Diagnostic Imaging Services
12 VAC 5-320-10 through 480

PART I.
Definitions.

12 VAC 5-320-10. Definitions.

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

"Board certified diagnostic radiologist" means a physician certified by the American Board of Radiology, in diagnostic radiology or in diagnostic radiology with special competence in nuclear radiology.

"Body study" means a study of a part of the body other than the head.

"Computed tomography (CT)" means the construction of images through the detection and computer analysis of numerous X-ray beams directed through a part of the body.

"Contrast" or "contrast medium" means a substance that is strongly imaged and that, when ingested by or injected into a patient, increases the difference in image brightness between parts of the patient's body containing the substance and those where it is absent.

"Cyclotron" means a nuclear accelerator which is used to generate the radiopharmaceuticals which are injected into the patient so that computerized images can be generated through the use of a PET scanner to provide physiological and biochemical information about the patient. Cyclotrons are of two types: positive ion and negative ion.

"Department" means the Virginia Department of Health (VDH).

"Dual study" means a study consisting of two parts: one with contrast and the other without.

"Head equivalent computed tomogram (HECT)" means a relative workload value for CT studies where: a head study without contrast equals 1.00, a head study with contrast equals 1.25, a dual head study equals 1.75, a body study without contrast equals 1.50, a body study with contrast equals 1.75; and a dual body study equals 2.75.

"Head study" means a study of the head.

"HECTs attributable to current patient mix" means 1.45 times the following sum: 3.03 times the

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number of patients with a principal diagnosis involving neoplasms (ICD-9-CM codes 140-239), plus 3.00 times the number of patients with a principal diagnosis involving cerebrovascular disease (ICD-9-CM codes 430-438), plus 1.35 times the number of patients with a principal diagnosis involving other diseases of the digestive system (ICD-9-CM codes 570-579), plus 1.23 times the number of patients with a principal diagnosis involving dorsopathies (ICD-9-CM codes 720-724). All such patients in these categories shall have been discharged by the applicant during the most recent 12-month reporting period.

"Hospital" means an institution licensed by the department as a general, community, or special hospital but does not include those facilities licensed as freestanding ambulatory surgery centers.

"Hospital-based" means operating physically within or connected to a hospital, or legally associated with or physically associated with one or more hospitals.

"Magnetic resonance imaging (MRI)" means the construction of images through the detection and computer analysis of minute changes in magnetic properties of atomic particles within a strong magnetic field in response to the transmission of selected radiofrequency pulse sequences. Magnetic resonance imaging uses the magnetic spin properties of certain atomic nuclei to visualize and analyze body tissues.

"Magnetic resonance spectroscopy" means the use of the magnetic spin properties of certain atomic nuclei to perform chemical analyses of tissues.

"Mobile" means periodically relocated among more than one site of operation.

"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) or 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). All such patients in these categories shall have been discharged by the applicant during the most recent 12-month reporting period.

"Network" means a group of institutions sharing an MRI or CT scanning unit.

"Nuclear medicine imaging service" means the provision of nuclear medicine imaging

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capabilities at a site at which one or more single or multi-head Anger camera devices are available.

"Nuclear medicine procedure" means a complete examination involving one or more imaging procedures which are billed as a unit using one CPT-4 code.

"PET study or scan" means the gathering of data during a single patient visit from which one or more images may be constructed of a single anatomical region of the patient's body.

"PET system" means a PET service which includes two major elements: a cyclotron which produces the radiopharmaceuticals, and a PET scanner which includes a data acquisition system and a computer.

"Physician" means a person licensed by the Virginia State Board of Medicine to practice medicine or osteopathy.

"Positron emission tomography" or "PET" means a non-invasive diagnostic technology which enables the body's physiological and biochemical processes to be observed through the use of positron emitting radiopharmaceuticals which are injected into the body and whose interaction with body tissues and organs is able to be pictured through a computerized positron transaxial reconstruction tomography scanner. The radiopharmaceuticals are positron emitting isotopes which usually include carbon-11, oxygen-15, nitrogen-13, and fluorine-18 (i.e., fluorine deoxyglucose or FDG).

"Relevant reporting period" means the most recent 12-month period, prior to the beginning of the certificate of public need application's review cycle, for which data are available and acceptable to the department.

"Single photon emission computed tomography" or "SPECT" means a non-invasive diagnostic technique involving the injection or ingestion of a single-photon emitting radionuclide, prepared as a radiopharmaceutical, which is imaged at 180 to 360 degrees by a single or multiple crystal detector which detects the emitted gamma rays; the instrument, with the aid of a computer, creates 3-dimensional images from the data, displaying them as transaxial slices, as angled slices, as a 3-dimensional image, or as a functional image of the contained information.

Currently, there are SPECT instruments available using one, two, three, or four Anger single-crystal camera devices (often called "heads") or using an array of multiple-crystal detectors. Some of these devices are intended for a particular part of the human anatomy, such as the head or the heart, while others are more versatile by virtue of an expanding diameter of rotation. Many of these instruments are created for multiple purposes, such as SPECT and planar whole body bone imaging, and all of them will permit planar imaging.

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Clinically SPECT appears to be most useful for the study of cardiovascular disease, bone imaging, and disorders of the brain such as cerebrovascular disease, epilepsy, and dementia. There is a general trend in nuclear medicine today to use Tc-99m for as many of the examinations as possible because of its ready on-site availability from a generator, the lack of waste because of decay of unused doses, and the adaptation of the Anger camera instruments to the gamma-ray energy of Tc-99m.

It should be noted that SPECT is the only instrument being used in certain kinds of imaging: cardiac imaging with Tc-99m sestamibi and Tc-99m teboroxime, brain perfusion studies performed with Tc-99m HMPAO, liver hemangioma studies performed with Tc-99m labeled red cells and tumor imaging in the head, abdomen, and pelvis for comparison with CT and MRI anatomic images. Since SPECT technology does not require a cyclotron to produce radiopharmaceuticals, this technology is substantially less expensive than a complete PET system.

"SPECT procedure" means a complete examination involving one or more SPECT rotations, and perhaps some planar imaging, which is billed as a unit using one CPT-4 code.

"SPECT rotation" means one pass of the SPECT instrument around the patient leading to a single set of transaxial images and the possible formation of 3-dimensional images from other angles than transaxial.

"SPECT service" means the provision of SPECT scanning capabilities at a site at which one or more single or multi-head SPECT scanners are available.

"SPECT study or scan" means the gathering of data during a single patient visit from which one or more images may be constructed of a single anatomical region of the patient's body.

"Study" or "scan" means the gathering of data during a single patient visit from which one or more images may be constructed of a single anatomical region for the purpose of reaching a definitive clinical diagnosis.

"Under development" means currently authorized through the state's certificate of public need program but not yet operational, or exempted by the Commissioner of Health per provisions of §32.1-102.11 of the Code of Virginia.

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PART II.
Criteria and Standards for Computed Tomography (CT).

Article 1.
Acceptability.

12 VAC 5-320-20. Consumer acceptance of services offered.

The patient or his family or both should be fully informed and involved in decision making regarding CT service and diagnostic information that is being provided.

Article 2.
Accessibility.

12 VAC 5-320-30. Location.

A. CT services should be within 30 minutes driving time, under normal conditions, of 95% of the population.

B. Preference will be given to CT service proposals located at a general hospital.

12 VAC 5-320-40. Financial considerations; ability to pay.

CT services should be accessible to all patients in need of such services without regard to their ability to pay or the payment source.

Article 3.
Availability.

12 VAC 5-320-50. Need for new service.

A. Preference will be given to proposals involving the provision of full-body CT scanning rather than units which can perform only CT head scans.

B. No CT service should be approved at a site which is within 30 minutes driving time of: (i) a COPN approved or exempted CT service that is not yet operational; or (ii) an existing CT unit that has performed fewer than 3,500 HECTs or 3,000 combined CT head and body scans during the relevant reporting period.

C. A proposed new CT service may be approved if: (i) in the case of a proposed stationary, hospital-based service, the applicant provides diagnostic-specific hospital discharge

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data for the relevant reporting period that is acceptable to the department which demonstrates that the HECTs attributable to the patient mix of the hospital where the proposed CT is to be located equates to at least 3,500 HECTs; or (ii) in the case of a proposed non-hospital based service, the applicant demonstrates that the number of outpatient studies performed by other CT services on the applicant's patients during the relevant reporting period is at least 3,500 HECTs or 3,000 combined CT head and body scans.

Consideration will be given to approval of CT services that project fewer than 3,500 HECTs or 3,000 combined CT head and body scans when such services are proposed for sites located beyond 30 minutes driving time of any existing CT facilities.

D. No new, non-hospital-based CT service or network may be approved unless all existing CT services or networks in the planning district, whether hospital-based, non-hospital-based, mobile or fixed, performed an average of at least 5,000 HECTs or 4,500 combined CT head and body scans per machine during the relevant reporting period.

12 VAC 5-320-60. Expansion of existing service.

Proposals to increase the number of CT scanners in an existing hospital-based CT system or network may be approved only if the existing service or network performed an average of at least 5,000 HECTs per existing fixed or mobile scanner in the system or 4,500 combined CT head and body scans for the relevant reporting period.

12 VAC 5-320-70. Replacement of existing equipment.

A. Proposals to replace equipment for CT services may be approved if the unit has been in operation for at least five consecutive years and the unit performed at least 5,000 HECTS or 4,500 combined CT head and body scans for the relevant reporting period.

B. Notwithstanding subsection A of this section, consideration will be given to proposals to replace equipment which has been in operation for less than five consecutive years or has been utilized to perform less than 5,000 HECTs or 4,500 combined CT head and body scans if the applicant can reasonably demonstrate that such replacement is in substantial compliance with these standards, and that such replacement is necessary to achieve comparability and competitiveness with existing providers of CT services in the planning district where the replacement is proposed, and the applicant can demonstrate that the equipment to be replaced was fully utilized, given the type of equipment, the mode of service, or the area served, for the relevant reporting period. Such replacement will not qualify for expedited review under Part VI of the Virginia Medical Care Facilities COPN Rules and Regulations (12VAC5-220-10 et seq.).

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**Article 4.
Continuity of Care.**

12 VAC 5-320-80. Coordination of service.

Providers of CT services should provide courtesy privileges to qualified physicians for use by their patients who are expected to be treated on an outpatient basis.

**Article 5.
Cost.**

12 VAC 5-320-90. Cost and charges.

The total costs (direct and indirect) for providing CT services should be comparable to other similar service providers in the planning district.

**Article 6.
Quality.**

12 VAC 5-320-100. Staffing.

A. Providers of CT services should be under the direct, on-site supervision of one or more physicians with documented formal training in the production and interpretation of cross-sectional computed tomography images.

B. CT services should be staffed by qualified and experienced technologists consistent with the types and volumes of computer tomography services offered.

12 VAC 5-320-110. Space.

A. Applicants for certificates of public need should document to the satisfaction of the department that (i) an appropriate environment will be provided for the proposed CT services, including protection against radiant energy and other known hazards; and (ii) adequate 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.

B. Applicants for certificates of public need should document to the satisfaction of the department that the proposed CT service's physical relationship to the applicant's other diagnostic imaging services will be logical and practical with respect to transportation and staff activity patterns.

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PART III.
Criteria and Standards for Magnetic Resonance Imaging (MRI).

Article 1.
Acceptability.

12 VAC 5-320-120. Consumer acceptance of services offered.

The patient or his family or both should be fully informed and involved in decision making regarding MRI service and diagnostic information that is being provided.

Article 2.
Accessibility.

12 VAC 5-320-130. Location.

A. MRI services should be within 45 minutes driving time, under normal conditions, of 95% of the population.

B. Preference will be given to MRI service proposals involving provision of services within a general hospital.

12 VAC 5-320-140. Financial.

MRI services should be accessible to all patients in need of such services without regard to their ability to pay or the payment source.

Article 3.
Availability.

12 VAC 5-320-150. Need for new service.

A. Preference will be given to applications that intend to provide hospital-based MRI services.

B. No MRI service should be approved at a site that is within 45 minutes driving time of: (i) a COPN approved or exempted MRI service that is not yet operational; or (ii) an existing MRI service that has performed fewer than 3,500 MRI scans or at least 3,000 MRI scans excluding those performed on behalf of the applicant during the relevant reporting period.

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Consideration will be given to approval of proposed MRI services that project less than full utilization of MRI equipment when such services are proposed for sites located beyond 45 minutes driving time of any existing MRI facilities.

12 VAC 5-320-160. Alternative need for new MRI service.

A. Notwithstanding 12VAC5-320-150, consideration will be given to proposals that are hospital based and can reasonably demonstrate that for the relevant reporting period: (i) the number of MRI relevant patients among all Virginia hospitals committed to use the proposed MRI service exceeds 1,600; (ii) at least 4,000 HECTs or a combined 3,000 head and body CT scans were performed during the relevant reporting period on patients from each hospital committed to use the proposed MRI service; and (iii) the proposed MRI service will be under the operational control of at least one hospital with at least 800 MRI relevant patients for the relevant reporting period.

B. In the case of proposals for nonhospital-based MRI services, the applicant must reasonably demonstrate, using data available and acceptable to the department, that at least 4,000 HECTs or a combined total of at least 3,000 head and body CT scans were performed on patients referred by the applicant to other providers of CT services during the relevant reporting period.

12 VAC 5-320-170. Expansion of services.

Proposals to expand existing MRI services through the addition of a new scanning unit may be approved if (i) the existing service performed at least 4,000 scans per existing unit during the relevant reporting period, and (ii) the average utilization of all existing MRI units in the planning district was at least 4,000 for the relevant reporting period.

12 VAC 5-320-180. Mobile services.

Consideration shall be given to proposals for new MRI units to be operated at more than one site if the applicant demonstrates that, compared with a single MRI unit located at a hospital or freestanding site relatively central to the proposed service location, the proposed mobile arrangement would serve the target population more efficiently and effectively overall in terms of the following factors:

1. Travel time from a majority of the proposed sites to a centrally located fixed or hospital-based unit exceeds 45 minutes;
2. Improved geographic access for the population outweighs the clinical advantages of providing the MRI service at a hospital or freestanding fixed site, which could handle higher Tesla strength and more sophisticated hardware and software; and
3. Based upon the number of MRI relevant patients who would have originated from each

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of the proposed sites for the relevant reporting period, that the total costs resulting from otherwise unnecessary extended lengths of stay for inpatients awaiting MRI services would have been shorter if the mobile service had been available at each of the proposed sites 2.5 days per week than the total costs which would have been incurred had those patients been transferred to the closest available fixed MRI location.

12 VAC 5-320-190. Replacement of existing equipment.

A. Proposals to replace equipment for the provision of MRI services may be approved if the service has been in operation for at least five consecutive years and the unit being replaced or upgraded performed at least 4,000 scans during the relevant reporting period.

B. Notwithstanding subsection A of this section, consideration will be given to proposals to replace MRI equipment which has been in operation for less than five consecutive years or has been utilized to perform less than 4,000 scans if the applicant can reasonably demonstrate that such replacement is in substantial compliance with these standards, and that such replacement is necessary to achieve comparability and competitiveness with existing providers of MRI services in the planning district where the replacement is proposed and the applicant can demonstrate that the equipment to be replaced was fully utilized, given the type of equipment, the mode of service, or the area served, for the relevant reporting period. Such replacement will not qualify for expedited review under Part VI of the Virginia Medical Care Facilities COPN Rules and Regulations (12VAC5-220-10 et seq.).

**Article 4.
Continuity of Care.**

12 VAC 5-320-200. Coordination of service.

Providers of MRI services should provide courtesy privileges to qualified physicians for use for their patients who are expected to be treated on an outpatient basis.

**Article 5.
Cost.**

12 VAC 5-320-210. Cost.

The total costs (direct and indirect) for providing MRI services should be comparable to other similar service providers in the planning district.

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**Article 6.
Quality.**

12 VAC 5-320-220. Staffing.

A. Providers of MRI services should provide assurances and a description of the proposed operating arrangement which shows that the production and interpretation of all images made by MRI machines will be under the direct, on-site control and supervision of one or more board certified diagnostic radiologists with training and experience in the interpretation of CT images, who have at least 60 hours of documented instruction in magnetic resonance imaging physics, instrumentation and the interpretation and clinical application of MRI images prior to the initiation of the service. This standard does not preclude the involvement of other staff judged qualified by an appropriate governing board.

B. MRI services should be staffed by technologists qualified and experienced in the operation and maintenance of MRI equipment during all hours of operation of the MRI service.

12 VAC 5-320-230. Space.

A. Applicants for certificates of public need should document to the satisfaction of the department (i) that an appropriate environment will be provided for the proposed MRI services, including protection against radiant energy and other known hazards; (ii) that adequate 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.

B. Applicants for certificates of public need should document to the satisfaction of the department that the proposed MRI service's physical relationship to the applicant's other diagnostic imaging services will be logical and practical with respect to transportation and staff activity patterns.

**PART IV.
Magnetic Resource Imaging (MSI).**

12 VAC 5-320-240. 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 appropriate for widespread use and distribution on a cost-effective basis, it is the policy of the Commonwealth of Virginia that the entry and development of this technology in the

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state should initially occur at, or in affiliation with, the academic medical centers in the state. Regional consortiums of hospitals in affiliation with academic medical centers could also be one possible approach to the initial distribution of this technology in the Commonwealth.

12 VAC 5-320-250. Potential clinical applications of MSI technology.

Magnetic Source Imaging (MSI) is quite different from conventional imaging and electro-diagnostic techniques. Specifically, while computerized tomography (CT) scanning and magnetic resonance imaging (MRI) generally provide anatomical information, which is to say information about physiological structure, they cannot provide specific information about physiological function. Conversely, the nuclear medicine technologies of single-photon emission computed tomography (SPECT) and positron emission tomography (PET) are both used to study function (though SPECT can apparently be used to clarify the relationship between anatomical structures in some instances), but the information provided by these two technologies is biochemical in nature rather than bioelectrical in nature. Both SPECT and PET scanning require that radioisotopes be injected or ingested into the patient in order to perform the study.

Traditionally, the nuclear technique for measuring bioelectrical activity of the brain has been electroencephalography (EEG), and the technique for measuring bioelectrical activity in the heart has been electrocardiography (ECG). Both EEG and ECG have the virtue that they can provide good temporal resolution, which is to say that they can measure bioelectrical activity that occurs in milliseconds. However, both techniques generally have poor spatial (locational) resolution since the surface electrodes used for EEGs and ECGs, when placed on the patient's body surface, record only a general view of the brain and heart. This is because the detected bioelectrical currents are substantially distorted by the tissues that intervene between the bioelectrical current sources and the recording electrodes. The only way the spatial resolution problems of EEG and ECG can be overcome is to have the electrodes surgically implanted in the patient with direct contact to brain or heart tissue. Such implantations put the patient at some risk and are quite costly.

In contrast, both the SPECT and PET technologies have the advantage of providing good spatial resolution, though PET seems to be superior in this regard, but they are weak in terms of temporal resolution. Moreover, as noted, both of these technologies provide biochemical rather than bioelectrical information.

It is believed that MSI will ultimately play as large a role in the diagnosis and treatment of patients with functional disease as CT and MRI now play in the management of patients with pathologies that disrupt normal physiological structure. Where CT and MRI are quite helpful in facilitating diagnoses as well as assessing treatment responses to pathologies that leave structural lesions, MSI's potential clinical usefulness lies in its ability to noninvasively image diseases that cannot be visualized by anatomic imaging methods.

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Thus, the MSI technology can potentially provide noninvasively similar, if not better information than can be gained by EEG and ECG only when electrodes are surgically implanted in heart or brain tissue at some risk to the patient. The literature suggests that, with the relatively recent development of MSI units with expanded arrays of magnetic signal detectors or channels (presently the most sophisticated units have 37 detectors), it is possible to get both excellent temporal resolution (in terms of milliseconds) and excellent spatial resolution (in terms of millimeters) without the problem of surgical intervention.

Consequently, MSI appears to have the potential clinical ability to assess the extent and type of neural damage resulting from a stroke, and such information can be helpful in estimating a patient's potential for recovery from the stroke. Also, MSI may be a way to confirm the occurrence of a transient ischemic attack (TIA) which is often the first warning sign of a stroke.

Another very important potential of MSI is providing presurgical functional brain mapping which could help neurosurgeons to avoid damaging vital regions of the brain during tumor or lesion surgery. Presently, brain mapping occurs during the course of the surgery itself, and this prolongs the surgery which adds both to the patient's risk and to the surgery's cost. In this regard, a good deal of the neurological work that has been done with MSI has apparently focused on the evaluation of patients with medically intractable epilepsy since, by being able to locate regions of epileptogenic tissue, valuable information is gained which can be helpful in determining if surgical treatment is feasible. Notably, a major potential of PET technology is also in the area of partial complex epilepsy and being able to locate lesions for surgical intervention.

In the area of cardiology, MSI potentially can locate noninvasively and quickly the site of arrhythmogenic tissue in the heart at an accuracy level which could enable surgical intervention to remove the tissue. Such intervention might be through open heart surgery or catheter ablation. This potential of MSI is important because national data indicate that approximately two-thirds of all sudden cardiac deaths are caused by arrhythmias rather than by coronary occlusions. Historically, PTCA (percutaneous transluminal coronary angioplasty) and CABG (coronary artery bypass graft surgery) have been used to rectify occluded coronary artery problems that have either been detected/located prior to a myocardial infarction through cardiac catheterization or are the result of, and in response to, a myocardial infarction.

National data indicate that many of those who survive myocardial infarctions each year are left with disturbances in electrical condition in the heart tissue and are, consequently, at risk of sudden cardiac death caused by cardiac arrhythmias. Where the PET technology can be used to determine the size and extent of an infarction and the extent of tissue damage around the area of the infarction, as well as to distinguish viable from nonviable tissue, only MSI can noninvasively determine if disturbances in electrical conduction in heart tissue have occurred.

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Additionally, MSI may also potentially be clinically useful in monitoring incipient rejection of a transplanted heart on a noninvasive basis. Preliminary tests seem to indicate that MSI procedures are at least as sensitive as the standard biopsy method used presently for this purpose. Notably, PET scanning can also be potentially helpful in evaluating metabolism in transplanted organs which can indicate selective rejection of tissue.

12 VAC 5-320-260. MSI technology described.

MSI relies on ultra-sensitive, low-noise amplifiers called SQUIDS (superconducting quantum interference devices) to detect changes in the minute magnetic fields associated with nerve activity in the body. Processes that force ions to flow across an electrically charged membrane are essential to the normal functioning of the brain, heart, and neuromuscular systems. Consequently, disorders of these organs affect their electrical activity, and detection of these changes in electrical activity can often be detected and amplified so that they can provide diagnostic information for potential treatment of the patient.

Apparently, the development of the very sophisticated 37 detector MSI units has enabled MSI to move from a basic research tool to a clinical research tool. Earlier MSI studies which used units with fewer detectors resulted in exams sometimes lasting as long as two to three hours which was too long to be suitable for many patients. With the 37 detector units recording simultaneously from an area of 20 centimeters in diameter, the new sophisticated systems can apparently gather enough data to complete an exam in less than 10 minutes.

The temporal resolution problems experienced by both SPECT and PET scanning technologies, noted earlier, are perhaps best understood when it is remembered that most brain processes occur in a one to ten millisecond time frame. Thus, even with a one minute PET acquisition, much brain activity can be obscured. In other words, the temporal resolution problem limits the sensitivity of SPECT and PET scanning for detecting abnormalities that are bracketed by normal activity and last for only short periods of time.

Notably, because the magnetic fields being measured are so small, the major engineering requirement for MSI units has been to screen out noise in the forms of both magnetic and radio-frequency interference. Thus, the instruments are constructed using nonmagnetic materials and isolated in shielded rooms. MSI units are basically built using the same principles required to contain the strong magnetic fields needed for MRI scanners. Thus, about half the cost for MSI systems comes from building the shielded rooms. Moreover, the entire assembly must be built on an isolated foundation so that the measured signals remain undisturbed by building vibrations.

One article describes the MSI scanning process as follows:

"Both the SQUIDS and the magnetic field sensors (gradiometers) they monitor must be

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immersed in liquid helium within a cylindrical, thermally isolated cryogenic container called a dewar. During an exam, the patient lies on a table and the sensor end of the dewar is brought within a few millimeters of the heart or body. The gradiometers then transmit the magnetic signals they detect to the SQUIDS which then convert the magnetic signals into corresponding electrical ones. Following amplification, filtering, and digitizing, computer processing of the SQUID electrical signals results in raw data that appear similar to those obtained by EEG and ECG. Further processing produces topographic "field maps" of the distribution and time evolution of the nerve activity being examined. The MSI information can also be superimposed on anatomic images such as those obtained by MRI." (Source: Diagnostic Imaging, March 1990, p. 131.)

Finally, the literature indicates that the cost for the 37 detector MSI units is presently in the \$2-3 million range and that less than 10 MSI units of all types are located at facilities within the United States. Units are also presently located in Japan and Germany. Additionally, it is anticipated that, as with other technologies such as MRI, PET, SPECT, and CT, the capital costs associated with MSI units will decrease as the technology evolves and distribution of the units becomes more widespread.

(Note: Source for all information contained in 12VAC5-320-250 and 12VAC5-320-260 were articles which appeared in Diagnostic Imaging, January 1991, pp. A74-76; Diagnostic Imaging, March 1990, pp. 124-132; and information provided by Biomagnetic Technologies, Inc., of San Diego, CA.)

PART V.

Criteria and Standards for Positron Emission tomography (PET).

Article 1.

Acceptability.

12 VAC 5-320-270. Consumer acceptance of services offered.

The patient or his family or both should be fully informed and involved in decision making regarding the service.

Article 2.

Accessibility.

12 VAC 5-320-280. Service area.

The service area for each proposed PET service should be either an entire regional health planning area designated by the state, or an area with a population of at least 1.5 million people.

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12 VAC 5-320-290. Hours of operation.

The PET service should be available for clinical operation at least eight hours a day, five days a week.

12 VAC 5-320-300. Location of service.

A. The PET service should be located, if possible, at a site which would allow the shortest driving time and distance one way for approximately 75% of the service area's population.

B. Preference will be given to a proposed PET service which is jointly owned and operated by a consortium of hospitals in the regional health planning area and which is located at a general or community hospital which also provides a full range of tertiary services.

**Article 3.
Availability.**

12 VAC 5-320-310. Service capacity.

At least 1,500 PET scans should be performed annually by a single-scanner PET service.

12 VAC 5-320-320. Projecting demand for service.

A. If the applicant for a proposed new PET service is a consortium of hospitals, the applicant shall provide on a hospital-specific basis documentation satisfactory to the department which indicates that the sum of thallium stress tests performed by the hospitals in the consortium for the most relevant reporting period was at least equal to 28% of the total number of inpatient and outpatient nuclear medicine procedures reported by all of the hospitals in the consortium for that same period, and that 50% of that number would be equivalent to at least 1,500 PET scans annually.

B. If the applicant for a proposed new PET service is an individual hospital, the applicant shall provide documentation satisfactory to the department which indicates that the total number of thallium stress tests performed by the hospital for the most relevant reporting period was at least equivalent to 28% of the total number of inpatient and outpatient nuclear medicine procedures reported by the hospital for that same period, and that 50% of that number would be equivalent to at least 1,500 PET scans annually. The hospital shall also provide open heart surgery services and document that for the most relevant reporting period its per room volume of open heart surgery services complies with standards and criteria specified in the Cardiac Services section of the State Medical Facilities Plan (12VAC5-260-10 et seq.).

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12 VAC 5-320-330. Minimum utilization.

The applicant shall provide documentation satisfactory to the department that it can achieve a minimum utilization level of 900 PET scans in the first 12 months of operation of the service, of 1,200 PET scans in the second 12 months of operation of the service, and of 1,500 PET scans in the third 12 months of operation of the service.

12 VAC 5-320-340. Additional scanners.

No additional PET scanner shall be allowed to be added in a regional health planning area or in a service area having at least 1.5 million people until such time as it is demonstrated that the utilization of the existing single-scanner PET service was at least 1,500 PET scans for the most relevant reporting year and that the proposed new service would not reduce the utilization of the existing service below 1,500 PET scans per year. The applicant shall also provide documentation satisfactory to the department that it complies with 12VAC5-320-310 and 12VAC5-320-320.

12 VAC 5-320-350. Replacement of service.

An application to replace or upgrade an existing PET service may be approved when the hardware/software for the existing PET service has been in operation for at least five consecutive years. However, if the proposed replacement or upgrade would also add a new service capability or application that the existing PET service has not provided in the past, then the department may determine that such a replacement or upgrade constitutes the addition of a new service and that the application shall be reviewed as a proposed new service.

**Article 4.
Continuity.**

12 VAC 5-320-360. Coordination of services.

A. In order to facilitate close multi-hospital coordination and close interdisciplinary cooperation, preference in review of applications for a proposed new PET service will be given to applications which are consortiums of hospitals located within a designated regional health planning area.

B. If an applicant for a proposed new PET service is a single hospital, that hospital should provide documentation for the most relevant reporting period that it has provided open heart surgery services at a utilization level consistent with the criteria and standards stated in the Cardiac Services section of the State Medical Facilities Plan (12VAC5-260-10 et seq.).

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C. If an applicant for a proposed new PET service is a single hospital, that hospital should provide documentation that referral arrangements exist with other hospitals and physicians to receive referrals for patients who potentially could benefit from PET scanning services, particularly those patients who are either nonemergent candidates for open heart surgery or PTCA procedures and those patients with a diagnosis of partial complex epilepsy for whom surgical intervention is being considered.

Article 5.
Cost.

12 VAC 5-320-370. Less costly alternatives.

A. Any individual hospital that is an applicant for a proposed new PET service should provide documentation satisfactory to the department that shared service arrangements, such as consortiums with other area hospitals, have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality.

B. Any individual hospital or consortium of hospitals in a regional health planning area that is an applicant for a proposed new PET service should provide documentation that other lower cost technology alternatives to PET scanning, such as SPECT scanning, have been investigated and found to be less advantageous in terms of accessibility, availability, continuity, cost and quality.

12 VAC 5-320-380. Financial access.

Any applicant for proposed new PET service should provide documentation that the services shall be accessible to all patients in need of service regardless of the ability to pay or payment source.

Article 6.
Quality.

12 VAC 5-320-390. Staffing.

A. A proposed new PET service should be under the medical direction of a physician who is board certified in nuclear medicine or nuclear radiology or trained and licensed in nuclear cardiology and has additional documented experience and training in PET technology including radiochemistry. Such physician should be licensed by the Nuclear Regulatory Commission to possess radiopharmaceuticals and perform diagnostic procedures employing radiopharmaceuticals in human beings.

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B. Additional staff for a proposed new clinical PET service should include at a minimum the following staff:

1. A radiochemist trained at the master's or Ph.D. level in radiochemistry or radiopharmacy who also has a background in PET physics or radiochemistry and experience in radiopharmaceutical production.
2. A nuclear medicine technologist with training on-site or off-site in cyclotron operation and radiopharmaceutical production, and who will work under direction and supervision of the medical director.
3. Two radiological technologists with documented training in radiology, nuclear medicine, or MRI/CT scanning and who are able to provide support in the areas of PET imaging system operation, patient preparation for PET studies, and image analysis and processing.
4. Such administrative staff as shall be necessary to handle billing and other clerical functions.

PART VI.

Single Photon emission Computed Tomography (SPECT).

**Article 1.
Acceptability.**

12 VAC 5-320-400. Consumer acceptance of services offered.

The patient or his family or both should be fully informed and involved in decision making regarding the service and specifically the type of diagnostic information which is being provided.

**Article 2.
Accessibility.**

12 VAC 5-320-410. Location.

A. SPECT services should be available within 45 minutes driving time, under normal driving conditions, of 95% of the population.

B. Preference will be given to SPECT service proposals involving provision of service within a general hospital.

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12 VAC 5-320-420. Financial considerations; ability to pay.

SPECT scanning services should be accessible to all persons in need of such services without regard to their ability to pay or the payment source.

**Article 3.
Availability.**

12 VAC 5-320-430. Introduction of SPECT as a new service.

Any applicant establishing a specialized center, clinic, or portion of a physician's office for the provision of SPECT or introducing SPECT as a new service at an existing medical care facility which has not previously provided nuclear medicine imaging services should provide documentation satisfactory to the department that it can achieve a minimum utilization level of 650 SPECT scans in the first 12 months of operation of the service, and 1,000 such procedures in the second 12 months of services if the imaging unit would be a single-head device; or that it can achieve a minimum utilization level of 1,000 SPECT scans in the first 12 months of operation of the service, 1,250 such procedures in the second 12 months of operation, and 1,500 such procedures in the third 12 months of operation if the imaging unit would be a multi-head device.

Consideration will be given to the approval of proposed nuclear medicine imaging services that project utilization below that outlined in the preceding paragraph when such services are proposed for sites located beyond 45 minutes driving time of any existing nuclear medicine imaging facilities.

12 VAC 5-320-440. Additional scanners.

No additional nuclear medicine imaging systems should be added to an existing SPECT service until the utilization of the applicant's existing imaging unit(s) for the relevant reporting period is equivalent to at least 1,000 SPECT procedures per unit per year for a single-head scanning unit and 1,500 SPECT procedures per year per unit for a multi-head scanning unit.

12 VAC 5-320-450. Replacement of existing equipment.

A. An application to replace equipment for the provision of SPECT nuclear medicine imaging services may be approved when the existing SPECT equipment has been in operation for at least five consecutive years and utilization of the replaced equipment was at least 1,000 SPECT procedures for a single-head scanning unit and 1,500 SPECT procedures for a multi-head scanning unit in the relevant reporting period.

B. An application to replace non-SPECT nuclear imaging equipment with SPECT nuclear

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medicine imaging equipment may be approved when the existing nuclear medicine imaging equipment has been in operation for at least five consecutive years and utilization of the replaced equipment was at least 500 procedures.

C. Notwithstanding subsection A of this section, consideration will be given to proposals to replace SPECT equipment which has been in operation for less than five consecutive years or has been utilized to perform less than 1,000 SPECT procedures for a single-head scanning unit and 1,500 SPECT procedures for a multi-head scanning unit if the applicant can reasonably demonstrate that such replacement is in substantial compliance with these standards, and that such replacement is necessary to achieve comparability and competitiveness with existing providers of SPECT services in the planning district where the replacement is proposed, and the applicant can demonstrate that the equipment to be replaced was fully utilized, given the type of equipment, the mode of service, or the area served, for the relevant reporting period. Such replacement will not qualify for expedited review under Part VI of the Virginia Medical Care Facilities COPN Rules and Regulations (12VAC5-220-10 et seq.).

Article 4.
Cost.

12 VAC 5-320-460. Comparability of charges.

The total costs for providing SPECT service should be comparable to the costs for similar service providers in the planning district.

Article 5.
Quality.

12 VAC 5-320-470. Medical director.

A. The proposed new, expanded, or replacement SPECT service should be under the medical direction of a physician who is board certified or board eligible in nuclear medicine or nuclear radiology or trained and licensed in nuclear cardiology, and has additional documented experience and training in SPECT technology. Such physicians should be licensed by the Nuclear Regulatory Commission to possess radiopharmaceuticals and perform diagnostic procedures employing radiopharmaceuticals in human beings.

B. Any neurologist involved in the performance or interpretation of SPECT studies should have verifiable credentials which indicate that all of the training and education requirements pertaining to the 1990 "Performance/Interpretation Qualifications" statement of the American Academy of Neurology for SPECT have been, or are being, complied with.

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12 VAC 5-320-480. Additional staff.

SPECT services should be staffed by technologists qualified and experienced in the operation and routine maintenance of nuclear medical imaging systems during all hours of operation of the SPECT services.

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Lithotripsy Services
12 VAC 5-330-10 through 70

PART I.
Definitions.

12 VAC 5-330-10. Definitions.

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

"Biliary ESWL" or "gallstone ESWL" means a noninvasive procedure that uses shock waves produced outside the body to fragment biliary stones, or gallstones.

"Capacity" means that a single ESWL machine or unit has been used to perform 1,7500 procedures annually.

"Department" means the Virginia Department of Health.

"ESWL procedure" means a single noninvasive procedure, during a single visit, using ESWL.

"Extracorporeal shock wave lithotripsy (ESWL)" means a noninvasive procedure that uses shock waves produced outside the body to fragment matter, such as stones that occur in the kidney or upper urinary tract (renal stones).

"Relevant reporting period" means the most recent 12 month period, prior to the beginning of the Certificate of Public Need application's review cycle, for which data are available and acceptable to the department.

PART II.
Criteria and Standards.

12 VAC 5-330-20. Acceptability; waiting time; consumer participation.

A. The waiting time for elective ESWL procedure should be less than two weeks.

B. Providers of ESWL services should provide a program of patient education regarding the nature and extent of the stones and the available methods of diagnosis and treatment of the patient in the management of the stone.

12 VAC 5-330-30. Accessibility; financial considerations.

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ESWL services should be accessible to all patients in need of services without regard to their ability to pay or the payment source.

12 VAC 5-330-40. Availability; need for new services; expanded or replaced.

A. No new ESWL service should be approved through the acquisition of ESWL equipment unless the total number of ESWL procedures performed in the Health Planning Region during the relevant reporting period, divided by the number of ESWL machines approved to operate in the Health Planning Region, exceeds 1,750.

B. Notwithstanding the standards for approval of new ESWL services outlined above, consideration will be given to the approval of new ESWL services established at a general hospital through lease of equipment of an existing mobile service approved to operate in Virginia, if the hospital where the new service will be located has referred at least six patients per month or 72 patients annually, for the relevant reporting period, to other facilities for ESWL procedures.

C. Proposals for the expansion of existing ESWL services through the acquisition of additional ESWL equipment should not be approved unless the number of ESWL procedures performed by that existing service during the relevant reporting period divided by the number of ESWL machines operated by the existing service exceeds 2,000.

D. 1. Proposals for replacement of ESWL equipment should not be approved unless the equipment to be replaced has been in service five years and has performed at least 1,7500 ESWL procedures for the relevant reporting period.

2. Additionally, all proposals for the replacement of ESWL equipment should comply with all applicable sections of this State Medical Facilities Plan component, as determined by the department.

12 VAC 5-330-50. Continuity; coordination of services.

Facilities providing ESWL services should provide courtesy privileges to qualified physicians for use for their patients who are expected to be treated on an outpatient basis.

12 VAC 5-330-60. Cost comparability.

The total costs (direct and indirect) of providing ESWL services should be comparable to the costs of other ESWL services providers in the health planning region of the Commonwealth.

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12 VAC 5-330-70. Quality; staffing.

A. Each ESWL procedure should be under the direct supervision of a urologist who is board certified or board eligible and who is trained in ESWL.

B. All ESWL services should be staffed with technologists qualified and trained in ESWL procedures.

Radiation Therapy Services
12 VAC 5-340-10 through 120

PART I.
Definitions.

12 VAC 5-340-10. Definitions.

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

"Capacity" means that a megavoltage radiation therapy unit has been used to treat 320 cancer patients or to perform 8,000 treatment visits on an annual basis.

"Course of treatment" means a patient therapy program designed to result in the delivery of a prescribed overall dose of radiation, which is typically divided into a number of treatment fractions delivered during a series of treatment visits to the radiation therapy facility.

"Department" means Virginia Department of Health.

"Gamma knife" or "gamma unit" means a stereotactic radiosurgical instrument with cobalt 60 sources arrayed in a semicircular arc so that they may be very precisely focused and the radiation dose may be very precisely distributed, permitting treatment in neurosurgical cases where the site is inaccessible or otherwise unsuitable for other invasive methods.

"Gamma knife procedure" means a single treatment of a patient using the unit. One procedure is performed per patient.

"Megavoltage radiation therapy units" means the machine, including linear accelerators and Cobalt-60 teletherapy units, used to generate radiation with an energy range of 2-50 megavolts, or millions of electron volts (MeV).

"Orthovoltage radiation therapy units" means the machine used to generate x-rays with an energy range of 200-400 kilovolts. Although these machines have been largely replaced by megavoltage radiation therapy units, they are sometimes used for treatment of deep-seated tumors.

"Radiation therapy" means a clinical specialty in which ionizing radiation is used for treatment of cancer, often in conjunction with surgery or chemotherapy or both of these treatment methods. The predominant form of radiation therapy involves an external source of radiation whose energy is focused on the diseased area.

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"Radioisotope therapy" means a process that involves 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 Certificate of Public Need application's review cycle, for which data are available and acceptable to the department.

"Stereotactic radiosurgery" means a noninvasive therapeutic procedure in which narrow beams of radiant energy are directed at the treatment target in the head so as to produce tissue destruction, using computerized tomography (CT), radiography, magnetic resonance imaging (MRI), and angiography for localization.

"Superficial radiation therapy units" means the machine used to generate x-rays with an energy range of 85-180 kilovolts and used to treat lesions on the surface or just below the skin.

"Treatment fraction" means a single portion of the overall prescribed dose of radiation for a radiation therapy patient.

"Treatment visit" or "procedure" means a single procedure performed to deliver an amount of radiation to the radiation therapy patient.

PART II.

Criteria and Standards for Megavoltage Radiation Therapy Services.

12 VAC 5-340-20. Acceptability; consumer participation.

Providers of radiation therapy services should provide a program of patient and family education regarding the nature of the patient's cancer and the available methods of diagnosis and treatment, and the medical, clinical, technical, psycho-social, financial, and nutritional aspects of the patient's condition and the family's role in caring for the patient.

12 VAC 5-340-30. Accessibility; time; financial considerations.

A. 1. Radiation therapy services should be available within the institution, on a regularly scheduled basis, for a minimum of 40 hours a week.

2. Convenient hours of operation should be provided for the benefit of outpatients (early morning hours, lunch hours, evening hours, weekends).

B. Radiation therapy services should be available within one hour normal driving time, under normal conditions, for 95% of the population.

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C. Radiation therapy services should be accessible to all patients in need of services without regard to their ability to pay or the payment source.

D. Providers of radiation therapy services serving rural areas should facilitate the transport of patients residing in rural areas to needed radiation therapy services, directly or through coordinated efforts with other organizations. Preference will be given in the review of competing applications to applicants who can demonstrate a commitment to the development of transportation resources for rural populations.

12 VAC 5-340-40. Availability; need for new service; expanded; replacement of service.

A. 1. No new radiation therapy service should be approved unless: (i) existing radiation therapy machines located in the health planning region in which the proposed new service is to be located were used for at least 320 cancer cases and at least 8,000 treatment visits for the relevant reporting period; and (ii) it can be reasonably projected that the new service will be used for 240 cancer patients and will perform at least 6,000 procedures by the third year without reducing the utilization of existing radiation therapy machines in the health planning region such that less than 8,000 procedures will be performed by any existing machine.

2. The number of megavoltage radiation therapy machines needed in a health planning region will be determined as follows:

$$\frac{\text{Population} \times \text{Cancer Incidence Rate} \times 45\%}{320}$$

where:

the population is that projected for three years from the current year and is at least 150,000 (population data will be the most recently available from the Virginia Employment Commission);

Cancer incidence rates are those for the applicant's proposed service area, are specific to Virginia, and are based on data from the Virginia Tumor Registry, or the American Cancer Society;

45% is used to estimate the number of new cancer cases in a given area that are treatable with radiation therapy; and

320 is the 100% utilization of a radiation therapy machine.

B. Notwithstanding the standards for approval of new radiation therapy services outlined above, consideration will be given to the approval of new radiation therapy services which will be located at a general hospital located 60 minutes or more driving time, under normal conditions, from any site at which radiation therapy services are available if it can be reasonably projected that the proposed new services will perform at least 6,000 treatment

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procedures by the third year of operation, without reducing the utilization of existing machines located within 60 to 70 minutes driving time, under normal conditions, from the proposed new service location.

C. 1. Proposals for the expansion of radiation therapy services should not be approved unless all existing radiation therapy machines operated by the applicant have performed at least 9,000 procedures for the relevant reporting period.

2. Additionally, all proposals for the expansion of radiation therapy services should comply with all applicable sections of this State Medical Facilities Plan component, as determined by the department.

D. 1. Proposals for the replacement of existing radiation therapy services should not be approved unless the equipment to be replaced has been in service for at least five years; and it can be reasonably demonstrated that replacement is necessary because the existing unit is inefficient or too costly to maintain, or because the existing unit is no longer appropriate for the projected caseload and mix of cancer patients that the applicant proposes to serve.

2. Additionally, all proposals for the replacement of radiation therapy services should comply with all applicable sections of this State Medical Facilities Plan component, as determined by the department.

3. Any replaced radiation therapy units should be totally decommissioned within 30 days of the start of the replacement equipment.

12 VAC 5-340-50. Continuity; tumor registry; discharge and follow-up care.

A. Facilities with radiation therapy services should participate in an accredited tumor registry.

1. All radiation therapy services should have written procedures and policies for discharge planning and follow-up care for the patient and family which are part of the institution's overall discharge planning program.

2. All radiation therapy services should have established protocols for referring physicians to assure adequate post-operative diagnostic evaluation for radiation therapy patients.

12 VAC 5-340-60. Cost; cost comparability.

The cost of radiation therapy services to be offered should be comparable to unit costs experienced by other similar radiation therapy services within the health planning region.

12 VAC 5-340-70. Quality; staffing; financial considerations; patient care; support; care.

A. 1. Radiation therapy services should have a medical director who is a licensed

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physician that is board certified in radiation oncology.

2. The staffing pattern for radiation therapy services should include the following nonphysician personnel:

- a. Dosimetrist(s);
- b. Radiation therapy technologists certified by the American Registry of Radiation Technologists;
- c. A radiation physicist, who is certified by the American Board of Radiology or its equivalent, or who holds an advanced degree in physics and has two to three years of full-time radiation therapy experience working under the direction of a certified radiation physicist; and
- d. A clinical registered nurse.

3. All radiation therapy services should have access to a medical social worker, psychologist, or psychiatrist to counsel those patients and families who need assistance with emotional and financial problems prior to and following radiation therapy services.

B. 1. In addition to the radiation therapy machine, simulation equipment capable of precisely producing the geometric relations of the megavoltage equipment to be used for treatment of the patient should be available.

2. Radiation therapy services should have access on-site to a computerized treatment planning system.

3. Radiation therapy services should have access to a custom block design and cutting system.

C. 1. Facilities providing radiation therapy services should have diagnostic, laboratory, medical and surgical oncology services.

2. Facilities providing radiation therapy services should have written policies and procedures for concurrent, retrospective, and prospective consideration of cancer cases by an in-house multi-specialty tumor board or committee per American College of Surgeons accreditation guidelines.

3. Facilities providing radiation therapy services should have available support services such as nutrition information, physical therapy, and social and vocational rehabilitation to assure that the patient attains the optimal functional capacity during and after course treatments.

D. There should be adequate space in the therapeutic radiation treatment facility to provide for: (i) reception and waiting areas; (ii) consultation and examination; (iii) planning and conferences; (iv) work and utility areas including stretcher and wheelchair space; (v) treatment units; (vi) mechanical and supporting facilities; (vii) record storage; and (viii) a recovery area.

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PART III.

Criteria and Standards for Gamma Knife Surgery.

12 VAC 5-340-80. Accessibility; travel time; financial considerations.

A. Gamma knife services should be located so as to optimize accessibility for all Virginia residents.

B. Gamma knife services should be accessible to all patients in need of the services without regard to ability to pay or payment source.

12 VAC 5-340-90. Availability; need for new service.

No new gamma knife surgery services should be approved unless: (i) the number of procedures performed with existing units in the Commonwealth average more than 475 per year; and (ii) it can be reasonably projected that the proposed new service will perform at least 250 gamma knife surgery procedures in the third year of operation.

12 VAC 5-340-100. Continuity; coordination of services; tumors registry; discharge and follow-up.

A. Facilities providing gamma knife surgery services should have an established neurosurgery program and a complete range of therapeutic radiation services.

B. Facilities providing gamma knife surgery services should participate in an accredited tumor registry.

C. 1. All gamma knife surgery services should have written procedures and policies for discharge planning and follow-up care for the patient and family as part of the institution's overall discharge planning program.

2. All gamma knife surgery services should have established protocols for referring physicians to assure adequate post-operative diagnostic evaluation for radiosurgery patients.

12 VAC 5-340-110. Cost comparability.

A. The total costs of providing gamma knife surgery services projected by prospective providers should be comparable to the costs of other similar service providers in the state.

B. The usual and customary charge to the patient for gamma knife surgery should be commensurate with cost.

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12 VAC 5-340-120. Quality; staffing; equipment.

A. 1. Gamma knife surgery programs should have a medical director who is board certified in neurosurgery, with experience in all phases of gamma knife surgical procedures.

2. In addition to the medical director, all gamma knife surgery programs should have a radiation physicist who is certified in radiology, or who holds an advanced degree in physics with two to three years full- time radiation therapy experience working under the direction of a radiation therapist, present for each gamma knife surgery procedure performed.

3. The staffing pattern for the team performing each gamma knife surgery procedure should be composed of at least the following nonphysician personnel with experience in gamma knife procedures: (i) radiotherapists; (ii) radiation technologists; and (iii) a clinical registered nurse.

B. 1. Facilities providing gamma knife surgery services should have dosimetry and calibration equipment and a computer with appropriate software for performing gamma knife surgery procedures.

2. Facilities providing gamma knife surgery services should also have access to magnetic resonance imaging, computed tomography, and angiography services.

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Miscellaneous Capital Expenses
12 VAC 5-350-10 through 60

PART I.
Purpose.

12 VAC 5-350-10. Purpose.

This component of the State Medical Facilities Plan (SMFP) is intended to provide general guidance in the review of:

A. Projects which require certificate of public need (COPN) authorization by virtue of their expense but do not involve changes in the bed or service capacity of a medical care facility which are specifically addressed in other components of the SMFP; and

B. All projects involving expenditures for expansion, contraction, modernization, renovation, replacement, retrofit, or reconfiguration of a medical care facility, a substantial proportion of which do not involve changes in bed or service capacity which are specifically addressed in other components of the SMFP. Thus, in the case of certain projects, this section of the SMFP and certain other SMFP components which specifically address changes in bed or service capacity will be used as guidance in the COPN review process.

PART II.
Guidelines and General Considerations.

12 VAC 5-350-20. Project need.

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

1. The expenditure can be reasonably related to the service mission or business plan of the facility;
2. The expenditure represents the most cost-effective approach to meeting the identified need; and
3. The expenditure and the ongoing operational costs related to the capital expenditure will not result in unreasonable increases in the cost of delivering the services provided by the facility.

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12 VAC 5-350-30. Facilities expansion.

Proposals 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:

A. An analysis of the historical volume of work activity or other activity performed in the area or department;

B. The projected volume of work activity or other activity performed in the area or department;

C. 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; and

D. A comparative analysis of the space provided in the relevant areas and departments of other similar medical care facilities in the planning district and/or health planning region.

12 VAC 5-350-40. Renovation or modernization.

A. Proposals 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(s); and

2. That 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 to be renovated and/or modernized.

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

Proposals for the general renovation or modernization of medical care facilities should involve the downsizing of bed or other service capacity when such capacity has not operated at a reasonable level of efficiency, as identified in the relevant components of the State Medical Facilities Plan, during the most recent three year period.

12 VAC 5-350-50. Equipment.

Proposals for the purchase and installation of equipment by medical care facilities which are not specifically addressed in another component of the SMFP should document that the

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equipment is needed. Such documentation should clearly indicate (i) that the proposed equipment is needed to maintain the current level of service provided by the facility; or (ii) if the equipment involves the provision of a new service or an increase in the quantitative or qualitative level of an existing service provided by the facility, that the benefits of the change in service resulting from the new equipment exceed the costs of purchasing (leasing) and operating the equipment over its useful life.

12 VAC 5-350-60. Assurances.

Proposals which alter assurances provided by a medical care facility in a previous COPN award or the intentions stated by a medical care facility in a previous COPN request which received approval should be identified as a significant change. This significant change will be included as an explicit priority consideration in the review of the proposal such that denial of the significant change will constitute denial of the proposal.

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Nursing Home Services
12 VAC 5-360-10 through 70

PART I.
Definitions.

12 VAC 5-360-10. Definitions.

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

"Competing applications" means nursing home bed applications accepted for review in the same review cycle which propose facilities to be located in the same planning district.

"Continuing care contract" means the written agreement which provides for continuing care consistent with the requirements of Chapter 49 (§38.2-4900, et seq.) of Title 38.2 of the Code of Virginia. It functions as an insurance policy, whereby the individual resident purchases from a Continuing Care Retirement Community (CCRC), through an entrance fee and periodic adjustable payments, a package of residential and healthcare services which the CCRC is obligated to provide at the time these residential and health care services are required. The health care services include adult care residence services (also known as domiciliary care, assisted living services or personal care) and nursing home services. Continuing care contracts are regulated by the Virginia Bureau of Insurance of the Virginia State Corporation Commission.

"Continuing Care Retirement Community (CCRC)" means those retirement communities for the elderly that provide residential, health care and support services through a continuing care contract. CCRCs can have nursing home services available either on-site, or at licensed facilities off-site.

"Department" means the Virginia Department of Health.

"Health planning region" means a contiguous geographical area of the Commonwealth with a population base of at least 500,000 persons which is characterized by the availability of multiple levels of medical care services, reasonable travel time for tertiary care, and congruence with planning districts.

"Life care contract" means a continuing care contract.

"Nursing home facility" means those facilities or components thereof licensed by the department to provide long-term nursing care, including facilities known by varying nomenclature or designation such as convalescent homes, skilled nursing facilities or skilled care facilities,

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intermediate care facilities, extended care facilities and nursing or nursing care facilities.

"Nursing home services" means nursing and health related services provided to inpatients, on a continuing basis, in a licensed nursing home facility.

"Planning district" means a contiguous area within the boundaries established by the Department of Planning and Budget as set forth in §15.1-1402 of the Code of Virginia.

"Use rate" means the rate at which an age cohort or the population uses nursing home beds. The rates are determined from periodic patient origin surveys conducted by the department and the regional health planning agencies.

PART II.
Criteria and Standards.

12 VAC 5-360-20. Acceptability.

A. Consumer participation. Providers of nursing home services should have written policies and procedures regarding the treatment of residents and the management of resident care which are available to residents and their families.

B. Consumer satisfaction. Providers of nursing home services should have established mechanisms for evaluating resident and resident family satisfaction with the services they provide. Preference will be given in the review of competing applications to providers who can demonstrate high levels of resident and resident family satisfaction with their services through their active and on-going evaluation process.

12 VAC 5-360-30. Accessibility.

A. Travel time. Nursing home beds should be accessible within a 45 minute driving time, under normal conditions, to 90 percent of all Virginians. Preference will be given in the review of competing applications to proposed nursing home facilities which substantively improve geographic access and reduce travel time to nursing home services within a planning district.

B. Access to highway system. Nursing home facilities should be linked by paved roads to a state or federal highway and should be accessible by public transportation, when such systems exist in an area.

C. Financial. Nursing home services should be accessible to all persons in need of such services without regard to their ability to pay or the payment source. Preference will be given in the review of competing applications to proposed nursing facilities which will be accessible to all

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persons in need of such services without regard to their ability to pay or the payment source and can demonstrate a record of such accessibility.

D. Distribution of beds. Preference will be given in the review of competing applications to proposals that correct any maldistribution of beds within a planning district.

12 VAC 5-360-40. Availability.

A. Need for additional nursing home beds. No planning district will be considered to have a need for additional nursing home facility beds unless: (i) the resulting number of licensed and approved bed need forecast for nursing home beds in that planning district (see subsection C of this section) exceeds the current inventory of non-federal licensed and authorized beds in that planning district; and (ii) the estimated average annual occupancy of all existing non-federal Medicaid-certified nursing facility beds in the planning district was at least 95% for the most recent three years for which bed utilization has been reported to the department. (The bed inventory and utilization of the Virginia Veterans Care Center will be excluded from consideration in the determination of nursing home facility bed need.)

No planning district will be considered to have a need for additional nursing home beds if there are uncompleted nursing facility beds authorized for the planning district that will be Medicaid-certified beds.

B. Expansion of existing nursing facilities. Proposals for the expansion of existing nursing facilities should not be approved unless the facility has operated for at least three years and average annual occupancy of the facility's existing beds was at least 95% in the most recent year for which bed utilization has been reported to the department.

Exceptions to this standard will be considered for facilities that have operated at less than 95% average annual occupancy in the most recent year for which bed utilization has been reported to the department when the facility can demonstrate that it has a rehabilitative or other specialized care focus which results in a relatively short average length of stay and, consequently, cannot achieve an average annual occupancy rate of 95%.

Preference will be given in the review of competing applications to proposals which involve the expansion of free-standing nursing home facilities of 60 or fewer beds when such facilities can demonstrate substantial compliance with the standards of the State Medical Facilities Plan.

In a case where no competing applicant is a freestanding nursing home facility with 60 or fewer beds or where free-standing nursing homes of 60 or fewer and 61 to 90 beds are competing, preference will also be given in the review of competing applications to proposals

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which involve the expansion of freestanding nursing home facilities of 90 or fewer beds when such facilities can demonstrate substantial compliance with the standards of the State Medical Facilities Plan.

C. Bed need forecasting method. The number of nursing home facility beds forecast to be needed in a given planning district will be computed as follows:

$$PDBN = (UR64 * PP64) + (UR69 * PP69) + (UR74 * PP74) + (UR79 * PP79) + (UR84 * PP84) + (UR85+ * PP85+)$$

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.

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.

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.

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.

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.

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.

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.

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.

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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.

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.

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.

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.

Planning district bed need forecasts will be rounded as follows:

Planning District Bed Need (from above method)	Rounded Bed Need
1 - 29	0
30 - 44	30
45 - 84	60
85 - 104	90
105 - 184	120
185+	240

except in the case of a planning district which has two or more nursing facilities, has had an average annual occupancy rate of nursing home facility beds in excess of 95% for the most recent three years for which bed utilization has been reported to the department, and has a forecasted bed need of 15 to 29 beds. In such a case, the bed need for this planning district will be rounded to 30.

D. Minimum size of new nursing home facilities. No new freestanding nursing home facilities of less than 120 beds should be authorized. Consideration will be given to the authorization of new freestanding facilities with fewer than 120 nursing home facility beds when such facilities are proposed for development in a rural area and can be justified on the basis of a lack of local demand for a larger facility and a maldistribution of nursing home facility beds within the planning district.

E. Continuing Care Retirement Communities. Proposals for the development of new

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nursing home facilities or the expansion of existing facilities by Continuing Care Retirement communities will be considered in accordance with the following standards:

1. The total number of new or additional beds plus any existing nursing home 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 population;
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 pursuant to continuing care contracts meeting the requirements of §38.2-4905 of the Code of Virginia;
3. The applicant agrees in writing not to seek certification for the use of such new or additional beds by persons eligible to receive medical assistance services pursuant to Title XIX of the United States Social Security Act;
4. The applicant agrees in writing to obtain, prior to admission of every resident of the Continuing Care Retirement Community, the resident's written acknowledgment that the provider does not serve recipients of medical assistance services and that, in the event such resident becomes a medical assistance services recipient who is eligible for nursing facility placement, such resident shall not be eligible for placement in the provider's nursing facility unit;
5. The applicant agrees in writing that only continuing care contract holders who have resided in the Continuing Care Retirement Community as independent living residents or adult care residents and are holders of standard continuing care contracts will be admitted to the nursing home facility beds after the first three years of operation.

12 VAC 5-360-50. Continuity.

A. Coordination of services. Nursing home facilities should have written agreements with acute care hospitals for the transfer of residents in need of acute medical services, and should be located within reasonable access to acute care facilities.

B. Emergency medical care. Emergency medical services should be within a 15 minute response time of a nursing home facility, under normal conditions.

C. Care continuum. Preference will be given in the review of competing applications to projects which provide multiple levels of long-term care and can demonstrate that they function effectively as a continuum of care which optimizes the match between resident needs and the facilities and services provided.

D. Family support. Nursing home facilities should provide services, such as adult day care services and respite care programs, and engage in activities, such as caregiver education, caregiver support groups, and referral programs, which support the ability of families to provide

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long-term care to their family members within the home. Preference will be given in the review of competing applications to project applicants who can demonstrate a history or commitment to the provision of services and activities which support the ability of families to provide long-term care to their family members within the home.

E. Noninstitutional service support. Nursing home facilities should facilitate the use of noninstitutional long-term care services whenever such services are an appropriate alternative for persons in need of long-term care. Preference will be given in the review of competing applications to project applicants who can demonstrate a history of or commitment to investing in noninstitutional long-term care services in their communities.

12 VAC 5-360-60. Costs.

A. Development costs. The direct construction cost of proposed nursing facilities should be within the construction cost index used as a cap by the Department of Medical Assistance Services or be comparable with the recently observed cost for similar facilities in the same health planning region. Other development costs of proposed nursing facilities should be comparable with the recently observed costs for similar facilities in the same health planning region. Preference will be given in the review of competing applications to proposals which have lower development costs than their competitors and can demonstrate that their cost estimates are creditable.

B. Consideration will be given to the experience of applicants in completing similar projects on time and within the authorized capital costs. Preference will be given in the review of competing applications to applicants who have a good record of performance in completing projects on time and within the authorized capital costs.

C. Operating costs and charges. The operating costs and charges of nursing home facilities should be comparable with those of nursing home facilities operating in the same health planning region that provide similar staffing levels and a similar range of services. Preference will be given in the review of competing applications to applicants who can reasonably project lower operating costs and charges than their competitors at staffing levels appropriate to their intended level of care.

Proponents of the replacement and relocation of nursing home facility beds should reasonably demonstrate that the replacement and relocation will allow for comparable operating costs and charges over the life of the replacement facility than continued operation of the existing facility.

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12 VAC 5-360-70. Quality.

A. Licensure and accreditation. Nursing home facilities should be maintained and operated in compliance with all applicable state licensure regulations. Preference will be given in the review of competing applications to applicants who can demonstrate a consistent history of compliance with state licensure regulations.

Nursing home facilities should be accredited by the Joint Commission on Accreditation of Health Care Organizations or another appropriate accrediting body. Preference will be given in the review of competing applications to applicants who are accredited or can demonstrate a history of operating accredited facilities.

B. Record in the provision of quality care. Preference will be given in the review of competing applications to applicants who can demonstrate a consistent pattern of licensure surveys with few deficiencies and a consistent history of few complaints.