VIRGINIA MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED RULES AND REGULATIONS; STATE MEDICAL FACILITIES PLAN

12 VAC 5-220-10. Definitions.

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

"Acquisition" means an expenditure of $600,000 or more that changes the ownership of a medical care facility. It shall also include the donation or lease of a medical care facility. An acquisition of a medical care facility shall not include a capital expenditure involving the purchase of stock. See 12 VAC 5-220-120.

"Amendment" means any modification to an application which is made following the public hearing and prior to the issuance of a certificate and includes those factors that constitute a significant change as defined in this chapter. An amendment shall not include a modification to an application which serves to reduce the scope of a project.

"Applicant" means the owner of an existing medical care facility or the sponsor of a proposed medical care facility project submitting an application for a certificate of public need.

"Application" means a prescribed format for the presentation of data and information deemed necessary by the board to determine a public need for a medical care facility project.

"Application fees" means fees required for a project application and application for a significant change. Fees shall not exceed the lesser of 1.0% of the proposed capital expenditure or cost increase for the project or $20,000.

"Board" means the State Board of Health.

"Capital expenditure" means any expenditure by or in behalf of a medical care facility which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance. Such expenditure shall also include a series of related expenditures during a 12-month period or a financial obligation or a series of related financial obligations made during a 12-month period by or in behalf of a medical care facility. Capital expenditures need not be made by a medical care facility so long as they are made in behalf of a medical care facility by any person. See definition of "person."

"Certificate of public need" means a document which legally authorizes a medical care facility project as defined herein and which is issued by the commissioner to the owner of such project.

"Clinical health service" means a single diagnostic, therapeutic, rehabilitative, preventive or palliative procedure or a series of such procedures that may be separately identified for billing and accounting purposes.

"Commissioner" means the State Health Commissioner who has authority to make a determination respecting the issuance or revocation of a certificate.

"Competing applications" means applications for the same or similar services and facilities which are proposed for the same planning district or medical service area and which are in the same review cycle. See 12 VAC 5-220-220.

"Completion" means conclusion of construction activities necessary for substantial performance of the contract.

"Construction" means the building of a new medical facility or the expansion, remodeling, or alteration of an existing medical care facility.

"Construction, initiation of" means that a project shall be considered under construction for the purpose of certificate extension determinations upon the presentation of evidence by the owner of: (i) a signed construction contract; (ii) the completion of short term financing and a commitment for long term (permanent) financing when applicable; (iii) the completion of predevelopment site work; and (iv) the completion of building foundations.

"Date of issuance" means the date of the commissioner's decision awarding a certificate of public need.

"Department" means the State Department of Health.

"Designated medically underserved areas" means (i) areas designated as medically underserved areas pursuant to § 32.1-122.5 of the Code of Virginia; (ii) federally designated Medically Underserved Areas (MUA); or (iii) federally designated Health Professional Shortage Areas (HPSA).

"Ex parte" means any meeting which takes place between (i) any person acting in behalf of the applicant or holder of a certificate of public need or any person opposed to the issuance or in favor of the revocation of a certificate of public need and (ii) any person who has authority in the department to make a decision respecting the issuance or revocation of a certificate of public need for which the department has not provided 10 days written notification to opposing parties of the time and place of such meeting. An ex parte contact shall not include a meeting between the persons identified in (i) and staff of the department.

"Gamma knife surgery" means stereotactic radiosurgery, where stereotactic radiosurgery is the noninvasive therapeutic procedure performed by directing radiant energy beams from any source at a treatment target in the head to produce tissue destruction. See definition of "project."

"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.

"Informal fact-finding conference" means a conference held pursuant to § 9-6.14:11 of the Code of Virginia.

"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 varying nomenclatures including but not limited to: nursing beds, intensive care beds, minimal or self care beds, isolation 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 a maternity department and beds located in labor or birthing rooms, recovery rooms, emergency rooms, preparation or anesthesia inductor rooms, diagnostic or treatment procedures rooms, or on-call staff rooms are excluded from this definition.

"Medical care facility" means any institution, place, building, or agency, at a single site, whether or not licensed or required to be licensed by the board or the State Mental Health, Mental Retardation and Substance Abuse Services Board, whether operated for profit or nonprofit and whether privately owned or operated or owned or operated by a local governmental unit, (i) by or in which facilities are maintained, furnished, conducted, operated, or offered for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition, whether medical or surgical, of two or more non-related mentally or physically sick or injured persons, or for the care of two or more non-related persons requiring or receiving medical, surgical, or nursing attention or services as acute, chronic, convalescent, aged, physically disabled, or crippled or (ii) which is the recipient of reimbursements from third party health insurance programs or prepaid medical service plans. For purposes of this chapter, only the following medical care facility classifications shall be subject to review:

1. General hospitals.

2. Sanitariums.

3. Nursing homes.

4. Intermediate care facilities.

5. Extended care facilities.

6. Mental hospitals.

7. Mental retardation facilities.

8. Psychiatric hospitals and intermediate care facilities established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts.

9. Specialized centers or clinics or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery, cardiac catheterization, computed tomographic (CT) scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, radiation therapy, nuclear medicine imaging, or such other specialty services as may be designated by the Board by regulation.

10. Rehabilitation hospitals.

11. Any facility licensed as a hospital.

For purposes of this chapter, the following medical care facility classifications shall not be subject to review:

1. Any facility of the Department of Mental Health, Mental Retardation and Substance Abuse Services.

2. Any nonhospital substance abuse residential treatment program operated by or contracted primarily for the use of a community services board under the Department of Mental Health, Mental Retardation and Substance Abuse Services Comprehensive Plan.

3. Any physician's office, except that portion of the physician's office which is described in subdivision 9 of the definition of "medical care facility".

4. The Woodrow Wilson Rehabilitation Center of the Virginia Department of Rehabilitative Services.

"Medical service area" means the geographic territory from which at least 75% of patients come or are expected to come to existing or proposed medical care facilities, the delineation of which is based on such factors as population characteristics, natural geographic boundaries, and transportation and trade patterns, and all parts of which are reasonably accessible to existing or proposed medical care facilities.

"Modernization" means the alteration, repair, remodeling, replacement or renovation of an existing medical care facility or any part thereto, including that which is incident to the initial and subsequent installation of equipment in a medical care facility. See definition of "construction."

"Operating expenditure" means any expenditure by or in behalf of a medical care facility which, under generally accepted accounting principles, is properly chargeable as an expense of operation and maintenance and is not a capital expenditure.

"Operator" means any person having designated responsibility and legal authority from the owner to administer and manage a medical care facility. See definition of "owner."

"Other plans" means any plan(s) which is formally adopted by an official state agency or regional health planning agency and which provides for the orderly planning and development of medical care facilities and services and which is not otherwise defined in this chapter.

"Owner" means any person who has legal responsibility and authority to construct, renovate or equip or otherwise control a medical care facility as defined herein.

"Person" means an individual, corporation, partnership, association or any other legal entity, whether governmental or private. Such person may also include the following:

1. The applicant for a certificate of public need;

2. The regional health planning agency for the health planning region in which the proposed project is to be located;

3. Any resident of the geographic area served or to be served by the applicant;

4. Any person who regularly uses health care facilities within the geographic area served or

to be served by the applicant;

5. Any facility or health maintenance organization (HMO) established under § 38.2-4300 et seq. of the Code of Virginia which is located in the health planning region in which the project is proposed and which provides services similar to the services of the medical care facility project under review;

6. Third party payors who provide health care insurance or prepaid coverage to 5.0% or more patients in the health planning region in which the project is proposed to be located; and

7. Any agency which reviews or establishes rates for health care facilities.

"Physician's office" means a place, owned or operated by a licensed physician or group of physicians practicing in any legal form whatsoever, which is designed and equipped solely for the provision of fundamental medical care whether diagnostic, therapeutic, rehabilitative, preventive or palliative to ambulatory patients and which does not participate in cost-based or facility reimbursement from third party health insurance programs or prepaid medical service plans excluding pharmaceuticals and other supplies administered in the office. See definition of "medical care facility".

"Planning district" means a contiguous area within the boundaries established by the Department of Housing and Community Development as set forth in § 15.2-4202 of the Code of Virginia, except that for purposes of this chapter, Planning District 23 shall be divided into two planning districts; Planning District 20 consisting of the counties of Isle of Wight and Southampton and cities of Chesapeake, Franklin, Norfolk, Portsmouth, Suffolk and Virginia Beach; and Planning District 21 consisting of the counties of James City and York and the cities of Hampton, Newport News, Poquoson and Williamsburg.

"Predevelopment site work" means any preliminary activity directed towards preparation of the site prior to the completion of the building foundations. This includes, but is not limited to, soil testing, clearing, grading, extension of utilities and power lines to the site.

"Primary medical care services" means first-contact, whole-person medical and health services delivered by broadly trained, generalist physicians, nurses and other professionals, intended to include, without limitation, obstetrics/gynecology, family practice, internal medicine and pediatrics.

"Progress" means actions which are required in a given period of time to complete a project for which a certificate of public need has been issued. See 12 VAC 5-220-450, Demonstration of Progress.

"Project" means

1. The establishment of a medical care facility. See definition of "medical care facility."

2. An increase in the total number of beds or operating rooms in an existing or authorized medical care facility.

3. Relocation at the same site of 10 beds or 10% of the beds, whichever is less, from one existing physical facility to another in any two-year period; however, a hospital shall not be required to obtain a certificate for the use of 10% of its beds as nursing home beds as provided in § 32.1-132 of the Code of Virginia.

4. The introduction into any existing medical care facility of any new nursing home service such as intermediate care facility services, extended care facility services or skilled nursing facility services except when such medical care facility is an existing nursing home as defined in § 32.1-123 of the Code of Virginia.

5. The introduction into an existing medical care facility of any new cardiac catheterization, computed tomography (CT), gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), medical rehabilitation, neonatal special care services, obstetrical services, open heart surgery, positron emission tomographic (PET) scanning, organ or tissue transplant service, radiation therapy, nuclear medicine imaging, psychiatric, substance abuse treatment, or such other specialty clinical services as may be designated by the board by regulation, which the facility has never provided or has not provided in the previous 12 months.

6. The conversion of beds in an existing medical care facility to medical rehabilitation beds or psychiatric beds.

7. The addition ~~or replacement~~ by an existing medical care facility of any medical equipment for the provision of cardiac catheterization, computed tomography (CT), gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, or other specialized service designated by the Board by regulation.~~; except for the replacement of any medical equipment identified in this Part which the commissioner has determined to be an emergency in accordance with 12 VAC 5-220-150 or for which it has been determined that a certificate of public need has been~~

~~previously issued for replacement of the specific equipment according to 12 VAC 5-220-105.~~

8. Any capital expenditure of $5 million or more, not defined as reviewable in subdivisions 1 through 7 of this definition, by or in behalf of a medical care facility. However, capital expenditures between $1 million and $5 million shall be registered with the commissioner.

"Public hearing" means a proceeding conducted by a regional health planning agency at which an applicant for a certificate of public need and members of the public may present oral or written testimony in support of or opposition to the application which is the subject of the proceeding and for which a verbatim record is made. See subsection A of 12 VAC 5-220-230.

"Regional health plan" means the regional plan adopted by the regional health planning agency board.

"Regional health planning agency" means the regional agency, including the regional health planning board, its staff and any component thereof, designated by the Virginia Health Planning Board to perform health planning activities within a health planning region.

"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, Economics and Statistics Administration.

"Schedule for completion" means a timetable which identifies the major activities required to complete a project as identified by the applicant and which is set forth on the certificate of public need. The timetable is used by the commissioner to evaluate the applicant's progress in completing an approved project.

"Significant change" means any alteration, modification or adjustment to a reviewable project for which a certificate of public need has been issued or requested following the public hearing which:

1. Changes the site;

2. Increases the capital expenditure amount authorized by the commissioner on the certificate of public need issued for the project by 10% or more;

3. Changes the service(s) proposed to be offered;

4. Extends the schedule for completion of the project beyond three years (36 months) from the date of certificate issuance or beyond the time period approved by the commissioner at the date of certificate issuance, whichever is greater. See 12 VAC 5-220-440 and 12 VAC 5-220-450.

"Standard review process" means the process utilized in the review of all certificate of public need requests with the exception of:

1. Certain bed ~~relocations equipment replacement, and new service introduction projects~~ relocations as specified in 12 VAC 5-220-280;

2. Certain projects which involve an increase in the number of beds in which nursing facility or extended care services are provided as specified in 12 VAC 5-220-325.

"State Medical Facilities Plan" means the planning document adopted by the Board of Health which shall include, but not be limited to (i) methodologies for projecting need for medical care facility beds and services; (ii) statistical information on the availability of medical care facilities and services; and (iii) procedures, criteria and standards for review of applications for projects for medical care facilities and services. The most recent applicable State Medical Facilities Plan shall remain in force until any such chapter is amended, modified or repealed by the Board of Health.

"Virginia Health Planning Board" means the statewide health planning body established pursuant to § 32.1-122.02 of the Code of Virginia which serves as the analytical and technical resource to the Secretary of Health and Human Resources in matters requiring health analysis and planning.

12 VAC 5-220-90. Annual report

~~The department shall prepare and shall distribute upon request an annual report on all certificate of public need applications considered by the State Health Commissioner. Such report shall include a general statement of the findings made in the course of each review, the status of applications for which there is a pending determination, an analysis of the consistency of the decisions with the recommendation made by the regional health planning agency and an analysis of the costs of authorized projects.~~

The commissioner shall annually report to the Governor and the General Assembly on the status of Virginia's certificate of public need program. The report shall be issued by October 1 of each year and shall include, but need not be limited to:

A summary of the commissioner's actions during the previous fiscal year pursuant to Virginia's certificate of public need law;

A five-year schedule for analysis of all project categories which provides for the analysis of at least three project categories per year;

An analysis of the appropriateness of continuing the certificate of public need program for at least three project categories in accordance with the five-year schedule for analysis of all project categories;

An analysis of the effectiveness of the application review procedures used by the regional health planning agencies and the department required by § 32.1-102.6 which details the review time required during the past year for various project categories, the number of contested or opposed applications and the project categories of these contested or opposed projects, the number of applications upon which the regional health planning agencies have failed to act in accordance with the timelines of § 32.1-102.6 B, and the number of deemed approvals from the department because of their failure to comply with the timelines required by § 32.1-102.6 E, and any other data determined by the commissioner to be relevant to the efficient operation of the program;

An analysis of health care market reform in the Commonwealth and the extent, if any, to which such reform obviates the need for the certificate of public need program;

An analysis of the accessibility by the indigent to care provided by medical care facilities regulated pursuant to Virginia's certificate of public need law;

An analysis of the relevance of Virginia's certificate of public need law to the quality of care provided by medical care facilities regulated pursuant to this law; and

An analysis of equipment registrations required pursuant to § 32.1-102.1:1 including type of equipment, whether an addition or replacement, and the equipment costs.

12 VAC 5-220-105. Requirements for registration of the replacement of existing medical equipment ~~which has been previously authorized as replacement equipment~~.

~~At least~~ Within 30 days ~~before~~ of any person ~~contracts~~ contracting to make, or ~~is~~ otherwise legally ~~obligated~~ obligating to make, a capital expenditure for the replacement of medical equipment or otherwise acquiring replacement medical equipment for the provision of services listed in subdivision 7

of the definition of "project" in 12 VAC 5-220-10, ~~which have been previously authorized for replacement through the issuance of a certificate of public need~~, the person shall register in writing such equipment replacement with ~~notify~~ the commissioner and the appropriate regional health planning agency. Such registration shall be made on forms provided by the department. The ~~notification~~ registration shall identify the specific unit of equipment to be replaced and the estimated capital cost of the replacement, and shall include documentation that the equipment to be replaced has previously been authorized ~~as replacement equipment~~ through issuance of a certificate of public need, registered pursuant to former § 32.1-102.3:4 of the Code of Virginia or exempted pursuant to § 32.1-102.11 of the Code of Virginia.

12 VAC 5-220-150. ~~Requirements for emergency replacement of equipment; notification of decision.~~ Reserved for future use.

~~The commissioner shall consider requests for emergency replacement of medical equipment as identified in Part I of this chapter. Such an emergency replacement is not a "project" of a medical care facility requiring a certificate of public need. To request authorization for such replacement, the owner of such equipment shall submit information to the commissioner to demonstrate that (i) the equipment is inoperable as a result of a mechanical failure, Act of God, or other reason which may not be attributed to the owner and the repair of such equipment is not practical or feasible; or (ii) the immediate replacement of the medical equipment is necessary to maintain an essential clinical health service or to assure the safety of patients or staff.~~

~~In determining that an application for emergency replacement of medical equipment is not a "project," the commissioner may condition an applicantion on the provision of a level of care at a reduced rate to indigents or acceptance of patients receiving specialized care.~~

~~For purposes of this section, "inoperable" means that the equipment cannot be put into use, operation, or practice to perform the diagnostic or therapeutic clinical health service for which it was intended.~~

~~Within 15 days of the receipt of such requests the commissioner will notify the owner in the form of a letter of the decision to deny or authorize the emergency replacement of equipment.~~

12 VAC 5-220-160. Required considerations

In determining whether a public need exists for a proposed project, the following factors shall be taken into account when applicable:

1. The recommendation and the reasons therefor of the appropriate regional health planning agency.

2. The relationship of the project to the applicable health plans of the regional health planning agency, the Virginia Health Planning Board and the Board of Health.

3. The relationship of the project to the long-range development plan, if any, of the person applying for a certificate.

4. The need that the population served or to be served by the project has for the project, including, but not limited to, the needs of rural populations in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

5. The extent to which the project will be accessible to all residents of the area proposed to be served.

6. The area, population, topography, highway facilities and availability of the services to be provided by the project in the particular part of the health planning region in which the project is proposed, in particular, the distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

7. Less costly or more effective alternate methods of reasonably meeting identified health service needs.

8. The immediate and long-term financial feasibility of the project.

9. The relationship of the project to the existing health care system of the area in which the project is proposed; however, for projects proposed in rural areas, the relationship of the project to the existing health care services in the specific rural locality shall be considered.

10. The availability of resources for the project.

11. The organizational relationship of the project to necessary ancillary and support services.

12. The relationship of the project to the clinical needs of health professional training

programs in the area in which the project is proposed.

13. The special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multidisciplinary clinic, specialty center or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health planning region in which the project is to be located.

14. The need and the availability in the health planning region for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.

15. The special needs and circumstances of health maintenance organizations. When considering the special needs and circumstances of health maintenance organizations, the commissioner may grant a certificate for a project if the commissioner finds that the project is needed by the enrolled or reasonably anticipated new members of the health maintenance organizations or the beds or services to be provided are not available from providers which are not health maintenance organizations or from other health maintenance organizations in a reasonable and cost effective manner.

16. The special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.

17. The costs and benefits of the construction associated with the proposed project.

18. The probable impact of the project on the costs of and charges for providing health services by the applicant for a certificate and on the costs and charges to the public for providing health services by other persons in the area.

19. Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.

20. In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities in the area similar to those proposed, including, in the case of rural localities, any distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

12 VAC 5-220-180. Application forms.

A. Letter of intent. An applicant shall file a letter of intent with the commissioner to request appropriate application forms, and submit a copy of that letter to the appropriate regional health planning agency, by the later of (i) 30 days prior to the submission of an application for a project included within a particular batch group or (ii) 10 days after the first letter of intent is filed for a project within a particular batch group for the same or similar services and facilities which are proposed for the same planning district or medical service area. The letter shall identify the owner, the type of project for which an application is requested, and the proposed scope (size) and location of the proposed project. The department shall transmit application forms to the applicant within seven days of the receipt of the letter of intent. A letter of intent filed with the department shall be considered void one year after the date of receipt of such letter. (See 12 VAC 5-220-310 C.)

B. Application fees. The department shall collect application fees for applications that request a certificate of public need. The fee required for an application shall be one percent of the proposed expenditure for the project, but not less than $1,000 and no more than $20,000.~~computed as follows:~~

~~1. For projects with a capital expenditure of $0 up to and including $1,000,000, the application fee is the greater of 1% of the total capital expenditure or $1,000;~~

~~2. For projects with a capital expenditure of $1,000,001 up to and including $2,000,000, the application fee is $10,000 plus .25% of the capital expenditure above $1,000,000;~~

~~3. For projects with a capital expenditure of $2,000,001 up to and including $3,000,000, the application fee is $12,500 plus .25% of the capital expenditure above $2,000,000;~~

~~4. For projects with a capital expenditure of $3,000,001 up to and including $4,000,000, the application fee is $15,000 plus .25% of the capital expenditure above $3,000,000:~~

~~5. For projects with a capital expenditure of $4,000,001 up to and including $5,000,000, the application fee is $17,500 plus .25% of the capital expenditure above $4,000,000;~~

~~6. For projects with a capital expenditure of $5,000,001 or more, the application fee is $20,000.~~

No application will be deemed to be complete for review until the required application fee is paid. (See

12 VAC 5-220-310 C.)

C. Filing application forms. Applications must be submitted at least 40 days prior to the first day of a scheduled review cycle to be considered for review in the same cycle. All applications including the required data and information shall be prepared in triplicate; two copies to be submitted to the department; one copy to be submitted to the appropriate regional health planning agency. In order to verify the date of the department's and the appropriate regional health planning agency's receipt of the application, the applicant shall transmit the document by certified mail or a delivery service, return receipt requested, or shall deliver the document by hand, with a signed receipt to be provided. No application shall be deemed to have been submitted until required copies have been received by the department and the appropriate regional health planning agency. (See 12 VAC 5-220-200.)

12 VAC 5-220-200. One hundred [~~twenty-day~~ ninety-day] review cycle.

The department shall review the following groups of completed applications in accordance with the following [~~120-day~~ 190-day] scheduled review cycles and the following descriptions of projects within each group, except as provided for in 12 VAC 5-220-220.

BATCH GROUP	GENERAL DESCRIPTION	REVIEW CYCLE Begins	Ends
A	General Hospitals/Obstetrical Services/ Neonatal Special Care Services	Feb. 10	[~~Jun. 10~~ Aug. 18]
		Aug. 10	[~~Dec. 8~~ Feb. 16]
B	Open Heart Surgery/Cardiac Catheterization/ Ambulatory Surgery Centers/Operating Room Additions/Transplant Services	Mar. 10	[~~Jul. 8~~ Sep. 16]
		Sep. 10	[~~Jan. 8~~ Mar. 19]
C	Psychiatric Facilities/Substance Abuse Treatment/Mental Retardation Facilities	Apr. 10	[~~Aug. 8~~ Oct. 17]
		Oct. 10	[~~Feb. 7~~ Apr. 18]
D	Diagnostic Imaging Facilities/Services	May 10	[~~Sep. 7~~ Nov. 16]
		Nov. 10	[~~Mar. 10~~ May 19]
E	Medical Rehabilitation Beds/Services	Jun. 10	[~~Oct. 8~~ Dec. 17]
		Dec. 10	[~~Apr. 9~~ Jun. 18]
F	Selected Therapeutic Facilities/Services	Jul. 10	[~~Nov. 7~~ Jan. 16]

		Jan. 10	[~~May 10~~ Jul. 18]
G	Nursing Home Beds	Jan. 10	[~~May 10~~ Jul. 18]
	at Retirement Communities/	Mar. 10	[~~July 8~~ Sep. 16]
	Bed Relocations/Miscellaneous	May 10	[~~Sep. 7~~ Nov. 16]
	Expenditures by Nursing Homes	July 10	[~~Nov. 7~~ Jan. 16]
		Sep. 10	[~~Jan. 8~~ Mar. 19]
		Nov. 10	[~~Mar. 10~~ May 19]

Batch Group A includes:

1. The establishment of a general hospital.

2. An increase in the total number of general acute care beds in an existing or authorized general hospital.

3. The relocation at the same site of 10 general hospital beds or 10% of the general hospital beds of a medical care facility, whichever is less, from one existing physical facility to another in any two-year period if such relocation involves a capital expenditure of $ 5 million or more (see 12 VAC 5-220-280) .

4. The introduction into an existing medical care facility of any new neonatal special care or obstetrical services which the facility has not provided in the previous 12 months.

5. Any capital expenditure of $5 million or more, not defined as a project category included in Batch Groups B through G, by or in behalf of a general hospital.

Batch Group B includes:

1. The establishment of a specialized center, clinic, or portion of a physician's office developed for the provision of outpatient or ambulatory surgery or cardiac catheterization services.

2. An increase in the total number of operating rooms in an existing medical care facility or establishment of operating rooms in a new facility.

3. The introduction into an existing medical care facility of any new cardiac catheterization, open heart surgery, or organ or tissue transplant services which the facility has not

provided in the previous 12 months.

4. The addition ~~or replacement~~ by an existing medical care facility of any medical equipment for the provision of cardiac catheterization services ~~unless a certificate of public need authorizing replacement of equipment was previously issued for the specific unit of equipment to be replaced~~.

5. Any capital expenditure of $5 million or more, not defined as a project category in Batch Group A or Batch Groups C through G, by or in behalf of a specialized center, clinic, or portion of a physician's office developed for the provision of outpatient or ambulatory surgery or cardiac catheterization services.

6. Any capital expenditure of $5 million or more, not defined as a project category in Batch Group A or Batch Groups C through G, by or in behalf of a medical care facility, which is primarily related to the provision of surgery, cardiac catheterization, open heart surgery, or organ or tissue transplant services.

Batch Group C includes:

1. The establishment of a mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facility.

2. An increase in the total number of beds in an existing or authorized mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facility.

3. An increase in the total number of mental hospital, psychiatric hospital, substance abuse treatment and rehabilitation, or mental retardation beds in an existing or authorized medical care facility which is not a dedicated mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facility.

4. The relocation at the same site of 10 mental hospital, psychiatric hospital, substance abuse treatment and rehabilitation, or mental retardation beds or 10% of the mental hospital, psychiatric hospital, substance abuse treatment and rehabilitation, or mental

retardation beds of a medical care facility, whichever is less, from one existing physical facility to another in any two-year period if such relocation involves a capital expenditure of $5 million or more (see 12 VAC 5-220-280).

5. The introduction into an existing medical care facility of any new psychiatric or substance abuse treatment service which the facility has not provided in the previous 12 months.

6. Any capital expenditure of $5 million or more, not defined as a project category in Batch Groups A and B or Batch Groups D through G, by or in behalf of a mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facilities.

7. Any capital expenditure of $5 million or more, not defined as a project category in Batch Groups A through B or Batch Groups D through G, by or in behalf of a medical care facility, which is primarily related to the provision of mental health, psychiatric, substance abuse treatment or rehabilitation, or mental retardation services.

Batch Group D includes:

1. The establishment of a specialized center, clinic, or that portion of a physician's office developed for the provision of computed tomographic (CT) scanning, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging [, except for the purpose of nuclear cardiac imaging].

2. The introduction into an existing medical care facility of any new computed tomography (CT), magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging services [, except for the purpose of nuclear cardiac imaging], which the facility has not provided in the previous 12 months.

3. The addition ~~or replacement~~ by an existing medical care facility of any equipment for the provision of computed tomography (CT), magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning~~unless a certificate of public need authorizing replacement of equipment was previously issued for the specific unit of equipment to be replaced~~.

4. Any capital expenditure of $5 million or more, not defined as a project category

in Batch Groups A through C or Batch Groups E through G, by or in behalf of a specialized center, clinic, or that portion of a physician's office developed for the provision of computed tomographic (CT) scanning, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging [, except that portion of a physician's office dedicated to providing nucelar cardiac imaging].

5. Any capital expenditure of $5 million or more, not defined as a project category in Batch Groups A through C or Batch Groups E through G, by or in behalf of a medical care facility, which is primarily related to the provision of computed tomographic (CT) scanning, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging [, except for the purpose of nuclear cardiac imaging].

Batch Group E includes:

1. The establishment of a medical rehabilitation hospital.

2. An increase in the total number of beds in an existing or authorized medical rehabilitation hospital.

3. An increase in the total number of medical rehabilitation beds in an existing or authorized medical care facility which is not a dedicated medical rehabilitation hospital.

4. The relocation at the same site of 10 medical rehabilitation beds or 10% of the medical rehabilitation beds of a medical care facility, whichever is less, from one existing physical facility to another in any two-year period, if such relocation involves a capital expenditure of $5 million or more (see 12 VAC 220-280).

5. The introduction into an existing medical care facility of any new medical rehabilitation service which the facility has not provided in the previous 12 months.

6. Any capital expenditure of $5 million or more, not defined as a project category in Batch Groups A through D or Batch Groups F through G, by or in behalf of a medical rehabilitation hospital.

7. Any capital expenditure of $5 million or more, not defined as a project category in Batch Groups A through D or Batch Groups F through G, by or in behalf of a medical care facility, which is primarily related to the provision of medical rehabilitation services.

Batch Group F includes:

1. The establishment of a specialized center, clinic, or that portion of a physician's office developed for the provision of gamma knife surgery, lithotripsy, or radiation therapy.

2. Introduction into an existing medical care facility of any new gamma knife surgery, lithotripsy, or radiation therapy services which the facility has not provided in the previous 12 months.

3. The addition ~~or replacement~~ by an existing medical care facility of any medical equipment for the provision of gamma knife surgery, lithotripsy, or radiation therapy ~~unless a certificate of public need authorizing replacement of equipment was previously issued for the specific unit of equipment to be replaced~~.

4. Any capital expenditure of $5 million or more, not defined as a project in Batch Groups A through E or Batch Group G, by or in behalf of a specialized center, clinic, or that portion of a physician's office developed for the provision of gamma knife surgery, lithotripsy, or radiation therapy.

5. Any capital expenditure of $5 million or more, not defined as a project in Batch Groups A through E or Batch Group G, by or in behalf of a medical care facility, which is primarily related to the provision of gamma knife surgery, lithotripsy, or radiation therapy.

Batch Group G includes:

1. The establishment of a nursing home, intermediate care facility, or extended care facility of a continuing care retirement community by a continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.

2. The establishment of a nursing home, intermediate care facility, or extended care facility that does not involve an increase in the number of nursing home facility beds ~~in Virginia~~ within a planning district.

3. An increase in the total number of beds in an existing or authorized nursing home, intermediate care facility, or extended care facility of a continuing care retirement community by a continuing care provider registered with the State Corporation

Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.

4 An increase in the total number of beds in an existing or authorized nursing home, intermediate care facility, or extended care facility that does not involve an increase in the number of nursing home facility beds ~~in Virginia~~ within a planning district.

5. The relocation at the same site of 10 nursing home, intermediate care facility, or extended care facility beds or 10% of the nursing home, intermediate care facility, or extended care facility beds of a medical care facility, whichever is less, from one physical facility to another in any two-year period, if such relocation involves a capital expenditure of $5 million or more (see 12 VAC 5-220-280).

6. Any capital expenditure of $5 million or more, not defined as a project category in Batch Groups A through F, by or in behalf of a nursing home, intermediate care facility, or extended care facility, which does not increase the total number of beds of the facility.

7. Any capital expenditure of $5 million or more, not defined as a project category in Batch Groups A through F, by or in behalf of a medical care facility, which is primarily related to the provision of nursing home, intermediate care, or extended care services, and does not increase the number of beds of the facility.

12 VAC 5-220-230. Review of complete application.

A. Review cycle. At the close of the work day on the ~~10th~~ tenth day of the month, the department shall provide written notification to applicants specifying the acceptance date and review schedule of completed applications including ~~a proposed~~ the date for any informal fact-finding conference that may be held between the eightieth and ninetieth day of the review cycle. The regional health planning agency shall conduct no more than two meetings, one of which must be a public hearing conducted by the regional health planning agency board or a sub-committee of the board and provide applicants with an opportunity, prior to the vote, to respond to any comments made about the project by the regional health planning agency staff, any information in a staff report, or comments by those voting in completing its review and recommendation by the sixtieth ~~60th~~ day of the cycle. By the ~~70th~~ seventieth day of the review cycle, the department shall complete its review and recommendation of an application and transmit the same to the applicant(s) and other appropriate persons. ~~Such notification shall also include the proposed date, time and place of any informal fact-finding conference.~~ By the seventy-fifth day of the review cycle, the department shall transmit to the applicant and the appropriate

other persons its determination whether an informal fact-finding conference is necessary.

An informal fact-finding conference shall be held when (i) determined necessary by the department or (ii) requested by any person ~~showing~~ seeking to demonstrate good cause. Any person seeking to demonstrate good cause shall file, no later than ~~ten~~ four days after the department has completed its review and recommendation of an application and has transmitted the same to the applicants and to persons who have prior to the issuance of the report requested a copy in writing, written notification with the commissioner, applicant(s) and other competing applicants, and regional health planning agency stating the grounds for good cause and providing the factual basis therefor under oath.

For purposes of this section, "good cause" means that (i) there is significant, relevant information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing or (iii) there is a substantial material mistake of fact or law in the department staff's report on the application or in the report submitted by the regional health planning agency. See § 9-6.14:11 of the Code of Virginia~~. The commissioner shall within five days of receipt review any filing that claims good cause and determine whether the facts presented in writing demonstrate a likelihood that good cause will be shown. If there is such a likelihood, an informal fact-finding conference shall be held on the project and on the issue of whether or not good cause was shown. If such a likelihood is not demonstrated, the person asserting good cause may seek further to demonstrate good cause at any informal fact-finding conference otherwise scheduled on the project. If no conference has otherwise been scheduled, an informal conference shall be scheduled promptly to ascertain whether facts exist that demonstrate good cause. Within five days of any such conference the commissioner shall issue his final decision on whether or not good cause has been shown. No informal fact-finding conference shall be required on any project solely upon the request of a person claiming good cause unless the commissioner finds that good cause has been shown. Where good cause is not found by the commissioner to have been shown, the person claiming it may not participate as a party to the case in any administrative proceeding.~~

~~The commissioner shall render a final determination by the 120th day of the review cycle. Unless agreed to by the applicant and, when applicable, the parties to any informal fact-finding conference held, the review schedule shall not be extended.~~

B. Time period for review. The review period shall begin on the first day of the applicable review cycle within which an application is determined to be complete, in accordance with scheduled batch review cycles described in 12 VAC 5-220-200. If the application is not determined to be complete for the applicable batch cycle within forty calendar days from the date of submission, the application may be refiled in the next applicable batch cycle.

If the regional health planning agency has not completed its review by the sixtieth day of the review cycle, or such other period in accordance with the applicant's request for extension, and submitted its recommendation within ten calendar days after the completion of its review, the Department shall, on the eleventh day after expiration of the regional health planning agency's review period, proceed as if the regional health planning agency has recommended approval of the proposed project.

In any case in which an informal fact-finding conference is not held, the project record shall be closed on the earlier of (i) the date established for holding the informal fact- finding conference or (ii) the date that the Department determines that an informal fact-finding conference is not necessary (See 12 VAC 5 220-230 A).

In any case in which an informal fact-finding conference is held, a date shall be established for closing of the record which shall not be more than forty-five calendar days after the date for holding the informal fact-finding conference. Any informal fact-finding conference shall be to consider the information and issues in the record and shall not be a de novo review.

C. Determination by the Commissioner. If a determination whether a public need exists for a project is not made by the commissioner within fifteen calendar days of the closing of the record, the commissioner shall notify the attorney general, in writing, that the application shall be deemed approved unless the determination shall be made within forty calendar days of the closing of the record. The commissioner shall transmit copies of such notice to the attorney general and to other parties to the case and any person petitioning for good cause standing.

In any case when a determination whether a public need exists for a project is not made by the commissioner within forty calendar days after closing of the record, the Department shall immediately refund fifty-percent of the application fee paid in accordance with 12 VAC 5-220-180.B, and the application shall be deemed approved and a certificate shall be granted.

If a determination whether a public need for a project exists is not made by the commissioner within fifteen calendar days of the closing of the record, any person who has filed an application competing in the relevant batch review cycle or who has filed an application in response to the relevant Request for Applications issued pursuant to 12 VAC 5-220-355 may, prior to the application being deemed approved, institute a proceeding for mandamus against the commissioner in any circuit court of competent jurisdiction.

If the court issues a writ of mandamus against the commissioner, the Department shall be liable for the costs of the action together with reasonable attorney's fee as determined by the court.

Upon the filing of a petition for a writ of mandamus, the relevant application shall not be deemed approved, regardless of the lapse of time between the closing of the record and the final decision.

Deemed approvals shall be construed as the commissioner's case decision on the application pursuant to the Administrative Process Act (§ 9-6.14:1 et seq.) and shall be subject to judicial review on appeal as the commissioner's case decision in accordance with such act.

Any person who has sought to participate in the Department's review of such deemed-to-be-approved application as a person showing good cause who has not received a final determination from the commissioner concerning the good cause petition prior to the date on which the application was approved, shall be deemed to be a person showing good cause for purposes of appeal of a deemed-to-be-approved certificate.

The applicant, and only the applicant, shall have the authority to extend any of the time periods for review of the application, which are specified in 12 VAC 5-220-230.

For purposes project review, any scheduled deadlines that fall on a weekend or state holiday shall be advanced to the next work day.

~~B~~ D. Regional health planning agency required notifications. Upon notification of the acceptance date of a complete application as set forth in subsection A of this section of these regulations, the regional health planning agency shall provide written notification of its review schedule to the applicant. The regional health planning agency shall notify health care providers and specifically identifiable consumer groups who may be affected by the proposed project directly by mail and shall also give notice of the public hearing in a newspaper of general circulation in such county or city wherein a project is proposed or a contiguous county or city at least nine days prior to such public hearing. Such notification by the regional health planning agency shall include: (i) the date and location of the public hearing which shall be conducted on the application except as otherwise provided in this chapter, in the county or city wherein a project is proposed or a contiguous county or city and (ii) the date, time and place the final recommendation of the regional health planning agency shall be made. The regional health planning agency shall maintain a verbatim record which may be a tape recording of the public hearing. Such public hearing record shall be maintained for at least a one year time period following the final decision on a certificate of public need application. See definition of "public hearing."

~~C~~ E. Ex parte contact. After commencement of a public hearing and before a final decision is made, there shall be no ex parte contacts between the State Health Commissioner and any person acting on behalf of the applicant or holder of a certificate or any person opposed to the issuance or in favor of revocation of a certificate of public need, unless written notification has been provided. See

definition of "ex parte."

12 VAC 5-220-270. Action on an application.

A. Commissioner's responsibility. Decisions as to approval or disapproval of applications or a portion thereof for certificates of public need shall be rendered by the commissioner. Any decision to issue or approve the issuance of a certificate shall be consistent with the most recent applicable provisions of the State Medical Facilities Plan. 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.

Conditions of approval. The commissioner may condition the approval of an application for a project (i) on the agreement by the applicant to provide an acceptable level of care at a reduced rate to indigents or, (ii) on the agreement of the applicant to provide care to persons with special needs, or (iii) upon the agreement of the applicant to facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area. The terms of such agreements shall be specified in writing prior to the commissioner's decision to approve a project. Any person willfully refusing, failing or neglecting to honor such agreements shall be subject to a civil penalty of $100 per violation per day from the date of receipt from the department of written notice of non-compliance until the date of compliance. Upon information and belief that a person has failed to honor such agreement in accordance with this provision, the department shall notify the person in writing and 15 days shall be provided for a response in writing including a plan for immediate correction. In the absence of an adequate response or necessary compliance or both, a judicial action shall be initiated in accordance with the provisions of § 32.1-27 of the Code of Virginia.

B. Notification process-extension of review time. The commissioner shall make a final determination on an application for a certificate of public need and provide written notification detailing the reasons for such determination to the applicant with a copy to the regional health planning agency within the time frames specified in subsection B of 12 VAC 5-220-230 unless authorization is given by the applicant(s) to extend the time period. ~~by the 120th day of the review cycle unless an extension agreed to by the applicant and an informal fact-finding conference described in 12 VAC 5-220-230 is held. When an informal fact-finding conference is held, the 120-day review cycle shall not be extended unless agreed to by the parties to the conference.~~ Such written notification shall also reference the factors and bases considered in making a decision on the application and, if applicable, the remedies available for appeal of such decision and the progress reporting requirements. The commissioner may approve a portion of a project provided the portion to be approved is agreed to by the applicant

following consultation, which may be subject to the ex parte provision of this chapter, between the commissioner and the applicant.

12 VAC 5-220-280. Applicability.

Projects of medical care facilities that involve relocation at the same site of 10 beds or 10% of the beds, whichever is less from one existing physical facility to another, when the cost of such relocation is less than $ 5 million, shall be subject to an expedited review process. ~~satisfy the criteria set forth below as determined by the State Health Commissioner shall be subject to an expedited review process:~~

~~1. relocation at the same site of 10 beds or 10% of the beds, whichever is less, from one existing physical facility to another, when the cost of such relocation is less than $5 million.~~

~~2. The replacement at the same site by an existing medical care facility, of any medical equipment for the provision of cardiac catheterization, computed tomography (CT), lithotripsy, magnetic resonance imaging (MRI), open heart surgery, positron emission tomographic scanning (PET), or radiation therapy when the medical care facility meets applicable standards for replacement of such medical equipment which are set forth in the State Medical Facilities Plan.~~

12 VAC 5-220-355. Application forms.

A. Letter of intent. A nursing home bed applicant shall file a letter of intent with the commissioner to request appropriate application forms, and submit a copy of that letter to the appropriate regional health planning agency by the letter of intent deadline specified in the RFA. The letter shall identify the owner, the type of project for which an application is requested, and the proposed scope (size) and location of the proposed project. The department shall transmit application forms to the applicant within seven days of the receipt of the letter of intent. A letter of intent filed with the department shall be considered void if an application is not filed for the project by the application deadline specified in the RFA.

B. Application fees. The department shall collect application fees for applications that request a nursing home bed certificate of public need. The fee required for an application is ~~the lesser of~~ 1.0% of the proposed capital expenditure for the project ~~or $10,000~~ but no less than $1,000 and no more than $20,000. No application will be deemed to be complete for review until the required application fee is paid.

C. Filing application forms. Applications must be submitted to the department and the appropriate regional health planning agency by the application filing deadline specified in the RFA. All applications including the required data and information shall be prepared in triplicate; two copies to be

submitted to the department; one copy to be submitted to the appropriate regional health planning agency. In order to verify the department and the appropriate regional health planning agency's receipt of the application, the applicant shall transmit the document by certified mail or a delivery service, return receipt requested, or shall deliver the document by hand, with the signed receipt to be provided. No application shall be deemed to have been submitted until required copies have been received by the department and the appropriate regional health planning agency.

12 VAC 5-220-385. Review of complete application.

A. Review Cycle. The department shall provide written notification to applicants specifying the acceptance date and review schedule of completed applications including ~~a proposed~~ the date for any informal fact-finding conference that may be held between the eightieth and ninetieth day of the review cycle . The regional health planning agency shall conduct no more than two meetings, one of which must be a public hearing conducted by the regional health planning agency board or a sub-committee of the board and provide applicants with an opportunity, prior to the vote, to respond to any comments made about the project by the regional health planning agency staff, any information in a staff report, or comments by those voting in completing its review and recommendation by the sixtieth ~~60th~~ day of the cycle. By the ~~70th~~ seventieth day of the review cycle, the department shall complete its review and recommendation of an application and transmit the same to the applicant or applicants and other appropriate persons. ~~Such notification shall also include the proposed date, time and place of any informal fact-finding conference.~~ By the seventy-fifth day of the review cycle, the department shall transmit to the applicant(s) and other appropriate persons, its determination whether an informal fact-finding conference is necessary.

An informal fact-finding conference shall be held when (i) determined necessary by the department or (ii) requested by any person ~~showing~~ seeking to demonstrate good cause. Any person seeking to demonstrate good cause shall file, no later than ~~ten~~ four days after the department has completed its review and recommendation of an application and has transmitted the same to the applicants and to persons who have prior to the issuance of the report requested a copy in writing, written notification with the commissioner, applicant or applicants and other competing applicants, and regional health planning agency stating the grounds for good cause and providing the factual basis therefor under oath.

For purposes of this section, "good cause" means that (i) there is significant, relevant information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing or (iii) there is a substantial material mistake of fact or law in the department staff's report on the application or in the report submitted by the regional health planning agency. (See [~~§ 9-6.14:11~~ § 32.1-102.6] of the Code of Virginia.) ~~The commissioner shall within five days of receipt review any filing that~~

~~claims good cause and determine whether the facts presented in writing demonstrate a likelihood that good cause will be shown. If there is such a likelihood, an informal fact-finding conference shall be held on the project and on the issue of whether or not good cause was shown. If such a likelihood is not demonstrated, the person asserting good cause may seek further to demonstrate good cause at any informal fact-finding conference otherwise scheduled on the project. If no conference has otherwise been scheduled, an informal conference shall be scheduled promptly to ascertain whether facts exist that demonstrate good cause. Within five days of any such conference the Commissioner shall issue his final decision on whether or not good cause has been shown. No informal fact-finding conference shall be required on any project solely upon the request of a person claiming good cause unless the commissioner finds that good cause has been shown. Where good cause is not found by the commissioner to have been shown, the person claiming it may not participate as a party to the case in any administrative proceeding.~~

~~The commissioner shall render a final determination by the 120th day of the review cycle. Unless agreed to by the applicant or applicants and, when applicable, the parties to any informal fact-finding conference held, the review schedule shall not be extended.~~

B. Time period for review. The review period shall begin on the first day of the applicable review cycle within which an application is determined to be complete, in accordance with scheduled batch review cycles described in 12 VAC 5-220-200. If the application is not determined to be complete for the applicable batch cycle within forty calendar days from the date of submission, the application may be refiled in the next applicable batch cycle.

If the regional health planning agency has not completed its review by the sixtieth day of the review cycle, or such other period in accordance with the applicant's request for extension, and submitted its recommendation within ten calendar days after the completion of its review, the Department shall, on the eleventh day after expiration of the regional health planning agency's review period, proceed as if the regional health planning agency has recommended approval of the proposed project.

In any case in which an informal fact-finding conference is not held, the project record shall be closed on the earlier of (i) the date established for holding the informal fact-finding conference or (ii) the date that the Department determines that an informal fact-finding conference is not necessary (See 12 VAC 5 220-230 A).

In any case in which an informal fact-finding conference is held, a date shall be established for closing of the record which shall not be more than [~~forty-five~~ thirty] calendar days after the date for holding the informal fact-finding conference. [~~Any informal fact-finding conference shall be to consider the information and issues in the record and shall not be a de novo review.~~]

C. Determination by the Commissioner. If a determination whether a public need exists for a project is not made by the commissioner within [~~fifteen~~ forty-five] calendar days of the closing of the record, the commissioner shall notify [the ~~attorney general~~ applicant or applicants and any person seeking to show good cause], in writing, that the [application or the applications of each] shall be deemed approved [~~unless the determination shall be made within forty calendar days of the closing of the record. The commissioner shall transmit copies of such notice to the attorney general and to other parties to the case and any person petitioning for good cause standing~~ twenty-five calendar days after the expiration of such forty-five-calendar-day period, unless the receipt of recommendations from the person performing the hearing officer functions permits the commissioner to issue his case decision within that twenty-five-calendar-day period. The validity or timeliness of the aforementioned notice shall not, in any event, prevent, delay or otherwise impact the effectiveness of this section.]

In any case when a determination whether a public need exists for a project is not made by the commissioner within [~~forty~~ seventy] calendar days after closing of the record, [~~the Department shall immediately refund fifty percent of the application fee paid in accordance with 12 VAC 5-220-180.B, and~~] the application shall be deemed approved and a certificate shall be granted.

If a determination whether a public need for a project exists is not made by the commissioner within [~~fifteen~~ forty-five] calendar days of the closing of the record, any applicant who is competing in the relevant batch review cycle or who has filed an application in response to the relevant Request for Applications issued pursuant to 12 VAC 5-220-355 may, prior to the application being deemed approved [~~, institute a proceeding for mandamus against the commissioner in any circuit court of competent jurisdiction~~ petition for immediate injunctive relief pursuant to § 9.6-14.21 of the Code of Virginia, naming as respondents the commissioner and all parties to the case. During the pendency of proceeding, no applications shall be deemed to be approved. In such a proceeding, the provisions of § 9-6.14.21 of the Code of Virginia shall apply.]

[~~If the court issues a writ of mandamus against the commissioner, the Department shall be liable for the costs of the action together with reasonable attorney's fee as determined by the court~~.

~~Upon the filing of a petition for a writ of mandamus, the relevant application shall not be deemed approved, regardless of the lapse of time between the closing of the record and the final decision.~~]

Deemed approvals shall be construed as the commissioner's case decision on the application pursuant to the Administrative Process Act (§ 9-6.14:1 et seq.) and shall be subject to judicial review on appeal as the commissioner's case decision in accordance with such act.

Any person who has sought to participate in the Department's review of such deemed-to-to-be-approved application as a person showing good cause who has not received a final determination from the commissioner concerning [~~the~~ such attempt to show] good cause petition prior to the date on which the application was approved, shall be deemed to be a person showing good cause for purposes of appeal of a deemed-to-be-approved certificate.

[In any appeal of the commissioner's case decision granting a certificate of public need pursuant to a Request for Applications issued pursuant to § 32.1-102.3:2 of the Code of Virginia, the court may require the appellant to file a bond pursuant to § 8.01-676.1 of the Code of Virginia, in such sum as shall be fixed by the court for protection of all parties interested in the case decision, conditioned on the payment of all damages and costs incurred in consequence of such appeal]

The [~~applicant~~ applicants], and only the [~~applicant~~ applicants], shall have the authority to extend any of the time periods for review of the application, which are specified in 12 VAC 5-220-230 . [If all applicants consent to extending any time period in this section, the commissioner, with the concurrence of the applicants, shall establish a new schedule for the remaining time periods.]

~~B~~ D. Regional health planning agency required notifications. Upon notification of the acceptance date of a complete application as set forth in subsection A of this section, the regional health planning agency shall provide written notification of its review schedule to the applicant. The regional health planning agency shall notify health care providers and specifically identifiable consumer groups who may be affected by the proposed project directly by mail and shall also give notice of the public hearing in a newspaper of general circulation in such county or city wherein a project is proposed or a contiguous county or city at least nine days prior to such public hearing. Such notification by the regional health planning agency shall include: (i) the date and location of the public hearing which shall be conducted on the application except as otherwise provided in this chapter, in the county or city wherein a project is proposed or a contiguous county or city and (ii) the date, time and place the final recommendation of the regional health planning agency shall be made. The regional health planning agency shall maintain a verbatim record which may be a tape recording of the public hearing. Such public hearing record shall be maintained for at least a one year time period following the final decision on a certificate of public need application. See definition of "public hearing."

Ex parte contact. After commencement of a public hearing and before a final decision is made, there shall be no ex parte contacts between the State Health Commissioner and any person acting on behalf of the applicant or holder of a certificate or any person opposed to the issuance or in favor of revocation of a certificate of public need, unless written notification has been provided. See definition of "ex parte."

12 VAC 5-220-420. Action on an application.

A. Commissioner's responsibility. Decisions as to approval or disapproval of applications or a portion thereof for certificates of public need shall be rendered by the commissioner. Any decision to issue or approve the issuance of a certificate shall be consistent with the most recent applicable provisions of the State Medical Facilities Plan. 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.

The commissioner may condition the approval of an application for a project (i) on the agreement by the applicant to provide an acceptable level of care at a reduced rate to indigents or, (ii) on the agreement of the applicant to provide care to persons with special needs, or (iii) upon the agreement of the applicant to facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area. The terms of such agreements shall be specified in writing prior to the commissioner's decision to approve a project. Any person willfully refusing, failing or neglecting to honor such agreements shall be subject to a civil penalty of $100 per violation per day from the date of receipt from the department of written notice of noncompliance until the date of compliance. Upon information and belief that a person has failed to honor such agreement in accordance with this provision, the department shall notify the person in writing and 15 days shall be provided for a response in writing including a plan for immediate correction. In the absence of an adequate response or necessary compliance or both, a judicial action shall be initiated in accordance with the provisions of § 32.1-27 of the Code of Virginia.

B. Notification process-extension of review time. The commissioner shall make a final determination on an application for a certificate of public need and provide written notification detailing the reasons for such determination to the applicant with a copy to the regional health planning agency ~~by the 120th day of the review cycle unless an extension is agreed to by the applicant and an informal fact-finding conference described in 12 VAC 5-220-380 is held. When an informal fact-finding conference is held, the 120-day review cycle shall not be extended unless agreed to by the parties to the conference~~ within the time frames specified in subsection B of 12 VAC 5-220-385 unless an authorization is given by the applicant(s) to extend the time period. Such written notification shall also reference the factors and bases considered in making a decision on the application and, if applicable, the remedies available for appeal of such decision and the progress reporting requirements. The commissioner may approve a portion of a project provided the portion to be approved is agreed to by the applicant following consultation, which may be subject to the ex parte provision of this chapter, between the commissioner

and the applicant.

12 VAC 5-220-470. Court review.

A. Appeal to circuit court. Appeals to a circuit court shall be governed by applicable provisions of Virginia's Administrative Process Act, § 9-6.14:15 et seq. of the Code of Virginia.

Any applicant aggrieved by a final administrative decision on its application for a certificate, any third party payor providing health care insurance or prepaid coverage to 5.0% or more of the patients in the applicant's service area, a regional health planning agency operating in the applicant's service area, ~~or~~ any person showing good cause, any person who has sought to participate in the Department's review of a deemed-to-be-approved project as a person showing good cause who has not received a final determination from the commissioner concerning the good cause petition, or any person issued a certificate aggrieved by a final administrative decision to revoke said certificate, within 30 days after the decision, may obtain a review, as provided in § 9-6.14:17 of the Code of Virginia, by the circuit court of the county or city where the project is intended to be or was constructed, located or undertaken. Notwithstanding the provisions of § 9-6.14:16 of the Administrative Process Act, no other person may obtain such review.

[In any appeal of the commissioner's case decision granting a certificate of public need pursuant to a Request for Applications issued pursuant to § 32.1-102.3:2 of the Code of Virginia, the court may require the appellant to file a bond pursuant to § 8.01-676.1 of the Code of Virginia, in such sum as shall be fixed by the court for protection of all parties interested in the case decision, conditioned on the payment of all damages and costs incurred in consequence of such appeal.]

B. Designation of judge. The judge of the court referred to in subsection A of this section shall be designated by the Chief Justice of the Supreme Court from a circuit other than the circuit where the project is or will be under construction, located or undertaken.

C. Court review procedures. Within five days after the receipt of notice of appeal, the department shall transmit to the appropriate court all of the original papers pertaining to the matter to be reviewed. The matter shall thereupon be reviewed by the court as promptly as circumstances will reasonably permit. The court review shall be upon the record so transmitted. The court may request and receive such additional evidence as it deems necessary in order to make a proper disposition of the appeal. The court shall take due account of the presumption of official regularity and the experience and specialized competence of the commissioner. The court may enter such orders pending the completion of the proceedings as are deemed necessary or proper. Upon conclusion of review, the court may affirm, vacate or modify the final administrative decision.

D. Further appeal. Any party to the proceeding may appeal the decision of the circuit court in the same manner as appeals are taken and as provided by law.

I certify that this regulation is full, true, and correctly dated.

_____

E. Anne Peterson, M.D., M.P.H.
State Health Commissioner

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:

"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.

"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.

"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.

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 Health Plan and~~ the State Medical Facilities Plan; provided, however, if the commissioner finds, upon presentation of appropriate evidence, that the provisions of ~~either~~ such plan are not relevant to a rural locality's needs, inaccurate, outdated, inadequate or otherwise inapplicable, the commissioner, consistent with such finding, may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to such plan."

Subsection B of Section 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.

I certify that this regulation is full, true, and correctly dated.

_____

E. Anne Peterson, M.D., M.P.H.
State Health Commissioner

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.

"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.

~~"Metropolitan statistical area (MSA)" means a general concept of a metropolitan area that consists of a large population nucleus together with adjacent communities which have a high degree of economic and social integration with the nucleus. Each MSA has one or more central counties containing the area's main population concentration: an urbanized area with at least 50,000 inhabitants. An MSA may also include outlying counties which have close economic and social relationships with the central counties. The outlying counties must have a specified level of commuting to the central counties and and must also meet standards regarding metropolitan character, such as population density, urban population, and population growth.~~

"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 requried 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.

"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.

12 VAC 5-240-20. Accessibility.

Acute care inpatient facility beds should be within ~~45~~ 30 minutes ~~average~~ 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 history and 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 metropolitan statistical area~~ a non-rural area should be approved unless: (i) the average annual occupancy rate, based on the number of licensed beds in the ~~MSA~~ non-rural area where the project is proposed, is at least 65% for the relevant reporting period; or (ii) for hospitals ~~outside of an MSA~~ 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.

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;

(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 fifty percent or more of the population resides in non-rural areas and .75 in planning districts in which less than fifty percent 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 2 a above from the number of beds needed as determined in 2 b (2). 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;

(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:

Number of pediatric beds allowable = PADC + 2.33vPADC

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:

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

a. 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;

b. Sum the planning district projected population for the same three year period as

reported by the Virginia Employment Commission;

c. 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;

d. 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.

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

a. Divide the number of days projected in 1 d by 365 to yield the projected average daily census (PADC);

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

Number of intensive care beds needed = PADC + 2.33vPADC

3. 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:

a. 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.

b. ~~Substract~~ Subtract the number of licensed and approved beds identified in 3 a above from the number of beds needed as determined in 2 b. 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.

I certify that this regulation is full, true, and correctly dated.

_____

E. Anne Peterson, M.D., M.P.H.
State Health Commissioner

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 ~~provude~~ 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 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.

"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.

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.

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 ~~elvel~~ 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.

I certify that this regulation is full, true, and correctly dated.

_____

E. Anne Peterson, M.D., M.P.H., State Health Commissioner

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 history of 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 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 ~~remote~~ 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.

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, transseptal 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.

2 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.

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 ~~remote~~ 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.

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.

I certify that this regulation is full, true, and correctly dated.

_____

E. Anne Peterson, M.D., M.P.H.
State Health Commissioner

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

Surgical services should be available within a maximum driving time, under normal conditions, of ~~45~~ 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 history of 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

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. PORV = CSUR * 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 ~~Economic~~ Employment Commission.

3. FORH = PORV * 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. FOR = 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 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.

I certify that this regulation is full, true, and correctly dated.

_____

E. Anne Peterson, M.D., M.P.H.
State Health Commissioner

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.

"Health care financing administration (HCFA) medicare requirements" means those clinical, certification and administrative requirements and standards set by the HCFA 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- and/or post-transplant patients conducted at a site remote from the facility in which the organ transplant surgical services are provided which allows patients to obtain outpatient services associated with organ transplantation closer to their city or county of residence.

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.

I certify that this regulation is full, true, and correctly dated.

_____

E. Anne Peterson, M.d., M.P.H.
State Health Commissioner

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....[~~12~~ 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%

Heart 70-80%

Heart/Lung (none set)

Liver 50-60%

Pancreas 80-90%

2. Survival rates beyond one year should be consistent with the Health Care Financing Administration (HCFA) Medicare program requirements, or with applicable professional society recommended standards acceptable to the department where there are no HCFA 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.

I certify that this regulation is full, true, and correctly dated.

_____

E. Anne Peterson, M.D., M.P.H.
State Health Commissioner

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 which 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 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 which allows patients to obtain needed outpatient services for their psychiatric illness and/or substance abuse closer to their city or county of residence.

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

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 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.

I certify that this regulation is full, true, and correctly dated.

_____

E. Anne Peterson, M.D., M.P.H.
State Health Commissioner

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;

4. There are ~~specific local conditions~~ 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.

I certify that this regulation is full, true, and correctly dated.

_____

E. Anne Peterson, M.D., M.P.H.
State Health Commissioner

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 and/or rural areas, directly or through the establishment of referral linkages with general hospitals or other appropriate organizations.

I certify that this regulation is full, true, and correctly dated.

_____

E. Anne Peterson, M.D., M.P.H.
State Health Commissioner

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 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 5-320-150. Need for new service.

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

B. No MRI service should be approved at a site which 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.

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 5-320-430. 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.

I certify that this regulation is full, true, and correctly dated.

_____

E. Anne Peterson, M.D., M.P.H.
State Health Commissioner

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.

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 history of commitment to the development of transportation resources for rural populations.

I certify that this regulation is full, true, and correctly dated.

_____

E. Anne Peterson, M.D., M.P.H.
State Health Commissioner

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. ~~In urban areas, preference will be given in the review of competing applications to proposed nursing facilities which are fully accessible by private and public modes of transportation.~~

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 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 which 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 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.

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 ~~these beds~~ such facilities are ~~combined with adult care residence facilities~~ 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 nursing home facilities or the expansion of existing facilities by Continuing Care Retirements 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 ~~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.

I certify that this regulation is full, true, and correctly dated.

_____

E. Anne Peterson, M.D., M.P.H.
State Health Commissioner

mds/4upld/ENTIRE COPN SMFP EMERG-PERM'T REGS.doc