VIRGINIA MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED RULES AND REGULATIONS

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 ə 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 ə 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 ə 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 э 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 ɜ 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 ɜ 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 ə 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 э 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 Aproject≅ 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 Aproject,≅ 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 review cycle.

The department shall review the following groups of completed applications in accordance with the following 120-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 Aug. 10	Jun. 10 Dec. 8
B	Open Heart Surgery/Cardiac Catheterization/ Ambulatory Surgery Centers/Operating Room Additions/Transplant Services	Mar. 10 Sep. 10	Jul. 8 Jan. 8
C	Psychiatric Facilities/Substance Abuse Treatment/Mental Retardation Facilities	Apr. 10 Oct. 10	Aug. 8 Feb. 7

D	Diagnostic Imaging Facilities/Services	May 10	Sep. 7	
			Nov. 10	Mar. 10
E	Medical Rehabilitation Beds/Services	Jun. 10	Oct. 8	
			Dec. 10	Apr. 9
F	Selected Therapeutic Facilities/Services	Jul. 10	Nov. 7	
			Jan. 10	May 10
G	Nursing Home Beds		Jan. 10	May 10
	at Retirement Communities/		Mar. 10	July 8
	Bed Relocations/Miscellaneous	May 10	Sep. 7	
	Expenditures by Nursing Homes		July 10	Nov. 7
			Sep. 10	Jan. 8
			Nov. 10	Mar. 10

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 <u>if such relocation involves a capital expenditure of $ 5 million or more (see 12 VAC 5-220-280)</u> .

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 <u>if such relocation involves a capital expenditure of $5 million or more (see 12 VAC 5-220-280)</u>.

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.

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 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.

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.

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 (ə 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 (ə 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 ɔ 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 (ə 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 ə 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 seventieth ~~70th~~ 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 ə 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 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 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 application 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.

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 (ə 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 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.

~~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 ə 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 5-220-385 unless an authorization is given by the applicant(s) to extend the time period ~~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~~. 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.

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.
Acting State Health Commissioner