VIRGINIA ACTS OF ASSEMBLY -- 1999 SESSION

CHAPTER 922

An Act to amend and reenact §§ 32.1-102.1, 32.1-102.2, 32.1-102.6, and 32.1-102.12 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 32.1-102.1:1, relating to medical care facilities certificate of public need.

[H 2369]

Approved March 29, 1999

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-102.1, 32.1-102.2, 32.1-102.6, and 32.1-102.12 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 32.1-102.1:1 as follows:

§ 32.1-102.1. Definitions.

As used in this article, unless the context indicates otherwise:

"Certificate" means a certificate of public need for a project required by this article.

"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.

"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.

"Medical care facility," as used in this title, means any institution, place, building or agency, 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 privately operated or owned or operated by a local governmental unit, (i) by or in which health services are 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 nonrelated mentally or physically sick or injured persons, or for the care of two or more nonrelated 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 article, only the following medical care facilities 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.

The term "medical care facility" shall not include any facility of (i) the Department of Mental Health, Mental Retardation and Substance Abuse Services; or (ii) 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; or (iii) a physician's office, except that portion of a physician's office described above in subdivision 9 of the definition of "medical care facility"; or (iv) the Woodrow Wilson Rehabilitation Center of the Department of Rehabilitative Services.

"Project" means:

1. Establishment of a medical care facility;
2. An increase in the total number of beds or operating rooms in an existing medical care facility;
3. Relocation at the same site of ten beds or ten percent 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 ten percent of its beds as nursing home beds as provided in § 32.1-132;

4. Introduction into an 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, regardless of the type of medical care facility in which those services are provided;

5. Introduction into an existing medical care facility of any new cardiac catheterization, computed tomographic (CT) scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), medical rehabilitation, neonatal special care, obstetrical, open heart surgery, positron emission tomographic (PET) scanning, psychiatric, organ or tissue transplant service, radiation therapy, nuclear medicine imaging, 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 twelve months;

6. 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 tomographic (CT) scanning, 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. ~~Notwithstanding the provisions of this subdivision, the Commissioner shall develop regulations (i) providing for the replacement by a medical care facility of existing medical equipment, which is determined by the Commissioner to be inoperable or otherwise in need of replacement without requiring issuance of a certificate of public need, if the applicant agrees to such conditions as the Commissioner may establish, in compliance with regulations promulgated by the Board, requiring the applicant to provide a level of care at a reduced rate to indigents or accept patients requiring specialized care; and (ii) providing for the replacement by a medical care facility of existing medical equipment without the issuance of a certificate of public need if the Commissioner has determined a certificate of public need has been previously issued for replacement of the specific equipment.~~ Replacement ~~or upgrade~~ of existing ~~magnetic resonance imaging (MRI)~~ *equipment* shall not ~~have to obtain~~ *require* a certificate of public need; or

8. Any capital expenditure of five million dollars 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 one and five million dollars shall be registered with the Commissioner pursuant to regulations developed by the 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 the health planning activities set forth in this chapter within a health planning region.

"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.

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

§ 32.1-102.1:1. Equipment registration required.

Within thirty calendar days of becoming contractually obligated to acquire any medical equipment for the provision of cardiac catheterization, computed tomographic (CT) scanning, 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, any person shall register such purchase with the Commissioner and the appropriate health systems agency.

§ 32.1-102.2. Regulations.

A. The Board shall promulgate regulations which are consistent with this article and:

1. Shall establish *concise* procedures for the *prompt* review of applications for certificates consistent with the provisions of this article which may include a structured batching process which incorporates, but is not limited to, authorization for the Commissioner to request proposals for certain projects;

2. May classify projects and may eliminate one or more or all of the procedures prescribed in § 32.1-102.6 for different classifications;

3. May provide for exempting from the requirement of a certificate projects determined by the Commissioner, upon application for exemption, to be subject to the economic forces of a competitive market or to have no discernible impact on the cost or quality of health services; and

4. ~~Shall~~ *May* establish, *on or after July 1, 1999,* a schedule of fees for applications for certificates to be applied to expenses for the administration and operation of the certificate of public need program. Such fees shall not be less than $1,000 nor exceed the lesser of one percent of the proposed expenditure

for the project or $20,000. *Until such time as the Board shall establish a schedule of fees, such fees shall be one percent of the proposed expenditure for the project; however, such fees shall not be less than $1,000 or more than $20,000.*

B. The Board shall promulgate regulations providing for time limitations for schedules for completion and limitations on the exceeding of the maximum capital expenditure amount for all reviewable projects. The Commissioner shall not approve any such extension or excess unless it complies with the Board's regulations.

C. The Board shall also promulgate regulations authorizing the Commissioner to condition approval of a certificate on the agreement of the applicant to provide a level of care at a reduced rate to indigents or accept patients requiring specialized care. In addition, the Board's licensure regulations shall direct the Commissioner to ~~consider,~~ ~~when~~ *condition the* issuing or renewing *of* any license for any applicant whose certificate was approved upon such condition~~,~~ *on* whether such applicant has complied with any agreement to provide a level of care at a reduced rate to indigents or accept patients requiring specialized care.

§ 32.1-102.6. Administrative procedures.

A. To obtain a certificate for a project, the applicant shall file a completed application for a certificate with the Department and the appropriate health systems agency. *In order to verify the date of the Department's and the appropriate health systems 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 signed receipt to be provided.*

Within ten calendar days of the date on which the document is received, the Department and the appropriate health systems agency shall determine whether the application is complete or not and the Department shall notify the applicant, if the application is not complete, of the information needed to complete the application.

At least thirty *calendar* days before any person is contractually obligated to acquire an existing medical care facility, the cost of which is $600,000 or more, that person shall notify the Commissioner and the appropriate health systems agency of the intent, the services to be offered in the facility, the bed capacity in the facility and the projected impact that the cost of the acquisition will have upon the charges for services to be provided. If clinical services or beds are proposed to be added as a result of the acquisition, the Commissioner may require the proposed new owner to obtain a certificate prior to the acquisition.

B. The appropriate health systems agency shall ~~begin~~ ~~to~~ review each ~~complete~~ *completed* application for a certificate within ~~such~~ ~~time~~ ~~as~~ ~~the~~ ~~Board~~ ~~may~~ ~~prescribe~~ ~~by~~ ~~regulation~~ *sixty calendar days of the day which begins the 120-calendar-day review period.* The health systems agency shall hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city. The health systems agency shall cause notice of the public hearing to be published in a newspaper of general circulation in the county or city where a project is proposed to be located at least nine *calendar* days prior to the public hearing. In no case shall a health systems agency hold more than two meetings on any application, one of which shall be ~~a~~ *the* public hearing conducted by the board of the health systems agency or a subcommittee of the board. The applicant shall be given the opportunity, prior to the vote *by the board of the health systems agency or a committee of the agency, if acting for the board, on its recommendation*, to respond to any comments made about the project by the health systems agency staff, any information in a staff report, or comments by those voting*; however, such opportunity shall not increase the sixty-calendar-day period designated herein for the health systems agency's review unless the applicant requests a specific extension in the health systems agency's review period*.

The health systems agency shall submit its recommendations on each application and its reasons therefor to the Department within ~~such~~ ~~time~~ ~~as~~ ~~may~~ ~~be~~ ~~prescribed~~ ~~by~~ ~~the~~ ~~Board~~ ~~by~~ ~~regulation~~ *ten calendar days after the completion of its sixty-calendar-day review or such other period in accordance with the applicant's request for extension*.

If the health systems agency has not completed its review within the specified sixty calendar days or such other period in accordance with the applicant's request for extension and submitted its recommendations on the application and the reasons therefor within ten calendar days after the completion of its review, the Department shall, on the eleventh calendar day after the expiration of the health systems agency's review period, proceed as though the health systems agency has recommended project approval without conditions or revision.

C. After commencement of ~~a~~ *any* public hearing and before a decision is made there shall be no ex parte contacts concerning the subject certificate or its application between (i) 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 and (ii) any person in the Department who has authority to make a determination respecting the issuance or revocation of a certificate of public need, unless the Department has provided advance notice to all parties referred to in (i) of the time and place of such proposed contact.

D. *The Department and the Commissioner shall commence the review of the application upon receipt*

of the completed application and simultaneously with the review conducted by the health systems agency.

A determination whether a public need exists for a project shall be made by the Commissioner within 120 *calendar* days of the receipt of a completed application.

The 120-calendar-day review period shall begin on the date upon which the application is determined to be complete within the batching process specified in subdivision A 1 of § 32.1-102.2.

If the application is not determined to be complete within forty calendar days from submission, the application shall be refiled in the next batch for like projects.

~~Such determination shall be made in accordance with~~ The provisions of the Administrative Process Act (§ 9-6.14:1 et seq.) ~~except that~~ *shall only apply to those parts of the determination process for which timelines and specifications are not delineated in subsection E of this section. Further,* the parties to the case shall include only the applicant, any person showing good cause, any third-party payor providing health care insurance or prepaid coverage to five percent or more of the patients in the applicant's service area, or the health systems agency if its recommendation was to deny the application.

E. Upon accepting an application as complete, the following procedure, in lieu of the Administrative Process Act, shall control:

1. The Department shall establish, for every application, a date between the eightieth and ninetieth calendar days within the 120-calendar-day review period for holding an informal fact-finding conference, if such conference is necessary.

2. The Department shall review every application at or before the seventy-fifth calendar day within the 120-calendar-day review period to determine whether an informal fact-finding conference is necessary.

3. Any informal fact-finding conference shall be to consider the information and issues in the record and shall not be a de novo review.

4. In any case in which an informal fact-finding conference is held, a date shall be established for the closing of the record which shall not be more than forty-five calendar days after the date for holding the informal fact-finding conference.

5. In any case in which an informal fact-finding conference is not held, the 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 an informal fact-finding conference is not necessary.

6. 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 the Attorney General's notice to the other parties to the case and to any person petitioning for good cause standing.

7. 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 the closing of the record, the Department shall immediately refund fifty percent of the fee paid in accordance with § 32.1-102.2 A 4, the application shall be deemed to be approved, and the certificate shall be granted.

8. 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, any applicant who is competing in the relevant batch or who has filed an application in response to the relevant Request For Applications issued pursuant to § 32.1-102.3:2 may, prior to the application being deemed approved, institute a proceeding for mandamus against the Commissioner in any circuit court of competent jurisdiction.

9. If a writ of mandamus is issued against the Commissioner by the court, the Department shall be liable for the costs of the action together with reasonable attorney's fees as determined by the court.

10. 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.

F. 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 shall be deemed to be a person showing good cause for purposes of appeal of the deemed approval of the certificate.

G. For purposes of this ~~subsection~~ *section*, "good cause" shall mean 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 health systems agency.

~~E.~~ *H.* The project review procedures shall provide for separation of the project review manager functions from the hearing officer functions. No person serving in the role of project review manager

shall serve as a hearing officer.

I. The applicant, and only the applicant, shall have the authority to extend any of the time periods specified in this section.

§ 32.1-102.12. Report required.

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:

1. A summary of the Commissioner's actions during the previous fiscal year pursuant to this article;

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

3. 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;

4. An analysis of the effectiveness of the application review procedures used by the health systems 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 health systems 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;

~~4.~~ *5.* 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;

~~5.~~ *6.* An analysis of the accessibility by the indigent to care provided by the medical care facilities regulated pursuant to this article and the relevance of this article to such access; ~~and~~

~~6.~~ *7.* An analysis of the relevance of this article to the quality of care provided by medical care facilities regulated pursuant to this article*; and*

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

2. That an emergency exists and the provisions of this act amending and reenacting § 32.1-102.1 and adding § 32.1-102.1:1 are in force from its passage.

3. That, except for the provisions of this act amending and reenacting § 32.1-102.1 and adding § 32.1-102.1:1, the amendments in this act shall become effective on October 1, 1999.

4. That any applications for medical care facilities certificates of public need pending on October 1, 1999, for which the record has been closed on or before October 1, 1999, shall be subject to the provisions of this act as if the record had closed on October 1, 1999. Applications for certificates of public need pending on October 1, 1999, for which the record has not been closed on or before October 1, 1999, shall be subject to the provisions of this act as if the applications were filed on October 1, 1999.

5. That the Board of Health shall promulgate regulations to implement the provisions of this act within 280 days of the date of its enactment.