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HOUSE BILL NO. 2177

Offered January 14, 2015

Prefiled January 14, 2015

A BILL to amend and reenact §§ 15.2-5307, 32.1-102.1, 32.1-102.1:1, 32.1-102.2, 32.1-102.2:1, 32.1-102.3, 32.1-102.6, 32.1-102.11, 32.1-122.01, 32.1-122.03, 32.1-122.04, and 32.1-122.07 of the Code of Virginia, to amend the Code of Virginia by adding a section numbered 32.1-102.1:2, and to repeal §§ 32.1-122.05 and 32.1-122.06 of the Code of Virginia, relating to certificate of public need; regional health planning agencies.

Patron—Orrock

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 15.2-5307, 32.1-102.1, 32.1-102.1:1, 32.1-102.2, 32.1-102.2:1, 32.1-102.3, 32.1-102.6, 32.1-102.11, 32.1-122.01, 32.1-122.03, 32.1-122.04, and 32.1-122.07 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 32.1-102.1:2 as follows:

§ 15.2-5307. Appointment, qualifications, tenure, and compensation of commissioners.

An authority shall consist of not more than 15 commissioners appointed by the mayor, and he shall designate the first chairman. No more than three commissioners shall be practicing physicians. No officer or employee of the city, with the exception of the director of a local health department, shall be eligible for appointment; however, no director of a local health department shall serve as chairman of the authority. ~~No local health director who serves as a hospital authority commissioner shall serve as a member of the regional health planning agency board simultaneously. No practicing physician shall be appointed to such authority in the City of Hopewell.~~

One-third of the commissioners who are first appointed shall be designated by the mayor to serve for terms of two years, one-third to serve for terms of four years, and one-third to serve for terms of six years, respectively, from the date of their appointment. Thereafter, the term of office shall be six years. No person shall be appointed to succeed himself following four successive terms in office; no term of less than six years shall be deemed a term in office for the purposes of this sentence.

A commissioner shall hold office until the earlier of the effective date of his resignation or the date on which his successor has been appointed and has qualified. Vacancies shall be filled for the unexpired term. In the event of a vacancy in the office of commissioner by expiration of term of office or otherwise, the remaining commissioners shall submit to the mayor nominations for appointments. The mayor may successively require additional nominations and shall have power to appoint any person so nominated. All such vacancies shall be filled from such nominations. A majority of the commissioners currently in office shall constitute a quorum. The mayor may file with the city clerk a certificate of the appointment or reappointment of any commissioner, and such certificate shall be conclusive evidence of the due and proper appointment of such commissioner. A commissioner shall receive no compensation for his services, but he shall be entitled to the necessary expenses including traveling expenses incurred in the discharge of his duties.

§ 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 Department of Behavioral Health and Developmental Services, 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 persons who are injured or physically sick or have mental illness, or for the care of two or more nonrelated persons requiring or receiving medical, surgical or nursing attention or services as

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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, except those intermediate care facilities established for individuals with intellectual disability (ICF/MR) that have no more than 12 beds and are in an area identified as in need of residential services for individuals with intellectual disability in any plan of the Department of Behavioral Health and Developmental Services.

5. Extended care facilities.

6. Mental hospitals.

7. Facilities for individuals with intellectual disability.

8. Psychiatric hospitals and intermediate care facilities established primarily for the medical, psychiatric or psychological treatment and rehabilitation of individuals with substance abuse.

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, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy, proton beam therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac 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~~ *does* not include any facility of (i) the Department of Behavioral Health and Developmental Services; (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 Behavioral Health and Developmental Services' Comprehensive State Plan; (iii) an intermediate care facility for individuals with intellectual disability (ICF/MR) that has no more than 12 beds and is in an area identified as in need of residential services for individuals with intellectual disability in any plan of the Department of Behavioral Health and Developmental Services; (iv) a physician's office, except that portion of a physician's office described in subdivision 9 of the definition of "medical care facility"; (v) the Woodrow Wilson Rehabilitation Center of the Department for Aging and Rehabilitative Services; (vi) the Department of Corrections; or (vii) the Department of Veterans Services. "Medical care facility" shall also not include that portion of a physician's office dedicated to providing nuclear cardiac imaging.

"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, *except that "project" does not include an increase in the total number of non-nursing home beds in an existing general hospital, psychiatric hospital, or rehabilitation hospital or operating rooms in an existing general hospital*;

3. Relocation of beds from one existing facility to another, provided that "project" ~~shall~~ *does* not include the relocation of up to 10 beds or 10 percent of the beds, whichever is less, (i) from one existing facility to another existing facility at the same site in any two-year period, or (ii) in any three-year period, from one existing nursing home facility to any other existing nursing home facility owned or controlled by the same person that is located either within the same planning district, or within another planning district out of which, during or prior to that three-year period, at least 10 times that number of beds have been authorized by statute to be relocated from one or more facilities located in that other planning district and at least half of those beds have not been replaced, provided further that, however, a hospital shall not be required to obtain a certificate for the use of 10 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, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), medical rehabilitation, neonatal special care *except as provided in § 32.1-102.1:2*, obstetrical, open heart surgery *except as provided in § 32.1-102.1:2*, positron emission tomographic (PET) scanning, psychiatric, organ or tissue transplant service, radiation therapy, stereotactic radiotherapy, proton beam therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac 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 12

months;

6. ~~Conversion of beds in an existing medical care facility to medical rehabilitation beds or psychiatric beds;~~

~~7.~~ The addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization, computed tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery *except as provided in § 32.1-102.1:2*, positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy, proton beam therapy, or other specialized service designated by the Board by regulation. Replacement of existing equipment shall not require a certificate of public need;

~~8.~~ *7.* Any capital expenditure of $15 million or more, not defined as reviewable in subdivisions 1 through ~~7~~ *6* of this definition, by or in behalf of a medical care facility, *except for a capital expenditure by or on behalf of a general hospital*. However, capital expenditures between $5 and $15 million shall be registered with the Commissioner pursuant to regulations developed by the Board, *except for capital expenditures by or on behalf of a general hospital*. The amounts specified in this subdivision shall be revised effective July 1, 2008, and annually thereafter to reflect inflation using appropriate measures incorporating construction costs and medical inflation; or

~~9.~~ *8.* Conversion in an existing medical care facility of psychiatric inpatient beds approved pursuant to a Request for Applications (RFA) to nonpsychiatric inpatient beds.

~~"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.

§ 32.1-102.1:1. Equipment registration required.

Within ~~thirty~~ *30* calendar days of becoming contractually obligated to acquire any medical equipment for the provision of cardiac catheterization, computed tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy, proton beam therapy, or other specialized service designated by the Board by regulation, any person shall register such purchase with the Commissioner ~~and the appropriate regional health planning agency~~.

§ 32.1-102.1:2. Service registration required.

A. A general hospital may introduce new open heart surgery services and any medical equipment for the provision thereof without first obtaining a certificate of public need for such service and equipment if (i) the general hospital registers the open heart surgery service and medical equipment for the provision of open heart surgery with the Commissioner prior to establishing such service and (ii) the general hospital performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 were therapeutic catheterizations, or discharged at least 800 patients with the principal diagnosis of ischemic heart disease during the 12 months immediately preceding such registration.

B. A general hospital may introduce new intermediate-level or specialty-level neonatal special care services without first obtaining a certificate of public need for such services if (i) the general hospital registers the new intermediate-level or specialty-level neonatal special care service with the Commissioner prior to establishing such service and (ii) the general hospital delivered at least 1,000 infants during the 12 months immediately preceding such registration.

§ 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. In any structured batching process established by the Board, applications, combined or separate, for computed tomographic (CT) scanning, magnetic resonance imaging (MRI), positron emission tomographic (PET) scanning, radiation therapy, sterotactic radiotherapy, proton beam therapy, or nuclear imaging shall be considered in the radiation therapy batch. A single application may be filed for a combination of (i) radiation therapy, sterotactic radiotherapy and proton beam therapy, and (ii) any or all of the computed tomographic (CT) scanning, magnetic resonance imaging (MRI), positron emission tomographic (PET) scanning, and nuclear medicine imaging;

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;

4. Shall establish specific criteria for determining need in rural areas, giving due consideration to distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care in such areas and providing for weighted calculations of need based on the barriers to health care access in such rural areas in lieu of the determinations of need used for the particular proposed project within the relevant health systems area as a whole; *and*

5. 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~~;~~ ~~and~~

~~6. Shall establish an expedited application and review process for any certificate for projects reviewable pursuant to subdivision 8 of the definition of "project" in § 32.1-102.1. Regulations establishing the expedited application and review procedure shall include provisions for notice and opportunity for public comment on the application for a certificate, and criteria pursuant to which an application that would normally undergo the review process would instead undergo the full certificate of public need review process set forth in § 32.1-102.6~~.

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. However, the Commissioner may approve a significant change in cost for an approved project that exceeds the authorized capital expenditure by more than 20 percent, provided the applicant has demonstrated that the cost increases are reasonable and necessary under all the circumstances and do not result from any material expansion of the project as approved.

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 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.

§ 32.1-102.2:1. State Medical Facilities Plan; task force.

The Board shall appoint and convene a task force of no fewer than 15 individuals to meet at least once every two years. The task force shall consist of representatives from the Department and the Division of Certificate of Public Need~~, representatives of regional health planning agencies~~, representatives of the health care provider community, representatives of the academic medical community, experts in advanced medical technology, and health insurers. The task force shall complete a review of the State Medical Facilities Plan updating or validating existing criteria in the State Medical Facilities Plan at least every four years.

§ 32.1-102.3. Certificate required; criteria for determining need.

A. No person shall commence any project without first obtaining a certificate issued by the Commissioner. No certificate may be issued unless the Commissioner has determined that a public need for the project has been demonstrated. If it is determined that a public need exists for only a portion of a project, a certificate may be issued for that portion and any appeal may be limited to the part of the decision with which the appellant disagrees without affecting the remainder of the decision. 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. In cases in which a provision of the State Medical Facilities Plan has been previously set aside by the Commissioner and relevant amendments to the Plan have not yet taken effect, the Commissioner's decision shall be consistent with the applicable portions of the State Medical Facilities Plan that have not been set aside and the remaining considerations in subsection B.

B. In determining whether a public need for a project has been demonstrated, the Commissioner shall consider:

1. The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care;

2. The extent to which the project will meet the needs of the residents of the area to be served, as demonstrated by each of the following: (i) the level of community support for the project demonstrated by citizens, businesses, and governmental leaders representing the area to be served; (ii) the availability of reasonable alternatives to the proposed service or facility that would meet the needs of the population in a less costly, more efficient, or more effective manner; (iii) ~~any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6;~~ ~~(iv)~~ any costs and benefits of the project; ~~(v)~~ *(iv)* the financial accessibility of the project to the residents of the area to be served, including indigent residents; and ~~(vi)~~ *(v)* at the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a project;

3. The extent to which the application is consistent with the State Medical Facilities Plan;

4. The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area to be served;

5. The relationship of the project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities;

6. The feasibility of the project, including the financial benefits of the project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital;

7. The extent to which the project provides improvements or innovations in the financing and delivery of health services, as demonstrated by: (i) the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) the potential for provision of services on an outpatient basis; (iii) any cooperative efforts to meet regional health care needs; and (iv) at the discretion of the Commissioner, any other factors as may be appropriate; and

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served, (i) the unique research, training, and clinical mission of the teaching hospital or medical school~~,~~ and (ii) any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

§ 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 regional health planning agency if a regional health planning agency has been designated for that region~~. 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 electronically, by certified mail or a delivery service, return receipt requested, or shall deliver the document by hand, with signed receipt to be provided.

Within 10 calendar days of the date on which the document is received, the Department ~~and the appropriate regional health planning agency, if a regional health planning agency has been designated,~~ 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. ~~If no regional health planning agency is designated for the health planning region in which the project will be located, no filing with a regional health planning agency is required and the Department shall determine if the application is complete and notify the applicant, if the application is not complete, of the information needed to complete the application.~~

At least 30 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 regional health planning agency, if a regional health planning agency has been designated,~~ 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. ~~If no regional health planning agency is designated for the health planning region in which the acquisition will take place, no notification to a regional health planning agency shall be required.~~

B. ~~For projects proposed in health planning regions with regional planning agencies, the appropriate regional health planning agency shall (i) review each completed application for a certificate within 60 calendar days of the day which begins the appropriate batch review cycle as established by the Board by regulation pursuant to subdivision A 1 of § 32.1-102.2, such cycle not to exceed 190 days in duration, and (ii) 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. Prior to the public hearing, the regional health planning agency shall notify the local governing bodies in the planning district. At least nine days prior to the public hearing, the regional health planning agency shall cause notice of the public hearing to be published in a newspaper of general circulation in the county or city where the project is proposed to be~~

~~located. The regional health planning agency shall consider the comments of the local governing bodies in the planning district and all other public comments in making its decision. Such comments shall be part of the record. In no case shall a regional health planning agency hold more than two meetings on any application, one of which shall be the public hearing conducted by the board of the regional health planning agency or a subcommittee of the board. The applicant shall be given the opportunity, prior to the vote by the board of the regional health planning 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 regional health planning agency staff, any information in a regional health planning agency staff report, or comments by those voting members of the regional health planning agency board; however, such opportunity shall not increase the 60-calendar-day period designated herein for the regional health planning agency's review unless the applicant or applicants request a specific extension of the regional health planning agency's review period.~~

~~The regional health planning agency shall submit its recommendations on each application and its reasons therefor to the Department within 10 calendar days after the completion of its 60-calendar-day review or such other period in accordance with the applicant's request for extension.~~

~~If the regional health planning agency has not completed its review within the specified 60 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 10 calendar days after the completion of its review, the Department shall, on the eleventh calendar day after the expiration of the regional health planning agency's review period, proceed as though the regional health planning agency has recommended project approval without conditions or revision.~~

~~If no regional health planning agency has been designated for a region, the~~ *The* Department shall hold one hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city. Prior to the hearing, the Department shall notify the local governing bodies in the planning district in which the project is proposed. At least nine days prior to the public hearing, the Department shall cause notice of the public hearing to be published in a newspaper of general circulation in the county or city where the project is proposed to be located. The Department shall consider the comments of the local governing bodies in the planning district and all other public comments in making its decision. Such comments shall be part of the record.

C. After commencement of 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 *clause* (i) of the time and place of such proposed contact.

D. The Department shall commence the review of each completed application upon the day which begins the appropriate batch review cycle ~~and simultaneously with the review conducted by the regional health planning agency, if a regional health planning agency has been designated~~.

A determination whether a public need exists for a project shall be made by the Commissioner within 190 calendar days of the day which begins the appropriate batch cycle.

The 190-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 40 calendar days from submission, the application shall be refiled in the next batch for like projects.

The Commissioner shall make determinations in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq.) except for those parts of the determination process for which timelines and specifications are delineated in subsection E ~~of this section~~. Further, if an informal fact-finding conference is determined to be necessary by the Department or is requested by a person seeking good cause standing, the parties to the case shall include only the applicant, any person showing good cause, *and* 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~~, and the relevant health planning agency~~.

E. Upon entry of each completed application or applications into the appropriate batch review cycle:

1. The Department shall establish, for every application, a date between the eightieth and ninetieth calendar days within the 190-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 190-calendar-day review period to determine whether an informal fact-finding conference is necessary.

3. Any person seeking to be made a party to the case for good cause shall notify the Department of his request and the basis therefor on or before the eightieth calendar day following the day which begins the appropriate batch review cycle.

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 30 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. The provisions of subsection C of § 2.2-4021 notwithstanding, if a determination whether a public need exists for a project is not made by the Commissioner within 45 calendar days of the closing of the record, the Commissioner shall notify the applicant or applicants and any persons seeking to show good cause, in writing, that the application or the application of each shall be deemed approved 25 calendar days after expiration of such 45-calendar-day period, unless the receipt of recommendations from the person performing the hearing officer functions permits the Commissioner to issue his case decision within that 25-calendar-day period. The validity or timeliness of the aforementioned notice shall not, in any event, prevent, delay or otherwise impact the effectiveness of this section.

7. In any case when a determination whether a public need exists for a project is not made by the Commissioner within 70 calendar days after the closing of the record, 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 45 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, petition for immediate injunctive relief pursuant to § 2.2-4030, naming as respondents the Commissioner and all parties to the case. During the pendency of the proceeding, no applications shall be deemed to be approved. In such a proceeding, the provisions of § 2.2-4030 shall apply.

F. Deemed approvals shall be construed as the Commissioner's case decision on the application pursuant to the Administrative Process Act (§ 2.2-4000 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 such attempt to show good cause shall be deemed to be a person showing good cause for purposes of appeal of the deemed approval of the certificate.

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

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

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 applicants, and only the applicants, shall have the authority to extend any of the time periods specified in this section. If all applicants consent to extending any time period in this section, the Commissioner, with the concurrence of the applicants, shall establish a new schedule for the remaining time periods.

~~J. This section shall not apply to applications for certificates for projects defined in subdivision 8 of the definition of "project" in § 32.1-102.1. Such projects shall be subject to an expedited application and review process developed by the Board in regulation pursuant to subdivision A 2 of § 32.1-102.2.~~

§ 32.1-102.11. Application of article.

A. On and after July 1, 1992, every project of an existing or proposed medical care facility, as defined in § 32.1-102.1, shall be subject to all provisions of this article unless, with respect to such project, the owner or operator of an existing medical care facility or the developer of a proposed medical care facility (i) has, by February 1, 1992, purchased or leased equipment subject to registration pursuant to former § 32.1-102.3:4, (ii) has, by February 1, 1992, initiated construction requiring a capital expenditure exceeding one million dollars, or (iii) has made or contracted to make or otherwise legally obligated to make, during the three years ending February 1, 1992, preliminary expenditures of $350,000 or more for a formal plan of construction of the specific project, including expenditures for site acquisition, designs, preliminary or working drawings, construction documents, or other items essential

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to the construction of the specific project.

Any project exempted pursuant to subdivisions (ii) and (iii) of this subsection shall be limited to such construction, services, and equipment as specifically identified in the formal plan of construction which shall have existed and been formally committed to by February 1, 1992. Further, the equipment to be exempted pursuant to subdivisions (ii) and (iii) shall be limited to the number of units and any types of medical equipment~~, in the case of medical equipment intended to provide any services included in subdivision 6 of the definition of project in § 32.1-102.1,~~ as are specifically identified in such plan and, in the case of all other equipment, such equipment as is appropriate for the construction and services included in such plan.

None of the exemptions provided in this subsection shall be applicable to projects which required a certificate of public need pursuant to this article on January 1, 1992.

B. Any medical care facility or entity claiming to meet one of the conditions set forth in subsection A of this section shall file a completed application for an exemption from the provisions of this article with the Commissioner by August 1, 1992. Forms for such application shall be made available by the Commissioner no later than April 1, 1992. The Commissioner may deny an exemption if the application is not complete on August 1, 1992, and the medical care facility or entity has not filed a completed application within forty-five days after notice of deficiency in the filing of the completed application. After receiving a completed application, the Commissioner shall determine whether the project has met one of the criteria for an exemption and is, therefore, exempt or has not met any of the criteria for an exemption and is, therefore, subject to all provisions of this article and shall notify the medical care facility or entity of his determination within sixty days of the date of filing of the completed application. If it is determined that an exemption exists for only a portion of a project, the Commissioner may approve an exemption for that portion and any appeal may be limited to the part of the decision with which the appellant disagrees without affecting the remainder of the decision. The Commissioner's determination shall be made in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq.), except that parties to the case shall include only those parties specified in § 32.1-102.6.

C. For the purposes of this section:

"Formal plan of construction" means documentary evidence indicating that the facility, the owner or operator of the facility, or the developer of a proposed facility was formally committed to the project by February 1, 1992, and describing the specific project in sufficient detail to reasonably define and confirm the scope of the project including estimated cost, intended location, any clinical health services to be involved and any types of equipment to be purchased. Such documentary evidence shall include designs, preliminary or working drawings, construction documents or other documents which have been used to explicitly define and confirm the scope of the project for the purposes of seeking architectural or construction plans or capital to the extent that such capital was committed or agreed to be provided for such project prior to February 1, 1992.

"Initiated construction" means an owner or operator of an existing facility or the developer of a proposed facility can present evidence for a specific project that (i) a construction contract has been executed; (ii) if applicable, short-term financing has been completed; (iii) if applicable, a commitment for long-term financing has been obtained; and (iv) if the project is for construction of a new facility or expansion of an existing facility, predevelopment site work and building foundations have been completed.

"Leased" means that the owner or operator of an existing medical care facility or the developer of a proposed facility has a legally binding commitment to lease the equipment pursuant to an agreement providing for fixed, periodic payments commencing no later than June 30, 1992, including a lease-purchase agreement in which the owner or operator of the facility or developer has an option to purchase the equipment for less than fair market value upon conclusion of the lease or an installment sale agreement with fixed periodic payments commencing no later than June 30, 1992.

"Purchased" means that the equipment has been acquired by the owner or operator of an existing medical care facility or the developer of a proposed medical care facility, or the owner or operator of the facility or the developer can present evidence of a legal obligation to acquire the equipment in the form of an executed contract or appropriately signed order or requisition and payment has been made in full by June 30, 1992.

§ 32.1-122.01. Definitions.

As used in this article, unless the context requires a different meaning:

"Board" means the State Board of Health.

"Commissioner" means the State Health Commissioner.

"Consumer" means a person who is not a provider of health care services.

"Department" means the Virginia Department of Health.

"Health planning region" means a contiguous geographical area of the Commonwealth with a

population base of at least 500,000 persons, which is characterized by the availability of multiple levels of medical care services, reasonable travel time for tertiary care, and congruence with planning districts.

"Provider" means a licensed or certified health care practitioner, a licensed health care facility or service administrator, or an individual who has a personal interest in a health care facility or service as defined in the ~~Virginia~~ *State and Local Government* Conflict of Interests Act (§ 2.2-3100 et seq.).

~~"Regional health planning agency" means the regional agency, including the regional health planning board, its staff and any component thereof, designated by the Board to perform the health planning activities set forth in this chapter within a health planning region.~~

~~"Regional health planning board" means the governing board of the regional health planning agency as described in § 32.1-122.05.~~

"Secretary" means the Secretary of Health and Human Resources of the Commonwealth of Virginia.

"State Health Plan" means the document so designated by the Board, which may include analysis of priority health issues, policies, needs, methodologies for assessing statewide health care needs, and such other matters as the Board shall deem appropriate.

"Tertiary care" means health care delivered by facilities that provide specialty acute care including, but not limited to, trauma care, neonatal intensive care and cardiac services.

§ 32.1-122.03. State Health Plan.

A. The Board may develop, and revise as it deems necessary, the State Health Plan with the support of the Department ~~and the assistance of the regional health planning agencies~~. Following review and comment by interested parties, including appropriate state agencies, the Board may develop and approve the State Health Plan. The State Health Plan shall be developed in accordance with components and methodologies that take into account special needs or circumstances of local areas. The Plan shall ~~reflect data and analyses provided by the regional health planning agencies and~~ include regional differences where appropriate. The Board, in preparation of the State Health Plan and to avoid unnecessary duplication, may consider and utilize all relevant and formally adopted plans of agencies, councils, and boards of the Commonwealth.

B. In order to develop and approve the State Health Plan, the Board may conduct such studies as may be necessary of critical health issues as identified by the Governor, General Assembly, Secretary or by the Board. Such studies may include, but not be limited to: (i) collection of data and statistics; (ii) analyses of information with subsequent recommendations for policy development, decision making and implementation; and (iii) analyses and evaluation of alternative health planning proposals and initiatives.

§ 32.1-122.04. Responsibilities of the Department.

The Department shall have the following responsibilities as directed by the Board:

1. To conduct the research for the health planning activities of the Commonwealth.

2. To prepare, review and revise the State Health Plan when so directed by the Board.

3. To develop, under the direction of the Board ~~and with the cooperation of the regional health planning agencies~~, the components and methodology for the State Health Plan, including any research, issue analyses, and related reports.

4. ~~To provide technical assistance to the regional health planning agencies.~~

~~5.~~ To perform such other functions relating to health planning in the Commonwealth as may be requested by the Governor or the Secretary.

§ 32.1-122.07. Authority of Commissioner for certain health planning activities; rural health plan; designation as a rural hospital.

A. The Commissioner, with the approval of the Board, is authorized to make application for federal funding and to receive and expend such funds in accordance with state and federal regulations.

B. The Commissioner shall administer ~~section~~ *§* 1122 of the United States Social Security Act if the Commonwealth has made an agreement with the United States Secretary of Health and Human Services pursuant to such section.

C. In compliance with the provisions of the Balanced Budget Act of 1997, P.L. 105-33, and any amendments to such provisions, the Commissioner shall submit to the appropriate regional administrator of the Centers for Medicare & Medicaid Services (CMS) an application to establish a Medicare Rural Hospital Flexibility Program in Virginia.

D. The Commissioner shall develop and the Board of Health shall approve a rural health care plan for the Commonwealth to be included with the application to establish a Medicare Rural Hospital Flexibility Program. In cooperation and consultation with the Virginia Hospital and Health Care Association, the Medical Society of Virginia, representatives of rural hospitals, and experts within the Department of Health on rural health programs, the plan shall be developed and revised as necessary or as required by the provisions of the Balanced Budget Act of 1997, P.L. 105-33, and any amendments to such provisions. ~~In the development of the plan, the Commissioner may also seek the assistance of the regional health planning agencies.~~ The plan shall verify that the Commonwealth is in the process of designating facilities located in Virginia as critical access hospitals, shall note that the Commonwealth

wishes to certify facilities as "necessary providers" of health care in rural areas, and shall describe the process, methodology, and eligibility criteria to be used for such designations or certifications. Virginia's rural health care plan shall reflect local needs and resources and shall, at minimum, include, but need not be limited to, a mechanism for creating one or more rural health networks, ways to encourage rural health service regionalization, and initiatives to improve access to health services, including hospital services, for rural Virginians.

E. Notwithstanding any provisions of this chapter or the Board's regulations to the contrary, the Commissioner shall, in the rural health care plan, (i) use as minimum standards for critical access hospitals, the certification regulations for critical access hospitals promulgated by the Centers for Medicare & Medicaid Services (CMS) pursuant to Title XVIII of the Social Security Act, as amended~~;~~, and (ii) authorize critical access hospitals to utilize a maximum of ~~ten~~ *10* beds among their inpatient hospital beds as swing beds for the furnishing of services of the type which, if furnished by a nursing home or certified nursing facility, would constitute skilled care services without complying with nursing home licensure requirements or retaining the services of a licensed nursing home administrator. Such hospital shall include, within its plan of care, assurances for the overall well-being of patients occupying such beds.

F. Nothing herein or set forth in Virginia's rural health care plan shall prohibit any hospital designated as a critical access hospital from leasing the unused portion of its facilities to other health care organizations or reorganizing its corporate structure to facilitate the continuation of the nursing home beds that were licensed to such hospital prior to the designation as a critical access hospital. The health care services delivered by such other health care organizations shall not be construed as part of the critical access hospital's services or license to operate.

G. Any medical care facility licensed as a hospital shall be considered a rural hospital on and after September 30, 2004, pursuant to 42 U.S.C. § 1395ww(d)(8)(E)(ii)(II), if (i) the hospital is located in an area defined as rural by federal statute or regulation; (ii) the Board of Health defines, in regulation, the area in which the hospital is located as a rural health area or the hospital as a rural hospital; or (iii) the hospital was designated, prior to October 1, 2004, as a Medicare-dependent small rural health hospital, as defined in 42 U.S.C. § 1395ww(d)(5)(G)(iv).

2. That §§ 32.1-122.05 and 32.1-122.06 of the Code of Virginia are repealed.

3. That the provisions of this act shall not affect any application for a certificate of public need filed with the Department of Health on or before December 31, 2014, or any appeal to a court of competent jurisdiction taken therefrom, or any appeal of the issuance or denial of a certificate of public need pending in a court with appropriate jurisdiction as of December 31, 2014.