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HOUSE BILL NO. 2337

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare and Institutions on January 31, 2017)

(Patron Prior to Substitute—Delegate O'Bannon)

A BILL to amend and reenact §§ 2.2-4006, 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, 32.1-102.4, 32.1-102.6, 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 in Article 1.1 of Chapter 4 of Title 32.1 a section numbered 32.1-102.14 and by adding in Chapter 4 of Title 32.1 an article numbered 9, consisting of sections numbered 32.1-122.23 and 32.1-122.24; and to repeal §§ 32.1-122.05 and 32.1-122.06 of the Code of Virginia, relating to certificate of public need.

Be it enacted by the General Assembly of Virginia:

1. That §§ 2.2-4006, 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, 32.1-102.4, 32.1-102.6, 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 in Article 1.1 of Chapter 4 of Title 32.1 a section numbered 32.1-102.14 and by adding in Chapter 4 of Title 32.1 an article numbered 9, consisting of sections numbered 32.1-122.23 and 32.1-122.24, as follows:

§ 2.2-4006. Exemptions from requirements of this article.

A. The following agency actions otherwise subject to this chapter and § 2.2-4103 of the Virginia Register Act shall be exempted from the operation of this article:

1. Agency orders or regulations fixing rates or prices.

2. Regulations that establish or prescribe agency organization, internal practice or procedures, including delegations of authority.

3. Regulations that consist only of changes in style or form or corrections of technical errors. Each promulgating agency shall review all references to sections of the Code of Virginia within their regulations each time a new supplement or replacement volume to the Code of Virginia is published to ensure the accuracy of each section or section subdivision identification listed.

4. Regulations that are:

a. Necessary to conform to changes in Virginia statutory law or the appropriation act where no agency discretion is involved. However, such regulations shall be filed with the Registrar within 90 days of the law's effective date;

b. Required by order of any state or federal court of competent jurisdiction where no agency discretion is involved; or

c. Necessary to meet the requirements of federal law or regulations, provided such regulations do not differ materially from those required by federal law or regulation, and the Registrar has so determined in writing. Notice of the proposed adoption of these regulations and the Registrar's determination shall be published in the Virginia Register not less than 30 days prior to the effective date of the regulation.

5. Regulations of the Board of Agriculture and Consumer Services adopted pursuant to subsection B of § 3.2-3929 or clause (v) or (vi) of subsection C of § 3.2-3931 after having been considered at two or more Board meetings and one public hearing.

6. Regulations of the regulatory boards served by (i) the Department of Labor and Industry pursuant to Title 40.1 and (ii) the Department of Professional and Occupational Regulation or the Department of Health Professions pursuant to Title 54.1 that are limited to reducing fees charged to regulants and applicants.

7. The development and issuance of procedural policy relating to risk-based mine inspections by the Department of Mines, Minerals and Energy authorized pursuant to §§ 45.1-161.82 and 45.1-161.292:55.

8. General permits issued by the (a) State Air Pollution Control Board pursuant to Chapter 13 (§ 10.1-1300 et seq.) of Title 10.1 or (b) State Water Control Board pursuant to the State Water Control Law (§ 62.1-44.2 et seq.), Chapter 24 (§ 62.1-242 et seq.) of Title 62.1 and Chapter 25 (§ 62.1-254 et seq.) of Title 62.1, (c) Virginia Soil and Water Conservation Board pursuant to the Dam Safety Act (§ 10.1-604 et seq.), and (d) the development and issuance of general wetlands permits by the Marine Resources Commission pursuant to subsection B of § 28.2-1307, if the respective Board or Commission (i) provides a Notice of Intended Regulatory Action in conformance with the provisions of § 2.2-4007.01, (ii) following the passage of 30 days from the publication of the Notice of Intended Regulatory Action forms a technical advisory committee composed of relevant stakeholders, including potentially affected citizens groups, to assist in the development of the general permit, (iii) provides notice and receives oral and written comment as provided in § 2.2-4007.03, and (iv) conducts at least one public hearing on the proposed general permit.

9. The development and issuance by the Board of Education of guidelines on constitutional rights and restrictions relating to the recitation of the pledge of allegiance to the American flag in public schools pursuant to § 22.1-202.

10. Regulations of the Board of the Virginia College Savings Plan adopted pursuant to § 23.1-704.

11. Regulations of the Marine Resources Commission.

12. Regulations adopted by the Board of Housing and Community Development pursuant to (i) Statewide Fire Prevention Code (§ 27-94 et seq.), (ii) the Industrialized Building Safety Law (§ 36-70 et seq.), (iii) the Uniform Statewide Building Code (§ 36-97 et seq.), and (iv) § 36-98.3, provided the Board (a) provides a Notice of Intended Regulatory Action in conformance with the provisions of § 2.2-4007.01, (b) publishes the proposed regulation and provides an opportunity for oral and written comments as provided in § 2.2-4007.03, and (c) conducts at least one public hearing as provided in §§ 2.2-4009 and 36-100 prior to the publishing of the proposed regulations. Notwithstanding the provisions of this subdivision, any regulations promulgated by the Board shall remain subject to the provisions of § 2.2-4007.06 concerning public petitions, and §§ 2.2-4013 and 2.2-4014 concerning review by the Governor and General Assembly.

13. Amendments to regulations of the Board to schedule a substance in Schedule I or II pursuant to subsection D of § 54.1-3443.

14. Waste load allocations adopted, amended, or repealed by the State Water Control Board pursuant to the State Water Control Law (§ 62.1-44.2 et seq.), including but not limited to Article 4.01 (§ 62.1-44.19:4 et seq.) of the State Water Control Law, if the Board (i) provides public notice in the Virginia Register; (ii) if requested by the public during the initial public notice 30-day comment period, forms an advisory group composed of relevant stakeholders; (iii) receives and provides summary response to written comments; and (iv) conducts at least one public meeting. Notwithstanding the provisions of this subdivision, any such waste load allocations adopted, amended, or repealed by the Board shall be subject to the provisions of §§ 2.2-4013 and 2.2-4014 concerning review by the Governor and General Assembly.

15. Regulations of the Workers' Compensation Commission adopted pursuant to § 65.2-605, including regulations that adopt, amend, adjust, or repeal Virginia fee schedules for medical services, provided the Workers' Compensation Commission (i) utilizes a regulatory advisory panel constituted as provided in subdivision F 2 of § 65.2-605 to assist in the development of such regulations and (ii) provides an opportunity for public comment on the regulations prior to adoption.

16. Amendments to the State Medical Facilities Plan adopted by the Board of Health following review by the State Medical Facilities Plan task force pursuant to § 32.1-102.2:1 if the Board (i) provides a Notice of Intended Regulatory Action in accordance with the requirements of § 2.2-4007.01, (ii) provides notice and receives comment as provided in § 2.2-4007.03, and (iii) conducts at least one public hearing on the proposed amendments.

B. Whenever regulations are adopted under this section, the agency shall state as part thereof that it will receive, consider and respond to petitions by any interested person at any time with respect to reconsideration or revision. The effective date of regulations adopted under this section shall be in accordance with the provisions of § 2.2-4015, except in the case of emergency regulations, which shall become effective as provided in subsection B of § 2.2-4012.

C. A regulation for which an exemption is claimed under this section or § 2.2-4002 or 2.2-4011 and that is placed before a board or commission for consideration shall be provided at least two days in advance of the board or commission meeting to members of the public that request a copy of that regulation. A copy of that regulation shall be made available to the public attending such meeting.

§ 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.

"Charity care" means health care services for which no compensation is received provided to an individual whose income is less than or equal to 200 percent of the federal poverty level for a household of such individual's household size.

"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 innovation district" means (i) a locality with a population density of at least 200 people per square mile as reported by the United States Bureau of the Census in the 2010 census report that (a) is contiguous with at least one other locality with such population density or (b) has a population of at least 75,000 people or (ii) a locality that does not meet the criteria set forth in clause (i) but that is contiguous to a locality that meets the criteria set forth in clause (i) and that has adopted an ordinance opting to participate in the health innovation district.

"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 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.~~ *2.* 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.~~ *3.* 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,~~ *or* 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.~~ *4.* Rehabilitation hospitals, *including inpatient rehabilitation facilities and long-term care hospitals*.

~~11. Any facility licensed as a hospital.~~

5. Specialized centers or clinics or that portion of a hospital established for the provision of organ or tissue transplant services.

6. Specialized centers or clinics or that portion of a hospital established for the provision of open heart surgery that performs fewer than 1,100 adult inpatient and outpatient cardiac catheterizations, at

least 400 of which are therapeutic catheterizations, or discharges fewer than 800 patients with the principal diagnosis of ischemic heart disease in a calendar year.

7. Specialized centers or clinics or that portion of a hospital established for the provision of neonatal special care services that deliver fewer than 1,000 infants in a calendar year.

8. General hospitals and any other facility licensed as a hospital, facilities for individuals with intellectual disability, and specialized centers or clinics or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery, cardiac catheterization, stereotactic radiosurgery, lithotripsy, radiation therapy, stereotactic radiotherapy, proton beam therapy, or such other specialty services as may be designated by the Board by regulation, which are located outside of a health innovation district.

The term "medical care facility" 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~~ *3* of the definition of "medical care facility"; (v) the Wilson Workforce and 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.

"Nursing home" means any facility or any identifiable component of any facility licensed pursuant to Article 1 (§ 32.1-123 et seq.) of Chapter 5 in which the primary function is the provision, on a continuing basis, of nursing services and health-related services for the treatment and inpatient care of two or more nonrelated individuals, including facilities known by varying nomenclature or designation such as convalescent homes, skilled nursing facilities or skilled care facilities, intermediate care facilities, extended care facilities, nursing facilities or nursing care facilities, or any other facility or component thereof with medical rehabilitation beds or long-term care beds.

"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 of beds from one existing facility to another, provided that "project" 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, *medical rehabilitation beds, or long-term care beds,* 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, obstetrical, open heart surgery, 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~~ *Increase in the number of medical rehabilitation beds or long-term care beds at an existing medical facility or conversion* of beds in an existing medical care facility to medical rehabilitation beds or ~~psychiatric~~ *long-term care hospital* 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, 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. Any capital expenditure of $15 million or more, not defined as reviewable in subdivisions 1 through 7 of this definition, by or on behalf of a medical care facility other than a general hospital. Capital expenditures of $5 million or more by a general hospital and capital expenditures between $5 and $15 million by a medical care facility other than a general hospital shall be registered with the Commissioner pursuant to regulations developed by the Board. 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. Nothing in this subdivision shall be construed to modify or eliminate the reviewability of any project described in subdivisions 1 through 7 of this definition when undertaken by or on behalf of a general hospital; ~~or~~

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

10. For any existing general hospital or other facility licensed as a hospital located in a health innovation district, (i) introduction of any new computed tomographic (CT) scanning, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging, other than nuclear cardiac imaging, service or (ii) addition of any medical equipment 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, other than nuclear cardiac imaging.

~~"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~~.

§ 32.1-102.2. Regulations.

A. The Board shall promulgate regulations ~~which~~ *that* 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~~ *stereotactic* 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~~ *stereotactic* 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;

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 *(i) an expedited 45-day application and review process for any certificate for projects determined by the Department to be uncontested and to present minimal health planning impacts, in accordance with criteria established by the Board, and for which the applicant agrees to comply with quality assurance requirements established by the Board and consents to provide charity care in an amount specified by the Board pursuant to § 32.1-102.4 and (ii)* an expedited *120-day* application and review process for any certificate for projects reviewable pursuant to subdivision 8 of the definition of "project" in § 32.1-102.1 *and projects identified by the Department to be uncontested and to present minimal health planning impacts that require a level of scrutiny greater than that required pursuant to clause (i) but do not require a full review pursuant to § 32.1-102.6, in accordance with criteria established by the Board, and for which the applicant agrees to comply with quality assurance requirements established by the Board and consents to provide charity care in an amount specified by the Board pursuant to § 32.1-102.4*. Regulations establishing ~~the~~ expedited application and review ~~procedure~~ *procedures in accordance with this subdivision* shall include *(a)* provisions for notice and opportunity for public comment on the application for a certificate~~, and~~*; (b)* 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*; (c) provisions for conditioning the approval of a certificate upon the agreement of the applicant to (1) provide a level of care at a reduced rate to indigents in an amount that is equal to the average amount of indigent care provided by holders of certificates of public need in the applicant's health planning region or to accept patients requiring specialized medical care or (2) facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area; and (d) provisions for conditioning the approval of a certificate upon the agreement of the applicant to comply with quality assurance requirements established by the Board*.

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 *cases in which an application for a proposed project is consistent with the State Medical Facilities Plan, the Commissioner*

shall approve the application. In all other cases, 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.

§ 32.1-102.4. Conditions of certificates; monitoring; revocation of certificates.

A. A certificate shall be issued with a schedule for the completion of the project and a maximum capital expenditure amount for the project. The schedule may not be extended and the maximum capital expenditure may not be exceeded without the approval of the Commissioner in accordance with the regulations of the Board.

B. The Commissioner shall monitor each project for which a certificate is issued to determine its progress and compliance with the schedule and with the maximum capital expenditure. The Commissioner shall also monitor all continuing care retirement communities for which a certificate is issued authorizing the establishment of a nursing home facility or an increase in the number of nursing home beds pursuant to § 32.1-102.3:2 and shall enforce compliance with the conditions for such applications which are required by § 32.1-102.3:2. Any willful violation of a provision of § 32.1-102.3:2 or conditions of a certificate of public need granted under the provisions of § 32.1-102.3:2 shall be subject to a civil penalty of up to $100 per violation per day until the date the Commissioner determines that such facility is in compliance.

C. A certificate may be revoked when:

1. Substantial and continuing progress towards completion of the project in accordance with the schedule has not been made;

2. The maximum capital expenditure amount set for the project is exceeded;

3. The applicant has willfully or recklessly misrepresented intentions or facts in obtaining a certificate; or

4. A continuing care retirement community applicant has failed to honor the conditions of a certificate allowing the establishment of a nursing home facility or granting an increase in the number of nursing home beds in an existing facility which was approved in accordance with the requirements of § 32.1-102.3:2.

D. Further, the Commissioner shall not approve an extension for a schedule for completion of any project or the exceeding of the maximum capital expenditure of any project unless such extension or excess complies with the limitations provided in the regulations promulgated by the Board pursuant to § 32.1-102.2.

E. Any person willfully violating the Board's regulations establishing limitations for schedules for completion of any project or limitations on the exceeding of the maximum capital expenditure of any project shall be subject to a civil penalty of up to $100 per violation per day until the date of completion of the project.

F. The Commissioner may condition, pursuant to the regulations of the Board, the approval of a certificate (i) upon the agreement of the applicant to provide a level of *charity* care at a reduced rate to indigents *in an amount that is equal to the average amount of such care provided by holders of certificates of public need in the applicant's health planning region* or accept patients requiring specialized care or (ii) 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 value of care provided to individuals pursuant to this subsection shall be based on provider reimbursement methodology utilized by the Department of Medical Assistance Services for reimbursements under the state plan for medical assistance.*

The certificate holder shall provide documentation to the Department demonstrating that the certificate holder has satisfied the conditions of the certificate. If the certificate holder is unable or fails to satisfy the conditions of a certificate, the Department may approve alternative methods to satisfy the conditions pursuant to a plan of compliance. The plan of compliance shall identify a timeframe within which the certificate holder will satisfy the conditions of the certificate, and identify how the certificate holder will satisfy the conditions of the certificate, which may include ~~(i)~~ *(a)* making direct payments to an organization authorized under a memorandum of understanding with the Department to receive contributions satisfying conditions of a certificate, ~~(ii)~~ *(b)* making direct payments to a private nonprofit foundation that funds basic insurance coverage for indigents authorized under a memorandum of understanding with the Department to receive contributions satisfying conditions of a certificate, or ~~(iii)~~ *(c)* other documented efforts or initiatives to provide primary or specialized care to underserved populations. In determining whether the certificate holder has met the conditions of the certificate pursuant to a plan of compliance, only such direct payments, efforts, or initiatives made or undertaken after issuance of the conditioned certificate shall be counted towards satisfaction of conditions.

Any person willfully refusing, failing, or neglecting to honor such agreement shall be subject to a civil penalty of up to $100 per violation per day until the date of compliance.

G. Pursuant to regulations of the Board, the Commissioner may accept requests for and approve amendments to conditions of existing certificates related to the provision of care at reduced rates or to patients requiring specialized care or related to the development and operation of primary medical care services in designated medically underserved areas of the certificate holder's service area.

H. For the purposes of this section, "completion" means conclusion of construction activities necessary for the substantial performance of the contract.

§ 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~~. *An application submitted for review shall be considered complete when all relevant sections of the application form have responses. The applicant shall provide sufficient information to prove that public need for the requested project exists without the addition of supplemental or supporting material at a later date. Nothing in this section shall prevent the Department from seeking, at its discretion, additional information from the applicant or other sources.*

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 *(i) solicit public comment on such application by posting notice of such application and a summary of the proposed project on a website maintained by the Department together with information about how comments may be submitted to the Department and the date on which the public comment period shall expire and (ii) in the case of competing applications or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public,* 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~~ *any required* 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 (i) of the time and place of such proposed contact.

D. The Department shall commence the review of each completed application ~~upon~~ *on* the *first* day ~~which begins~~ *of* 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 eighteith 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~~, *no later than four days after the Department has completed its review and submitted its recommendation on 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, notify the Commissioner and all applicants, in writing and under oath, stating the grounds for good cause and providing the factual basis therefor.*

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.

§ 32.1-102.14. Transparency.

The Department shall develop a website to make information and materials related to the Medical Care Facilities Certificate of Public Need Program available to the public in order to increase transparency. Such website shall include an automated mechanism for receiving, posting, and tracking letters of intent received by the Department so that information about such letters is available to the public upon receipt of such letters.

§ 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 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, *the* General Assembly, *the* 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~~ *U.S.* 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~~ *Healthcare* 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 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).

Article 9.

Permits for Medical Care Facility Projects.

§ 32.1-122.23. Definitions.

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

"Health innovation district" means (i) a locality with a population density of at least 200 people per square mile as reported by the United States Bureau of the Census in the 2010 census report that (a) is contiguous with at least one other locality with such population density or (b) has a population of at least 75,000 people or (ii) a locality that does not meet the criteria set forth in clause (i) but that is contiguous to a locality that meets the criteria set forth in clause (i) and that has adopted an ordinance opting to participate in the health innovation district.

"Medical care facility" means:

1. Any facility licensed as a hospital, other than a psychiatric hospital or a rehabilitation hospital which shall include an inpatient rehabilitation facility or long-term care hospital, that is located in a health innovation district. "Medical care facility" does not include that portion of a hospital established for the provision of organ or tissue transplant services; that portion of a hospital established for the provision of open heart surgery when such portion of a hospital performs at least 1,100 adult inpatient and outpatient cardiac catheterizations, at least 400 of which are therapeutic catheterizations, or discharges at least 800 patients with the principal diagnosis of ischemic heart disease in a calendar year; or that portion of a hospital established for the provision of neonatal special care services that delivers at least 1,000 infants in a calendar year.

2. The following types of facilities, when they are located in a health innovation district: facilities for individuals with intellectual disability and specialized centers or clinics or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery, cardiac catheterization, stereotactic radiosurgery, lithotripsy, radiation therapy, stereotactic radiotherapy, proton beam therapy, or such other specialty services as may be designated by the Board by regulation.

"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 of beds from one existing medical care facility to another, provided that "project" does not include the relocation of up to 10 beds or 10 percent of the beds, whichever is less, from one existing medical care facility to another existing facility at the same site in any two-year period;

4. Conversion in an existing medical care facility of psychiatric inpatient beds approved pursuant to a Request for Applications (RFA) to nonpsychiatric inpatient beds;

5. Introduction into an existing medical care facility of any new cardiac catheterization, stereotactic radiosurgery, lithotripsy, medical rehabilitation, neonatal special care, obstetrical, open heart surgery, organ or tissue transplant service, radiation therapy, stereotactic radiotherapy, proton beam therapy, 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 addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization, stereotactic radiosurgery, lithotripsy, open heart surgery, 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 permit; or

7. Any capital expenditure of $15 million or more, not defined as reviewable in subdivisions 1 through 6 of this definition, by or on behalf of a medical care facility other than a general hospital. The amounts specified in this subdivision shall be revised annually to reflect inflation using appropriate measures incorporating construction costs and medical inflation.

§ 32.1-122.24. Permit required; conditions on permits.

A. No person shall commence any project without first obtaining a permit from the Commissioner.

B. At least 90 days prior to initiating a project for which a permit is required, a person shall file with the Department an application for a permit, together with a fee determined by the Board. The Commissioner shall issue the permit within 30 days of receipt of the application.

C. The Commissioner shall condition the issuance of a permit to undertake a project upon the agreement of the applicant to (i) provide a specified level of care at a reduced rate to indigents in an amount that matches the average amount of indigent care provided by holders of certificates of public need in the applicant's health planning region, (ii) accept patients requiring specialized care, or (iii) facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area.

The holder of a permit that is subject to conditions pursuant to this subsection shall provide such documentation as may be required by the Commissioner to demonstrate compliance with the conditions imposed.

The Commissioner shall monitor compliance with permit conditions pursuant to this subsection and may impose penalties on a permit holder that fails to comply with such permit conditions. If the permit holder is unable or fails to comply with the conditions imposed by the Commissioner, the Commissioner may, upon request of the permit holder, approve a plan of compliance with alternate methods to satisfy the permit conditions. Such alternate methods may include (a) a direct payment by the permit holder to an organization authorized under a memorandum of understanding with the Department to receive contributions satisfying conditions of the permit; (b) a direct payment by the permit holder to a private nonprofit foundation that funds basic insurance coverage for indigents authorized under a memorandum of understanding with the Department to receive contributions satisfying conditions of a permit; (c) provision by the permit holder of on-call coverage at a hospital, including the emergency department of a hospital; or (d) such other methods for the provision of primary or specialized care to indigent patients or patients requiring specialized care as may be approved by the Commissioner. Any permit

holder that fails or refuses to comply with the requirements of a plan of compliance entered into in accordance with this subsection is subject to a civil penalty of up to $100 per violation per day until the date of compliance.

The Commissioner may, pursuant to regulations of the Board, accept requests for and approve amendments to permit conditions pursuant to this subsection upon request of the permit holder.

The Board shall adopt regulations governing the issuance and revocation of permits in accordance with the provisions of this subsection.

D. The Commissioner shall condition the issuance of a permit to undertake a project upon the compliance of the applicant with quality of care standards established by the Board and may revoke a permit issued in accordance with this section in any case in which the permit holder fails to maintain compliance with such standards.

The Board shall adopt regulations governing the issuance and revocation of permits in accordance with the provisions of this subsection, which shall include:

1. Quality of care standards for the specific specialty service that are consistent with nationally recognized standards for such specialty service;

2. A list of those national accrediting organizations having quality of care standards, compliance with which shall be deemed satisfactory to comply with quality of care standards adopted by the Board;

3. Equipment standards and standards for appropriate utilization of equipment and services;

4. Requirements for monitoring compliance with quality of care standards, including data reporting and periodic inspections; and

5. Procedures for the issuance and revocation of permits pursuant to this subsection.

2. That § 32.1-102.1 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding in Chapter 4 of Title 32.1 an article numbered 9, consisting of sections numbered 32.1-122.23 and 32.1-122.24, 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.

"Charity care" means health care services for which no compensation is received provided to an individual whose income is less than or equal to 200 percent of the federal poverty level for a household of such individual's household size.

"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 innovation district" means (i) a locality with a population density of at least 200 people per square mile as reported by the United States Bureau of the Census in the 2010 census report that (a) is contiguous with at least one other locality with such population density or (b) has a population of at least 75,000 people or (ii) a locality that does not meet the criteria set forth in clause (i) but that is contiguous to a locality that meets the criteria set forth in clause (i) and that has adopted an ordinance opting to participate in the health innovation district.

"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 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.~~ *1.* Nursing homes.

~~4.~~ *2.* 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.~~ *3.* Rehabilitation hospitals, *including inpatient rehabilitation facilities and long-term care hospitals*.

~~11. Any facility licensed as a hospital.~~

4. Specialized centers or clinics or that portion of a hospital established for the provision of organ or tissue transplant services.

5. Specialized centers or clinics or that portion of a hospital established for the provision of open heart surgery that performs fewer than 1,100 adult inpatient and outpatient cardiac catheterizations, at least 400 of which are therapeutic catheterizations, or discharges fewer than 800 patients with the principal diagnosis of ischemic heart disease in a calendar year.

6. Specialized centers or clinics or that portion of a hospital established for the provision of neonatal special care services that delivers fewer than 1,000 infants in a calendar year.

7. General hospitals and any other facility licensed as a hospital; facilities for individuals with intellectual disability; and 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, or 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, which is located outside of a health innovation district.

The term "medical care facility" 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 Wilson Workforce and 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.

"Nursing home" means any facility or any identifiable component of any facility licensed pursuant to Article 1 (§ 32.1-123 et seq.) of Chapter 5 in which the primary function is the provision, on a continuing basis, of nursing services and health-related services for the treatment and inpatient care of two or more nonrelated individuals, including facilities known by varying nomenclature or designation such as convalescent homes, skilled nursing facilities or skilled care facilities, intermediate care facilities, extended care facilities, nursing facilities or nursing care facilities, or any other facility or component thereof with medical rehabilitation beds or long-term care beds.

"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 of beds from one existing facility to another, provided that "project" 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, *medical rehabilitation beds, or long-term care beds,* 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, obstetrical, open heart surgery, 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~~ *Increase in the number of medical rehabilitation beds or long-term care beds at an existing medical facility or conversion* of beds in an existing medical care facility to medical rehabilitation beds or ~~psychiatric~~ *long-term care hospital* 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, 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. Any capital expenditure of $15 million or more, not defined as reviewable in subdivisions 1 through 7 of this definition, by or on behalf of a medical care facility other than a general hospital. Capital expenditures of $5 million or more by a general hospital and capital expenditures between $5 and $15 million by a medical care facility other than a general hospital shall be registered with the Commissioner pursuant to regulations developed by the Board. 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. Nothing in this subdivision shall be construed to modify or eliminate the reviewability of any project described in subdivisions 1 through 7 of this definition when undertaken by or on behalf of a general hospital; or

9. 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.

Article 9.

Permits for Medical Care Facility Projects.

§ 32.1-122.23. Definitions.

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

"Health innovation district" means (i) a locality with a population density of at least 200 people per square mile as reported by the United States Bureau of the Census in the 2010 census report that (a) is contiguous with at least one other locality with such population density or (b) has a population of at least 75,000 people or (ii) a locality that does not meet the criteria set forth in clause (i) but that is contiguous to a locality that meets the criteria set forth in clause (i) and that has adopted an ordinance opting to participate in the health innovation district.

"Medical care facility" means:

1. Any facility licensed as a hospital, other than a psychiatric hospital or a rehabilitation hospital which shall include an inpatient rehabilitation facility or long-term care hospital, that is located in a health innovation district. "Medical care facility" does not include that portion of a hospital established for the provision of organ or tissue transplant services; that portion of a hospital established for the provision of open heart surgery when such portion of a hospital performs at least 1,100 adult inpatient and outpatient cardiac catheterizations, at least 400 of which are therapeutic catheterizations, or discharges at least 800 patients with the principal diagnosis of ischemic heart disease in a calendar year; or that portion of a hospital established for the provision of neonatal special care services that delivers at least 1,000 infants in a calendar year.

2. The following types of facilities, when they are located in a health innovation district: facilities for individuals with intellectual disability; and 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.

"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 of beds from one existing medical care facility to another, provided that "project" does not include the relocation of up to 10 beds or 10 percent of the beds, whichever is less, from one existing medical care facility to another existing facility at the same site in any two-year period;

4. Conversion in an existing medical care facility of psychiatric inpatient beds approved pursuant to a Request for Applications (RFA) to nonpsychiatric inpatient beds;

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, obstetrical, open heart surgery, positron emission tomographic (PET) scanning, organ or tissue transplant service, radiation therapy, stereotactic radiotherapy, proton beam therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac imaging, 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 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, 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; or

7. Any capital expenditure of $15 million or more, not defined as reviewable in subdivisions 1 through 6 of this definition, by or on behalf of a medical care facility other than a general hospital. The amounts specified in this subdivision shall be revised annually to reflect inflation using appropriate measures incorporating construction costs and medical inflation.

§ 32.1-122.24. Permit required; conditions on permits.

A. No person shall commence any project without first obtaining a permit from the Commissioner.

B. At least 90 days prior to initiating a project for which a permit is required, a person shall file with the Department an application for a permit, together with a fee determined by the Board. The Commissioner shall issue the permit within 30 days of receipt of the application.

C. The Commissioner shall condition the issuance of a permit to undertake a project upon the agreement of the applicant to (i) provide a specified level of care at a reduced rate to indigents in an amount that matches the average amount of indigent care provided by holders of certificates of public need in the applicant's health planning region, (ii) accept patients requiring specialized care, or (iii) facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area.

The holder of a permit that is subject to conditions pursuant to this subsection shall provide such documentation as may be required by the Commissioner to demonstrate compliance with the conditions imposed.

The Commissioner shall monitor compliance with permit conditions pursuant to this subsection and may impose penalties on a permit holder that fails to comply with such permit conditions. If the permit holder is unable or fails to comply with the conditions imposed by the Commissioner, the Commissioner may, upon request of the permit holder, approve a plan of compliance with alternate methods to satisfy the permit conditions. Such alternate methods may include (a) a direct payment by the permit holder to an organization authorized under a memorandum of understanding with the Department to receive contributions satisfying conditions of the permit; (b) a direct payment by the permit holder to a private nonprofit foundation that funds basic insurance coverage for indigents authorized under a memorandum of understanding with the Department to receive contributions satisfying conditions of a permit; (c) provision by the permit holder of on-call coverage at a hospital, including the emergency department of a hospital; or (d) such other methods for the provision of primary or specialized care to indigent patients or patients requiring specialized care as may be approved by the Commissioner. Any permit holder that fails or refuses to comply with the requirements of a plan of compliance entered into in accordance with this subsection is subject to a civil penalty of up to $100 per violation per day until the date of compliance.

The Commissioner may, pursuant to regulations of the Board, accept requests for and approve

amendments to permit conditions pursuant to this subsection upon request of the permit holder.

The Board shall adopt regulations governing the issuance and revocation of permits in accordance with the provisions of this subsection.

D. The Commissioner shall condition the issuance of a permit to undertake a project upon the compliance of the applicant with quality of care standards established by the Board and may revoke a permit issued in accordance with this section in any case in which the permit holder fails to maintain compliance with such standards.

The Board shall adopt regulations governing the issuance and revocation of permits in accordance with the provisions of this subsection, which shall include:

1. Quality of care standards for the specific specialty service that are consistent with nationally recognized standards for such specialty service;

2. A list of those national accrediting organizations having quality of care standards, compliance with which shall be deemed satisfactory to comply with quality of care standards adopted by the Board;

3. Equipment standards and standards for appropriate utilization of equipment and services;

4. Requirements for monitoring compliance with quality of care standards, including data reporting and periodic inspections; and

5. Procedures for the issuance and revocation of permits pursuant to this subsection.

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

4. That the provisions of the second enactment of this act shall become effective on January 1, 2018.

5. That the Secretary of Health and Human Resources shall review requirements governing imposition and implementation of charity care requirements for certificates of public need, including provisions for defining charity care and calculating the amount and value of charity care required and provided, and shall develop recommendations for standardizing and enforcing such requirements. The Secretary shall report his findings to the Governor and the General Assembly by December 1, 2017.

6. That the Department of Health shall work cooperatively with Virginia Health Information to develop a process for the collection of utilization data for recipients of certificates of public need describing specific types of equipment utilized.