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HOUSE BILL NO. 2458

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 Stolle)

A BILL to amend and reenact §§ 2.2-4006, 32.1-102.1, 32.1-102.2, 32.1-102.2:1, 32.1-102.3, and 32.1-102.6 of the Code of Virginia and to amend the Code of Virginia by adding in Article 1.1 of Chapter 4 of Title 32.1 a section numbered 32.1-102.01, by adding a section numbered 32.1-102.2:2, and by adding in Chapter 4 of Title 32.1 an article numbered 9, consisting of a section numbered 32.1-122.23, relating to Certificate of Public Need Program; reports.

Be it enacted by the General Assembly of Virginia:

1. That §§ 2.2-4006, 32.1-102.1, 32.1-102.2, 32.1-102.2:1, 32.1-102.3, and 32.1-102.6 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 32.1-102.01, by adding a section numbered 32.1-102.2:2, and by adding in Chapter 4 of Title 32.1 an article numbered 9, consisting of a section numbered 32.1-122.23, 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 Health Services Plan adopted by the Board of Health following review by the State Health Services Advisory Council 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.

§ 32.1-102.01. Certificate of Public Need Program.

The Board of Health shall establish a Certificate of Public Need Program to (i) improve the health of all residents of the Commonwealth, (ii) meet the health care needs of indigent and uninsured residents of the Commonwealth, (iii) ensure availability of essential health care services in all areas of the Commonwealth, (iv) improve the patient experience in the delivery of health care, and (v) reduce the per capita cost of health care.

§ 32.1-102.1. Definitions.

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

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

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

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

"Health planning region" means a contiguous geographical area of the Commonwealth with a population base of at least 500,000 persons which is characterized by the availability of multiple levels of medical care services, reasonable travel time for tertiary care, and congruence with planning districts.

"Medical care facility," as used in this title, means any institution, place, building or agency, whether or not licensed or required to be licensed by the Board or the Department of Behavioral Health and

Developmental Services, whether operated for profit or nonprofit and whether privately owned or privately operated or owned or operated by a local governmental unit, (i) by or in which health services are furnished, conducted, operated or offered for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition, whether medical or surgical, of two or more nonrelated persons who are injured or physically sick or have mental illness, or for the care of two or more nonrelated persons requiring or receiving medical, surgical or nursing attention or services as 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.~~ *3.* 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.~~ *4.* Extended care facilities.

~~6. Mental hospitals.~~

~~7.~~ *5.* 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.~~ *6.* 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.~~ *7.* Rehabilitation hospitals.

~~11.~~ *8.* Any facility licensed as a hospital.

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.~~

"Project" means:

1. Establishment of a medical care facility *other than a specialized center or clinic or that portion of a physician's office developed for the provision of outpatient tor ambulatory surgery*;

2. An increase in *(i)* the total number of beds ~~or operating rooms~~ in an existing medical care facility *or (ii) the total number of operating rooms in an existing medical care facility when the operating room is proposed to be added to an existing medical care facility located in a health planning district in which the utilization of existing operating rooms in the health planning district does not exceed 80 percent of the maximum operating room hour availability for the health planning district when the determination of maximum operating room hour availability is based on the assumption that each operating room in the health planning district is available 40 hours per week, 50 weeks per year*;

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, 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 of beds in an existing medical care facility to medical rehabilitation beds or psychiatric beds;

7. The addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization, computed tomographic (CT) scanning, stereotactic radiosurgery~~,~~ ~~lithotripsy~~, magnetic resonance imaging (MRI)~~,~~ ~~magnetic source imaging (MSI)~~, open heart surgery, 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. The establishment of any specialized center or clinic or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery when such specialized center or clinic or portion of a physician's office is proposed to be established in a health planning district in which the utilization of existing operating rooms in the health planning district does not exceed 80 percent of the maximum operating room hour availability for the health planning district when the determination of maximum operating room hour availability is based on the assumption that each operating room in the health planning district is available 40 hours per week, 50 weeks per year.

"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~~ *Health Services* 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.

§ 32.1-102.2. 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, *or* 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), *and* 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 *or registration of a project* 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~~ *Certificate of Public Need Program*; and

~~6.~~ *5.* Shall establish an expedited *45-day* application and review process for any certificate for *(i)* projects reviewable pursuant to subdivision 8 of the definition of "project" in § 32.1-102.1 *and (ii) projects identified by the Board in regulations to be generally uncontested and to present limited health planning impacts*. Regulations establishing the expedited application and review procedure shall include provisions for notice and opportunity for public comment on the application for a certificate, and criteria pursuant to which an application that would normally undergo the review process would instead undergo the full certificate of public need review process set forth in § 32.1-102.6.

B. The Board shall promulgate regulations providing for time limitations for schedules for completion and limitations on the exceeding of the maximum capital expenditure amount for all reviewable projects. The Commissioner shall not approve any such extension or excess unless it complies with the Board's regulations. However, the Commissioner may approve a significant change in cost for an approved project that exceeds the authorized capital expenditure by more than 20 percent, provided the applicant has demonstrated that the cost increases are reasonable and necessary under all the circumstances and do not result from any material expansion of the project as approved.

C. The Board shall also promulgate regulations authorizing the Commissioner to condition approval of a certificate on the agreement of the applicant to provide a level of care at a reduced rate to indigents or accept patients requiring specialized care. *Such regulations shall set forth a methodology and formulas for uniform application of, active measuring and monitoring of compliance with, and approval of alternative plans for compliance in satisfaction of such conditions.* 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.

D. The Board shall also promulgate regulations to require the registration of a project; for introduction into an existing medical care facility of any new lithotripsy, obstetrical, or nuclear imaging services that the facility has never provided or has not provided in the previous 12 months; and for the addition by an existing medical care facility of any medical equipment for lithotripsy. Replacement of existing equipment for lithotripsy or nuclear imaging services shall not require registration. Such regulations shall include provisions for (i) establishing the agreement of the applicant to provide a level of care in services or funds that match the average percentage of indigent care provided in the appropriate health planning region and to participate in Medicaid at a reduced rate to indigents, (ii) obtaining accreditation from a nationally recognized accrediting organization approved by the Board for the purpose of quality assurance, and (iii) reporting utilization and other data required by the Board to monitor and evaluate effects on health planning and availability of health care services in the Commonwealth.

§ 32.1-102.2:1. State Health Services Plan Advisory Council established.

~~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.~~

A. There is hereby established in the executive branch of state government the State Health Services Plan Advisory Council for the purpose of advising the Board on the content of the State Health Services Plan. The Advisory Council shall provide recommendations related to (i) periodic revisions to the State Health Services Plan, (ii) the appropriateness of a certificate of public need review for certain projects, (iii) whether certain projects should be subject to expedited review rather than the full review process, and (iv) improvements in the certificate of public need process. All such recommendations shall be developed in accordance with an analytical framework established by the Commissioner for such

purpose.

B. The Advisory Council shall consist of the Commissioner and 13 citizen members appointed by the Commissioner as follows: two representatives each of the Virginia Hospital and Healthcare Association, the Medical Society of Virginia, the Virginia Health Care Association, and of physicians or administrators representing teaching hospitals affiliated with a public institution of higher education; one representative each of the Virginia Association of Health Plans, a company that is self-insured or full-insured for health coverage, a nonprofit organization located in the Commonwealth that engages in addressing access to health coverage for low-income individuals, and a rural locality recognized as a medically underserved area; and one individual with experience in health facilities planning. In making such appointments, the Commissioner shall, to the extent feasible, assure that the membership of the Advisory Council is broadly representative of the interests of all residents of the Commonwealth and of the various geographic regions. The Commissioner shall serve a term coincident with his term in office. All other members of the Advisory Council shall serve two-year terms and may be reappointed. Appointments to fill vacancies, other than by expiration of a term, shall be made for the unexpired term. All vacancies shall be filled in the same manner as the original appointment.

C. The Commissioner shall serve as chairman of the Advisory Council. A majority of the members appointed and serving shall constitute a quorum. Final action by the Advisory Council shall only be by affirmative vote of the majority of the members appointed and serving.

D. The Advisory Council shall meet quarterly at places and dates fixed by the Commissioner. Special meetings may be called by the Commissioner, the Board, or at least three members of the Advisory Council. The Department shall make available the times and places of meetings of the Advisory Council and shall keep minutes of such meetings and a record of the actions of the Advisory Council and make a brief summary of such meetings and actions available to the public for review.

E. Members of the Advisory Council shall receive no compensation but shall be reimbursed for all reasonable and necessary expenses incurred in the performance of their duties as provided in §§ 2.2-2813 and 2.2-2825. The cost of such reimbursements shall be made from existing appropriations for the Advisory Council.

F. Staffing and administrative assistance shall be provided to the Advisory Council by the Department, which shall have charge of the Advisory Council's offices, records, and accounts. The Department shall provide such staff as may be necessary to allow the proper exercise of the powers and duties of the Advisory Council.

§ 32.1-102.2:2. Powers and duties of State Health Services Plan Advisory Council.

A. The powers and duties of the State Health Services Plan Advisory Council shall be:

1. To develop, by November 1, 2017 or as soon as practicable thereafter, recommendations for a comprehensive State Health Services Plan for adoption by the Board that includes (i) specific formulas for projecting need for medical care facilities and services subject to the requirement to obtain a certificate of public need; (ii) current statistical information on the availability of medical care facilities and services; (iii) objective criteria and standards for review of applications for projects for medical care facilities and services; and (iv) methodologies for integrating the goals and metrics of the State Health Improvement Plan established by the Commissioner into the criteria and standards for review. Criteria and standards for review included in the State Health Services Plan shall take into account current data on drive times, utilization, availability of competing services and patient choice within and among localities included in the health planning district or region, changes and availability of new technology, and other relevant factors identified by the Advisory Council. The State Health Services Plan shall also include 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 planning district or region as a whole.

2. To engage the services of private consultants or request the Department to contract with any private organization for professional and technical assistance and advice or other services to assist the Advisory Council in carrying out its duties and functions pursuant to this section. The Advisory Council may also solicit the input of experts with professional competence in the subject matter of the State Health Services Plan, including representatives of licensed health care providers or health care provider organizations owning or operating licensed health facilities, and representatives of organizations concerned with health care consumers and the purchasers and payers of health care services; and

3. To review annually and, if necessary, develop recommendations for revisions to each section of the State Health Services Plan on a rotating schedule defined by the Advisory Council at least every two years following the last date of adoption by the Board.

B. The Advisory Council shall exercise its powers and carry out its duties to ensure:

1. The availability and accessibility of quality health services at a reasonable cost and within a reasonable geographic proximity for all people in the Commonwealth, competitive markets, and patient

choice;

2. Appropriate differential consideration of the health care needs of residents in rural localities in ways that do not compromise the quality and affordability of health care services for those residents;

3. Elimination of barriers to access to care and introduction and availability of new technologies and care delivery models that result in greater integration and coordination of care, reduction in costs, and improvements in quality; and

4. Compliance with the goals of the State Health Improvement Plan and improvement in population health.

C. Not less than 30 days prior to final action on any recommendation of the Advisory Council, the Advisory Council shall (i) submit the proposed action and a concise summary of the expected impact of the proposed action for comment to each member of the Board for review and comment and (ii) solicit public comment on such recommendation. All comments received by the Advisory Council shall be submitted to and reviewed by the Commissioner. If the Commissioner determines that a public hearing is necessary or appropriate to seek further input on a recommendation, the Commissioner may hold one public hearing. Any public hearing shall be conducted no more than 30 days after the close of the public comment period. Prior to such public hearing, the Commissioner shall notify the Board and shall cause notice of the public hearing to be published on the Department's website. Following completion of the public comment period, and if applicable, the public hearing, the Advisory Council shall either approve or disapprove of the proposed recommendation. All final recommendations shall be communicated to the Board for consideration at its next regularly scheduled meeting. No recommendation of the Advisory Council shall become effective until such time as it is approved by the Board.

§ 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~~ *Health Services* 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~~ *Health Services* 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~~ *Health Services* Plan that have not been set aside and the remaining considerations in subsection B.

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

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

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

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

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

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

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

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

§ 32.1-102.6. Administrative procedures.

A. To obtain a certificate for a project, the applicant shall file a completed application for a certificate with the Department and the appropriate regional health planning agency if a regional health planning agency has been designated for that region. *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 public need for the requested project exists without the addition of supplemental or supporting material at a later date. The Department shall ensure that only data necessary for review of an application is required to be submitted and that the application reflects statutory requirements. 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)~~ *(i) within 10 calendar days following receipt of the completed application, 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; such notice shall include information about how comments may be submitted to the regional health planning agency and the date on which the public comment period shall expire, which shall be no later than 45 calendar days following the date of the public notice, and (ii) in the case of competing applications or in response to a written request by an elected local government representative, member of the General Assembly, the Commissioner, the applicant, or a member of the public,* 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~~ *any required* 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 *required pursuant to clause (ii), if any,* 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 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, 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~~ *any required* 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 the day which begins the appropriate batch review cycle and simultaneously with the review conducted by the regional health planning agency, if a regional health planning agency has been designated.

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

The 190-calendar-day review period shall begin on the date upon which the application is determined to be complete within the batching process specified in subdivision A 1 of § 32.1-102.2.

If the application is not determined to be complete within 40 calendar days from submission, the application shall be refiled in the next batch for like projects.

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

Article 9.

Permits for Certain Medical Care Facility Projects.

§ 32.1-122.23. Permit required; conditions on permits.

A. No person shall (i) add any operating room at any medical care facility as defined in § 32.1-102.1 in a health planning district in which the utilization of existing operating rooms in the health planning district exceeds 80 percent of the maximum operating room hour availability for the health planning district when the determination of maximum operating room hour availability is based on the assumption that each operating room in the health planning district is available 40 hours per week, 50 weeks per year, or (ii) establish any specialized center or clinic or portion of a physician's office for the provision of outpatient or ambulatory surgery in a health planning district in which the utilization of existing operating rooms in the health planning district exceeds 80 percent of the maximum operating room hour availability for the health planning district when the determination of maximum operating room hour availability is based on the assumption that each operating room in the health planning district is available 40 hours per week, 50 weeks per year without first obtaining a permit from the Commissioner.

B. At least 90 days prior to adding an operating room at an existing medical care facility or establishing any specialized center or clinic or portion of a physician's office for the provision of outpatient or ambulatory surgery in a health planning district described in subsection A, 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 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) establish charity care policies governing the provision of the permitted services to patients free of charge or at a reduced rate due to the indigence or medical indigence of the patient. Such policies shall include eligibility criteria for charity care and a process whereby a patient may apply for charity care. Such information shall be conspicuously posted in public areas of the applicant's place of practice and shall be (a) provided, in writing, to a patient at the time services are provided; (b) included with any billing statements sent to uninsured patients; and (c) included on any website maintained by the applicant.

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 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 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 the Secretary of Health and Human Resources shall review charity care services delivered throughout the Commonwealth and shall recommend changes to the definition of charity care and the types of charity care requirements imposed upon various providers of health care services. The

Secretary shall report his findings to the Governor and the General Assembly by December 1, 2017.

3. That the Secretary of Health and Human Resources shall implement a system by January 1, 2018, or as soon as possible thereafter to ensure that data needed to evaluate whether an application for a certificate of public need is consistent with the State Health Services Plan requirements are timely and reliable, with such funds as are available.

4. That the Secretary of Health and Human Resources implement a system by January 1, 2018, or as soon as possible thereafter to make all public records pertaining to certificate of public need applications and review process, including letters of intent, available in real time in a searchable, digital format online, with such funds as are available.

5. That the Secretary of Health and Human Resources implement a system by January 1, 2018, or as soon as possible thereafter to make an inventory of capacity authorized by certificates of public need, both operational and not yet operational, available in a digital format online, with such funds as are available.

6. That the Secretary of Health and Human Resources implement a system by January 1, 2018, or as soon as possible thereafter to make charity care conditions, charity care compliance reporting status, details on the exact amount of charity care provided or contributed, and to whom it was provided or contributed available in a digital format online, with such funds as are available.

7. That the Commissioner of Health shall develop and implement, by November 1, 2017, an analytical framework that incorporates review of the State Health Services Plan to support the State Health Services Plan Advisory Council in developing recommendations concerning the appropriateness of certificate of public need for specific medical care facilities and projects, or whether such projects should be subject to expedited review, and improvements in the certificate of public need process. The analytical framework shall include a specific evaluation of whether certificate of public need review is consistent with the goals of (i) meeting the health care needs of the indigent and uninsured citizens of the Commonwealth, (ii) protecting the public health and safety of the citizens of the Commonwealth, (iii) promoting the teaching missions of academic medical centers and private teaching hospitals, and (iv) ensuring the availability of essential health care services in the Commonwealth, and should be aligned with the goals and metrics of the Commonwealth's State Health Improvement Plan. The analytical framework shall also (a) take into consideration components of the approach utilized prior to 2012 in development of the Certificate of Public Need Annual Report; (b) include a recurrent three-year schedule for analysis of all project categories, with procedures for analysis of at least three project categories per year, which shall be developed in such a manner as to ensure that projects that are of relatively low complexity and low cost are analyzed first, and projects that are of relatively high complexity and high cost are analyzed subsequently; (c) include appropriate metrics to evaluate the impact of introducing a more competitive health care framework that could reduce costs and increase access to health care services; and (d) include a process for stakeholder involvement in review and public comment on any recommendations.

8. That the Joint Commission on Health Care shall review the current role of regional health planning agencies in the process for issuance of certificates of public need and shall develop recommendations for methods of eliminating differences in the certificate of public need review process from one region to another, including developing mechanisms to include region-specific analysis and encourage more local input in the certificate of public need review process for all regions, including those that do not have regional health planning agencies. The Joint Commission on Health Care shall develop specific recommendations for eliminating differences in the certificate of public need review process from one region to another and report on the recommendations to the Chairmen of the House Health, Welfare and Institutions and Senate Education and Health Committees by December 1, 2017.

9. That the State Health Services Plan Advisory Council shall review the appropriateness of requiring a certificate of public need for certain projects and make recommendations for the continued requirement of a certificate for those projects reviewed. The first category of projects to be reviewed shall include the addition of any new medical care facility for the provision of computed tomographic (CT) scanning or magnetic resonance imaging (MRI), the addition by any existing medical care facility of any new computed tomographic (CT) scanning or magnetic resonance imaging (MRI) service, and the addition by any existing medical care facility of any new equipment for computed tomographic (CT) scanning or magnetic resonance imaging (MRI).