CHAPTER 1271

An Act to amend and reenact §§ 2.2-4006, 32.1-3, 32.1-102.1, 32.1-102.2, 32.1-102.2:1, 32.1-102.3, 32.1-102.4, 32.1-102.6, 32.1-102.8, 32.1-102.10, 32.1-102.11, 32.1-239, and 32.1-276.5 of the Code of Virginia and to amend the Code of Virginia by adding sections numbered 32.1-102.1:2, 32.1-102.1:3, and 32.1-102.6:1, relating to certificate of public need.

[S 764]

Approved April 22, 2020

Be it enacted by the General Assembly of Virginia:

1. That §§ 2.2-4006, 32.1-3, 32.1-102.1, 32.1-102.2, 32.1-102.2:1, 32.1-102.3, 32.1-102.4, 32.1-102.6, 32.1-102.8, 32.1-102.10, 32.1-102.11, 32.1-239, and 32.1-276.5 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding sections numbered 32.1-102.1:2, 32.1-102.1:3, and 32.1-102.6:1 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 (i) the regulatory boards served by the Department of Labor and Industry pursuant to Title 40.1 and the Department of Professional and Occupational Regulation or the Department of Health Professions pursuant to Title 54.1 and (ii) the Board of Accountancy 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 pursuant to subsection D or E 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 receipt of recommendations by the State Health Services 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 comments 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.

§ 32.1-3. Definitions.

As used in this title unless the context requires otherwise or it is otherwise provided:

~~1.~~ "Board" or "State Board" means the State Board of Health.

~~2.~~ "Commissioner" means the State Health Commissioner.

~~3.~~ "Department" means the State Department of Health.

~~4.~~ *"Medical care facility" 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, nursing, acute, chronic, convalescent, or long-term care services, or services for individuals with disabilities, or (ii) which is the recipient of reimbursements from third-party health insurance programs or prepaid medical service plans.*

The term "medical care facility" does not include any facility of (a) the Department of Behavioral Health and Developmental Services; (b) 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; (c) an intermediate care facility for individuals with intellectual disability (ICF/IID) 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; (d) a physician's office, except that portion of a physician's office described in subdivision A 6 of § 32.1-102.1:3; (e) the Wilson Workforce and Rehabilitation Center of the Department for Aging and Rehabilitative Services; (f) the Department

of Corrections; or (g) the Department of Veterans Services.

"Person" means an individual, corporation, partnership, *or* association or any other legal entity.

§ 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.

"Bad debt" means revenue amounts deemed uncollectable as determined after collection efforts based upon sound credit and collection policies.

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

"Charity care" means health care services delivered to a patient who has a family income at or below 200 percent of the federal poverty level and for which it was determined that no payment was expected (i) at the time the service was provided because the patient met the facility's criteria for the provision of care without charge due to the patient's status as an indigent person or (ii) at some time following the time the service was provided because the patient met the facility's criteria for the provision of care without charge due to the patient's status as an indigent person. "Charity care" does not include care provided for a fee subsequently deemed uncollectable as bad debt. For a nursing home as defined in § 32.1-123, "charity care" means care at a reduced rate to indigent persons.

"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. Intermediate care facilities, except those intermediate care facilities established for individuals with intellectual disability (ICF/IID) 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 developmental disabilities.~~

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

~~9. Specialized centers or clinics or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery, cardiac catheterization, computed tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy, proton beam therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac imaging, or such other specialty services as may be designated by the Board by regulation.~~

~~10. Rehabilitation hospitals.~~

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

~~The term "medical care facility" 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/IID) 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;~~

~~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, 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~~ *any action described in subsection B of § 32.1-102.1:3*.

"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 *each type of* medical care facility ~~beds and services~~ *described in subsection A of § 32.1-102.1:3 and each type of project described in subsection B of § 32.1-102.1:3*; (ii) statistical information on the availability of *each type of* medical care ~~facilities and services~~ *facility described in subsection A of § 32.1-102.1:3 and each type of project described in subsection B of § 32.1-102.1:3*; and (iii) procedures, criteria, and standards for review of applications for projects for *each type of* medical care ~~facilities and services~~ *facility described in subsection A of § 32.1-102.1:3 and each type of project described in subsection B of § 32.1-102.1:3*.

§ 32.1-102.1:2. Certificate of public need required; registration of certain equipment and capital projects required.

A. No person shall undertake a project described in subsection B of § 32.1-102.1:3 or regulations of the Board at or on behalf of a medical care facility described in subsection A of § 32.1-102.1:3 without first obtaining a certificate from the Commissioner.

B. No person shall acquire any replacement medical equipment for the provision of cardiac

catheterization, computed tomographic (CT) scanning, magnetic resonance imaging (MRI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation therapy, proton beam therapy, or other specialized service designated by the Board by regulation without first registering such purchase with the Commissioner and the appropriate regional health planning agency. Such registration shall be made at least 30 calendar days prior to the date on which the person will become contractually obligated to acquire such medical equipment.

C. No general hospital shall make any capital expenditure of $5 million or more and no medical care facility other than a general hospital shall make any capital expenditure between $5 million and the amount established by the Board as the minimum capital expenditure by a medical care facility other than a general hospital for which a certificate is required pursuant to subdivision B 8 of § 32.1-102.1:3 without first registering such capital expenditure with the Commissioner pursuant to regulations of the Board. The amounts specified in this subsection shall be revised annually to reflect inflation using appropriate measures incorporating construction costs and medical inflation.

§ 32.1-102.1:3. Medical care facilities and projects for which a certificate is required.

A. The following medical care facilities shall be subject to the provisions of this article:

1. Any facility licensed as a hospital, as defined in § 32.1-123;

2. Any hospital licensed as a provider by the Department of Behavioral Health and Developmental Services in accordance with Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2;

3. Any facility licensed as a nursing home, as defined in § 32.1-123;

4. Any intermediate care facility established primarily for the medical, psychiatric, or psychological treatment and rehabilitation of individuals with substance abuse licensed by the Department of Behavioral Health and Developmental Services in accordance with Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2;

5. Any intermediate care facility for individuals with developmental disabilities other than an immediate care facility established for individuals with intellectual disability (ICF/IID) that has not 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; and

6. Any specialized center or clinic or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery, cardiac catheterization, computed tomographic (CT) scanning, magnetic resonance imaging (MRI), positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation therapy, or proton beam therapy.

B. The following actions undertaken by or on behalf of a medical care facility described in subsection A shall constitute a project for which a certificate of public need is required pursuant to subsection A of § 32.1-102.1:2:

1. Establishment of a medical care facility described in subsection A;

2. An increase in the total number of beds or operating rooms in an existing medical care facility described in subsection A;

3. Relocation of beds from an existing medical care facility described in subsection A to another existing medical care facility described in subsection A;

4. Addition of any new nursing home service at an existing medical care facility described in subsection A;

5. Introduction into an existing medical care facility described in subsection A of any cardiac catheterization, computed tomographic (CT) scanning, magnetic resonance imaging (MRI), medical rehabilitation, neonatal special care, open heart surgery, positron emission tomographic (PET) scanning, psychiatric, organ or tissue transplant service, radiation therapy, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation therapy, proton beam therapy, or substance abuse treatment when such medical care facility has not provided such service in the previous 12 months;

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

7. The addition by an existing medical care facility described in subsection A of any new medical equipment for the provision of cardiac catheterization, computed tomographic (CT) scanning, magnetic resonance imaging (MRI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation therapy, or proton beam therapy, other than new medical equipment for the provision of such service added to replace existing medical equipment for the provision of such service;

8. Any capital expenditure of $15 million or more, not defined as reviewable in subdivisions 1

through 7, by or on behalf of a medical care facility described in subsection A 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. Nothing in this subdivision shall be construed to modify or eliminate the reviewability of any project described in subdivisions 1 through 7 when undertaken by or on behalf of a general hospital; and

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

C. Notwithstanding the provisions of subsection A, any nursing home affiliated with a facility that, on January 1, 1982, and thereafter, (i) is operated as a nonprofit institution, (ii) is licensed jointly by the Department as a nursing home and by the Department of Social Services as an assisted living facility, and (iii) restricts admissions such that (a) admissions to the facility are only allowed pursuant to the terms of a "life care contract" guaranteeing that the full complement of services offered by the facility is available to the resident as and when needed, (b) admissions to the assisted living facility unit of the facility are restricted to individuals defined as ambulatory by the Department of Social Services, and (c) admissions to the nursing home unit of the facility are restricted to those individuals who are residents of the assisted living facility unit of the facility shall not be subject to the requirements of this article.

D. Notwithstanding the provisions of subsection B, a certificate of public need shall not be required for the following actions undertaken by or on behalf of a medical care facility described in subsection A:

1. Relocation of up to 10 beds or 10 percent of the beds, whichever is less, (i) from one existing medical care facility described in subsection A to another existing medical care facility described in subsection A at the same site in any two-year period or (ii) in any three-year period, from one existing medical care facility described in subsection A licensed as a nursing home to any other existing medical care facility described in subsection A licensed as a nursing home that is owned or controlled by the same person and 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 medical care facilities described in subsection A located in that other planning district, and at least half of those beds have not been replaced; or

2. Use of up to 10 percent of beds as nursing home beds by a medical care facility described in subsection A licensed as a hospital, as provided in § 32.1-132.

E. The Department shall regularly review the types of medical care facilities subject to the provisions of this article and projects for which a certificate is required and provide to the Governor and the General Assembly, at least once every five years, a recommendation related to the continued appropriateness of requiring such types of medical care facilities to be subject to the provisions of this article and such types of projects to be subject to the requirement of a certificate. In developing such recommendations, the Department shall consider, for each type of medical care facility and project, the following criteria:

1. The current and projected future availability of the specific type of medical care facility or project;

2. The current and projected future demand for the specific type of medical care facility or project;

3. The current and projected future rate of utilization of the specific type of medical care facility or project;

4. The current and projected future capacity of existing medical care facilities or projects of that specific type;

5. The anticipated impact of changes in population and demographics, reimbursement structures and rates, and technology on demand for and availability, utilization, and capacity of existing medical care facilities or projects of that specific type;

6. Existing quality, utilization, and other controls applicable to the specific type of medical care facility or project; and

7. Any risk to the health or well-being of the public resulting from inclusion of the specific type of medical care facility or project on such list.

§ 32.1-102.2. Regulations.

A. The Board shall promulgate regulations 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, stereotactic radiotherapy~~,~~ *other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation therapy, and* 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, stereotactic radiotherapy *other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation*

therapy, 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*;

~~6.~~ *5.* Shall establish an expedited application and review process for any certificate for projects reviewable pursuant to subdivision *B* 8 of ~~the definition of "project" in § 32.1-102.1~~ *§ 32.1-102.1:3*. 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;

~~7.~~ *6.* Shall establish an exemption from the requirement for a certificate, for a period of no more than 30 days, for projects involving a temporary increase in the total number of beds in an existing hospital or nursing home when the Commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds; and

~~8.~~ *7.* Shall require every medical care facility subject to the requirements of this article, other than a nursing home, that is not a medical care facility for which a certificate with conditions imposed pursuant to subsection ~~F~~ *B* of § 32.1-102.4 has been issued and that provides charity care, as defined in § 32.1-102.1, to annually report the amount of charity care provided.

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 charity care to indigent persons or accept patients requiring specialized care. *Such regulations shall include a methodology and formulas for uniform application of, active measuring and monitoring of compliance with, and approval of alternative plans for 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 charity care to indigent persons or accept patients requiring specialized care. Except in the case of nursing homes, the value of charity care provided to individuals pursuant to this subsection shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

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, stereotactic radiosurgery, stereotactic radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation therapy, 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, stereotactic radiosurgery, stereotactic radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation therapy, or nuclear imaging services. Replacement of existing equipment for lithotripsy, stereotactic radiosurgery, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform

external beam radiation therapy, 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 matches 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 ~~Medical Facilities~~ *Health Services* Plan; ~~task force~~ *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.~~

A. The Board shall appoint and convene a State Health Services Plan Task Force for the purpose of advising the Board on the content of the State Health Services Plan. The Task Force shall provide recommendations related to (i) periodic revisions to the State Health Services Plan, (ii) specific objective standards of review for each type of medical care facility or project type for which a certificate of public need is required, (iii) project types that are generally noncontested and present limited health planning impacts, (iv) whether certain projects should be subject to expedited review rather than the full review process, and (v) improvements in the certificate of public need process. All such recommendations shall be developed in accordance with an analytical framework established by the Commissioner that includes a specific evaluation of whether State Health Services Plan standards are consistent with the goals of (a) meeting the health care needs of the indigent and uninsured citizens of the Commonwealth, (b) protecting the public health and safety of the citizens of the Commonwealth, (c) promoting the teaching missions of academic medical centers and private teaching hospitals, and (d) ensuring the availability of essential health care services in the Commonwealth, and are aligned with the goals and metrics of the Commonwealth's State Health Improvement Plan.

B. The Task Force shall consist of no fewer than 19 individuals appointed by the Commissioner who are broadly representative of the interests of all residents of the Commonwealth and of the various geographic regions, including two representatives of the Virginia Hospital and Healthcare Association, the Medical Society of Virginia, the Virginia Health Care Association, and physicians or administrators representing teaching hospitals affiliated with a public institution of higher education; one representative each of the Virginia Association of Health Plans, the Virginia Association of Free and Charitable Clinics, the Virginia Community Healthcare Association, LeadingAge Virginia, 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; one individual with experience in health facilities planning; and such other individuals as the Commissioner determines is appropriate.

C. The powers and duties of the Task Force shall be:

1. To develop, by November 1, 2022, 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 Task Force. 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 Task Force in carrying out its duties and functions pursuant to this section. The Task Force may also solicit the input of experts with professional competence in the subject matter of the State Health Services Plan, including (i) representatives of licensed health care providers or health care provider organizations owning or operating licensed health facilities and (ii) 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 Task Force at least every two years following the last date of adoption by the Board.

D. The Task Force 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 Services Plan and improvement in population health.

E. The Department shall post on its website information regarding the process by which the State Health Services Plan is created and the process by which the Department determines whether a proposed project complies with the State Health Services Plan on its website.

§ 32.1-102.3. Demonstration of public need 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~~ *project* will provide or increase access to ~~needed~~ *health care* services for residents of the area to be served~~,~~ and the effects that the proposed ~~service or facility~~ *project* will have on access to ~~needed~~ *health care* services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to *health* care;

2. The extent to which the *proposed* 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 *proposed* 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~~ *project* 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 *proposed* project; (v) the financial accessibility of the *proposed* 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 *proposed* project;

3. The extent to which the ~~application~~ *proposed project* is consistent with the State ~~Medical Facilities~~ *Health Services* Plan;

4. The extent to which the proposed ~~service or facility~~ *project* 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 *proposed* 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 *proposed* project, including the financial benefits of the *proposed* 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 *proposed* project provides improvements or innovations in the financing and delivery of health *care* 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 *health care* 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 *services* for citizens of the Commonwealth, including indigent or underserved populations.

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

A. ~~A certificate shall be issued~~ *The Commissioner may, in accordance with regulations of the Board, condition issuance of a certificate on compliance* with a schedule for the completion of the *proposed* project and a maximum capital expenditure amount for the *proposed* project. The *approved* schedule *and maximum capital expenditure for a proposed project shall be issued together with the certificate. The approved 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. *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.*

The Commissioner shall monitor each project to determine its progress and compliance with the approved schedule and with the maximum capital expenditure, and may revoke the certificate for (i) lack of substantial and continuing progress toward completion of the project in accordance with the schedule or (ii) expenditures in excess of the approved maximum capital expenditure for the project.

Any person willfully violating conditions imposed pursuant to this subsection shall be subject to a civil penalty of up to $100 per violation per day until the date of completion of the project which shall be collected by the Commissioner and paid into the Literary Fund.

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

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~~ *shall*, pursuant to the regulations of the Board, *condition* the approval of a certificate ~~(i)~~ upon the agreement of the applicant to *provide care to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. In addition, the Commissioner shall condition the approval of a certificate upon the agreement of the applicant to (i)* provide a *specified* level of charity care to indigent persons or accept patients requiring specialized care ~~or~~, (ii) ~~upon the agreement of the applicant to~~ facilitate the development and operation of primary *and specialty* medical care services in designated medically underserved areas of the applicant's service area, *or (iii) all of the above*. Except in the case of nursing homes, the value of charity care provided to individuals pursuant to this subsection shall be based on the provider reimbursement methodology

utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

Every certificate holder shall develop a financial assistance policy that includes specific eligibility criteria and procedures for applying for charity care, which shall be provided to a patient at the time of admission or discharge or at the time services are provided, included with any billing statements sent to uninsured patients, posted conspicuously in public areas of the medical care facility for which the certificate was issued and posted on a website maintained by the certificate holder.

The certificate holder shall *annually* provide documentation to the Department demonstrating that the certificate holder has satisfied the conditions of the certificate, including documentation of the amount of charity care provided to patients. 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~~, *which* 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 (a) making direct payments to an organization authorized under a memorandum of understanding with the Department to receive contributions satisfying conditions of a certificate, (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 (c) other documented efforts or initiatives to provide primary or specialized care to underserved populations. In cases in which the certificate holder holds more than one certificate with conditions pursuant to this subsection, and the certificate holder is unable to satisfy the conditions of one certificate, such plan of compliance may provide for satisfaction of the conditions on that certificate by providing care at a reduced rate to indigent individuals in excess of the amount required by another certificate issued to the same holder, in an amount approved by the Department provided such care is offered at the same facility. Nothing in the preceding sentence shall prohibit the satisfaction of conditions of more than one certificate among various affiliated facilities or certificates subject to a system-wide or all-inclusive charity care condition established by the Commissioner. 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~~ *actions* 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 *which shall be collected by the Commissioner and paid into the Literary Fund. For the purpose of determining the amount of a civil penalty imposed pursuant to this subsection, the date on which the person began providing services in accordance with the original certificate shall be the date from which the period of noncompliance shall be calculated.*

~~G.~~ *C.* The Commissioner shall (i) review every certificate of public need upon which conditions were imposed pursuant to subsection ~~F~~ *B* at least once every three years to determine whether such conditions continue to be appropriate or should be revised and (ii) notify each certificate holder of his conclusions regarding (a) the appropriateness of conditions imposed on the certificate and whether such conditions should be revised and (b) the process by which the certificate holder may request amendments to conditions imposed on a certificate in accordance with subsection ~~H~~ *D*.

~~H.~~ *D.* 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.

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

E. In determining whether conditions imposed on a certificate of public need pursuant to subsection B are appropriate for the purposes of subsection C or should be amended in response to a request submitted pursuant to subsection D, the Commissioner shall consider any changes in the circumstances of the certificate holder resulting from changes in the financing or delivery of health care services, including changes to the Commonwealth's program of medical assistance services, and any other specific circumstances of the certificate holder.

§ 32.1-102.6. Administrative procedures.

A. To obtain a certificate for a project, the applicant shall file a completed application for a certificate with the Department and the appropriate regional health planning agency if a regional health planning agency has been designated for that region. ~~In order to verify the date of the Department's and the appropriate regional health planning agency's receipt of the application, the applicant shall transmit the document electronically, by certified mail or a delivery service, return receipt requested, or shall deliver the document by hand, with signed receipt to be provided~~ *Such application shall be filed in accordance with procedures established by the Department. 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.

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~~ *that* 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~~,~~*; (ii) within 10 calendar days following the start of the review cycle, 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)~~ *(iii) 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 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 (iii), 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 *(a) within 10 calendar days following the start of the review cycle, 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 such information about how comments may be submitted to the Department 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 (b) 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~~ *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 public hearing, the Department shall cause notice of the public hearing to be published in a newspaper of general circulation in the county or city where the project is proposed to be located. The Department shall consider the comments of the local governing bodies in the planning district and all other public comments in making its decision. Such comments shall be part of the record.

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

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

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

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

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

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

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

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

2. The Department shall review every application at or before the seventy-fifth calendar day within the 190-calendar-day review period to determine whether an informal fact-finding conference is necessary.

3. Any person seeking to be made a party to the case for good cause ~~shall notify the Department of his request and the basis therefor on or before the eightieth calendar day following the day which begins the appropriate batch review cycle~~, *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, shall 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~~ *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 *A* 8 of ~~the definition of "project" in § 32.1-102.1~~ *§ 32.1-102.1:3*. 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.

§ 32.1-102.6:1. Revocation of a certificate.

The Commissioner shall revoke a certificate of public need for:

1. Failure to comply with the requirements of subsection A of § 32.1-102.4 regarding schedules for completion of a project or maximum capital expenditures for a project; or

2. Willfully or recklessly misrepresented intentions or facts in obtaining a certificate.

§ 32.1-102.8. Enjoining project undertaken without certificate or registration.

On petition of the Commissioner, the Board or the Attorney General, the circuit court of the county or city where a project is under construction or is intended to be constructed, located, or undertaken shall have jurisdiction to enjoin any project ~~which~~ *that* is constructed, undertaken, or commenced without a certificate *or registration required by this article* or to enjoin the admission of patients to the project or to enjoin the provision of services through the project.

§ 32.1-102.10. Commencing project without certificate *or registration* grounds for refusing to issue license.

Commencing any project without a certificate *or registration* required by this article shall constitute grounds for refusing to issue a license for such project. Persons commencing any project without a certificate *or registration* as required by this article shall be subject to the penalties set forth in §§ 32.1-27 and 32.1-27.1.

§ 32.1-102.11. Application of article.

A. ~~On and after July 1, 1992, every~~ *Every* project of an existing or proposed medical care facility~~, as defined in § 32.1-102.1,~~ *described in subsection A of § 32.1-102.1:3* shall be subject to all provisions of this article unless, with respect to such project, the owner or operator of an existing medical care facility or the developer of a proposed medical care facility (i) has, by February 1, 1992, purchased or leased equipment subject to registration pursuant to former § 32.1-102.3:4, (ii) has, by February 1, 1992, initiated construction requiring a capital expenditure exceeding one million dollars, or (iii) has made or contracted to make or otherwise legally obligated to make, during the three years ending February 1, 1992, preliminary expenditures of $350,000 or more for a formal plan of construction of the specific project, including expenditures for site acquisition, designs, preliminary or working drawings, construction documents, or other items essential to the construction of the specific project.

Any project exempted pursuant to subdivisions (ii) and (iii) of this subsection shall be limited to

such construction, services, and equipment as specifically identified in the formal plan of construction which shall have existed and been formally committed to by February 1, 1992. Further, the equipment to be exempted pursuant to subdivisions (ii) and (iii) shall be limited to the number of units and any types of medical equipment, in the case of medical equipment intended to provide any services included in subdivision *B* 6 of ~~the definition of project in § 32.1-102.1~~ *§ 32.1-102.1:3*, as are specifically identified in such plan and, in the case of all other equipment, such equipment as is appropriate for the construction and services included in such plan.

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

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

C. For the purposes of this section:

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

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

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

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

§ 32.1-239. Definitions.

As used in this article the following definitions shall apply:

"Commercial establishment" means any commercial or industrial establishment, mill, factory, plant, refinery and any other works in which any chemical substance is manufactured or used as a raw material, catalyst, final product or process solvent for such; however, this term shall not be construed in the administration of this act to include normal farming and timbering activities.

"Manufacturing" means producing, formulating, packaging or diluting any substance for commercial sale or resale.

"Person" includes, in addition to the entities enumerated in ~~subdivision~~ 4 ~~of~~ § 32.1-3, the Commonwealth and any of its political subdivisions.

"Toxic substance" means any substance, including any raw materials, intermediate products, catalysts, final products, or by-products of any manufacturing operation conducted in a commercial establishment,

that has the capacity, through its physical, chemical or biological properties, to pose a substantial risk of death or impairment either immediately or over time, to the normal functions of humans, aquatic organisms, or any other animal.

§ 32.1-276.5. Providers to submit data; civil penalty.

A. Every health care provider shall submit data as required pursuant to regulations of the Board, consistent with the recommendations of the nonprofit organization in its strategic plans submitted and approved pursuant to § 32.1-276.4, and as required by this section. Such data shall include relevant data and information for any parent or subsidiary company of the health care provider that operates in the Commonwealth. Notwithstanding the provisions of Chapter 38 (§ 2.2-3800 et seq.) of Title 2.2, it shall be lawful to provide information in compliance with the provisions of this chapter.

B. In addition, health maintenance organizations shall annually submit to the Commissioner, to make available to consumers who make health benefit enrollment decisions, audited data consistent with the latest version of the Health Employer Data and Information Set (HEDIS), as required by the National Committee for Quality Assurance, or any other quality of care or performance information set as approved by the Board. The Commissioner, at his discretion, may grant a waiver of the HEDIS or other approved quality of care or performance information set upon a determination by the Commissioner that the health maintenance organization has met Board-approved exemption criteria. The Board shall promulgate regulations to implement the provisions of this section.

The Commissioner shall also negotiate and contract with a nonprofit organization authorized under § 32.1-276.4 for compiling, storing, and making available to consumers the data submitted by health maintenance organizations pursuant to this section. The nonprofit organization shall assist the Board in developing a quality of care or performance information set for such health maintenance organizations and shall, at the Commissioner's discretion, periodically review this information set for its effectiveness.

C. Every medical care facility as that term is defined in ~~§ 32.1-102.1~~ *§ 32.1-3* that furnishes, conducts, operates, or offers any reviewable service shall report data on utilization of such service to the Commissioner, who shall contract with the nonprofit organization authorized under this chapter to collect and disseminate such data. For purposes of this section, "reviewable service" shall mean inpatient beds, operating rooms, nursing home services, cardiac catheterization, computed tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging, medical rehabilitation, neonatal special care, obstetrical services, open heart surgery, positron emission tomographic (PET) scanning, psychiatric services, organ and tissue transplant services, radiation therapy, stereotactic radiotherapy, proton beam therapy, nuclear medicine imaging except for the purpose of nuclear cardiac imaging, and substance abuse treatment.

Every medical care facility for which a certificate of public need with conditions imposed pursuant to § 32.1-102.4 is issued shall report to the Commissioner data on charity care, as that term is defined in § 32.1-102.1, provided to satisfy a condition of a certificate of public need, including (i) the total amount of such charity care the facility provided to indigent persons; (ii) the number of patients to whom such charity care was provided; (iii) the specific services delivered to patients that are reported as charity care recipients; and (iv) the portion of the total amount of such charity care provided that each service represents. The value of charity care reported shall be based on the medical care facility's submission of applicable Diagnosis Related Group codes and Current Procedural Terminology codes aligned with methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. Notwithstanding the foregoing, every nursing home as defined in § 32.1-123 for which a certificate of public need with conditions imposed pursuant to § 32.1-102.4 is issued shall report data on utilization and other data in accordance with regulations of the Board.

A medical care facility that fails to report data required by this subsection shall be subject to a civil penalty of up to $100 per day per violation, which shall be collected by the Commissioner and paid into the Literary Fund.

D. Every continuing care retirement community established pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 that includes nursing home beds shall report data on utilization of such nursing home beds to the Commissioner, who shall contract with the nonprofit organization authorized under this chapter to collect and disseminate such data.

E. Every hospital that receives a disproportionate share hospital adjustment pursuant to § 1886(d)(5)(F) of the Social Security Act shall report, in accordance with regulations of the Board consistent with recommendations of the nonprofit organization in its strategic plan submitted and provided pursuant to § 32.1-276.4, the number of inpatient days attributed to patients eligible for Medicaid but not Medicare Part A and the total amount of the disproportionate share hospital adjustment received.

F. The Board shall evaluate biennially the impact and effectiveness of such data collection.

2. That the Department of Health develop recommendations to reduce the duration of the average review cycle for applications for certificates of public need to not more than 120 days from the date of receipt of a letter of intent. In doing so, the Department shall consider changes to the current process that may result in a reduction in the duration of the review period, including

elimination or revision of the review of applications for completeness, reduction of the current 70-day period for review of an application by the Department, and a requirement that a public hearing be held earlier in the process. The Department shall report its recommendations to the Governor and the General Assembly by December 1, 2020.

3. That the Secretary of Health and Human Resources implement a system by January 1, 2023, or as soon as thereafter as practicable, 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 is timely and reliable, with such funds as are available.

4. That the Secretary of Health and Human Resources implement a system by January 1, 2021, or as soon thereafter as practicable, 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.

5. That the Secretary of Health and Human Resources establish, by January 1, 2021, a public education and outreach program designed to improve public awareness of the certificate of public need process and the public's role in such process, including the opportunity to provide written comments on applications and the process by which a member of the public may request a public hearing on an application.