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**HOUSE BILL NO. 350**

Offered January 13, 2016

Prefiled January 5, 2016

A *BILL to amend and reenact §§ 2.2-4006, 32.1-102.1, 32.1-102.2, 32.1-102.3, 32.1-102.4, and 32.1-102.6 of the Code of Virginia and to amend the Code of Virginia by adding in Article 1.1 of Chapter 4 of Title 32.1 a section numbered 32.1-102.14 and by adding in Chapter 4 of Title 32.1 an article numbered 9, consisting of sections numbered 32.1-122.23 and 32.1-122.24, relating to the Certificate of Public Need program.*

Patrons—Byron, O'Bannon, Peace, Bell, Richard P., Cole and LaRock

Referred to Committee on Health, Welfare and Institutions

**Be it enacted by the General Assembly of Virginia:**

1. That §§ 2.2-4006, 32.1-102.1, 32.1-102.2, 32.1-102.3, 32.1-102.4, and 32.1-102.6 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Article 1.1 of Chapter 4 of Title 32.1 a section numbered 32.1-102.14 and by adding in Chapter 4 of Title 32.1 an article numbered 9, consisting of sections numbered 32.1-122.23 and 32.1-122.24, as follows:

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

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

1. Agency orders or regulations fixing rates or prices.  
2. Regulations that establish or prescribe agency organization, internal practice or procedures, including delegations of authority.

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

4. Regulations that are:  
a. Necessary to conform to changes in Virginia statutory law or the appropriation act where no agency discretion is involved. However, such regulations shall be filed with the Registrar within 90 days of the law's effective date;  
b. Required by order of any state or federal court of competent jurisdiction where no agency discretion is involved; or

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

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

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

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

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

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59 one public hearing on the proposed general permit.

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

63 10. Regulations of the Board of the Virginia College Savings Plan adopted pursuant to § 23-38.77.

64 11. Regulations of the Marine Resources Commission.

65 12. Regulations adopted by the Board of Housing and Community Development pursuant to (i)  
66 Statewide Fire Prevention Code (§ 27-94 et seq.), (ii) the Industrialized Building Safety Law (§ 36-70 et  
67 seq.), (iii) the Uniform Statewide Building Code (§ 36-97 et seq.), and (iv) § 36-98.3, provided the  
68 Board (a) provides a Notice of Intended Regulatory Action in conformance with the provisions of  
69 § 2.2-4007.01, (b) publishes the proposed regulation and provides an opportunity for oral and written  
70 comments as provided in § 2.2-4007.03, and (c) conducts at least one public hearing as provided in §§  
71 2.2-4009 and 36-100 prior to the publishing of the proposed regulations. Notwithstanding the provisions  
72 of this subdivision, any regulations promulgated by the Board shall remain subject to the provisions of  
73 § 2.2-4007.06 concerning public petitions, and §§ 2.2-4013 and 2.2-4014 concerning review by the  
74 Governor and General Assembly.

75 13. Amendments to the list of drugs susceptible to counterfeiting adopted by the Board of Pharmacy  
76 pursuant to subsection B of § 54.1-3307 or amendments to regulations of the Board to schedule a  
77 substance in Schedule I or II pursuant to subsection D of § 54.1-3443.

78 14. Waste load allocations adopted, amended, or repealed by the State Water Control Board pursuant  
79 to the State Water Control Law (§ 62.1-44.2 et seq.), including but not limited to Article 4.01  
80 (§ 62.1-44.19:4 et seq.) of the State Water Control Law, if the Board (i) provides public notice in the  
81 Virginia Register; (ii) if requested by the public during the initial public notice 30-day comment period,  
82 forms an advisory group composed of relevant stakeholders; (iii) receives and provides summary  
83 response to written comments; and (iv) conducts at least one public meeting. Notwithstanding the  
84 provisions of this subdivision, any such waste load allocations adopted, amended, or repealed by the  
85 Board shall be subject to the provisions of §§ 2.2-4013 and 2.2-4014 concerning review by the  
86 Governor and General Assembly.

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

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

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

101 **§ 32.1-102.1. Definitions.**

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

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

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

107 "Charity care" means health care services for which no compensation is received provided to  
108 individuals whose income is less than or equal to 200 percent of the federal poverty level for a  
109 household of that size.

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

113 "Medical care facility," as used in this title, means any institution, place, building or agency, whether  
114 or not licensed or required to be licensed by the Board or the Department of Behavioral Health and  
115 Developmental Services, whether operated for profit or nonprofit and whether privately owned or  
116 privately operated or owned or operated by a local governmental unit, (i) by or in which health services  
117 are furnished, conducted, operated or offered for the prevention, diagnosis or treatment of human  
118 disease, pain, injury, deformity or physical condition, whether medical or surgical, of two or more  
119 nonrelated persons who are injured or physically sick or have mental illness, or for the care of two or  
120 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/MR) that have no more than 12 beds and are in an area identified as in need of residential services for individuals with intellectual disability in any plan of the Department of Behavioral Health and Developmental Services.
5. Extended care facilities.
6. ~~Mental hospitals.~~
7. Facilities for individuals with intellectual disability.
8. Psychiatric hospitals and intermediate care facilities established primarily for the medical, psychiatric or psychological treatment and rehabilitation of individuals with substance abuse.
9. 8. 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. 9. Rehabilitation hospitals.~~

~~11. 10. Any facility licensed as a hospital.~~

The term "medical care facility" does not include any facility of (i) the Department of Behavioral Health and Developmental Services; (ii) any nonhospital substance abuse residential treatment program operated by or contracted primarily for the use of a community services board under the Department of Behavioral Health and Developmental Services' Comprehensive State Plan; (iii) an intermediate care facility for individuals with intellectual disability (ICF/MR) that has no more than 12 beds and is in an area identified as in need of residential services for individuals with intellectual disability in any plan of the Department of Behavioral Health and Developmental Services; (iv) a physician's office, except that portion of a physician's office described in subdivision 9 8 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;

182 7. The addition by an existing medical care facility of any medical equipment for the provision of  
183 cardiac catheterization, computed tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy,  
184 magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery, positron  
185 emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy, proton beam therapy,  
186 or other specialized service designated by the Board by regulation. Replacement of existing equipment  
187 shall not require a certificate of public need;

188 8. Any capital expenditure of \$15 million or more, not defined as reviewable in subdivisions 1  
189 through 7 of this definition, by or on behalf of a medical care facility other than a general hospital.  
190 Capital expenditures of \$5 million or more by a general hospital and capital expenditures between \$5  
191 and \$15 million by a medical care facility other than a general hospital shall be registered with the  
192 Commissioner pursuant to regulations developed by the Board. The amounts specified in this subdivision  
193 shall be revised effective July 1, 2008, and annually thereafter to reflect inflation using appropriate  
194 measures incorporating construction costs and medical inflation. Nothing in this subdivision shall be  
195 construed to modify or eliminate the reviewability of any project described in subdivisions 1 through 7  
196 of this definition when undertaken by or on behalf of a general hospital; or

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

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

202 "State Medical Facilities Plan" means the planning document adopted by the Board of Health which  
203 shall include, but not be limited to, (i) methodologies for projecting need for medical care facility beds  
204 and services; (ii) statistical information on the availability of medical care facilities and services; and  
205 (iii) procedures, criteria and standards for review of applications for projects for medical care facilities  
206 and services.

207 **§ 32.1-102.2. Regulations.**

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

209 1. Shall establish concise procedures for the prompt review of applications for certificates consistent  
210 with the provisions of this article which may include a structured batching process which incorporates,  
211 but is not limited to, authorization for the Commissioner to request proposals for certain projects. In any  
212 structured batching process established by the Board, applications, combined or separate, for computed  
213 tomographic (CT) scanning, magnetic resonance imaging (MRI), positron emission tomographic (PET)  
214 scanning, radiation therapy, ~~stereotactic~~ stereotactic radiotherapy, proton beam therapy, or nuclear  
215 imaging shall be considered in the radiation therapy batch. A single application may be filed for a  
216 combination of (i) radiation therapy, ~~stereotactic~~ stereotactic radiotherapy and proton beam therapy, and  
217 (ii) any or all of the computed tomographic (CT) scanning, magnetic resonance imaging (MRI), positron  
218 emission tomographic (PET) scanning, and nuclear medicine imaging;

219 2. May classify projects and may eliminate one or more or all of the procedures prescribed in  
220 § 32.1-102.6 for different classifications;

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

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

229 5. May establish, on or after July 1, 1999, a schedule of fees for applications for certificates to be  
230 applied to expenses for the administration and operation of the certificate of public need program. Such  
231 fees shall not be less than \$1,000 nor exceed the lesser of one percent of the proposed expenditure for  
232 the project or \$20,000. Until such time as the Board shall establish a schedule of fees, such fees shall be  
233 one percent of the proposed expenditure for the project; however, such fees shall not be less than \$1,000  
234 or more than \$20,000; and

235 6. Shall establish (i) *an expedited 21-day application and review process for any certificate for*  
236 *projects determined by the Department to be uncontested and to present minimal health planning*  
237 *impacts, in accordance with criteria established by the Board, and for which the applicant agrees to*  
238 *comply with quality assurance requirements established by the Board and consents to provide charity*  
239 *care in an amount specified by the Board, and (ii) an expedited 45-day application and review process*  
240 *for any certificate for projects reviewable pursuant to subdivision 8 of the definition of "project" in §*  
241 *32.1-102.1 and projects identified by the Department to be uncontested and to present minimal health*  
242 *planning impacts that require a level of scrutiny greater than that required pursuant clause (i) but do*  
243 *not require a full review pursuant to § 32.1-102.6, in accordance with criteria established by the Board,*

and for which the applicant agrees to comply with quality assurance requirements established by the Board and consents to provide charity care in an amount specified by the Board. Regulations establishing the expedited application and review ~~procedure~~ procedures in accordance with this subdivision shall include (a) provisions for notice and opportunity for public comment on the application for a certificate, ~~and~~; (b) criteria pursuant to which an application that would normally undergo the review process would instead undergo the full certificate of public need review process set forth in § 32.1-102.6; (c) provisions for conditioning the approval of a certificate upon the agreement of the applicant to (1) provide a level of care at a reduced rate to indigents or accept patients requiring specialized medical care or (2) facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area; and (d) provisions for conditioning the approval of a certificate upon the agreement of the applicant to comply with quality assurance requirements established by the Board.

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

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

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

A. No person shall commence any project without first obtaining a certificate issued by the Commissioner. No certificate may be issued unless the Commissioner has determined that a public need for the project has been demonstrated. If it is determined that a public need exists for only a portion of a project, a certificate may be issued for that portion and any appeal may be limited to the part of the decision with which the appellant disagrees without affecting the remainder of the decision. Any decision to issue or approve the issuance of a certificate shall be consistent with the most recent applicable provisions of the State Medical Facilities Plan; however, if the Commissioner finds, upon presentation of appropriate evidence, that the provisions of such plan are not relevant to a rural locality's needs, inaccurate, outdated, inadequate or otherwise inapplicable, the Commissioner, consistent with such finding, may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to such plan. In cases in which a provision of the State Medical Facilities Plan has been previously set aside by the Commissioner and relevant amendments to the Plan have not yet taken effect, the Commissioner's decision shall be consistent with the applicable portions of the State Medical Facilities Plan that have not been set aside and the remaining considerations in subsection B.

B. In ~~determining whether a public need for a project has been demonstrated~~, cases in which an application for a proposed project is consistent with the State Medical Facilities Plan, the Commissioner shall approve the application. In all other cases, the Commissioner shall consider:

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

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

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

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

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

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

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

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

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

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

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

C. A certificate may be revoked when:

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

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

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

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

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

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

F. The Commissioner may condition, pursuant to the regulations of the Board, the approval of a certificate (i) upon the agreement of the applicant to provide a level of care at a reduced rate to indigents or accept patients requiring specialized care or (ii) upon the agreement of the applicant to facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area. *The value of care provided to individuals pursuant to this subsection shall be based on provider reimbursement methodology utilized by the Department of Medical Assistance Services for reimbursements under the state plan for medical assistance.*

The certificate holder shall provide documentation to the Department demonstrating that the certificate holder has satisfied the conditions of the certificate. If the certificate holder is unable or fails to satisfy the conditions of a certificate, the Department may approve alternative methods to satisfy the conditions pursuant to a plan of compliance. The plan of compliance shall identify a timeframe within which the certificate holder will satisfy the conditions of the certificate, and identify how the certificate holder will satisfy the conditions of the certificate, which may include (i) making direct payments to an organization authorized under a memorandum of understanding with the Department to receive contributions satisfying conditions of a certificate, (ii) making direct payments to a private nonprofit foundation that funds basic insurance coverage for indigents authorized under a memorandum of

understanding with the Department to receive contributions satisfying conditions of a certificate, or (iii) other documented efforts or initiatives to provide primary or specialized care to underserved populations. In determining whether the certificate holder has met the conditions of the certificate pursuant to a plan of compliance, only such direct payments, efforts, or initiatives made or undertaken after issuance of the conditioned certificate shall be counted towards satisfaction of conditions.

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

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

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

**§ 32.1-102.6. Administrative procedures.**

A. To obtain a certificate for a project, the applicant shall file a completed application for a certificate with the Department and the appropriate regional health planning agency if a regional health planning agency has been designated for that region. *An application submitted for review shall be considered complete when all relevant sections of the application form have responses. The applicant shall provide sufficient information to prove public need for the requested project exists without the addition of supplemental or supporting material at a later date. Nothing in this section shall prevent the Department from seeking, at its discretion, additional information from the applicant or other sources.*

In order to verify the date of the Department's and the appropriate regional health planning agency's receipt of the application, the applicant shall transmit the document electronically, by certified mail or a delivery service, return receipt requested, or shall deliver the document by hand, with signed receipt to be provided.

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

At least 30 calendar days before any person is contractually obligated to acquire an existing medical care facility, the cost of which is \$600,000 or more, that person shall notify the Commissioner and the appropriate regional health planning agency, if a regional health planning agency has been designated, of the intent, the services to be offered in the facility, the bed capacity in the facility and the projected impact that the cost of the acquisition will have upon the charges for services to be provided. If clinical services or beds are proposed to be added as a result of the acquisition, the Commissioner may require the proposed new owner to obtain a certificate prior to the acquisition. If no regional health planning agency is designated for the health planning region in which the acquisition will take place, no notification to a regional health planning agency shall be required.

B. For projects proposed in health planning regions with regional planning agencies, the appropriate regional health planning agency shall (i) review each completed application for a certificate within 60 calendar days of the day which begins the appropriate batch review cycle as established by the Board by regulation pursuant to subdivision A 1 of § 32.1-102.2, such cycle not to exceed 190 days in duration, and (ii) hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city. Prior to the public hearing, the regional health planning agency shall notify the local governing bodies in the planning district. At least nine days prior to the public hearing, the regional health planning agency shall cause notice of the public hearing to be published in a newspaper of general circulation in the county or city where the project is proposed to be located. The regional health planning agency shall consider the comments of the local governing bodies in the planning district and all other public comments in making its decision. Such comments shall be part of the record. In no case shall a regional health planning agency hold more than two meetings on any application, one of which shall be the public hearing conducted by the board of the regional health planning agency or a subcommittee of the board. The applicant shall be given the opportunity, prior to the vote by the board of the regional health planning agency or a committee of the agency, if acting for the board, on its recommendation, to respond to any comments made about the project by the regional health planning agency staff, any information in a regional health planning agency staff report, or comments by those voting members of the regional health planning agency board; however, such opportunity shall not increase the 60-calendar-day period designated herein for the regional health

428 planning agency's review unless the applicant or applicants request a specific extension of the regional  
429 health planning agency's review period.

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

433 If the regional health planning agency has not completed its review within the specified 60 calendar  
434 days or such other period in accordance with the applicant's request for extension and submitted its  
435 recommendations on the application and the reasons therefor within 10 calendar days after the  
436 completion of its review, the Department shall, on the eleventh calendar day after the expiration of the  
437 regional health planning agency's review period, proceed as though the regional health planning agency  
438 has recommended project approval without conditions or revision.

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

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

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

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

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

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

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

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

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

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

477 3. Any person seeking to be made a party to the case for good cause shall ~~notify the Department of~~  
478 ~~his request and the basis therefor on or before the eightieth calendar day following the day which begins~~  
479 ~~the appropriate batch review cycle, no later than four days after the Department has completed its~~  
480 ~~review and submitted its recommendation on an application and has transmitted the same to the~~  
481 ~~applicants and to persons who have, prior to the issuance of the report, requested a copy in writing,~~  
482 ~~notify the Commissioner, all applicants, and the regional health planning agency, in writing and under~~  
483 ~~oath, stating the grounds for good cause and providing the factual basis therefor.~~

484 4. In any case in which an informal fact-finding conference is held, a date shall be established for  
485 the closing of the record which shall not be more than 30 calendar days after the date for holding the  
486 informal fact-finding conference.

487 5. In any case in which an informal fact-finding conference is not held, the record shall be closed on  
488 the earlier of (i) the date established for holding the informal fact-finding conference or (ii) the date that  
489 the Department determines an informal fact-finding conference is not necessary.



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

7. In any case when a determination whether a public need exists for a project is not made by the Commissioner within 70 calendar days after the closing of the record, the application shall be deemed to be approved and the certificate shall be granted.

8. If a determination whether a public need exists for a project is not made by the Commissioner within 45 calendar days of the closing of the record, any applicant who is competing in the relevant batch or who has filed an application in response to the relevant Request For Applications issued pursuant to § 32.1-102.3:2 may, prior to the application being deemed approved, petition for immediate injunctive relief pursuant to § 2.2-4030, naming as respondents the Commissioner and all parties to the case. During the pendency of the proceeding, no applications shall be deemed to be approved. In such a proceeding, the provisions of § 2.2-4030 shall apply.

F. Deemed approvals shall be construed as the Commissioner's case decision on the application pursuant to the Administrative Process Act (§ 2.2-4000 et seq.) and shall be subject to judicial review on appeal as the Commissioner's case decision in accordance with such act.

Any person who has sought to participate in the Department's review of such deemed-to-be-approved application as a person showing good cause who has not received a final determination from the Commissioner concerning such attempt to show good cause shall be deemed to be a person showing good cause for purposes of appeal of the deemed approval of the certificate.

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

G. For purposes of this section, "good cause" shall mean that (i) there is significant relevant information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing, or (iii) there is a substantial material mistake of fact or law in the Department staff's report on the application or in the report submitted by the health planning agency.

H. The project review procedures shall provide for separation of the project review manager functions from the hearing officer functions. No person serving in the role of project review manager shall serve as a hearing officer.

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

J. This section shall not apply to applications for certificates for projects defined in subdivision 8 7 of the definition of "project" in § 32.1-102.1. Such projects shall be subject to an expedited application and review process developed by the Board in regulation pursuant to subdivision A 2 of § 32.1-102.2.

#### **§ 32.1-102.14. Transparency.**

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

#### **Article 9.**

#### **Permits for Medical Care Facility Projects.**

#### **§ 32.1-122.23. Definitions.**

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

*"Medical care facility" means a mental hospital.*

*"Project" means:*

*1. Establishment of a medical care facility;*

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

*3. Relocation of beds from one existing medical care facility to another, provided that "project" does not include the relocation of up to 10 beds or 10 percent of the beds, whichever is less, from one*

551 existing medical care facility to another existing medical care facility at the same site in any two-year  
552 period;

553 4. Conversion of beds in an existing medical care facility to medical rehabilitation beds;

554 5. Any capital expenditure of \$15 million or more, not defined as reviewable in subdivisions 1  
555 through 4 of this definition, by or on behalf of a medical care facility. The amounts specified in this  
556 subdivision shall be revised annually to reflect inflation using appropriate measures incorporating  
557 construction costs and medical inflation.

558 **§ 32.1-122.24. Permit required; conditions on permits.**

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

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

563 C. The Commissioner may condition the issuance of a permit to undertake a project upon the  
564 agreement of the applicant to (i) provide a specified level of care at a reduced rate to indigents, (ii)  
565 accept patients requiring specialized care, or (iii) facilitate the development and operation of primary  
566 medical care services in designated medically underserved areas of the applicant's service area.

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

570 The Commissioner shall monitor compliance with permit conditions pursuant to this subsection and  
571 may impose penalties on a permit holder that fails to comply with such permit conditions. If the permit  
572 holder is unable or fails to comply with the conditions imposed by the Commissioner, the Commissioner  
573 may, upon request of the permit holder, approve a plan of compliance with alternate methods to satisfy  
574 the permit conditions. Such alternate methods may include (i) a direct payment by the permit holder to  
575 an organization authorized under a memorandum of understanding with the Department to receive  
576 contributions satisfying conditions of the permit; (ii) a direct payment by the permit holder to a private  
577 nonprofit foundation that funds basic insurance coverage for indigents authorized under a memorandum  
578 of understanding with the Department to receive contributions satisfying conditions of a permit; or (iii)  
579 such other methods for the provision of primary or specialized care to indigent patients or patients  
580 requiring specialized care as may be approved by the Commissioner. Any permit holder that fails or  
581 refuses to comply with the requirements of a plan of compliance entered into in accordance with this  
582 subsection is subject to a civil penalty of up to \$100 per violation per day until the date of compliance.

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

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

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

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

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

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

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

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

600 E. The Commissioner may refuse to issue a permit if he determines that the project for which the  
601 permit is sought would be detrimental to the provision of health services in underserved areas of the  
602 Commonwealth.

603 2. That the Secretary of Health and Human Resources shall review requirements governing  
604 imposition and implementation of charity care requirements for certificates of public need,  
605 including provisions for defining charity care and calculating the amount and value of charity care  
606 required and provided, and shall develop recommendations for standardizing and enforcing such  
607 requirements. The Secretary shall report his findings to the Governor and the General Assembly  
608 by December 1, 2016.

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