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HOUSE BILL NO. 1600

Offered January 11, 2023

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A BILL to amend and reenact §§ 32.1-102.1 and 32.1-102.2 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 32.1-102.6:2, relating to certificate of public need; expedited review process.

Patron—Robinson

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-102.1 and 32.1-102.2 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 32.1-102.6:2 as follows:

§ 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 an indigent person 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 within 120 days after the date on which 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 for whom it was determined that no payment was expected.

"Clinical health service" "Health care service" means a single clinically related diagnostic, therapeutic, rehabilitative, preventive, or palliative procedure or a series of such procedures that may be separately identified for billing and accounting purposes, including those provided in a medical care facility.

"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.

"Indigent" means a family income at or below 250 percent of the current federal poverty level.

"Project" means 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 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 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 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 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.

§ 32.1-102.2. 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

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59 external beam radiation therapy, and proton beam therapy shall be considered in the radiation therapy  
60 batch. A single application may be filed for a combination of (i) radiation therapy, stereotactic  
61 radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment  
62 that uses concentrated doses of high-energy X-rays to perform external beam radiation therapy, and  
63 proton beam therapy and (ii) any or all of the computed tomographic (CT) scanning, magnetic resonance  
64 imaging (MRI), and positron emission tomographic (PET) scanning;

65 2. May classify projects and may eliminate one or more or all of the procedures prescribed in  
66 § 32.1-102.6 for different classifications;

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

70 4. May establish a schedule of fees for applications for certificates or registration of a project to be  
71 applied to expenses for the administration and operation of the Certificate of Public Need Program;

72 5. ~~Shall establish an expedited application and review process for any certificate for projects~~  
73 ~~reviewable pursuant to subdivision B 8 of § 32.1-102.1:3. Regulations establishing the expedited~~  
74 ~~application and review procedure shall include provisions for notice and opportunity for public comment~~  
75 ~~on the application for a certificate, and criteria pursuant to which an application that would normally~~  
76 ~~undergo the review process would instead undergo the full certificate of public need review process set~~  
77 ~~forth in § 32.1-102.6;~~

78 6. Shall establish an exemption from the requirement for a certificate for a project involving a  
79 temporary increase in the total number of beds in an existing hospital or nursing home, including a  
80 temporary increase in the total number of beds resulting from the addition of beds at a temporary  
81 structure or satellite location operated by the hospital or nursing home, provided that the ability remains  
82 to safely staff services across the existing hospital or nursing home, (i) for a period of no more than the  
83 duration of the Commissioner's determination plus 30 days when the Commissioner has determined that  
84 a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a  
85 public health emergency exists due to a shortage of hospital or nursing home beds or (ii) for a period of  
86 no more than the duration of the emergency order entered pursuant to § 32.1-13 or 32.1-20 plus 30 days  
87 when the Board, pursuant to § 32.1-13, or the Commissioner, pursuant to § 32.1-20, has entered an  
88 emergency order for the purpose of suppressing a nuisance dangerous to public health or a  
89 communicable, contagious, or infectious disease or other danger to the public life and health; ~~and~~

90 7. 6. Shall require every medical care facility subject to the requirements of this article, other than a  
91 nursing home, that is not a medical care facility for which a certificate with conditions imposed pursuant  
92 to subsection B of § 32.1-102.4 has been issued and that provides charity care, as defined in  
93 § 32.1-102.1, to annually report the amount of charity care provided; *and*

94 7. *Shall provide for the development of review criteria and standards for specific medical care*  
95 *facilities and health care services for each health planning region that take into account the unique*  
96 *needs and characteristics of such region.*

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

104 C. The Board shall also promulgate regulations authorizing the Commissioner to condition approval  
105 of a certificate on the agreement of the applicant to provide a level of charity care to indigent persons or  
106 accept patients requiring specialized care. Such regulations shall include a methodology and formulas for  
107 uniform application of, active measuring and monitoring of compliance with, and approval of alternative  
108 plans for satisfaction of such conditions. In addition, the Board's licensure regulations shall direct the  
109 Commissioner to condition the issuing or renewing of any license for any applicant whose certificate  
110 was approved upon such condition on whether such applicant has complied with any agreement to  
111 provide a level of charity care to indigent persons or accept patients requiring specialized care. Except in  
112 the case of nursing homes, the value of charity care provided to individuals pursuant to this subsection  
113 shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and  
114 Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et  
115 seq.

116 D. The Board shall also promulgate regulations to require the registration of a project; for  
117 introduction into an existing medical care facility of any new lithotripsy, stereotactic radiosurgery,  
118 stereotactic radiotherapy performed using a linear accelerator or other medical equipment that uses  
119 concentrated doses of high-energy X-rays to perform external beam radiation therapy, obstetrical, or  
120 nuclear imaging services that the facility has never provided or has not provided in the previous 12

121 months; and for the addition by an existing medical care facility of any medical equipment for  
 122 lithotripsy, stereotactic radiosurgery, stereotactic radiotherapy performed using a linear accelerator or  
 123 other medical equipment that uses concentrated doses of high-energy X-rays to perform external beam  
 124 radiation therapy, or nuclear imaging services. Replacement of existing equipment for lithotripsy,  
 125 stereotactic radiosurgery, stereotactic radiotherapy other than radiotherapy performed using a linear  
 126 accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform  
 127 external beam radiation therapy, or nuclear imaging services shall not require registration. Such  
 128 regulations shall include provisions for (i) establishing the agreement of the applicant to provide a level  
 129 of care in services or funds that matches the average percentage of indigent care provided in the  
 130 appropriate health planning region and to participate in Medicaid at a reduced rate to indigents, (ii)  
 131 obtaining accreditation from a nationally recognized accrediting organization approved by the Board for  
 132 the purpose of quality assurance, and (iii) reporting utilization and other data required by the Board to  
 133 monitor and evaluate effects on health planning and availability of health care services in the  
 134 Commonwealth.

135 **§ 32.1-102.6:2. Expedited review process.**

136 *A. The Department shall establish an expedited application and review process for projects*  
 137 *consisting of:*

138 *1. Establishment of a specialized center or clinic or portion of a physician's office for the provision*  
 139 *of outpatient or ambulatory surgery, provided that such specialized center or clinic or portion of a*  
 140 *physician's office is a facility in which the health care services delivered are limited to a single*  
 141 *specialty, and the applicant has provided health care services in the Commonwealth in that specialty for*  
 142 *at least three years prior to the date of the application;*

143 *2. Addition by an existing medical care facility of any new medical equipment for the provision of*  
 144 *computed tomographic (CT) scanning, magnetic resonance imaging (MRI), or positron emission*  
 145 *tomographic (PET) scanning other than new medical equipment for the provision of such service added*  
 146 *to replace existing medical equipment for the provision of such service, provided that (i) the applicant*  
 147 *has provided health care services in the Commonwealth for at least three years prior to the date of the*  
 148 *application; (ii) such equipment will be used to provide health care services to established patients of*  
 149 *the health care provider or to persons other than established patients of the health care provider solely*  
 150 *for the purpose of satisfying conditions of a certificate pursuant to § 32.1-102.4; (iii) the facility is one*  
 151 *at which health care services other than computed tomographic (CT) scanning, magnetic resonance*  
 152 *imaging (MRI), or positron emission tomographic (PET) scanning are provided; (iv) the medical care*  
 153 *facility has obtained accreditation from the appropriate accrediting body for the provision of computed*  
 154 *tomographic (CT) scanning, magnetic resonance imaging (MRI), or positron emission tomographic*  
 155 *(PET) scanning; (v) the medical care facility adheres to the American College of Radiology*  
 156 *Appropriateness Criteria or other evidence-based national standards to discourage overutilization of*  
 157 *computed tomographic (CT) scanning, magnetic resonance imaging (MRI), or positron emission*  
 158 *tomographic (PET) scanning; and (vi) all equipment used for imaging services, including computed*  
 159 *tomographic (CT) scanning, magnetic resonance imaging (MRI), and positron emission tomographic*  
 160 *(PET) scanning, meets current industry technology standards as determined by the Commissioner;*

161 *3. The addition of a single operating room at an existing medical care facility established for the*  
 162 *provision of ambulatory or outpatient surgery, provided that the medical care facility is a medical care*  
 163 *facility for which the most recent certificate for the establishment of or an increase in the number of*  
 164 *operating rooms in such medical care facility was granted at least 36 months prior to the date on which*  
 165 *the application for an expedited review is received; or*

166 *4. Addition of psychiatric beds or conversion of beds in an existing medical care facility to*  
 167 *psychiatric beds.*

168 *B. The applicant shall submit its proposed application to the Department for its review, comment,*  
 169 *and a determination as to whether the application meets the approval criteria developed by the*  
 170 *Department. The Board's review shall examine such applications for feasibility, community need,*  
 171 *financial soundness, and other objective criteria as the Department may establish, consistent with*  
 172 *existing state law. The Department's review and comment shall be for the purpose of ensuring that the*  
 173 *application conforms with such criteria, and the Department shall make a determination as to whether*  
 174 *the application meets the approval criteria developed by the Department within 60 days.*

175 **2. That the Department of Health (the Department) shall convene a work group to include**  
 176 **representatives of the Virginia Association of Free and Charitable Clinics, the Virginia Hospital**  
 177 **and Healthcare Association, the Medical Society of Virginia, the Virginia Orthopaedic Society, and**  
 178 **other relevant stakeholders to make recommendations of funding options to alleviate the risk of**  
 179 **financial insolvency for public and private hospitals with fewer than 100 licensed beds in the event**  
 180 **of a future public health emergency. In making its recommendations, the work group may**  
 181 **consider innovative funding mechanisms, any process for hospitals to receive direct grants from**

182 the Department, and an examination of the schedule of fees for applications for certificates of  
183 public need. The work group shall report its recommendations to the Chairmen of the Senate  
184 Committee on Education and Health and the House Committee on Health, Welfare and  
185 Institutions by November 1, 2023.