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HOUSE BILL NO. 2119

Offered January 13, 2025

Prefiled January 7, 2025

A BILL to amend and reenact §§ 32.1-102.2, and 32.1-102.6 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 32.1-102.3:9, relating to certificate of public need; expedited application and review; medical deserts.

Patrons—Walker and Willett

Referred to Committee on Health and Human Services

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-102.2, and 32.1-102.6 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 32.1-102.3:9 as follows:

§ 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 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;

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. May establish 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;

5. Shall establish an expedited application and review process for any certificate for projects reviewable pursuant to subdivision B 8 of § 32.1-102.1:3 or § 32.1-102.3:9. 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. For applications reviewed pursuant to § 32.1-102.3:9, the Commissioner shall issue a final determination no later than 90 days after the public comment period expires and no later than 120 days after the request for expedited application and review has been received;

6. Shall establish an exemption from the requirement for a certificate for a project involving a temporary increase in the total number of beds in an existing hospital or nursing home, including a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the hospital or nursing home, provided that the ability remains to safely staff services across the existing hospital or nursing home, (i) for a period of no more than the duration of the Commissioner's determination plus 30 days 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 or (ii) for a period of no more than the duration of the emergency order entered pursuant to § 32.1-13 or 32.1-20 plus 30 days when the Board, pursuant to § 32.1-13, or the Commissioner, pursuant to § 32.1-20, has entered an emergency order for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health; and

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 B of § 32.1-102.4 has been issued and that provides charity care, as defined in § 32.1-102.1, to

59 annually report the amount of charity care provided.

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

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

78 D. The Board shall also promulgate regulations to require the registration of a project; for introduction
 79 into an existing medical care facility of any new lithotripsy, stereotactic radiosurgery, stereotactic
 80 radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of
 81 high-energy X-rays to perform external beam radiation therapy, obstetrical, or nuclear imaging services that
 82 the facility has never provided or has not provided in the previous 12 months; and for the addition by an
 83 existing medical care facility of any medical equipment for lithotripsy, stereotactic radiosurgery, stereotactic
 84 radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of
 85 high-energy X-rays to perform external beam radiation therapy, or nuclear imaging services. Replacement of
 86 existing equipment for lithotripsy, stereotactic radiosurgery, stereotactic radiotherapy other than radiotherapy
 87 performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy
 88 X-rays to perform external beam radiation therapy, or nuclear imaging services shall not require registration.
 89 Such regulations shall include provisions for (i) establishing the agreement of the applicant to provide a level
 90 of care in services or funds that matches the average percentage of indigent care provided in the appropriate
 91 health planning region and to participate in Medicaid at a reduced rate to indigents, (ii) obtaining
 92 accreditation from a nationally recognized accrediting organization approved by the Board for the purpose of
 93 quality assurance, and (iii) reporting utilization and other data required by the Board to monitor and evaluate
 94 effects on health planning and availability of health care services in the Commonwealth.

95 **§ 32.1-102.3:9. Application for certificate in medical desert.**

96 A. As used in this section, "medical desert" means an area that meets at least two of the following criteria:

97 1. Does not have a hospital or health care provider:

98 a. Within a 30-mile radius where the area's population density is estimated to be less than 1,500 residents
 99 per square mile; or

100 b. Within a 15-mile radius where the area's population density is estimated to be more than 1,500
 101 residents per square mile.

102 2. Has less than one primary care physician per 3,500 residents.

103 3. Has an annual poverty rate of at least 20 percent, according to data provided by the U.S. Census
 104 Bureau.

105 4. Has been designated as a Health Professional Shortage Area by the U.S. Department of Health and
 106 Human Services.

107 B. Governing bodies of localities shall establish a local review process to determine whether an applicant
 108 may seek an expedited application and review process through subdivision A 8 of § 32.1-102.2 for any
 109 certificate of public need for projects that will serve a medical desert. Such review process shall include, at a
 110 minimum, an evaluation of (i) the financial feasibility of the proposed medical facility, project, or action; (ii)
 111 the applicant's history of regulatory compliance; and (iii) the potential impact on patient access to health
 112 services within the medical desert.

113 C. An applicant for a certificate of public need that is located in a locality that contains a medical desert
 114 may, through the review process established pursuant to subsection B, request an expedited application and
 115 review process for any certificate for a medical facility, project, or action that will serve the medical desert.
 116 In requesting such a review, the applicant shall (i) specify the type of project for which the request is being
 117 made; (ii) specify which criteria for qualifying as a medical desert under subsection A are met; and (iii)
 118 define the geographic area to be served by the project.

119 **§ 32.1-102.6. Administrative procedures.**

120 A. To obtain a certificate for a project, the applicant shall file a completed application for a certificate

121 with the Department and the appropriate regional health planning agency if a regional health planning agency
 122 has been designated for that region. Such application shall be filed in accordance with procedures established
 123 by the Department. An application submitted for review shall be considered complete when all relevant
 124 sections of the application form have responses. The applicant shall provide sufficient information to prove
 125 public need for the requested project exists without the addition of supplemental or supporting material at a
 126 later date. The Department shall ensure that only data necessary for review of an application is required to be
 127 submitted and that the application reflects statutory requirements. Nothing in this section shall prevent the
 128 Department from seeking, at its discretion, additional information from the applicant or other sources.

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

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

146 B. For projects proposed in health planning regions with regional planning agencies, the appropriate
 147 regional health planning agency shall (i) review each completed application for a certificate within 60
 148 calendar days of the day that begins the appropriate batch review cycle as established by the Board by
 149 regulation pursuant to subdivision A 1 of § 32.1-102.2, such cycle not to exceed 190 days in duration; (ii)
 150 within 10 calendar days following the start of the review cycle, solicit public comment on such application by
 151 posting notice of such application and a summary of the proposed project on a website maintained by the
 152 Department; such notice shall include information about how comments may be submitted to the regional
 153 health planning agency and the date on which the public comment period shall expire, which shall be no later
 154 than 45 calendar days following the date of the public notice; and (iii) in the case of competing applications
 155 or in response to a written request by an elected local government representative, a member of the General
 156 Assembly, the Commissioner, the applicant, or a member of the public, hold one public hearing on each
 157 application in a location in the county or city in which the project is proposed or a contiguous county or city.
 158 Prior to any required public hearing, the regional health planning agency shall notify the local governing
 159 bodies in the planning district. At least nine days prior to the public hearing, the regional health planning
 160 agency shall cause notice of the public hearing to be published in a newspaper of general circulation in the
 161 county or city where the project is proposed to be located. The regional health planning agency shall consider
 162 the comments of the local governing bodies in the planning district and all other public comments in making
 163 its decision. Such comments shall be part of the record. In no case shall a regional health planning agency
 164 hold more than two meetings on any application, one of which shall be the public hearing required pursuant
 165 to clause (iii), if any, conducted by the board of the regional health planning agency or a subcommittee of the
 166 board. The applicant shall be given the opportunity, prior to the vote by the board of the regional health
 167 planning agency or a committee of the agency, if acting for the board, on its recommendation, to respond to
 168 any comments made about the project by the regional health planning agency staff, any information in a
 169 regional health planning agency staff report, or comments by those voting members of the regional health
 170 planning agency board; however, such opportunity shall not increase the 60-calendar-day period designated
 171 herein for the regional health planning agency's review unless the applicant or applicants request a specific
 172 extension of the regional health planning agency's review period.

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

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

182 If no regional health planning agency has been designated for a region, the Department shall (a) within 10

183 calendar days following the start of the review cycle, solicit public comment on such application by posting
184 notice of such application and a summary of the proposed project on a website maintained by the
185 Department; such notice shall include such information about how comments may be submitted to the
186 Department and the date on which the public comment period shall expire, which shall be no later than 45
187 calendar days following the date of the public notice, and (b) in the case of competing applications or in
188 response to a written request by an elected local government representative, a member of the General
189 Assembly, the Commissioner, the applicant, or a member of the public, hold one hearing on each application
190 in a location in the county or city in which the project is proposed or a contiguous county or city. Prior to any
191 required hearing, the Department shall notify the local governing bodies in the planning district in which the
192 project is proposed. At least nine days prior to the public hearing, the Department shall cause notice of the
193 public hearing to be published in a newspaper of general circulation in the county or city where the project is
194 proposed to be located. The Department shall consider the comments of the local governing bodies in the
195 planning district and all other public comments in making its decision. Such comments shall be part of the
196 record.

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

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

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

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

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

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

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

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

223 2. The Department shall review every application at or before the seventy-fifth calendar day within the
224 190-calendar-day review period to determine whether an informal fact-finding conference is necessary.

225 3. Any person seeking to be made a party to the case for good cause, no later than four days after the
226 Department has completed its review and submitted its recommendation on an application and has
227 transmitted the same to the applicants and to persons who have, prior to the issuance of the report, requested a
228 copy in writing, shall notify the Commissioner, all applicants, and the regional health planning agency, in
229 writing and under oath, stating the grounds for good cause and providing the factual basis therefor.

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

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

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

244 7. In any case when a determination whether a public need exists for a project is not made by the

245 Commissioner within 70 calendar days after the closing of the record, the application shall be deemed to be
246 approved and the certificate shall be granted.

247 8. If a determination whether a public need exists for a project is not made by the Commissioner within 45
248 calendar days of the closing of the record, any applicant who is competing in the relevant batch or who has
249 filed an application in response to the relevant Request For Applications issued pursuant to § 32.1-102.3:2
250 may, prior to the application being deemed approved, petition for immediate injunctive relief pursuant to §
251 2.2-4030, naming as respondents the Commissioner and all parties to the case. During the pendency of the
252 proceeding, no applications shall be deemed to be approved. In such a proceeding, the provisions of §
253 2.2-4030 shall apply.

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

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

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

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

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

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

278 J. This section shall not apply to applications for certificates for projects defined in subdivision A 8 of §
279 32.1-102.1:3 or § 32.1-102.3:9. Such projects shall be subject to an expedited application and review process
280 developed by the Board in regulation pursuant to subdivision A 2 of § 32.1-102.2 or § 32.1-102.3:9.