

24101587D

SENATE BILL NO. 277

Offered January 10, 2024

Prefiled January 9, 2024

A BILL to amend and reenact §§ 32.1-102.2 and 32.1-102.6 of the Code of Virginia, relating to certificate of public need; expansion of expedited application and review process.

Patron—Hashmi

Referred to Committee on Education and Health

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 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~~ *subsection B 8* of § 32.1-102.1:3. Regulations establishing the expedited application and review procedure shall include provisions for notice and opportunity for public comment on the application for a certificate, and criteria pursuant to which an application that would normally undergo the review process would instead undergo the full certificate of public need review process set forth in § 32.1-102.6;

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 annually report the amount of charity care provided.

B. The Board shall promulgate regulations providing for time limitations for schedules for completion and limitations on the exceeding of the maximum capital expenditure amount for all

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

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

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

§ 32.1-102.6. 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. Such application shall be filed in accordance with procedures established by the Department. An application submitted for review shall be considered complete when all relevant sections of the application form have responses. The applicant shall provide sufficient information to prove public need for the requested project exists without the addition of supplemental or supporting material at a later date. The Department shall ensure that only data necessary for review of an application is required to be submitted and that the application reflects statutory requirements. Nothing in this section shall prevent the Department from seeking, at its discretion, additional information from the applicant or other sources.

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

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

agency is designated for the health planning region in which the acquisition will take place, no notification to a regional health planning agency shall be required.

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

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

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

If no regional health planning agency has been designated for a region, the Department shall (a) within 10 calendar days following the start of the review cycle, solicit public comment on such application by posting notice of such application and a summary of the proposed project on a website maintained by the Department; such notice shall include such information about how comments may be submitted to the Department and the date on which the public comment period shall expire, which shall be no later than 45 calendar days following the date of the public notice, and (b) in the case of competing applications or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public, hold one hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city. Prior to any required hearing, the Department shall notify the local governing bodies in the planning district in which the project is proposed. At least nine days prior to the public hearing, the Department shall cause notice of the public hearing to be published in a newspaper of general circulation in the county or city where the project is proposed to be located. The Department shall consider the comments of the local governing bodies in the planning district and all other public comments in making its decision. Such comments shall be part of the record.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

242 In any appeal of the Commissioner's case decision granting a certificate of public need pursuant to a
243 Request for Applications issued pursuant to § 32.1-102.3:2, the court may require the appellant to file a

244 bond pursuant to § 8.01-676.1, in such sum as shall be fixed by the court for protection of all parties
245 interested in the case decision, conditioned on the payment of all damages and costs incurred in
246 consequence of such appeal.

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

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

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

259 J. This section shall not apply to applications for certificates for projects defined in subdivision A 8
260 of ~~§ 32.1-102.1:3~~ *that meet the criteria for the expedited review process as established in subdivision A*
261 *5 of § 32.1-102.2.* Such projects shall be subject to an expedited application and review process
262 developed by the Board in regulation pursuant to ~~subdivision~~ *subdivisions A 2 and A 5 of § 32.1-102.2.*