2025 SESSION

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1 2	SENATE BILL NO. 1064
2	Offered January 8, 2025
3	Prefiled January 7, 2025
4	A BILL to amend and reenact §§ 32.1-102.1:3, 32.1-102.2, 32.1-102.4, and 32.1-102.6 of the Code of
5	Virginia, relating to relocation, conversion, and addition of beds in medical care facilities; application
6	for certificate of public need; expedited review.
7	
	Patron—Hashmi
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9	Referred to Committee on Education and Health
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11	Be it enacted by the General Assembly of Virginia:
12	1. That §§ 32.1-102.1:3, 32.1-102.2, 32.1-102.4, and 32.1-102.6 of the Code of Virginia are amended and
13	reenacted as follows:
14	§ 32.1-102.1:3. Medical care facilities and projects for which a certificate is required.
15	A. The following medical care facilities shall be subject to the provisions of this article:
16	1. Any facility licensed as a hospital, as defined in § 32.1-123;
17	2. Any hospital licensed as a provider by the Department of Behavioral Health and Developmental
18	Services in accordance with Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2;
19	3. Any facility licensed as a nursing home, as defined in § 32.1-123;
20	4. Any intermediate care facility established primarily for the medical, psychiatric, or psychological
20	treatment and rehabilitation of individuals with substance abuse licensed by the Department of Behavioral
22	Health and Developmental Services in accordance with Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title
23	37.2;
24	5. Any intermediate care facility for individuals with developmental disabilities other than an intermediate
25	care facility established for individuals with intellectual disability (ICF/IID) that has not more than 12 beds
26	and is in an area identified as in need of residential services for individuals with intellectual disability in any
27	plan of the Department of Behavioral Health and Developmental Services; and
28	6. Any specialized center or clinic or that portion of a physician's office developed for the provision of
29	outpatient or ambulatory surgery, cardiac catheterization, computed tomographic (CT) scanning, magnetic
30	resonance imaging (MRI), positron emission tomographic (PET) scanning, radiation therapy, stereotactic
31	radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment that
32	uses concentrated doses of high-energy X-rays to perform external beam radiation therapy, or proton beam
33	therapy.
34	B. The following actions undertaken by or on behalf of a medical care facility described in subsection A
35	shall constitute a project for which a certificate of public need is required pursuant to subsection A of §
36	32.1-102.1:2:
37	1. Establishment of a medical care facility described in subsection A;
38	2. An increase in the total number of beds or operating rooms in an existing medical care facility
39	described in subsection A;
40	3. Relocation of beds from an existing medical care facility described in subsection A to another existing
41	medical care facility described in subsection A;
42	4. Addition of any new nursing home service at an existing medical care facility described in subsection
43	A;
44	5. Introduction into an existing medical care facility described in subsection A of any cardiac
45	catheterization, computed tomographic (CT) scanning, magnetic resonance imaging (MRI), medical
46	rehabilitation, neonatal special care, open heart surgery, positron emission tomographic (PET) scanning,
47	psychiatric, organ or tissue transplant service, radiation therapy, stereotactic radiotherapy other than
48	radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of
49	high-energy X-rays to perform external beam radiation therapy, proton beam therapy, or substance abuse
50	treatment when such medical care facility has not provided such service in the previous 12 months;
51	6. Conversion of beds in an existing medical care facility described in subsection A to medical
52	rehabilitation beds or psychiatric beds;
53	7. The addition by an existing medical care facility described in subsection A of any new medical
54	equipment for the provision of cardiac catheterization, computed tomographic (CT) scanning, magnetic
55	resonance imaging (MRI), open heart surgery, positron emission tomographic (PET) scanning, radiation
56	therapy, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other
57	medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation
58	therapy, or proton beam therapy, other than new medical equipment for the provision of such service added to

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59 replace existing medical equipment for the provision of such service;

60 8. Any capital expenditure of \$15 million or more, not defined as reviewable in subdivisions 1 through 7, by or on behalf of a medical care facility described in subsection A other than a general hospital. The 61 62 amounts specified in this subdivision shall be revised annually to reflect inflation using appropriate measures incorporating construction costs and medical inflation. Nothing in this subdivision shall be construed to 63 64 modify or eliminate the reviewability of any project described in subdivisions 1 through 7 when undertaken 65 by or on behalf of a general hospital; and

66 9. Conversion in an existing medical care facility described in subsection A of psychiatric inpatient beds approved pursuant to a Request for Applications (RFA) to nonpsychiatric inpatient beds. 67

68 C. Notwithstanding the provisions of subsection A, any nursing home affiliated with a facility that, on 69 January 1, 1982, and thereafter, (i) is operated as a nonprofit institution, (ii) is licensed jointly by the 70 Department as a nursing home and by the Department of Social Services as an assisted living facility, and 71 (iii) restricts admissions such that (a) admissions to the facility are only allowed pursuant to the terms of a 72 "life care contract" guaranteeing that the full complement of services offered by the facility is available to the resident as and when needed, (b) admissions to the assisted living facility unit of the facility are restricted to 73 74 individuals defined as ambulatory by the Department of Social Services, and (c) admissions to the nursing home unit of the facility are restricted to those individuals who are residents of the assisted living facility unit 75 76 of the facility shall not be subject to the requirements of this article.

77 D. Notwithstanding the provisions of subsection B, a certificate of public need shall not be required for 78 the following actions undertaken by or on behalf of a medical care facility described in subsection A:

79 1. Relocation of up to 10 beds or 10 percent of the beds, whichever is less, (i) from one existing medical 80 care facility described in subsection A to another existing medical care facility described in subsection A at the same site in any two-year period or (ii) in any three-year period, from one existing medical care facility 81 described in subsection A licensed as a nursing home to any other existing medical care facility described in 82 subsection A licensed as a nursing home that is owned or controlled by the same person and located either 83 within the same planning district or within another planning district out of which, during or prior to that 84 85 three-year period, at least 10 times that number of beds have been authorized by statute to be relocated from 86 one or more medical care facilities described in subsection A located in that other planning district, and at 87 least half of those beds have not been replaced; or

2. Use of up to 10 percent of beds as nursing home beds by a medical care facility described in subsection 88 89 A licensed as a hospital, as provided in § 32.1-132.

E. The Department shall regularly review the types of medical care facilities subject to the provisions of 90 91 this article and projects for which a certificate is required and provide to the Governor and the General 92 Assembly, at least once every five years, a recommendation related to the continued appropriateness of 93 requiring such types of medical care facilities to be subject to the provisions of this article and such types of 94 projects to be subject to the requirement of a certificate. In developing such recommendations, the 95 Department shall consider, for each type of medical care facility and project, the following criteria:

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

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

98 3. The current and projected future rate of utilization of the specific type of medical care facility or 99 project;

100 4. The current and projected future capacity of existing medical care facilities or projects of that specific 101 type;

5. The anticipated impact of changes in population and demographics, reimbursement structures and rates, 102 103 and technology on demand for and availability, utilization, and capacity of existing medical care facilities or 104 projects of that specific type;

6. Existing quality, utilization, and other controls applicable to the specific type of medical care facility or 105 106 project; and

7. Any risk to the health or well-being of the public resulting from inclusion of the specific type of 107 medical care facility or project on such list. 108

§ 32.1-102.2. Regulations.

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

110 1. Shall establish concise procedures for the prompt review of applications for certificates consistent with 111 the provisions of this article which may include a structured batching process which incorporates, but is not 112 limited to, authorization for the Commissioner to request proposals for certain projects. In any structured 113 batching process established by the Board, applications, combined or separate, for computed tomographic 114 (CT) scanning, magnetic resonance imaging (MRI), positron emission tomographic (PET) scanning, radiation 115 116 therapy, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other 117 medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation 118 therapy, and proton beam therapy shall be considered in the radiation therapy batch. A single application may 119 be filed for a combination of (i) radiation therapy, stereotactic radiotherapy other than radiotherapy 120 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;

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

126 3. May provide for exempting from the requirement of a certificate projects determined by the
127 Commissioner, upon application for exemption, to be subject to the economic forces of a competitive market
128 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 appliedto 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 131 pursuant to (i) subdivision $\mathbf{B} \otimes B \mathbf{I}$ of \mathbf{S} 32.1-102.1:3 for the establishment of a new medical care facility 132 described in subdivision A 2 of § 32.1-102.1:3 by an existing medical care facility described in subdivision A 133 134 1 or 2 of § 32.1-102.1:3 that has an existing certificate to provide psychiatric services pursuant to 135 subdivision B 6 of § 32.1-102.1:3, provided such new medical care facility is located in the same planning 136 district as the existing medical care facility; (ii) subdivision B 2 of § 32.1-102.1:3 for the addition of psychiatric beds at an existing medical care facility described in subdivision A 1 or 2 of § 32.1-102.1:3 that 137 has an existing certificate to provide psychiatric services pursuant to subdivision B 5 of § 32.1-102.1:3, not 138 139 to exceed 10 beds or 10 percent of all beds at the medical care facility, whichever is greater, and provided 140 that the applicant has not been awarded a certificate for the addition of psychiatric beds pursuant to this 141 provision in the previous two-year period; (iii) subdivision B 3 of § 32.1-102.1:3 for the relocation of psychiatric beds to an existing medical care facility described in subdivision A 1 or 2 of § 32.1-102.1:3 that 142 143 has had an existing certificate to introduce a psychiatric service for at least the previous 12 months pursuant 144 to subdivision B 5 of § 32.1-102.1:3 and that is within the same planning district; (iv) and subdivision B 8 of \$ 32.1-102.1:3. Regulations establishing the expedited application and review procedure shall include 145 146 provisions for (a) notice and opportunity for public comment on the application for a certificate, (b) a review 147 cycle that is complete within 90 days, (c) the filing of an expedited application in four batch cycles 148 specifically for expedited applications, (d) the ability of a member of the public to request a public hearing 149 for the expedited application, and (e) criteria pursuant to which an application that would normally undergo 150 the review process would instead undergo the full certificate of public need review process set forth in § 151 32.1-102.6;

152 6. Shall establish an exemption from the requirement for a certificate for a project involving a temporary 153 increase in the total number of beds in an existing hospital or nursing home, including a temporary increase in 154 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 155 existing hospital or nursing home, (i) for a period of no more than the duration of the Commissioner's 156 determination plus 30 days when the Commissioner has determined that a natural or man-made disaster has 157 158 caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a 159 shortage of hospital or nursing home beds or (ii) for a period of no more than the duration of the emergency 160 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 161 nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to 162 163 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.

175 C. The Board shall also promulgate regulations authorizing the Commissioner to condition approval of a 176 certificate on the agreement of the applicant to provide a level of charity care to indigent persons or accept 177 patients requiring specialized care. Such regulations shall include a methodology and formulas for uniform 178 application of, active measuring and monitoring of compliance with, and approval of alternative plans for 179 satisfaction of such conditions. In addition, the Board's licensure regulations shall direct the Commissioner to 180 condition the issuing or renewing of any license for any applicant whose certificate was approved upon such 181 condition on whether such applicant has complied with any agreement to provide a level of charity care to 182 indigent persons or accept patients requiring specialized care. Except in the case of nursing homes, the value 183 of charity care provided to individuals pursuant to this subsection shall be based on the provider 184 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. 185

D. The Board shall also promulgate regulations to require the registration of a project; for introduction 186 into an existing medical care facility of any new lithotripsy, stereotactic radiosurgery, stereotactic 187 radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of 188 high-energy X-rays to perform external beam radiation therapy, obstetrical, or nuclear imaging services that 189 190 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 191 192 radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of 193 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 194 performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy 195 196 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 197 198 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 199 accreditation from a nationally recognized accrediting organization approved by the Board for the purpose of 200 201 quality assurance, and (iii) reporting utilization and other data required by the Board to monitor and evaluate 202 effects on health planning and availability of health care services in the Commonwealth. 203

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

204 A. The Commissioner may, in accordance with regulations of the Board, condition issuance of a 205 certificate on compliance with a schedule for the completion of the proposed project and a maximum capital 206 expenditure amount for the proposed project. The approved schedule and maximum capital expenditure for a proposed project shall be issued together with the certificate. The approved schedule may not be extended 207 208 and the maximum capital expenditure may not be exceeded without the approval of the Commissioner in 209 accordance with the regulations of the Board. The Commissioner shall not approve an extension for a 210 schedule for completion of any project or the exceeding of the maximum capital expenditure of any project 211 unless such extension or excess complies with the limitations provided in the regulations promulgated by the 212 Board pursuant to § 32.1-102.2.

213 The Commissioner shall monitor each project to determine its progress and compliance with the approved 214 schedule and with the maximum capital expenditure, and may revoke the certificate for (i) lack of substantial and continuing progress toward completion of the project in accordance with the schedule or (ii) expenditures 215 216 in excess of the approved maximum capital expenditure for the project.

217 Any person willfully violating conditions imposed pursuant to this subsection shall be subject to a civil 218 penalty of up to \$100 per violation per day until the date of completion of the project which shall be collected 219 by the Commissioner and paid into the Literary Fund.

220 For the purposes of this subsection, "completion" means conclusion of construction activities necessary 221 for the substantial performance of the contract.

B. The Commissioner shall, pursuant to the regulations of the Board, condition the approval of a 222 223 certificate upon the agreement of the applicant to provide care to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act 224 225 (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. In addition, the Commissioner shall condition the 226 approval of a certificate upon the agreement of the applicant to (i) provide a specified level of charity care to indigent persons or accept patients requiring specialized care, (ii) facilitate the development and operation of 227 228 primary and specialty medical care services in designated medically underserved areas of the applicant's 229 service area, or (iii) all of the above. Except in the case of nursing homes, the value of charity care provided 230 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 231 232 Security Act, 42 U.S.C. § 1395 et seq.

233 Every certificate holder shall develop a financial assistance policy that includes specific eligibility criteria 234 and procedures for applying for charity care, which shall be provided to a patient at the time of admission or 235 discharge or at the time services are provided, included with any billing statements sent to uninsured patients, posted conspicuously in public areas of the medical care facility for which the certificate was issued and 236 237 posted on a website maintained by the certificate holder.

238 The certificate holder shall annually provide documentation to the Department demonstrating that the certificate holder has satisfied the conditions of the certificate, including documentation of the amount of 239 240 charity care provided to patients. If the certificate holder is unable or fails to satisfy the conditions of a 241 certificate, the Department may approve alternative methods to satisfy the conditions pursuant to a plan of 242 compliance, which shall identify a timeframe within which the certificate holder will satisfy the conditions of 243 the certificate, and identify how the certificate holder will satisfy the conditions of the certificate, which may 244 include (a) making direct payments to an organization authorized under a memorandum of understanding 245 with the Department to receive contributions satisfying conditions of a certificate, (b) making direct payments 246 to a private nonprofit foundation that funds basic insurance coverage for indigents authorized under a 247 memorandum of understanding with the Department to receive contributions satisfying conditions of a 248 certificate, or (c) other documented efforts or initiatives to provide primary or specialized care to underserved 249 populations. In cases in which the certificate holder holds more than one certificate with conditions pursuant 250 to this subsection, and the certificate holder is unable to satisfy the conditions of one certificate, such plan of 251 compliance may provide for satisfaction of the conditions on that certificate by providing care at a reduced 252 rate to indigent individuals in excess of the amount required by another certificate issued to the same holder, 253 in an amount approved by the Department provided such care is offered at the same facility. Nothing in the 254 preceding sentence shall prohibit the satisfaction of conditions of more than one certificate among various 255 affiliated facilities or certificates subject to a system-wide or all-inclusive charity care condition established 256 by the Commissioner. In determining whether the certificate holder has met the conditions of the certificate 257 pursuant to a plan of compliance, only such actions undertaken after issuance of the conditioned certificate 258 shall be counted towards satisfaction of conditions.

Any person refusing, failing, or neglecting to honor such agreement shall be subject to a civil penalty of up to \$100 per violation per day until the date of compliance which shall be collected by the Commissioner and paid into the Literary Fund. For the purpose of determining the amount of a civil penalty imposed pursuant to this subsection, the date on which the person began providing services in accordance with the original certificate shall be the date from which the period of noncompliance shall be calculated.

C. The Commissioner may, pursuant to the regulations of the Board, condition the approval of a certificate for any project to (i) establish a medical care facility pursuant to subdivision A 2 of § 32.1-102.1:3 ; (ii) introduce a psychiatric service pursuant to subdivision B 5 of § 32.1-102.1:3; or (iii) add psychiatric beds to an existing medical care facility described in subdivision A 1 or 2 of § 32.1-102.1:3 upon the agreement of the applicant to provide care to individuals who are the subject of an involuntary temporary detention under § 37.2-809.

270 D. The Commissioner shall (i) review every certificate of public need upon which conditions were 271 imposed pursuant to subsection B at least once every three years to determine whether such conditions 272 continue to be appropriate or should be revised and (ii) notify each certificate holder of his conclusions 273 regarding (a) the appropriateness of conditions imposed on the certificate and whether such conditions should 274 be revised and (b) the process by which the certificate holder may request amendments to conditions imposed 275 on a certificate in accordance with subsection $\mathbf{D} E$.

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

280 E. F. In determining whether conditions imposed on a certificate of public need pursuant to subsection B 281 are appropriate for the purposes of subsection $\in D$ or should be amended in response to a request submitted 282 pursuant to subsection $\oplus E$, the Commissioner shall consider any changes in the circumstances of the 283 certificate holder resulting from changes in the financing or delivery of health care services, including 284 changes to the Commonwealth's program of medical assistance services, and any other specific circumstances 285 of the certificate holder.

§ 32.1-102.6. Administrative procedures.

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A. To obtain a certificate for a project, the applicant shall file a completed application for a certificate 287 288 with the Department and the appropriate regional health planning agency if a regional health planning agency 289 has been designated for that region. Such application shall be filed in accordance with procedures established 290 by the Department. An application submitted for review shall be considered complete when all relevant 291 sections of the application form have responses. The applicant shall provide sufficient information to prove 292 public need for the requested project exists without the addition of supplemental or supporting material at a 293 later date. The Department shall ensure that only data necessary for review of an application is required to be 294 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. 295

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

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303 the application.

304 At least 30 calendar days before any person is contractually obligated to acquire an existing medical care 305 facility, the cost of which is \$600,000 or more, that person shall notify the Commissioner and the appropriate 306 regional health planning agency, if a regional health planning agency has been designated, of the intent, the 307 services to be offered in the facility, the bed capacity in the facility and the projected impact that the cost of 308 the acquisition will have upon the charges for services to be provided. If clinical services or beds are 309 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 310 311 planning region in which the acquisition will take place, no notification to a regional health planning agency shall be required. 312

313 B. For projects proposed in health planning regions with regional planning agencies, the appropriate 314 regional health planning agency shall (i) review each completed application for a certificate within 60 315 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) 316 317 within 10 calendar days following the start of the review cycle, solicit public comment on such application by 318 posting notice of such application and a summary of the proposed project on a website maintained by the 319 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 320 than 45 calendar days following the date of the public notice; and (iii) in the case of competing applications 321 or in response to a written request by an elected local government representative, a member of the General 322 323 Assembly, the Commissioner, the applicant, or a member of the public, hold one public hearing on each 324 application in a location in the county or city in which the project is proposed or a contiguous county or city. 325 Prior to any required public hearing, the regional health planning agency shall notify the local governing 326 bodies in the planning district. At least nine days prior to the public hearing, the regional health planning 327 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 328 the comments of the local governing bodies in the planning district and all other public comments in making 329 330 its decision. Such comments shall be part of the record. In no case shall a regional health planning agency 331 hold more than two meetings on any application, one of which shall be the public hearing required pursuant 332 to clause (iii), if any, conducted by the board of the regional health planning agency or a subcommittee of the 333 board. The applicant shall be given the opportunity, prior to the vote by the board of the regional health 334 planning agency or a committee of the agency, if acting for the board, on its recommendation, to respond to 335 any comments made about the project by the regional health planning agency staff, any information in a 336 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 337 338 herein for the regional health planning agency's review unless the applicant or applicants request a specific 339 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.

343 If the regional health planning agency has not completed its review within the specified 60 calendar days 344 or such other period in accordance with the applicant's request for extension and submitted its 345 recommendations on the application and the reasons therefor within 10 calendar days after the completion of 346 its review, the Department shall, on the eleventh calendar day after the expiration of the regional health 347 planning agency's review period, proceed as though the regional health planning agency has recommended 348 project approval without conditions or revision.

349 If no regional health planning agency has been designated for a region, the Department shall (a) within 10 350 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 351 Department; such notice shall include such information about how comments may be submitted to the 352 Department and the date on which the public comment period shall expire, which shall be no later than 45 353 354 calendar days following the date of the public notice, and (b) in the case of competing applications or in 355 response to a written request by an elected local government representative, a member of the General 356 Assembly, the Commissioner, the applicant, or a member of the public, hold one hearing on each application 357 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 358 project is proposed. At least nine days prior to the public hearing, the Department shall cause notice of the 359 360 public hearing to be published in a newspaper of general circulation in the county or city where the project is 361 proposed to be located. The Department shall consider the comments of the local governing bodies in the 362 planning district and all other public comments in making its decision. Such comments shall be part of the 363 record.

C. After commencement of any public hearing and before a decision is made there shall be no ex parte

365 contacts concerning the subject certificate or its application between (i) any person acting on behalf of the 366 applicant or holder of a certificate or any person opposed to the issuance or in favor of revocation of a 367 certificate of public need and (ii) any person in the Department who has authority to make a determination 368 respecting the issuance or revocation of a certificate of public need, unless the Department has provided 369 advance notice to all parties referred to in clause (i) of the time and place of such proposed contact.

370 D. The Department shall commence the review of each completed application upon the day which begins 371 the appropriate batch review cycle and simultaneously with the review conducted by the regional health 372 planning agency, if a regional health planning agency has been designated.

A determination whether a public need exists for a project shall be made by the Commissioner within 190 373 374 calendar days of the day which begins the appropriate batch cycle.

375 The 190-calendar-day review period shall begin on the date upon which the application is determined to 376 be complete within the batching process specified in subdivision A 1 of § 32.1-102.2.

377 If the application is not determined to be complete within 40 calendar days from submission, the 378 application shall be refiled in the next batch for like projects.

379 The Commissioner shall make determinations in accordance with the provisions of the Administrative 380 Process Act (§ 2.2-4000 et seq.) except for those parts of the determination process for which timelines and 381 specifications are delineated in subsection E. Further, if an informal fact-finding conference is determined to 382 be necessary by the Department or is requested by a person seeking good cause standing, the parties to the 383 case shall include only the applicant, any person showing good cause, any third-party payor providing health 384 care insurance or prepaid coverage to five percent or more of the patients in the applicant's service area, and 385 the relevant health planning agency. 386

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

387 1. The Department shall establish, for every application, a date between the eightieth and ninetieth 388 calendar days within the 190-calendar-day review period for holding an informal fact-finding conference, if 389 such conference is necessary.

390 2. The Department shall review every application at or before the seventy-fifth calendar day within the 391 190-calendar-day review period to determine whether an informal fact-finding conference is necessary.

392 3. Any person seeking to be made a party to the case for good cause, no later than four days after the 393 Department has completed its review and submitted its recommendation on an application and has 394 transmitted the same to the applicants and to persons who have, prior to the issuance of the report, requested a 395 copy in writing, shall notify the Commissioner, all applicants, and the regional health planning agency, in 396 writing and under oath, stating the grounds for good cause and providing the factual basis therefor.

397 4. In any case in which an informal fact-finding conference is held, a date shall be established for the 398 closing of the record which shall not be more than 30 calendar days after the date for holding the informal 399 fact-finding conference.

400 5. In any case in which an informal fact-finding conference is not held, the record shall be closed on the 401 earlier of (i) the date established for holding the informal fact-finding conference or (ii) the date that the Department determines an informal fact-finding conference is not necessary. 402

403 6. The provisions of subsection C of § 2.2-4021 notwithstanding, if a determination whether a public need 404 exists for a project is not made by the Commissioner within 45 calendar days of the closing of the record, the 405 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 406 407 expiration of such 45-calendar-day period, unless the receipt of recommendations from the person performing 408 the hearing officer functions permits the Commissioner to issue his case decision within that 25-calendar-day 409 period. The validity or timeliness of the aforementioned notice shall not, in any event, prevent, delay or 410 otherwise impact the effectiveness of this section.

411 7. In any case when a determination whether a public need exists for a project is not made by the 412 Commissioner within 70 calendar days after the closing of the record, the application shall be deemed to be 413 approved and the certificate shall be granted.

414 8. If a determination whether a public need exists for a project is not made by the Commissioner within 45 415 calendar days of the closing of the record, any applicant who is competing in the relevant batch or who has 416 filed an application in response to the relevant Request For Applications issued pursuant to § 32.1-102.3:2 417 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 418 419 proceeding, no applications shall be deemed to be approved. In such a proceeding, the provisions of § 420 2.2-4030 shall apply.

421 F. Deemed approvals shall be construed as the Commissioner's case decision on the application pursuant 422 to the Administrative Process Act (§ 2.2-4000 et seq.) and shall be subject to judicial review on appeal as the 423 Commissioner's case decision in accordance with such act.

424 Any person who has sought to participate in the Department's review of such deemed-to-be-approved 425 application as a person showing good cause who has not received a final determination from the

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426 Commissioner concerning such attempt to show good cause shall be deemed to be a person showing good427 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" means that (i) there is significant relevant information not
previously presented at and not available at the time of the public hearing, (ii) there have been significant
changes in factors or circumstances relating to the application subsequent to the public hearing, or (iii) there
is a substantial material mistake of fact or law in the Department staff's report on the application or in the
report submitted by the health planning agency.

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

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

445 J. This section shall not apply to applications for certificates for projects defined in subdivision A 8 of § 446 $\frac{32.1-102.1:3}{32.1-102.2}$ that meet the criteria for the expedited application and review process established in 447 subdivision A 5 of § 32.1-102.2. Such projects shall be subject to an expedited application and review process

448 developed by the Board in regulation pursuant to subdivision subdivisions A 2 and 5 of § 32.1-102.2.