2016 SESSION

16105052D **HOUSE BILL NO. 193** 1 2 AMENDMENT IN THE NATURE OF A SUBSTITUTE 3 (Proposed by the House Committee on Health, Welfare and Institutions 4 on February 4, 2016) 5 (Patron Prior to Substitute—Delegate O'Bannon) 6 A BILL to amend and reenact §§ 2.2-4006, 15.2-5307, 32.1-102.1, 32.1-102.1, 32.1-102.2, 32.1-102.3, 7 32.1-102.4, 32.1-102.6, 32.1-122.01, 32.1-122.03, 32.1-122.04, and 32.1-122.07 of the Code of 8 Virginia; to amend the Code of Virginia by adding in Article 1.1 of Chapter 4 of Title 32.1 a section 9 numbered 32.1-102.14 and by adding in Chapter 4 of Title 32.1 an article numbered 9, consisting of sections numbered 32.1-122.23 and 32.1-122.24; and to repeal §§ 32.1-122.05 and 32.1-122.06 of 10 11 the Code of Virginia, relating to certificate of public need. Be it enacted by the General Assembly of Virginia: 12 1. That §§ 2.2-4006, 15.2-5307, 32.1-102.1, 32.1-102.1:1, 32.1-102.2, 32.1-102.3, 32.1-102.4, 32.1-102.6, 32.1-122.01, 32.1-122.03, 32.1-122.04, and 32.1-122.07 of the Code of Virginia are 13 14 amended and reenacted and that the Code of Virginia is amended by adding in Article 1.1 of 15 16 Chapter 4 of Title 32.1 a section numbered 32.1-102.14 and by adding in Chapter 4 of Title 32.1 17 an article numbered 9, consisting of sections numbered 32.1-122.23 and 32.1-122.24, as follows: 18 § 2.2-4006. Exemptions from requirements of this article. A. The following agency actions otherwise subject to this chapter and § 2.2-4103 of the Virginia 19 20 Register Act shall be exempted from the operation of this article: 21 1. Agency orders or regulations fixing rates or prices. 22 2. Regulations that establish or prescribe agency organization, internal practice or procedures, 23 including delegations of authority. 24 3. Regulations that consist only of changes in style or form or corrections of technical errors. Each 25 promulgating agency shall review all references to sections of the Code of Virginia within their 26 regulations each time a new supplement or replacement volume to the Code of Virginia is published to 27 ensure the accuracy of each section or section subdivision identification listed. 28 4. Regulations that are: 29 a. Necessary to conform to changes in Virginia statutory law or the appropriation act where no 30 agency discretion is involved. However, such regulations shall be filed with the Registrar within 90 days 31 of the law's effective date; 32 b. Required by order of any state or federal court of competent jurisdiction where no agency 33 discretion is involved; or 34 c. Necessary to meet the requirements of federal law or regulations, provided such regulations do not 35 differ materially from those required by federal law or regulation, and the Registrar has so determined in 36 writing. Notice of the proposed adoption of these regulations and the Registrar's determination shall be 37 published in the Virginia Register not less than 30 days prior to the effective date of the regulation. 38 5. Regulations of the Board of Agriculture and Consumer Services adopted pursuant to subsection B 39 of § 3.2-3929 or clause (v) or (vi) of subsection C of § 3.2-3931 after having been considered at two or 40 more Board meetings and one public hearing. 6. Regulations of the regulatory boards served by (i) the Department of Labor and Industry pursuant 41 42 to Title 40.1 and (ii) the Department of Professional and Occupational Regulation or the Department of Health Professions pursuant to Title 54.1 that are limited to reducing fees charged to regulants and 43 44 applicants. 45 7. The development and issuance of procedural policy relating to risk-based mine inspections by the Department of Mines, Minerals and Energy authorized pursuant to §§ 45.1-161.82 and 45.1-161.292:55. 46 8. General permits issued by the (a) State Air Pollution Control Board pursuant to Chapter 13 47 (§ 10.1-1300 et seq.) of Title 10.1 or (b) State Water Control Board pursuant to the State Water Control **48** Law (§ 62.1-44.2 et seq.), Chapter 24 (§ 62.1-242 et seq.) of Title 62.1 and Chapter 25 (§ 62.1-254 et 49 seq.) of Title 62.1, (c) Virginia Soil and Water Conservation Board pursuant to the Dam Safety Act 50 51 (§ 10.1-604 et seq.), and (d) the development and issuance of general wetlands permits by the Marine Resources Commission pursuant to subsection B of § 28.2-1307, if the respective Board or Commission 52 53 (i) provides a Notice of Intended Regulatory Action in conformance with the provisions of 54 § 2.2-4007.01, (ii) following the passage of 30 days from the publication of the Notice of Intended Regulatory Action forms a technical advisory committee composed of relevant stakeholders, including 55 potentially affected citizens groups, to assist in the development of the general permit, (iii) provides 56 notice and receives oral and written comment as provided in § 2.2-4007.03, and (iv) conducts at least 57 one public hearing on the proposed general permit. 58 9. The development and issuance by the Board of Education of guidelines on constitutional rights 59

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60 and restrictions relating to the recitation of the pledge of allegiance to the American flag in public 61 schools pursuant to § 22.1-202.

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

63 11. Regulations of the Marine Resources Commission.

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

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

14. Waste load allocations adopted, amended, or repealed by the State Water Control Board pursuant 77 78 to the State Water Control Law (§ 62.1-44.2 et seq.), including but not limited to Article 4.01 79 (§ 62.1-44.19:4 et seq.) of the State Water Control Law, if the Board (i) provides public notice in the 80 Virginia Register; (ii) if requested by the public during the initial public notice 30-day comment period, forms an advisory group composed of relevant stakeholders; (iii) receives and provides summary 81 response to written comments; and (iv) conducts at least one public meeting. Notwithstanding the 82 83 provisions of this subdivision, any such waste load allocations adopted, amended, or repealed by the Board shall be subject to the provisions of §§ 2.2-4013 and 2.2-4014 concerning review by the Governor 84 85 and General Assembly.

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

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

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

§ 15.2-5307. Appointment, qualifications, tenure, and compensation of commissioners.

101 An authority shall consist of not more than 15 commissioners appointed by the mayor, and he shall 102 designate the first chairman. No more than three commissioners shall be practicing physicians. No officer or employee of the city, with the exception of the director of a local health department, shall be 103 104 eligible for appointment; however, no director of a local health department shall serve as chairman of 105 the authority. No local health director who serves as a hospital authority commissioner shall serve as a 106 member of the regional health planning agency board simultaneously. No practicing physician shall be 107 appointed to such authority in the City of Hopewell.

108 One-third of the commissioners who are first appointed shall be designated by the mayor to serve for terms of two years, one-third to serve for terms of four years, and one-third to serve for terms of six 109 110 years, respectively, from the date of their appointment. Thereafter, the term of office shall be six years. 111 No person shall be appointed to succeed himself following four successive terms in office; no term of 112 less than six years shall be deemed a term in office for the purposes of this sentence.

A commissioner shall hold office until the earlier of the effective date of his resignation or the date 113 114 on which his successor has been appointed and has qualified. Vacancies shall be filled for the unexpired term. In the event of a vacancy in the office of commissioner by expiration of term of office or 115 116 otherwise, the remaining commissioners shall submit to the mayor nominations for appointments. The mayor may successively require additional nominations and shall have power to appoint any person so 117 nominated. All such vacancies shall be filled from such nominations. A majority of the commissioners 118 currently in office shall constitute a quorum. The mayor may file with the city clerk a certificate of the 119 120 appointment or reappointment of any commissioner, and such certificate shall be conclusive evidence of the due and proper appointment of such commissioner. A commissioner shall receive no compensation 121

122 for his services, but he shall be entitled to the necessary expenses including traveling expenses incurred 123 in the discharge of his duties.

124 § 32.1-102.1. Definitions.

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

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

127 "Charity care" means health care services for which no compensation is received provided to 128 individuals whose income is less than or equal to 200 percent of the federal poverty level for a 129 household of that size.

130 "Clinical health service" means a single diagnostic, therapeutic, rehabilitative, preventive or palliative 131 procedure or a series of such procedures that may be separately identified for billing and accounting 132 purposes.

133 "Health planning region" means a contiguous geographical area of the Commonwealth with a 134 population base of at least 500,000 persons which is characterized by the availability of multiple levels 135 of medical care services, reasonable travel time for tertiary care, and congruence with planning districts.

136 "Medical care facility," as used in this title, means any institution, place, building or agency, whether 137 or not licensed or required to be licensed by the Board or the Department of Behavioral Health and 138 Developmental Services, whether operated for profit or nonprofit and whether privately owned or 139 privately operated or owned or operated by a local governmental unit, (i) by or in which health services 140 are furnished, conducted, operated or offered for the prevention, diagnosis or treatment of human 141 disease, pain, injury, deformity or physical condition, whether medical or surgical, of two or more 142 nonrelated persons who are injured or physically sick or have mental illness, or for the care of two or 143 more nonrelated persons requiring or receiving medical, surgical or nursing attention or services as 144 acute, chronic, convalescent, aged, physically disabled or crippled or (ii) which is the recipient of 145 reimbursements from third-party health insurance programs or prepaid medical service plans. For 146 purposes of this article, only the following medical care facilities shall be subject to review: 147

1. General hospitals. 148

2. Sanitariums.

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3. Nursing homes.

150 4. 3. Intermediate care facilities, except those intermediate care facilities established for individuals 151 with intellectual disability (ICF/MR) that have no more than 12 beds and are in an area identified as in 152 need of residential services for individuals with intellectual disability in any plan of the Department of 153 Behavioral Health and Developmental Services.

154 5. Extended care facilities.

155 6. Mental hospitals. 156

7. 4. Facilities for individuals with intellectual disability.

157 8. 5. Psychiatric hospitals and intermediate care facilities established primarily for the medical, 158 psychiatric or psychological treatment and rehabilitation of individuals with substance abuse.

159 9. 6. Specialized centers or clinics or that portion of a physician's office developed for the provision 160 of outpatient or ambulatory surgery, when such center, clinic, or portion of a physician's office is located outside of a metropolitan statistical area or in a rural census tract within a metropolitan 161 162 statistical area, or for the provision of cardiac catheterization, computed tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging 163 164 (MSI), positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy, 165 proton beam therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac imaging, or 166 such other specialty services as may be designated by the Board by regulation.

- 10. 7. Rehabilitation hospitals. 167
- 168 11. 8. Any facility licensed as a hospital.

169 The term "medical care facility" does not include any facility of (i) the Department of Behavioral 170 Health and Developmental Services; (ii) any nonhospital substance abuse residential treatment program 171 operated by or contracted primarily for the use of a community services board under the Department of 172 Behavioral Health and Developmental Services' Comprehensive State Plan; (iii) an intermediate care 173 facility for individuals with intellectual disability (ICF/MR) that has no more than 12 beds and is in an 174 area identified as in need of residential services for individuals with intellectual disability in any plan of 175 the Department of Behavioral Health and Developmental Services; (iv) a physician's office, except that portion of a physician's office described in subdivision 9 6 of the definition of "medical care facility"; 176 177 (v) the Wilson Workforce and Rehabilitation Center of the Department for Aging and Rehabilitative 178 Services; (vi) the Department of Corrections; or (vii) the Department of Veterans Services. "Medical 179 care facility" shall also not include that portion of a physician's office dedicated to providing nuclear 180 cardiac imaging.

181 "Nursing home" means any facility or any identifiable component of any facility licensed pursuant to Article 1 (§ 32.1-123 et seq.) of Chapter 5 in which the primary function is the provision, on a 182

continuing basis, of nursing services and health-related services for the treatment and inpatient care of
two or more nonrelated individuals, including facilities known by varying nomenclature or designation
such as convalescent homes, skilled nursing facilities or skilled care facilities, intermediate care
facilities, extended care facilities, nursing facilities or nursing care facilities, or any other facility or
component thereof with medical rehabilitation beds or long-term care beds.

188 "Project" means:

- **189** 1. Establishment of a medical care facility;
- 190 2. An increase in the total number of beds or operating rooms in an existing medical care facility;

191 3. Relocation of beds from one existing facility to another, provided that "project" does not include 192 the relocation of up to 10 beds or 10 percent of the beds, whichever is less, (i) from one existing 193 facility to another existing facility at the same site in any two-year period, or (ii) in any three-year period, from one existing nursing home facility to any other existing nursing home facility owned or 194 195 controlled by the same person that is located either within the same planning district, or within another planning district out of which, during or prior to that three-year period, at least 10 times that number of 196 197 beds have been authorized by statute to be relocated from one or more facilities located in that other 198 planning district and at least half of those beds have not been replaced, provided further that, however, a 199 hospital shall not be required to obtain a certificate for the use of 10 percent of its beds as nursing 200 home beds as provided in § 32.1-132;

4. Introduction into an existing medical care facility of any new nursing home service, such as
intermediate care facility services, extended care facility services, or skilled nursing facility services,
regardless of the type of medical care facility in which those services are provided;

204 5. Introduction into an existing medical care facility of any new cardiac catheterization, computed tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), 205 206 magnetic source imaging (MSI), medical rehabilitation, neonatal special care, obstetrical, open heart 207 surgery, positron emission tomographic (PET) scanning, psychiatric, organ or tissue transplant service, radiation therapy, stereotactic radiotherapy, proton beam therapy, nuclear medicine imaging, except for 208 209 the purpose of nuclear cardiac imaging, substance abuse treatment, or such other specialty clinical 210 services as may be designated by the Board by regulation, which the facility has never provided or has 211 not provided in the previous 12 months;

6. Conversion of beds in an existing medical care facility to medical rehabilitation beds or
 psychiatric beds;

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

220 8. Any capital expenditure of \$15 million or more, not defined as reviewable in subdivisions 1 221 through 7 of this definition, by or on behalf of a medical care facility that is located outside of a 222 metropolitan statistical area or in a rural census tract within a metropolitan statistical area, other than a nursing home, general hospital, rehabilitation hospital, specialized clinic or center or portion of a 223 224 hospital established for the provision of organ or tissue transplant services, or specialized center or 225 clinic or portion of a hospital established for the provision of open heart surgery. Capital expenditures 226 of \$5 million or more by a general hospital that is located outside of a metropolitan statistical area or 227 in a rural census tract within a metropolitan statistical area and capital expenditures between \$5 and 228 \$15 million by a medical care facility that is located outside of a metropolitan statistical area or in a rural census tract within a metropolitan statistical area, other than a nursing home, general hospital, rehabilitation hospital, specialized clinic or center or portion of a hospital established for the provision 229 230 231 of organ or tissue transplant services, or specialized centers or clinics or portion of a hospital established for the provision of open heart surgery shall be registered with the Commissioner pursuant 232 233 to regulations developed by the Board. The amounts specified in this subdivision shall be revised 234 effective July 1, 2008, and annually thereafter to reflect inflation using appropriate measures 235 incorporating construction costs and medical inflation. Nothing in this subdivision shall be construed to 236 modify or eliminate the reviewability of any project described in subdivisions 1 through 7 of this 237 definition when undertaken by or on behalf of a general hospital; or

238 9. Conversion in an existing medical care facility of psychiatric inpatient beds approved pursuant to a239 Request for Applications (RFA) to nonpsychiatric inpatient beds.

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

243 "State Medical Facilities Plan" means the planning document adopted by the Board of Health which244 shall include, but not be limited to, (i) methodologies for projecting need for medical care facility beds

and services; (ii) statistical information on the availability of medical care facilities and services; and 245 246 (iii) procedures, criteria and standards for review of applications for projects for medical care facilities 247 and services. 248

§ 32.1-102.1:1. Equipment registration required.

249 Within thirty 30 calendar days of becoming contractually obligated to acquire any medical equipment 250 for the provision of cardiac catheterization, computed tomographic (CT) scanning, stereotactic 251 radiosurgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart 252 surgery, positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy, 253 proton beam therapy, or other specialized service designated by the Board by regulation, any person 254 shall register such purchase with the Commissioner and the appropriate regional health planning agency. 255

§ 32.1-102.2. Regulations.

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

257 1. Shall establish concise procedures for the prompt review of applications for certificates consistent 258 with the provisions of this article which may include a structured batching process which incorporates, 259 but is not limited to, authorization for the Commissioner to request proposals for certain projects. In any 260 structured batching process established by the Board, applications, combined or separate, for computed 261 tomographic (CT) scanning, magnetic resonance imaging (MRI), positron emission tomographic (PET) 262 scanning, radiation therapy, sterotactic stereotactic radiotherapy, proton beam therapy, or nuclear 263 imaging shall be considered in the radiation therapy batch. A single application may be filed for a 264 combination of (i) radiation therapy, sterotactic stereotactic radiotherapy and proton beam therapy, and 265 (ii) any or all of the computed tomographic (CT) scanning, magnetic resonance imaging (MRI), positron 266 emission tomographic (PET) scanning, and nuclear medicine imaging;

2. May classify projects and may eliminate one or more or all of the procedures prescribed in 267 268 § 32.1-102.6 for different classifications:

269 3. May provide for exempting from the requirement of a certificate projects determined by the 270 Commissioner, upon application for exemption, to be subject to the economic forces of a competitive 271 market or to have no discernible impact on the cost or quality of health services;

272 4. Shall establish specific criteria for determining need in rural areas, giving due consideration to 273 distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to 274 care in such areas and providing for weighted calculations of need based on the barriers to health care 275 access in such rural areas in lieu of the determinations of need used for the particular proposed project 276 within the relevant health systems area as a whole;

277 5. May establish, on or after July 1, 1999, a schedule of fees for applications for certificates to be 278 applied to expenses for the administration and operation of the certificate of public need program. Such 279 fees shall not be less than \$1,000 nor exceed the lesser of one percent of the proposed expenditure for 280 the project or \$20,000. Until such time as the Board shall establish a schedule of fees, such fees shall be 281 one percent of the proposed expenditure for the project; however, such fees shall not be less than \$1,000 282 or more than \$20,000; and

283 6. Shall establish (i) an expedited 45-day application and review process for any certificate for 284 projects determined by the Department to be uncontested and to present minimal health planning 285 impacts, in accordance with criteria established by the Board, and for which the applicant agrees to 286 comply with quality assurance requirements established by the Board and consents to provide charity 287 care in an amount specified by the Board pursuant to § 32.1-102.4, and (ii) an expedited 120-day 288 application and review process for any certificate for projects reviewable pursuant to subdivision 8 of 289 the definition of "project" in § 32.1-102.1 and projects identified by the Department to be uncontested 290 and to present minimal health planning impacts that require a level of scrutiny greater than that 291 required pursuant to clause (i) but do not require a full review pursuant to § 32.1-102.6, in accordance 292 with criteria established by the Board, and for which the applicant agrees to comply with quality 293 assurance requirements established by the Board and consents to provide charity care in an amount 294 specified by the Board pursuant to § 32.1-102.4. Regulations establishing the expedited application and 295 review procedure procedures in accordance with this subdivision shall include (a) provisions for notice 296 and opportunity for public comment on the application for a certificate, and, (b) criteria pursuant to 297 which an application that would normally undergo the review process would instead undergo the full 298 certificate of public need review process set forth in § 32.1-102.6; (c) provisions for conditioning the 299 approval of a certificate upon the agreement of the applicant to (1) provide a level of care at a reduced 300 rate to indigents in an amount that is equal to the average amount of indigent care provided by holders 301 of certificates of public need in the applicant's health planning region or to accept patients requiring 302 specialized medical care or (2) facilitate the development and operation of primary medical care 303 services in designated medically underserved areas of the applicant's service area; and (d) provisions for conditioning the approval of a certificate upon the agreement of the applicant to comply with quality 304 305 assurance requirements established by the Board.

306 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 307 308 reviewable projects. The Commissioner shall not approve any such extension or excess unless it 309 complies with the Board's regulations. However, the Commissioner may approve a significant change in 310 cost for an approved project that exceeds the authorized capital expenditure by more than 20 percent, 311 provided the applicant has demonstrated that the cost increases are reasonable and necessary under all 312 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 313 314 of a certificate on the agreement of the applicant to provide a level of care at a reduced rate to indigents 315 or accept patients requiring specialized care. In addition, the Board's licensure regulations shall direct the 316 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 317 318 provide a level of care at a reduced rate to indigents or accept patients requiring specialized care. 319

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

320 A. No person shall commence any project without first obtaining a certificate issued by the Commissioner. No certificate may be issued unless the Commissioner has determined that a public need 321 322 for the project has been demonstrated. If it is determined that a public need exists for only a portion of 323 a project, a certificate may be issued for that portion and any appeal may be limited to the part of the 324 decision with which the appellant disagrees without affecting the remainder of the decision. Any 325 decision to issue or approve the issuance of a certificate shall be consistent with the most recent applicable provisions of the State Medical Facilities Plan; however, if the Commissioner finds, upon 326 327 presentation of appropriate evidence, that the provisions of such plan are not relevant to a rural locality's needs, inaccurate, outdated, inadequate or otherwise inapplicable, the Commissioner, consistent with such 328 329 finding, may issue or approve the issuance of a certificate and shall initiate procedures to make 330 appropriate amendments to such plan. In cases in which a provision of the State Medical Facilities Plan has been previously set aside by the Commissioner and relevant amendments to the Plan have not yet 331 332 taken effect, the Commissioner's decision shall be consistent with the applicable portions of the State 333 Medical Facilities Plan that have not been set aside and the remaining considerations in subsection B.

334 B. In determining whether a public need for a project has been demonstrated cases in which an 335 application for a proposed project is consistent with the State Medical Facilities Plan, the Commissioner 336 shall approve the application. In all other cases, the Commissioner shall consider:

1. The extent to which the proposed service or facility will provide or increase access to needed 337 338 services for residents of the area to be served, and the effects that the proposed service or facility will 339 have on access to needed services in areas having distinct and unique geographic, socioeconomic, 340 cultural, transportation, and other barriers to access to care;

2. The extent to which the project will meet the needs of the residents of the area to be served, as 341 342 demonstrated by each of the following: (i) the level of community support for the project demonstrated 343 by citizens, businesses, and governmental leaders representing the area to be served; (ii) the availability 344 of reasonable alternatives to the proposed service or facility that would meet the needs of the population 345 in a less costly, more efficient, or more effective manner; (iii) any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted 346 to the Commissioner pursuant to subsection B of § 32.1-102.6; (iv) any costs and benefits of the project; 347 348 (\mathbf{v}) (iv) the financial accessibility of the project to the residents of the area to be served, including 349 indigent residents; and (vi) (v) at the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a project; 350 351

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

352 4. The extent to which the proposed service or facility fosters institutional competition that benefits 353 the area to be served while improving access to essential health care services for all persons in the area 354 to be served;

355 5. The relationship of the project to the existing health care system of the area to be served, 356 including the utilization and efficiency of existing services or facilities;

357 6. The feasibility of the project, including the financial benefits of the project to the applicant, the 358 cost of construction, the availability of financial and human resources, and the cost of capital;

359 7. The extent to which the project provides improvements or innovations in the financing and 360 delivery of health services, as demonstrated by: (i) the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) the potential for provision 361 of services on an outpatient basis; (iii) any cooperative efforts to meet regional health care needs; and 362 363 (iv) at the discretion of the Commissioner, any other factors as may be appropriate; and

8. In the case of a project proposed by or affecting a teaching hospital associated with a public 364 institution of higher education or a medical school in the area to be served, (i) the unique research, 365 training, and clinical mission of the teaching hospital or medical school, and (ii) any contribution the 366 teaching hospital or medical school may provide in the delivery, innovation, and improvement of health 367

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368 care for citizens of the Commonwealth, including indigent or underserved populations.

369 § 32.1-102.4. Conditions of certificates; monitoring; revocation of certificates.

370 A. A certificate shall be issued with a schedule for the completion of the project and a maximum 371 capital expenditure amount for the project. The schedule may not be extended and the maximum capital 372 expenditure may not be exceeded without the approval of the Commissioner in accordance with the 373 regulations of the Board.

374 B. The Commissioner shall monitor each project for which a certificate is issued to determine its 375 progress and compliance with the schedule and with the maximum capital expenditure. The 376 Commissioner shall also monitor all continuing care retirement communities for which a certificate is 377 issued authorizing the establishment of a nursing home facility or an increase in the number of nursing 378 home beds pursuant to § 32.1-102.3:2 and shall enforce compliance with the conditions for such 379 applications which are required by § 32.1-102.3:2. Any willful violation of a provision of § 32.1-102.3:2 or conditions of a certificate of public need granted under the provisions of § 32.1-102.3:2 shall be 380 381 subject to a civil penalty of up to \$100 per violation per day until the date the Commissioner determines 382 that such facility is in compliance. 383

C. A certificate may be revoked when:

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384 1. Substantial and continuing progress towards completion of the project in accordance with the 385 schedule has not been made;

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

387 3. The applicant has willfully or recklessly misrepresented intentions or facts in obtaining a 388 certificate; or

389 4. A continuing care retirement community applicant has failed to honor the conditions of a 390 certificate allowing the establishment of a nursing home facility or granting an increase in the number of 391 nursing home beds in an existing facility which was approved in accordance with the requirements of 392 § 32.1-102.3:2.

393 D. Further, the Commissioner shall not approve an extension for a schedule for completion of any 394 project or the exceeding of the maximum capital expenditure of any project unless such extension or 395 excess complies with the limitations provided in the regulations promulgated by the Board pursuant to 396 § 32.1-102.2.

397 E. Any person willfully violating the Board's regulations establishing limitations for schedules for 398 completion of any project or limitations on the exceeding of the maximum capital expenditure of any 399 project shall be subject to a civil penalty of up to \$100 per violation per day until the date of 400 completion of the project.

401 \vec{F} . The Commissioner may condition, pursuant to the regulations of the Board, the approval of a 402 certificate (i) upon the agreement of the applicant to provide a level of care at a reduced rate to 403 indigents in an amount that is equal to the average amount of indigent care provided by holders of **404** certificates of public need in the applicant's health planning region or accept patients requiring 405 specialized care or (ii) upon the agreement of the applicant to facilitate the development and operation 406 of primary medical care services in designated medically underserved areas of the applicant's service 407 area. The value of care provided to individuals pursuant to this subsection shall be based on provider 408 reimbursement methodology utilized by the Department of Medical Assistance Services for 409 reimbursements under the state plan for medical assistance.

410 The certificate holder shall provide documentation to the Department demonstrating that the 411 certificate holder has satisfied the conditions of the certificate. If the certificate holder is unable or fails 412 to satisfy the conditions of a certificate, the Department may approve alternative methods to satisfy the 413 conditions pursuant to a plan of compliance. The plan of compliance shall identify a timeframe within 414 which the certificate holder will satisfy the conditions of the certificate, and identify how the certificate 415 holder will satisfy the conditions of the certificate, which may include (i) (a) making direct payments to 416 an organization authorized under a memorandum of understanding with the Department to receive 417 contributions satisfying conditions of a certificate, (ii) (b) making direct payments to a private nonprofit 418 foundation that funds basic insurance coverage for indigents authorized under a memorandum of understanding with the Department to receive contributions satisfying conditions of a certificate, or (iii) 419 420 (c) other documented efforts or initiatives to provide primary or specialized care to underserved 421 populations. In determining whether the certificate holder has met the conditions of the certificate 422 pursuant to a plan of compliance, only such direct payments, efforts, or initiatives made or undertaken 423 after issuance of the conditioned certificate shall be counted towards satisfaction of conditions.

424 Any person willfully refusing, failing, or neglecting to honor such agreement shall be subject to a 425 civil penalty of up to \$100 per violation per day until the date of compliance.

426 G. Pursuant to regulations of the Board, the Commissioner may accept requests for and approve 427 amendments to conditions of existing certificates related to the provision of care at reduced rates or to 428 patients requiring specialized care or related to the development and operation of primary medical care 429 services in designated medically underserved areas of the certificate holder's service area.

430 H. For the purposes of this section, "completion" means conclusion of construction activities 431 necessary for the substantial performance of the contract. 432

§ 32.1-102.6. Administrative procedures.

433 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 434 435 planning agency has been designated for that region. An application submitted for review shall be considered complete when all relevant sections of the application form have responses. The applicant 436 437 shall provide sufficient information to prove public need for the requested project exists without the 438 addition of supplemental or supporting material at a later date. Nothing in this section shall prevent the 439 Department from seeking, at its discretion, additional information from the applicant or other sources.

440 In order to verify the date of the Department's and the appropriate regional health planning agency's 441 receipt of the application, the applicant shall transmit the document electronically, by certified mail or a 442 delivery service, return receipt requested, or shall deliver the document by hand, with signed receipt to 443 be provided.

444 Within 10 calendar days of the date on which the document is received, the Department and the 445 appropriate regional health planning agency, if a regional health planning agency has been designated, 446 shall determine whether the application is complete or not and the Department shall notify the applicant, 447 if the application is not complete, of the information needed to complete the application. If no regional 448 health planning agency is designated for the health planning region in which the project will be located, 449 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 450 451 needed to complete the application.

At least 30 calendar days before any person is contractually obligated to acquire an existing medical 452 453 care facility, the cost of which is \$600,000 or more, that person shall notify the Commissioner and the 454 appropriate regional health planning agency, if a regional health planning agency has been designated, of 455 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 456 457 services or beds are proposed to be added as a result of the acquisition, the Commissioner may require 458 the proposed new owner to obtain a certificate prior to the acquisition. If no regional health planning 459 agency is designated for the health planning region in which the acquisition will take place, no 460 notification to a regional health planning agency shall be required.

461 B. For projects proposed in health planning regions with regional planning agencies, the appropriate 462 regional health planning agency shall (i) review each completed application for a certificate within 60 463 calendar days of the day which begins the appropriate batch review cycle as established by the Board by regulation pursuant to subdivision A 1 of § 32.1-102.2, such cycle not to exceed 190 days in duration, 464 465 and (ii) hold one public hearing on each application in a location in the county or city in which the 466 project is proposed or a contiguous county or city. Prior to the public hearing, the regional health 467 planning agency shall notify the local governing bodies in the planning district. At least nine days prior 468 to the public hearing, the regional health planning agency shall cause notice of the public hearing to be 469 published in a newspaper of general circulation in the county or city where the project is proposed to be 470 located. The regional health planning agency shall consider the comments of the local governing bodies 471 in the planning district and all other public comments in making its decision. Such comments shall be 472 part of the record. In no case shall a regional health planning agency hold more than two meetings on 473 any application, one of which shall be the public hearing conducted by the board of the regional health 474 planning agency or a subcommittee of the board. The applicant shall be given the opportunity, prior to 475 the vote by the board of the regional health planning agency or a committee of the agency, if acting for 476 the board, on its recommendation, to respond to any comments made about the project by the regional 477 health planning agency staff, any information in a regional health planning agency staff report, or 478 comments by those voting members of the regional health planning agency board; however, such 479 opportunity shall not increase the 60 calendar day period designated herein for the regional health 480 planning agency's review unless the applicant or applicants request a specific extension of the regional 481 health planning agency's review period.

The regional health planning agency shall submit its recommendations on each application and its 482 483 reasons therefor to the Department within 10 calendar days after the completion of its 60-calendar-day **484** review or such other period in accordance with the applicant's request for extension.

485 If the regional health planning agency has not completed its review within the specified 60 calendar 486 days or such other period in accordance with the applicant's request for extension and submitted its 487 recommendations on the application and the reasons therefor within 10 calendar days after the 488 completion of its review, the Department shall, on the eleventh calendar day after the expiration of the 489 regional health planning agency's review period, proceed as though the regional health planning agency 490 has recommended project approval without conditions or revision.

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491 If no regional health planning agency has been designated for a region, the The Department shall (i) 492 solicit public comment on such application by posting notice of such application and a summary of the 493 proposed project on a website maintained by the Department, together with information about how 494 comments may be submitted to the Department and the date on which the public comment period shall 495 expire, and (ii) in the case of competing applications or in response to a written request by an elected 496 local government representative, a member of the General Assembly, the Commissioner, the applicant, 497 or a member of the public, hold one hearing on each application in a location in the county or city in 498 which the project is proposed or a contiguous county or city. Prior to the hearing, the Department shall 499 notify the local governing bodies in the planning district in which the project is proposed. At least nine 500 days prior to the any required public hearing, the Department shall cause notice of the public hearing to 501 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 502 503 district and all other public comments in making its decision. Such comments shall be part of the 504 record.

505 C. After commencement of any public hearing and before a decision is made there shall be no ex 506 parte contacts concerning the subject certificate or its application between (i) any person acting on 507 behalf of the applicant or holder of a certificate or any person opposed to the issuance or in favor of 508 revocation of a certificate of public need and (ii) any person in the Department who has authority to 509 make a determination respecting the issuance or revocation of a certificate of public need, unless the 510 Department has provided advance notice to all parties referred to in (i) of the time and place of such 511 proposed contact.

512 D. The Department shall commence the review of each completed application upon on the first day 513 which begins of the appropriate batch review cycle and simultaneously with the review conducted by the 514 regional health planning agency, if a regional health planning agency has been designated.

515 A determination whether a public need exists for a project shall be made by the Commissioner 516 within 190 calendar days of the day which begins the appropriate batch cycle.

517 The 190-calendar-day review period shall begin on the date upon which the application is determined 518 to be complete within the batching process specified in subdivision A 1 of § 32.1-102.2.

519 If the application is not determined to be complete within 40 calendar days from submission, the 520 application shall be refiled in the next batch for like projects.

521 The Commissioner shall make determinations in accordance with the provisions of the Administrative 522 Process Act (§ 2.2-4000 et seq.) except for those parts of the determination process for which timelines 523 and specifications are delineated in subsection E of this section. Further, if an informal fact-finding 524 conference is determined to be necessary by the Department or is requested by a person seeking good 525 cause standing, the parties to the case shall include only the applicant, any person showing good cause, 526 and any third-party payor providing health care insurance or prepaid coverage to five percent or more of 527 the patients in the applicant's service area, and the relevant health planning agency. 528

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

529 1. The Department shall establish, for every application, a date between the eightieth and ninetieth 530 calendar days within the 190-calendar-day review period for holding an informal fact-finding conference, 531 if such conference is necessary.

532 2. The Department shall review every application at or before the seventy-fifth calendar day within 533 the 190-calendar-day review period to determine whether an informal fact-finding conference is 534 necessary.

535 3. Any person seeking to be made a party to the case for good cause shall notify the Department of 536 his request and the basis therefor on or before the eightieth calendar day following the day which begins 537 the appropriate batch review cycle, no later than four days after the Department has completed its 538 review and submitted its recommendation on an application and has transmitted the same to the 539 applicants and to persons who have, prior to the issuance of the report, requested a copy in writing, 540 notify the Commissioner and all applicants, in writing and under oath, stating the grounds for good 541 cause and providing the factual basis therefor.

4. In any case in which an informal fact-finding conference is held, a date shall be established for 542 543 the closing of the record which shall not be more than 30 calendar days after the date for holding the 544 informal fact-finding conference.

545 5. In any case in which an informal fact-finding conference is not held, the record shall be closed on 546 the earlier of (i) the date established for holding the informal fact-finding conference or (ii) the date that 547 the Department determines an informal fact-finding conference is not necessary.

548 6. The provisions of subsection C of \S 2.2-4021 notwithstanding, if a determination whether a public 549 need exists for a project is not made by the Commissioner within 45 calendar days of the closing of the 550 record, the Commissioner shall notify the applicant or applicants and any persons seeking to show good 551 cause, in writing, that the application or the application of each shall be deemed approved 25 calendar

days after expiration of such 45-calendar-day period, unless the receipt of recommendations from the
person performing the hearing officer functions permits the Commissioner to issue his case decision
within that 25-calendar-day period. The validity or timeliness of the aforementioned notice shall not, in
any event, prevent, delay or otherwise impact the effectiveness of this section.

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

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

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

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

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

578 G. For purposes of this section, "good cause" shall mean that (i) there is significant relevant 579 information not previously presented at and not available at the time of the public hearing, (ii) there 580 have been significant changes in factors or circumstances relating to the application subsequent to the 581 public hearing, or (iii) there is a substantial material mistake of fact or law in the Department staff's 582 report on the application or in the report submitted by the health planning agency.

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

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

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

§ 32.1-102.14. Transparency.

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

599 § 32.1-122.01. Definitions.

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- 600 As used in this article unless the context requires a different meaning:
- **601** "Board" means the State Board of Health.
- 602 "Commissioner" means the State Health Commissioner.
- 603 "Consumer" means a person who is not a provider of health care services.
- 604 "Department" means the Virginia Department of Health.

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

608 "Provider" means a licensed or certified health care practitioner, a licensed health care facility or service administrator, or an individual who has a personal interest in a health care facility or service as
610 defined in the Virginia Conflict of Interests Act (§ 2.2-3100 et seq.).

611 "Regional health planning agency" means the regional agency, including the regional health planning
612 board, its staff and any component thereof, designated by the Board to perform the health planning
613 activities set forth in this chapter within a health planning region.

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614 "Regional health planning board" means the governing board of the regional health planning agency 615 as described in § 32.1-122.05.

"Secretary" means the Secretary of Health and Human Resources of the Commonwealth of Virginia. 616

"State Health Plan" means the document so designated by the Board, which may include analysis of 617 618 priority health issues, policies, needs, methodologies for assessing statewide health care needs, and such 619 other matters as the Board shall deem appropriate.

620 "Tertiary care" means health care delivered by facilities that provide specialty acute care including, 621 but not limited to, trauma care, neonatal intensive care, and cardiac services.

622 § 32.1-122.03. State Health Plan.

623 A. The Board may develop, and revise as it deems necessary, the State Health Plan with the support 624 of the Department and the assistance of the regional health planning agencies. Following review and 625 comment by interested parties, including appropriate state agencies, the Board may develop and approve 626 the State Health Plan. The State Health Plan shall be developed in accordance with components and 627 methodologies that take into account special needs or circumstances of local areas. The Plan shall reflect data and analyses provided by the regional health planning agencies and include regional differences where appropriate. The Board, in preparation of the State Health Plan and to avoid unnecessary 628 629 630 duplication, may consider and utilize all relevant and formally adopted plans of agencies, councils, and 631 boards of the Commonwealth.

632 B. In order to develop and approve the State Health Plan, the Board may conduct such studies as 633 may be necessary of critical health issues as identified by the Governor, the General Assembly, the 634 Secretary, or by the Board. Such studies may include, but not be limited to: (i) collection of data and statistics; (ii) analyses of information with subsequent recommendations for policy development, decision 635 636 making, and implementation; and (iii) analyses and evaluation of alternative health planning proposals 637 and initiatives.

638 § 32.1-122.04. Responsibilities of the Department. 639

The Department shall have the following responsibilities as directed by the Board:

640 1. To conduct the research for the health planning activities of the Commonwealth.

641 2. To prepare, review and revise the State Health Plan when so directed by the Board.

642 3. To develop, under the direction of the Board and with the cooperation of the regional health 643 planning agencies, the components and methodology for the State Health Plan, including any research, 644 issue analyses, and related reports.

645 4. To provide technical assistance to the regional health planning agencies.

646 5. To perform such other functions relating to health planning in the Commonwealth as may be 647 requested by the Governor or the Secretary.

648 § 32.1-122.07. Authority of Commissioner for certain health planning activities; rural health 649 plan; designation as a rural hospital.

650 A. The Commissioner, with the approval of the Board, is authorized to make application for federal 651 funding and to receive and expend such funds in accordance with state and federal regulations.

652 B. The Commissioner shall administer section § 1122 of the United States Social Security Act if the 653 Commonwealth has made an agreement with the United States U.S. Secretary of Health and Human 654 Services pursuant to such section.

655 C. In compliance with the provisions of the Balanced Budget Act of 1997, P.L. 105-33, and any 656 amendments to such provisions, the Commissioner shall submit to the appropriate regional administrator 657 of the Centers for Medicare & Medicaid Services (CMS) an application to establish a Medicare Rural 658 Hospital Flexibility Program in Virginia.

D. The Commissioner shall develop and the Board of Health shall approve a rural health care plan 659 660 for the Commonwealth to be included with the application to establish a Medicare Rural Hospital Flexibility Program. In cooperation and consultation with the Virginia Hospital and Health Care **661** Healthcare Association, the Medical Society of Virginia, representatives of rural hospitals, and experts 662 663 within the Department of Health on rural health programs, the plan shall be developed and revised as **664** necessary or as required by the provisions of the Balanced Budget Act of 1997, P.L. 105-33, and any 665 amendments to such provisions. In the development of the plan, the Commissioner may also seek the 666 assistance of the regional health planning agencies. The plan shall verify that the Commonwealth is in 667 the process of designating facilities located in Virginia as critical access hospitals, shall note that the Commonwealth wishes to certify facilities as "necessary providers" of health care in rural areas, and 668 669 shall describe the process, methodology, and eligibility criteria to be used for such designations or 670 certifications. Virginia's rural health care plan shall reflect local needs and resources and shall, at 671 minimum, include, but need not be limited to, a mechanism for creating one or more rural health 672 networks, ways to encourage rural health service regionalization, and initiatives to improve access to 673 health services, including hospital services, for rural Virginians.

674 E. Notwithstanding any provisions of this chapter or the Board's regulations to the contrary, the 675 Commissioner shall, in the rural health care plan, (i) use as minimum standards for critical access 676 hospitals, the certification regulations for critical access hospitals promulgated by the Centers for Medicare & Medicaid Services (CMS) pursuant to Title XVIII of the Social Security Act, as amended; 677 678 and (ii) authorize critical access hospitals to utilize a maximum of ten beds among their inpatient 679 hospital beds as swing beds for the furnishing of services of the type which, if furnished by a nursing 680 home or certified nursing facility, would constitute skilled care services without complying with nursing 681 home licensure requirements or retaining the services of a licensed nursing home administrator. Such hospital shall include, within its plan of care, assurances for the overall well-being of patients occupying **682** 683 such beds.

684 F. Nothing herein or set forth in Virginia's rural health care plan shall prohibit any hospital 685 designated as a critical access hospital from leasing the unused portion of its facilities to other health care organizations or reorganizing its corporate structure to facilitate the continuation of the nursing 686 **687** home beds that were licensed to such hospital prior to the designation as a critical access hospital. The health care services delivered by such other health care organizations shall not be construed as part of 688 689 the critical access hospital's services or license to operate.

690 G. Any medical care facility licensed as a hospital shall be considered a rural hospital on and after 691 September 30, 2004, pursuant to 42 U.S.C. § 1395ww (d)(8)(E)(ii)(II), if (i) the hospital is located in an area defined as rural by federal statute or regulation; (ii) the Board of Health defines, in regulation, the **692** 693 area in which the hospital is located as a rural health area or the hospital as a rural hospital; or (iii) the 694 hospital was designated, prior to October 1, 2004, as a Medicare-dependent small rural health hospital, as defined in 42 U.S.C. § 1395ww (d)(5)(G)(iv). 695

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Article 9.

Permits for Medical Care Facility Projects.

§ 32.1-122.23. Definitions.

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

700 "Medical care facility" means any facility licensed as a hospital pursuant to Article 1 (§ 32.1-123 et 701 seq.) of Chapter 5; intermediate care facility established primarily for the medical, psychiatric, or 702 psychological treatment and rehabilitation of individuals with substance abuse; facility for individuals 703 with intellectual disability, specialized center or clinic or that portion of a doctor's office established for 704 the provision of outpatient or ambulatory surgery or for the provision of cardiac catheterization, 705 computed tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging 706 (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, radiation 707 therapy, stereotactic radiotherapy, proton beam therapy, nuclear medicine imaging, except for the 708 purpose of nuclear cardiac imaging, or such other specialty services as may be designated by the Board 709 by regulation. 710

"Project" means:

711 1. Establishment of a specialized center or clinic or that portion of a physician's office developed for 712 the provision of outpatient or ambulatory surgery, when such center, clinic, or portion of a physician's 713 office is located in a metropolitan statistical area but not in a rural census tract within a metropolitan 714 statistical area;

715 2. An increase in the total number of beds or operating rooms in a specialized center or clinic or 716 portion of a physician's office developed for the provision of outpatient or ambulatory surgery, when 717 such center, clinic, or portion of a physician's office is located in a metropolitan statistical area but not 718 in a rural census tract within a metropolitan statistical area; or

719 3. Any capital expenditure of \$15 million or more, not defined as reviewable in subdivisions 1 or 2 720 of this definition, by or on behalf of a medical care facility that is located in a metropolitan statistical 721 area but not in a rural census tract within a metropolitan statistical area. The amounts specified in this 722 subdivision shall be revised annually to reflect inflation using appropriate measures incorporating 723 construction costs and medical inflation. 724

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

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

726 B. At least 90 days prior to initiating a project for which a permit is required, a person shall file 727 with the Department an application for a permit, together with a fee determined by the Board. The 728 Commissioner shall issue the permit within 30 days of receipt of the application.

729 C. The Commissioner shall condition the issuance of a permit to undertake a project upon the 730 agreement of the applicant to (i) provide a specified level of care at a reduced rate to indigents in an amount that matches the average amount of indigent care provided by holders of certificates of public 731 732 need in the applicant's health planning region, (ii) accept patients requiring specialized care, or (iii) facilitate the development and operation of primary medical care services in designated medically 733 734 underserved areas of the applicant's service area.

The holder of a permit that is subject to conditions pursuant to this subsection shall provide such 735 736 documentation as may be required by the Commissioner to demonstrate compliance with the conditions 737 *imposed*.

738 The Commissioner shall monitor compliance with permit conditions pursuant to this subsection and 739 may impose penalties on a permit holder that fails to comply with such permit conditions. If the permit 740 holder is unable or fails to comply with the conditions imposed by the Commissioner, the Commissioner 741 may, upon request of the permit holder, approve a plan of compliance with alternate methods to satisfy 742 the permit conditions. Such alternate methods may include (a) a direct payment by the permit holder to 743 an organization authorized under a memorandum of understanding with the Department to receive 744 contributions satisfying conditions of the permit; (b) a direct payment by the permit holder to a private 745 nonprofit foundation that funds basic insurance coverage for indigents authorized under a memorandum 746 of understanding with the Department to receive contributions satisfying conditions of a permit; (c) 747 provision by the permit holder of on-call coverage at a hospital, including the emergency department of 748 a hospital, or (d) such other methods for the provision of primary or specialized care to indigent 749 patients or patients requiring specialized care as may be approved by the Commissioner. Any permit 750 holder that fails or refuses to comply with the requirements of a plan of compliance entered into in 751 accordance with this subsection is subject to a civil penalty of up to \$100 per violation per day until the 752 date of compliance.

753 The Commissioner may, pursuant to regulations of the Board, accept requests for and approve **754** amendments to permit conditions pursuant to this subsection upon request of the permit holder.

755 The Board shall adopt regulations governing the issuance and revocation of permits in accordance **756** with the provisions of this subsection.

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

761 The Board shall adopt regulations governing the issuance and revocation of permits in accordance 762 with the provisions of this subsection, which shall include:

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

765 2. A list of those national accrediting organizations having quality of care standards, compliance
766 with which shall be deemed satisfactory to comply with quality of care standards adopted by the Board;
767 3. Equipment standards and standards for appropriate utilization of equipment and services;

768 *4. Requirements for monitoring compliance with quality of care standards, including data reporting*

769 and periodic inspections; and

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

771 2. That § 32.1-102.1 of the Code of Virginia is amended and reenacted and that the Code of
772 Virginia is amended by adding in Chapter 4 of Title 32.1 an article numbered 9, consisting of
773 sections numbered 32.1-122.23 and 32.1-122.24, as follows:

774 § 32.1-102.1. Definitions. 775 As used in this article, unl

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

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

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

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

783 "Medical care facility," as used in this title, means any institution, place, building or agency, whether 784 or not licensed or required to be licensed by the Board or the Department of Behavioral Health and 785 Developmental Services, whether operated for profit or nonprofit and whether privately owned or 786 privately operated or owned or operated by a local governmental unit, (i) by or in which health services 787 are furnished, conducted, operated or offered for the prevention, diagnosis or treatment of human 788 disease, pain, injury, deformity or physical condition, whether medical or surgical, of two or more 789 nonrelated persons who are injured or physically sick or have mental illness, or for the care of two or 790 more nonrelated persons requiring or receiving medical, surgical or nursing attention or services as 791 acute, chronic, convalescent, aged, physically disabled or crippled or (ii) which is the recipient of 792 reimbursements from third-party health insurance programs or prepaid medical service plans. For 793 purposes of this article, only the following medical care facilities shall be subject to review:

794 1. General hospitals.

795 2. Sanitariums.

796 3. Nursing homes.

4. 2. Intermediate care facilities, except those intermediate care facilities established for individuals

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798 with intellectual disability (ICF/MR) that have no more than 12 beds and are in an area identified as in 799 need of residential services for individuals with intellectual disability in any plan of the Department of 800 Behavioral Health and Developmental Services.

801 5. Extended care facilities.

802 6. Mental hospitals.

803 3. Rehabilitation hospitals, including in-patient rehabilitation facilities and long-term care hospitals.

804 4. Specialized centers or clinics or that portion of a hospital established for the provision of organ 805 or tissue transplant services.

806 5. Specialized centers or clinics or that portion of a hospital established for the provision of open heart surgery that performs fewer than 1,100 adult inpatient and outpatient cardiac catheterizations, at 807 808 least 400 of which are therapeutic catheterizations, or discharges fewer than 800 patients with the principal diagnosis of ischemic heart disease in a calendar year. 809

810 7. Facilities 6. General hospitals, psychiatric hospitals established primarily for the medical, psychiatric, or psychological treatment and rehabilitation of individuals with substance abuse, and any 811 812 other facility licensed as a hospital; facilities for individuals with intellectual disability; intermediate 813 care facilities established primarily for the medical, psychiatric, or psychological treatment and rehabilitation of individuals with substance abuse; and specialized centers or clinics or that portion of a 814 815 physician's office developed for the provision of outpatient or ambulatory surgery, cardiac catheterization, computed tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy, magnetic 816 817 resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy, proton beam therapy, nuclear medicine imaging, 818 except for the purpose of nuclear cardiac imaging, or such other specialty services as may be 819 designated by the Board by regulation, which is located outside of a metropolitan statistical area or in 820 821 a rural census tract within a metropolitan statistical area.

822 8. Psychiatric hospitals and intermediate care facilities established primarily for the medical, 823 psychiatric or psychological treatment and rehabilitation of individuals with substance abuse.

824 9. Specialized centers or clinics or that portion of a physician's office developed for the provision of 825 outpatient or ambulatory surgery, cardiac catheterization, computed tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging 826 827 (MSI), positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy, 828 proton beam therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac imaging, or 829 such other specialty services as may be designated by the Board by regulation. 830

10. Rehabilitation hospitals. 831

11. Any facility licensed as a hospital.

The term "medical care facility" does not include any facility of (i) the Department of Behavioral Health and Developmental Services; (ii) any nonhospital substance abuse residential treatment program 832 833 834 operated by or contracted primarily for the use of a community services board under the Department of Behavioral Health and Developmental Services' Comprehensive State Plan; (iii) an intermediate care 835 836 facility for individuals with intellectual disability (ICF/MR) that has no more than 12 beds and is in an 837 area identified as in need of residential services for individuals with intellectual disability in any plan of 838 the Department of Behavioral Health and Developmental Services; (iv) a physician's office, except that 839 portion of a physician's office described in subdivision 9 of the definition of "medical care facility"; (v) 840 the Wilson Workforce and Rehabilitation Center of the Department for Aging and Rehabilitative 841 Services; (vi) the Department of Corrections; or (vii) the Department of Veterans Services. "Medical care facility" shall also not include that portion of a physician's office dedicated to providing nuclear 842 843 cardiac imaging.

844 "Nursing home" means any facility or any identifiable component of any facility licensed pursuant to 845 Article 1 (§ 32.1-123 et seq.) of Chapter 5 in which the primary function is the provision, on a 846 continuing basis, of nursing services and health-related services for the treatment and inpatient care of two or more nonrelated individuals, including facilities known by varying nomenclature or designation 847 848 such as convalescent homes, skilled nursing facilities or skilled care facilities, intermediate care 849 facilities, extended care facilities, nursing facilities or nursing care facilities, and any other facility or 850 component thereof with medical rehabilitation beds or long-term care beds.

851 "Project" means:

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- 1. Establishment of a medical care facility:
- 2. An increase in the total number of beds or operating rooms in an existing medical care facility;

854 3. Relocation of beds from one existing facility to another, provided that "project" does not include the relocation of up to 10 beds or 10 percent of the beds, whichever is less, (i) from one existing 855 856 facility to another existing facility at the same site in any two-year period, or (ii) in any three-year period, from one existing nursing home facility to any other existing nursing home facility owned or 857 858 controlled by the same person that is located either within the same planning district, or within another 859 planning district out of which, during or prior to that three-year period, at least 10 times that number of

beds have been authorized by statute to be relocated from one or more facilities located in that other
planning district and at least half of those beds have not been replaced, provided further that, however, a
hospital shall not be required to obtain a certificate for the use of 10 percent of its beds as nursing
home beds as provided in § 32.1-132;

864 4. Introduction into an existing medical care facility of any new nursing home service, such as
865 intermediate care facility services, extended care facility services, or skilled nursing facility services,
866 medical rehabilitation beds, or long-term care beds, regardless of the type of medical care facility in
867 which those services are provided;

868 5. Introduction into an existing medical care facility of any new cardiac catheterization, computed 869 tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), 870 magnetic source imaging (MSI), medical rehabilitation, neonatal special care, obstetrical, open heart 871 surgery, positron emission tomographic (PET) scanning, psychiatric, organ or tissue transplant service, 872 radiation therapy, stereotactic radiotherapy, proton beam therapy, nuclear medicine imaging, except for 873 the purpose of nuclear cardiac imaging, substance abuse treatment, or such other specialty clinical 874 services as may be designated by the Board by regulation, which the facility has never provided or has 875 not provided in the previous 12 months;

876 6. Conversion Increase in the number of medical rehabilitation beds or long-term care beds at an
877 existing medical facility or conversion of beds in an existing medical care facility to medical
878 rehabilitation beds, long-term care hospital beds, or psychiatric beds;

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

885 8. Any capital expenditure of \$15 million or more, not defined as reviewable in subdivisions 1 886 through 7 6 of this definition, by or on behalf of a medical care facility other than a general hospital. 887 Capital expenditures of \$5 million or more by a general hospital and capital expenditures between \$5 and \$15 million by a medical care facility other than a general hospital shall be registered with the 888 889 Commissioner pursuant to regulations developed by the Board. The amounts specified in this subdivision 890 shall be revised effective July 1, 2008, and annually thereafter to reflect inflation using appropriate 891 measures incorporating construction costs and medical inflation. Nothing in this subdivision shall be 892 construed to modify or eliminate the reviewability of any project described in subdivisions 1 through 7.6893 of this definition when undertaken by or on behalf of a general hospital; or

894 9. Conversion in an existing medical care facility of psychiatric inpatient beds approved pursuant to a895 Request for Applications (RFA) to nonpsychiatric inpatient beds.

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

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

904 905

Article 9.

Permits for Medical Care Facility Projects.

906 § 32.1-122.23. Definitions.

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

908 "Medical care facility" means:

909 1. Any facility licensed as a hospital, other than a rehabilitation hospital which shall include an 910 inpatient rehabilitation facility or long-term care hospital, that is located within a metropolitan 911 statistical area but is not located within a rural census tract in a metropolitan statistical area. "Medical 912 care facility" shall not include that portion of a hospital established for the provision of organ or tissue 913 transplant services or that portion of a hospital established for the provision of open heart surgery when such portion of a hospital performs at least 1,100 adult inpatient and outpatient cardiac 914 915 catheterizations, at least 400 of which are therapeutic catheterizations, or discharges at least 800 916 patients with the principal diagnosis of ischemic heart disease in a calendar year.

917 2. The following types of facilities, when they are located in a metropolitan statistical area but not in
918 a rural census tract within a metropolitan statistical area: facilities for individuals with intellectual
919 disability, intermediate care facilities established primary for the medical, psychiatric, or psychological
920 treatment and rehabilitation of individuals with substance abuse, and specialized centers for the

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921 provision of outpatient or ambulatory surgery, cardiac catheterization, computed tomographic (CT) 922 scanning, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source 923 imaging (MSI), positron emission tomographic (PET) scanning, radiation therapy, stereotactic 924 radiotherapy, proton beam therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac 925 imaging, or such other specialty services as may be designated by the Board by regulation, which is 926 located.

927 "Project" means:

928 1. Establishment of a medical care facility;

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

930 3. Relocation of beds from one existing facility to another, provided that "project" does not include the relocation of up to 10 beds or 10 percent of the beds, whichever is less, from one existing facility to 931 932 another existing facility at the same site in any two-year period;

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

934 5. Conversion in an existing medical care facility of psychiatric inpatient beds approved pursuant to 935 a Request for Applications (RFA) to nonpsychiatric inpatient beds;

936 6. Introduction into an existing medical care facility of any new cardiac catheterization, computed 937 tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), 938 magnetic source imaging (MSI), medical rehabilitation, neonatal special care, obstetrical, open heart 939 surgery, positron emission tomographic (PET) scanning, psychiatric, organ or tissue transplant service, 940 radiation therapy, stereotactic radiotherapy, proton beam therapy, nuclear medicine imaging, except for 941 the purpose of nuclear cardiac imaging, substance abuse treatment, or such other specialty clinical 942 services as may be designated by the Board by regulation, which the facility has never provided or has 943 not provided in the previous 12 months;

944 7. The addition by an existing medical care facility of any medical equipment for the provision of 945 cardiac catheterization, computed tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery, positron 946 947 emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy, proton beam 948 therapy, or other specialized service designated by the Board by regulation. Replacement of existing 949 equipment shall not require a certificate of public need; or

950 $\hat{8}$. Any capital expenditure of \$15 million or more, not defined as reviewable in subdivisions 1 951 through 7 of this definition, by or on behalf of a medical care facility other than a general hospital. The 952 amounts specified in this subdivision shall be revised annually to reflect inflation using appropriate 953 measures incorporating construction costs and medical inflation. 954

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

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

956 B. At least 90 days prior to initiating a project for which a permit is required, a person shall file 957 with the Department an application for a permit, together with a fee determined by the Board. The 958 Commissioner shall issue the permit within 30 days of receipt of the application.

C. The Commissioner shall condition the issuance of a permit to undertake a project upon the 959 960 agreement of the applicant to (i) provide a specified level of care at a reduced rate to indigents in an 961 amount that matches the average amount of indigent care provided by holders of certificates of public 962 need in the applicant's health planning region, (ii) accept patients requiring specialized care, or (iii) 963 facilitate the development and operation of primary medical care services in designated medically 964 underserved areas of the applicant's service area.

965 The holder of a permit that is subject to conditions pursuant to this subsection shall provide such 966 documentation as may be required by the Commissioner to demonstrate compliance with the conditions 967 imposed.

968 The Commissioner shall monitor compliance with permit conditions pursuant to this subsection and 969 may impose penalties on a permit holder that fails to comply with such permit conditions. If the permit 970 holder is unable or fails to comply with the conditions imposed by the Commissioner, the Commissioner 971 may, upon request of the permit holder, approve a plan of compliance with alternate methods to satisfy 972 the permit conditions. Such alternate methods may include (a) a direct payment by the permit holder to 973 an organization authorized under a memorandum of understanding with the Department to receive 974 contributions satisfying conditions of the permit; (b) a direct payment by the permit holder to a private 975 nonprofit foundation that funds basic insurance coverage for indigents authorized under a memorandum 976 of understanding with the Department to receive contributions satisfying conditions of a permit; (c) 977 provision by the permit holder of on-call coverage at a hospital, including the emergency department of a hospital, or (d) such other methods for the provision of primary or specialized care to indigent 978 979 patients or patients requiring specialized care as may be approved by the Commissioner. Any permit 980 holder that fails or refuses to comply with the requirements of a plan of compliance entered into in 981 accordance with this subsection is subject to a civil penalty of up to \$100 per violation per day until the **982** date of compliance.

- **983** The Commissioner may, pursuant to regulations of the Board, accept requests for and approve amendments to permit conditions pursuant to this subsection upon request of the permit holder.
- **985** The Board shall adopt regulations governing the issuance and revocation of permits in accordance **986** with the provisions of this subsection.

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

- 991 The Board shall adopt regulations governing the issuance and revocation of permits in accordance
 992 with the provisions of this subsection, which shall include:
- 993 1. Quality of care standards for the specific specialty service that are consistent with nationally 994 recognized standards for such specialty service;
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 996
 996 2. A list of those national accrediting organizations having quality of care standards, compliance
 996 with which shall be deemed satisfactory to comply with quality of care standards adopted by the Board;
 997 3. Equipment standards and standards for appropriate utilization of equipment and services;
- 998 4. Requirements for monitoring compliance with quality of care standards, including data reporting
 999 and periodic inspections; and
- **1000** 5. Procedures for the issuance and revocation of permits pursuant to this subsection.
- 1001 3. That §§ 32.1-122.05 and 32.1-122.06 of the Code of Virginia are repealed.
- 1002 4. That the provisions of the second enactment of this act shall become effective on January 1, 1003 2017.
- 1004 5. That the Secretary of Health and Human Resources shall review requirements governing 1005 imposition and implementation of charity care requirements for certificates of public need,
- 1006 including provisions for defining charity care and calculating the amount and value of charity care 1007 required and provided, and shall develop recommendations for standardizing and enforcing such
- 1008 requirements. The Secretary shall report his findings to the Governor and the General Assembly
- 1009 by December 1, 2016.
- 1010 6. That the Department of Health shall work cooperatively with Virginia Health Information to 1011 develop a process for the collection of utilization data for recipients of certificates of public need 1012 describing specific types of equipment utilized.