VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 32.1-102.1:3, 32.1-102.2, 32.1-102.4, and 32.1-102.6 of the Code of Virginia, relating to relocation, conversion, and addition of beds in medical care facilities; application for certificate of public need; expedited review.

5 Approved

[S 1064]

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-102.1:3, 32.1-102.2, 32.1-102.4, and 32.1-102.6 of the Code of Virginia are amended and reenacted as follows:

§ 32.1-102.1:3. Medical care facilities and projects for which a certificate is required.

- A. The following medical care facilities shall be subject to the provisions of this article:
- 1. Any facility licensed as a hospital, as defined in § 32.1-123;
- 2. Any hospital licensed as a provider by the Department of Behavioral Health and Developmental Services in accordance with Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2;
 - 3. Any facility licensed as a nursing home, as defined in § 32.1-123;
- 4. Any intermediate care facility established primarily for the medical, psychiatric, or psychological treatment and rehabilitation of individuals with substance abuse licensed by the Department of Behavioral Health and Developmental Services in accordance with Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2:
- 5. Any intermediate care facility for individuals with developmental disabilities other than an intermediate care facility established for individuals with intellectual disability (ICF/IID) that has not more than 12 beds and is in an area identified as in need of residential services for individuals with intellectual disability in any plan of the Department of Behavioral Health and Developmental Services; and
- 6. Any specialized center or clinic or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery, cardiac catheterization, computed tomographic (CT) scanning, magnetic resonance imaging (MRI), positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation therapy, or proton beam therapy.
- B. The following actions undertaken by or on behalf of a medical care facility described in subsection A shall constitute a project for which a certificate of public need is required pursuant to subsection A of § 32.1-102.1:2:
 - 1. Establishment of a medical care facility described in subsection A:
- 2. An increase in the total number of beds or operating rooms in an existing medical care facility described in subsection A:
- 3. Relocation of beds from an existing medical care facility described in subsection A to another existing medical care facility described in subsection A;
- 4. Addition of any new nursing home service at an existing medical care facility described in subsection A;
- 5. Introduction into an existing medical care facility described in subsection A of any cardiac catheterization, computed tomographic (CT) scanning, magnetic resonance imaging (MRI), medical rehabilitation, neonatal special care, open heart surgery, positron emission tomographic (PET) scanning, psychiatric, organ or tissue transplant service, radiation therapy, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation therapy, proton beam therapy, or substance abuse treatment when such medical care facility has not provided such service in the previous 12 months;
- 6. Conversion of beds in an existing medical care facility described in subsection A to medical rehabilitation beds or psychiatric beds;
- 7. The addition by an existing medical care facility described in subsection A of any new medical equipment for the provision of cardiac catheterization, computed tomographic (CT) scanning, magnetic resonance imaging (MRI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation therapy, or proton beam therapy, other than new medical equipment for the provision of such service added to replace existing medical equipment for the provision of such service;
 - 8. Any capital expenditure of \$15 million or more, not defined as reviewable in subdivisions 1 through 7,

by or on behalf of a medical care facility described in subsection A other than a general hospital. The amounts specified in this subdivision shall be revised annually to reflect inflation using appropriate measures incorporating construction costs and medical inflation. Nothing in this subdivision shall be construed to modify or eliminate the reviewability of any project described in subdivisions 1 through 7 when undertaken by or on behalf of a general hospital; and

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

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

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

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

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

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

- 1. The current and projected future availability of the specific type of medical care facility or project;
- 2. The current and projected future demand for the specific type of medical care facility or project;
- 3. The current and projected future rate of utilization of the specific type of medical care facility or project;
- 4. The current and projected future capacity of existing medical care facilities or projects of that specific type;
- 5. The anticipated impact of changes in population and demographics, reimbursement structures and rates, and technology on demand for and availability, utilization, and capacity of existing medical care facilities or projects of that specific type;
- 6. Existing quality, utilization, and other controls applicable to the specific type of medical care facility or project; and
- 7. Any risk to the health or well-being of the public resulting from inclusion of the specific type of medical care facility or project on such list.

§ 32.1-102.2. Regulations.

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

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

computed tomographic (CT) scanning, magnetic resonance imaging (MRI), and positron emission tomographic (PET) scanning;

- 2. May classify projects and may eliminate one or more or all of the procedures prescribed in § 32.1-102.6 for different classifications;
- 3. May provide for exempting from the requirement of a certificate projects determined by the Commissioner, upon application for exemption, to be subject to the economic forces of a competitive market or to have no discernible impact on the cost or quality of health services;
- 4. May establish a schedule of fees for applications for certificates or registration of a project to be applied to expenses for the administration and operation of the Certificate of Public Need Program;
- 5. Shall establish an expedited application and review process for any certificate for projects reviewable pursuant to (i) subdivision B & B I of § 32.1-102.1:3 for the establishment of a new medical care facility described in subdivision A 2 of § 32.1-102.1:3 by an existing medical care facility described in subdivision A 1 or 2 of § 32.1-102.1:3 that has an existing certificate to provide psychiatric services pursuant to subdivision B 6 of § 32.1-102.1:3, provided such new medical care facility is located in the same planning district as the existing medical care facility; (ii) subdivision B 2 of § 32.1-102.1:3 for the addition of psychiatric beds at an existing medical care facility described in subdivision A 1 or 2 of § 32.1-102.1:3 that has an existing certificate to provide psychiatric services pursuant to subdivision B 5 of § 32.1-102.1:3, not to exceed 10 beds or 10 percent of all beds at the medical care facility, whichever is greater, and provided that the applicant has not been awarded a certificate for the addition of psychiatric beds pursuant to this provision in the previous two-year period; (iii) subdivision B 3 of § 32.1-102.1:3 for the relocation of psychiatric beds to an existing medical care facility described in subdivision A 1 or 2 of § 32.1-102.1:3 that has had an existing certificate to introduce a psychiatric service for at least the previous 12 months pursuant to subdivision B 5 of § 32.1-102.1:3 and that is within the same planning district; (iv) and subdivision B 8 of § 32.1-102.1:3. Regulations establishing the expedited application and review procedure shall include provisions for (a) notice and opportunity for public comment on the application for a certificate, (b) a review cycle that is complete within 90 days, (c) the filing of an expedited application in four batch cycles specifically for expedited applications, (d) the ability of a member of the public to request a public hearing for the expedited application, and (e) criteria pursuant to which an application that would normally undergo the review process would instead undergo the full certificate of public need review process set forth in § 32.1-102.6;
- 6. Shall establish an exemption from the requirement for a certificate for a project involving a temporary increase in the total number of beds in an existing hospital or nursing home, including a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the hospital or nursing home, provided that the ability remains to safely staff services across the existing hospital or nursing home, (i) for a period of no more than the duration of the Commissioner's determination plus 30 days when the Commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds or (ii) for a period of no more than the duration of the emergency order entered pursuant to § 32.1-13 or 32.1-20 plus 30 days when the Board, pursuant to § 32.1-13, or the Commissioner, pursuant to § 32.1-20, has entered an emergency order for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health; and

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

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

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

reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

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

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

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

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

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

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

B. The Commissioner shall, pursuant to the regulations of the Board, condition the approval of a certificate upon the agreement of the applicant to provide care to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. In addition, the Commissioner shall condition the approval of a certificate upon the agreement of the applicant to (i) provide a specified level of charity care to indigent persons or accept patients requiring specialized care, (ii) facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area, or (iii) all of the above. Except in the case of nursing homes, the value of charity care provided to individuals pursuant to this subsection shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

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

The certificate holder shall annually provide documentation to the Department demonstrating that the certificate holder has satisfied the conditions of the certificate, including documentation of the amount of charity care provided to patients. If the certificate holder is unable or fails to satisfy the conditions of a certificate, the Department may approve alternative methods to satisfy the conditions pursuant to a plan of compliance, which shall identify a timeframe within which the certificate holder will satisfy the conditions of the certificate, and identify how the certificate holder will satisfy the conditions of the certificate, which may include (a) making direct payments to an organization authorized under a memorandum of understanding with the Department to receive contributions satisfying conditions of a certificate, (b) making direct payments

to a private nonprofit 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 (c) other documented efforts or initiatives to provide primary or specialized care to underserved populations. In cases in which the certificate holder holds more than one certificate with conditions pursuant to this subsection, and the certificate holder is unable to satisfy the conditions of one certificate, such plan of compliance may provide for satisfaction of the conditions on that certificate by providing care at a reduced rate to indigent individuals in excess of the amount required by another certificate issued to the same holder, in an amount approved by the Department provided such care is offered at the same facility. Nothing in the preceding sentence shall prohibit the satisfaction of conditions of more than one certificate among various affiliated facilities or certificates subject to a system-wide or all-inclusive charity care condition established by the Commissioner. In determining whether the certificate holder has met the conditions of the certificate pursuant to a plan of compliance, only such actions undertaken after issuance of the conditioned certificate shall be counted towards satisfaction of conditions.

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

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

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

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

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

§ 32.1-102.6. Administrative procedures.

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

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

At least 30 calendar days before any person is contractually obligated to acquire an existing medical care facility, the cost of which is \$600,000 or more, that person shall notify the Commissioner and the appropriate regional health planning agency, if a regional health planning agency has been designated, of the intent, the services to be offered in the facility, the bed capacity in the facility and the projected impact that the cost of

the acquisition will have upon the charges for services to be provided. If clinical services or beds are proposed to be added as a result of the acquisition, the Commissioner may require the proposed new owner to obtain a certificate prior to the acquisition. If no regional health planning agency is designated for the health planning region in which the acquisition will take place, no notification to a regional health planning agency shall be required.

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

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

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

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

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

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

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

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

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

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

- E. Upon entry of each completed application or applications into the appropriate batch review cycle:
- 1. The Department shall establish, for every application, a date between the eightieth and ninetieth calendar days within the 190-calendar-day review period for holding an informal fact-finding conference, if such conference is necessary.
- 2. The Department shall review every application at or before the seventy-fifth calendar day within the 190-calendar-day review period to determine whether an informal fact-finding conference is necessary.
- 3. Any person seeking to be made a party to the case for good cause, no later than four days after the Department has completed its review and submitted its recommendation on an application and has transmitted the same to the applicants and to persons who have, prior to the issuance of the report, requested a copy in writing, shall notify the Commissioner, all applicants, and the regional health planning agency, in writing and under oath, stating the grounds for good 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 the closing of the record which shall not be more than 30 calendar days after the date for holding the informal fact-finding conference.
- 5. In any case in which an informal fact-finding conference is not held, the record shall be closed on the earlier of (i) the date established for holding the informal fact-finding conference or (ii) the date that the Department determines an informal fact-finding conference is not necessary.
- 6. The provisions of subsection C of § 2.2-4021 notwithstanding, 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, the Commissioner shall notify the applicant or applicants and any persons seeking to show good cause, in writing, that the application or the application of each shall be deemed approved 25 calendar days after 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.
- 7. In any case when a determination whether a public need exists for a project is not made by the Commissioner within 70 calendar days after the closing of the record, the application shall be deemed to 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.
- F. Deemed approvals shall be construed as the Commissioner's case decision on the application pursuant to the Administrative Process Act (§ 2.2-4000 et seq.) and shall be subject to judicial review on 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.

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

appeal. **429** G. H

- G. For purposes of this section, "good cause" means that (i) there is significant relevant information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing, or (iii) there is a substantial material mistake of fact or law in the Department staff's report on the application or in the report submitted by the health planning agency.
- H. The project review procedures shall provide for separation of the project review manager functions from the hearing officer functions. No person serving in the role of project review manager shall serve as a hearing officer.
- I. The applicants, and only the applicants, shall have the authority to extend any of the time periods specified in this section. If all applicants consent to extending any time period in this section, the Commissioner, with the concurrence of the applicants, shall establish a new schedule for the remaining time periods.
- J. This section shall not apply to applications for certificates for projects defined in subdivision A 8 of § 32.1-102.1:3 that meet the criteria for the expedited application and review process established in subdivision A 5 of § 32.1-102.2. Such projects shall be subject to an expedited application and review process developed by the Board in regulation pursuant to subdivisions Subdivisions A 2 and 5 of § 32.1-102.2.