Explanation of Specific Proposed Changes and Their Impact

New language is in red and underlined, language to be deleted is red with strikethrough. Explanation and comments is in blue.

§ 32.1-102.1. Definitions

"*Medical care facility*," as used in this title, means…

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

These changes to the definition of "Medical Care Facility" support the deregulation of lithotripsy and nuclear medicine imaging from COPN. Gamma knife is a trademarked term for a particular manufacturer of a device that performs cranial stereotactic radiosurgery. Changing the term here and throughout the Code removes the use of a trademarked name and inserts the term used to describe the clinical procedure that was regulated.

§ 32.1-102.1. Definitions

"*Project*" means:

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;

~~3. Relocation at the same site of 10 beds or 10 percent of the beds, whichever is less, from one existing physical facility to another in any two-year period; 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;~~

There appears to be little, if any, public benefit to regulating the movement of beds within a facility but between buildings on a campus. If to move the beds would result in a capital expenditure meeting the threshold requiring review, then a certificate of public need (COPN) would be required, but this is addressed later in the definition of "Project".

In the last three years there have been no requests for projects meeting this definition of "Project".

§ 32.1-102.1. Definitions

"*Project*" means:

5. Introduction into an existing medical care facility of any new cardiac catheterization, computed tomographic (CT) scanning, ~~gamma knife surgery~~stereotactic radiosurgery, ~~lithotripsy~~, magnetic resonance imaging (MRI), magnetic source imaging (MSI), medical rehabilitation, neonatal special care, obstetrical, open heart surgery, positron emission tomographic (PET) scanning, psychiatric, organ or tissue transplant

service, radiation therapy, ~~nuclear medicine imaging, except for the purpose of nuclear cardiac imaging,~~ substance abuse treatment, or such other specialty clinical services as may be designated by the Board by regulation, which the facility has never provided or has not provided in the previous 12 months;

The technology of lithotripsy has changed dramatically since first regulated under COPN. The equipment has evolved from large apparatuses that required large rooms to accommodate full body immersion tubs to small, portable units. Lithotripsy, or external shock wave lithotripsy (ESWL) has expanded beyond use to smash renal, or kidney, stones to the treatment of orthopedic issues such as chronic plantar fasciitis and chronic lateral epicondylitis. It also is being tested for calcific tendonitis, shoulder calcifications, stress fractures and delayed union and nonunion, as well as other musculoskeletal problems. The FDA, to date, has not approved any lithotripsy device for treatment of these conditions. The use of lithotripsy to treat biliary, or gall, stones has not gained much clinical favor, at least not in Virginia. In past three years there have been nine requests for lithotripsy services, all were approved at a total capital authorization of $89,000. There seems to be little or no public good to be gained by regulating the supply of lithotripsy capacity. Deregulation of lithotripsy from COPN was recommended in the 2005 Annual Report On The Status Of Virginia's Medical Care Facilities Certificate Of Public Need Program.

Nuclear medicine imaging has already been partially de-regulated such that use of the technology for one of its primary indications no longer requires a COPN. Nuclear medicine imaging has become a basic element in any hospital's clinical inventory and no longer represents a significant capital expenditure. In past three years there have been three requests for non-cardiac nuclear medicine imaging. Two of the requests were part of requests for new hospitals. One of the hospitals was authorized and therefore so was the non-cardiac nuclear medicine imaging and one of the hospitals was denied and therefore so was the non-cardiac nuclear medicine imaging. The third request, the only on received in the last three years purely for the service, was authorized for a capital expenditure of $6,540. Deregulation of nuclear medicine imaging from COPN was recommended in the 2003 Annual Report On The Status Of Virginia's Medical Care Facilities Certificate Of Public Need Program.

The change also supports the removal of the trademarked term gamma knife and substitutes the term used to describe the clinical procedure that was regulated.

§ 32.1-102.1. Definitions

"*Project*" means:

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

This change to the Code would complete the deregulation of lithotripsy from COPN. The change also supports the removal of the trademarked term gamma knife and substitutes the term used to describe the clinical procedure that was regulated.

§ 32.1-102.1. Definitions

"*Project*" means:

8. Any capital expenditure of $15 million or more, not defined as reviewable in subdivisions 1 through 7 of this definition, by or in behalf of a medical care facility. However, capital expenditures between ~~$1~~ $5 and $15 million not defined as reviewable in subdivisions 1 through 7 of this definition, by or in behalf of a medical care facility shall be registered with the Commissioner pursuant to regulations developed by the Board.

It has been 10 years since the threshold for defining a capital expenditure needing COPN authorization (when not otherwise defined as a project) was increased from $1 million to $5 million. Inflation, especially in the medical environment, has resulted in little value in reviewing a miscellaneous capital project of $5 million. In the last 3 years 7 requests ($70,677,513) were received and approved for projects with estimated capital costs between $5 million and $15 million ($6,544,500 - $14,213,796). No requests for miscellaneous capital expenditures within this cost range were denied. These projects were generally physical plant renovations, infrastructure upgrades and minor expansions. During the same period 13 miscellaneous capital expenditure projects ranging from $17 million to $242 million were reviewed and approved. No requests for miscellaneous capital expenditures within this cost range were denied. These projects were generally major new construction, including parking structures, major information system replacements, major physical plant renovations, and infrastructure upgrades.

In the last five years the average capital expenditure per request was just under $47 million and none were denied. The lack of denied requests should not detract from the usefulness of requiring COPN review of this type of request. The COPN process requires a close review by both internal and external parties. Such a review can only lead to well thought out requests and the abandonment of less feasible projects. The lack of progress, either by withdrawal or allowing the request to expire, on 14% of all requests in this category in the last five years illustrates the success of this planning aspect of review.

§ 32.1-102.1. Definitions

~~"*Virginia Health Planning Board*" means the statewide health planning body established pursuant to § 32.1-122.02 which serves as the analytical and technical resource to the Secretary of Health and Human Resources in matters requiring health analysis and planning.~~

The Code of Virginia section establishing the Virginia Health Planning Board was repealed by Acts 2002, c. 83. Removing the term from this section is simply housekeeping.

§ 32.1-102.1:1. Equipment registration required.

Within thirty calendar days of becoming contractually obligated to acquire any replacement medical equipment for the provision of cardiac catheterization, computed tomographic (CT)

scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, or other specialized service designated by the Board by regulation, any person shall register such purchase with the Commissioner and the appropriate health planning agency.

Adding "replacement" makes it clear that registration of equipment is only required when equipment is replaced. Otherwise it appears that registration is required within thirty calendar days of becoming contractually obligated to acquire equipment, including that equipment already authorized with a COPN.

§ 32.1-102.2. Regulations. - A. The Board shall promulgate regulations which 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~~ or nuclear imaging and radiation therapy shall be considered in the radiation therapy batch. A single application may be filed for a combination of (i) radiation therapy and (ii) any or all of the computed tomographic (CT) scanning, magnetic resonance imaging (MRI), positron emission tomographic (PET) scanning, and nuclear medicine imaging;

Placing "radiation therapy" after "and" clarifies that the diagnostic imaging modalities listed may be reviewed in the radiation therapy batch only when combined with a request for radiation therapy. The original intent of this language was to allow the concurrent review of all the elements to make a comprehensive cancer care center, which included the diagnostic imaging and radiation therapy equipment. Prior to inclusion of the language beginning "In any structured batching process…" an applicant seeking to provide comprehensive cancer care at a single facility was required to apply for a COPN for the imaging equipment in the diagnostic imaging batch and the radiation therapy equipment in the radiation therapy batch, which may have been separated by as much as much as four months.

§ 32.1-102.3:2. Certificates of public need; applications ~~for increases in nursing home bed supplies~~ to be filed in response to Requests For Applications (RFAs). - A. Except for applications for continuing care retirement community nursing home bed projects filed by continuing care providers registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 which comply with the requirements established in this section, the Commissioner of Health shall only approve, authorize or accept applications for the issuance of any certificate of public need pursuant to this article for any project which would result in an increase in the number of beds in which nursing facility or extended care services are provided in a planning district ~~in which nursing facility or extended care services are provided,~~ establish a new radiation therapy service and/or stereotactic radiosurgery service or increase the number of radiation therapy or stereotactic radiosurgery machines at an existing medical care facility, establish a new neonatal special care service, establish a new obstetrical service, establish a new medical rehabilitation service, establish a new psychiatric service or increase the

number of psychiatric care beds or establish a new long term-acute care hospital when such applications are filed in response to Requests For Applications (RFAs).

B. The Board of Health shall adopt regulations establishing standards for the approval and issuance of Requests for Applications by the Commissioner of Health. The standards shall include, but shall not be limited to, a requirement that determinations of need take into account any limitations on access to existing ~~nursing home beds~~services in the planning districts. The RFAs, which shall be published at least annually, shall be jointly developed by the Department of Health and the Department of Medical Assistance Services and based on analyses of the need, or lack thereof, for increases in the ~~nursing home bed~~relevant service supply in each of the Commonwealth's planning districts in accordance with standards adopted by the Board of Health by regulation. The Commissioner shall only accept for review applications in response to such RFAs which conform with the geographic and ~~bed~~ need determinations of the specific RFA.

C. Sixty days prior to the Commissioner's approval and issuance of any Request For Applications, the Board of Health shall publish the proposed RFA in the Virginia Register for public comment together with an explanation of (i) the regulatory basis for the planning district ~~bed~~ needs set forth in the RFA and (ii) the rationale for the RFA's planning district designations. Any person objecting to the contents of the proposed RFA may notify, within fourteen days of the publication, the Board and the Commissioner of his objection and the objection's regulatory basis. The Commissioner shall prepare, and deliver by registered mail, a written response to each such objection within two weeks of the date of receiving the objection. The objector may file a rebuttal to the Commissioner's response in writing within five days of receiving the Commissioner's response. If objections are received, the Board may, after considering the provisions of the RFA, any objections, the Commissioner's responses, and if filed, any written rebuttals of the Commissioner's responses, hold a public hearing to receive comments on the specific RFA. Prior to making a decision on the Request for Applications, the Commissioner shall consider any recommendations made by the Board.

Use a Request for Applications (RFA) process to proactively conduct a statewide assessment and establish the existence of a public need for a service in advance and solicit applications for COPN authorization to fulfill that identified need has been used successfully to manage the inventory of nursing home beds for some years now. The changes to this section of the Code would expand the services subject to the RFA process to include radiation therapy, stereotactic radiosurgery, neonatal special care, medical rehabilitation and long term acute care hospitals in addition to nursing homes. Applications for the services subject to the RFA process would only be accepted in response to an RFA. Adoption of the RFA process for these services was recommended in the 2004 and 2005 Annual Report On The Status Of Virginia's Medical Care Facilities Certificate Of Public Need Program.

In past three years there have been; 15 radiation therapy requests approved ($82,577,676) and 10 denied ($57,772,318), 3 gamma knife/stereotactic radiosurgery requests approved ($149,764,976) and 4 denied ($21,156,316), 2 neonatal special care requests approved, one as part of an entire facility request, one to introduce the service at an existing hospital ($996,000), both were approved, 6 medical rehabilitation service requests approved ($10,533,167) and 1

denied ($13,064,757), and 3 long term acute care hospitals approved ($19,425,034) and 2 denied ($1,415,706).

Virginia does not have a problem with limiting the over supply of obstetric services but rather with assuring the availability of the service. Since 2001 seven Virginia hospitals have closed their obstetric programs. Each of the closed programs had delivered less than 255 babies in their last year of operation and each closed program was located at a hospital in an area designated as rural. Since 2000 there have been four COPN requests for new or expanded obstetric services. Two of the requests were to include obstetrics in relocated replacement hospitals, one was to add obstetric beds to an existing service, and one was to re-introduce obstetric services at a hospital that had previously had to discontinue the service. All four requests were approved.

Use of the RFA process would be expected to reduce the number of speculative COPN requests, since applications would only be accepted in response to a process that predetermined that a public need exists for the service. Use of the RFA process may attract applicants to areas of the State with an identified need since the potential applicants would know that a State determination of need had already been made and therefore the likelihood of successfully obtaining a COPN is increased.

§ 32.1-102.4. Conditions of certificates; monitoring; revocation of certificates. **- A.** A certificate shall be issued with a schedule for the completion of the project and a maximum capital expenditure amount for the project. The 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.

1. All facilities, whether licensed or not and whether or not required to be licensed, holding, or seeking, certificate of public need authorization for one or more projects will report their patient volume, gross patient revenue, net patient revenue and charity care for all certificate of public need regulated services annually to Virginia Health Information.
2. Failure of a facility holding a certificate of public need to provide the report required by this section will;
    a. render the facility, the facility's parent organization and the facility's owners ineligible to apply for additional certificates of public need until such time as all reporting is current to the later of the start of the service or January 1, 2007
    b. cause capacity at non-reporting services to not be counted in the calculations to determine need.

In order to fairly access a reasonable and equitable level of performance for indigent care conditions placed on COPNs the amount of indigent care being provided must be known. Currently the conditioned level is selected based on the average provided by all *hospitals* in the health planning region. No consideration is given to the charity care provided to the indigent by non-hospital providers. This is because non-hospital providers are not required to report their financial data, including charity care. Without their data they cannot be included in the calculation to determine a reasonable level for the condition.

A determination that additional resources are needed in a planning district or health planning region is based in part on how well utilized existing resources are as compared to the standard established in the State Medical Facilities Plan. Utilization data are reported by hospitals and nursing homes, the licensed providers, to Virginia Health Information. No such reports are required of non-licensed providers; the freestanding diagnostic imaging facilities, the cancer care centers, the physician's offices with COPN regulated services. As such, decisions are made with at best a partial view of the utilization, and therefore the need for, resources.

This change to the Code provides the data needed for the Commissioner to make decisions based on a complete picture, to assign conditions in the most fair and equitable manner, and to provide consequences for failure to comply.

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

F. The Commissioner may condition, pursuant to the regulations of the Board, the approval of a certificate (i) upon the agreement of the applicant to provide a level of care at a reduced rate to indigents or accept patients requiring specialized care or (ii) upon the agreement of the applicant to facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area.

Any person willfully 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. Failure to report compliance with any condition of a certificate of public need by the established deadline shall be grounds for denial of additional certificate of public need requests until full compliance is demonstrated and reported.

The current formal consequences of failure to report or failure to meet conditions include the $100 fine per day per violation. At most that is $36,500 per year per conditioned COPN, significantly less than the six and seven figure sums required to be provided as free care to indigents. The fines would not contribute to care for the indigent, thereby missing an opportunity on behalf of the indigent, and, establishing that any such failure to meet the condition is willful is extremely difficult such that to the best of my knowledge this provision has never been used.

The Code also states at § 32.1-102.2. Regulations, C., in relevant part;

> "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 care at a reduced rate to indigents or accept patients requiring specialized care."

This provision only has meaning for licensed facilities. Non-licensed providers such as freestanding diagnostic imaging facilities, cancer care centers, and physician's offices with COPN regulated services have no threat to their ability to operate if they fail to report or comply with a condition placed on a COPN. Compliance with reporting is currently less than 60%.

This change to the Code would provide additional incentive, applicable to all providers, for compliance with conditions.

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

This allows the electronic transmission of the application. The guidance document currently in development will allow the electronic transmission (email or CD) of all other documents related to a COPN request. This also allows for the ultimate development and adoption of an online web-based application process.

§ 32.1-102.6. Administrative procedures. - A

Within 10 calendar days of the date on which the document is received, the Department and the appropriate health planning agency shall determine whether the application is complete or not and the Department shall notify the applicant, if the application is complete, that the application has been accepted for review and if the application is not complete, of the information needed to complete the application, that the application will not be accepted for the current review cycle and the dates of the next available review cycle.

The Code at § 32.1-102.6. Administrative procedures, B., establishes that a cycle for the review of a COPN request is 190 days. There is, however, a 70-day period prior to the start of the review cycle for the submission of the letter of intent, the application and the review of the application for completeness. At the first meeting of the HWI Task Force this 70-day period was referred to as the Pre-application Phase. The result is effectively that the real time for a review is 260 days (approximately 8¾ months).

This change, with the appropriate adjustment to the Regulations, viewed in the context of the rest of the pre-application phase that would remain intact, establishes that applicants are to submit a complete application on or before the application deadline. Currently the submissions received on the deadline for applications are often incomplete and occasionally are barely shells of a completed form. By requiring that the initial submission be complete the opportunity for completeness review and follow-up submissions is removed and the pre-application phase is shortened from 70 days to 35 days, such that the over all process is shortened from 270 days to 235 days (7¾ months). Other states, including North Carolina, utilize this "complete upon submission" approach.

§ 32.1-102.6. Administrative procedures. - B

The health planning agency shall submit its recommendations on each application and its reasons therefor to the Department within ~~10~~ 5 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 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~~ 5 calendar days after the completion of its review, the Department shall, on the ~~eleventh~~ sixth calendar day after the expiration of the health planning agency's review period, proceed as though the health planning agency has recommended project approval without conditions or revision.

As written the Regional Health Planning Agency does not need to send their recommendation to the Department until the day the DCOPN staff report and recommendation is due. This housekeeping change allows the DCOPN five days to review and address, or incorporate, the Regional Health Planning Agency's recommendation into it's own analysis, as required by consideration number 1, B. - "In determining whether a public need for a project has been demonstrated, the Commissioner shall consider:

1. The recommendation and the reasons therefor of the appropriate health planning agency."

§ 32.1-102.6. Administrative procedures. - D

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

Additional change necessary to require an application to be complete upon submission, cutting 35 days from the pre-application phase.

§ 32.1-102.6. Administrative procedures.

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. Once scheduled by the department the informal fact-finding conference will be held on the scheduled date unless changed by the presiding Adjudication Officer in response to special, unavoidable circumstances and with the concurrence of all parties.

Frequently delays in reaching a final decision for a request that is to be heard before an informal fact-finding conference occur, at least in part, because the applicant delays the date of the informal fact-finding conference, which delays all other subsequent deadlines. The conference is scheduled with the date communicated to the applicant and all other parties to the review at the time the request is accepted for review, 80 – 90 days prior to the date for the conference. Frequently, it appears that an applicant makes no effort to plan their calendar to accommodate the scheduled conference. This results in a flurry of activity to find, on short notice, another date suitable to all parties, extending the review by weeks or even months. Keeping to the scheduled conference date will speed the review process.

§ 32.1-102.6. Administrative procedures. E.

3. Any person seeking to be made a party to the case for good cause at a necessary informal fact-finding conference shall notify the Department of his request and the basis therefor

on or before the eightieth calendar day following the day which begins the appropriate batch review cycle.

Paragraph 2 of this section establishes a deadline for a determination of a need for an informal fact-finding conference. Paragraph 3 sets a date for parties seeking good cause for a conference to submit their petition that is later than the date required to determine if a conference is necessary. This housekeeping change makes it clear that the eightieth day deadline for good cause submissions only applies if it was determined that the conference was necessary.

§ 32.1-102.6. Administrative procedures. E.

4. In any case in which an informal fact-finding conference is held, the informal fact-finding conference shall not be a de novo review of the request and shall be based on the material in the record on the 60th day of the review cycle, any material submitted prior to the informal fact-finding conference by a party with good cause and any informal fact-finding conference testimony made regarding the material in the record. Following the 60th day of the review cycle only the analysis and recommendation of the Regional Health Planning Agency, the analysis and recommendation of the Division of Certificate of Public Need, the transcript of the informal fact finding conference, the analysis and recommendation of the adjudication officer and the Commissioner's decision may be added to the record. The date for the close of the record shall not be more than 45 days after the date the informal fact-finding conference is concluded. ~~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.~~

Informal fact-finding conferences generally result in the addition of twice as much material to the record than was available to the Regional Health Planning Agency and the DCOPN for their review. This holdback of information by the applicant hampers the ability of the reviewing agencies to conduct a fair and complete assessment of the request. Potentially, requests have been reviewed at an informal fact-finding conference that would not have had to go that far had the supplemental information been available to the reviewing agencies for analysis.

This leads to informal fact-finding conferences often being new reviews, from scratch, increasing the burden on the adjudication officer. This change makes the adjudication officer's review based on the same material available to the other reviewing agencies. This would most likely result in applicant's providing full disclosure to the reviewing agencies and not holding information back for the informal fact-finding conference.

Informal fact-finding conferences typically include a 30-day period after the conference for the submission of additional material, proposed findings, and rebuttals. There then remains 45-days for the adjudication officer to complete his analysis and for the Commissioner to make his decision. Ending the submission of additional material to the record, except to specific documents, with the date of the Regional Health Planning Agency's review negates the need for the 30-day post conference filing period, shortening the review time by another 30 days. If the shortening of the pre-application phase is also accepted, combined the total review time is shortened from 260 days to 205 days (8⅔ months to 6¾ months).

§ 32.1-102.6. Administrative procedures. E.

5. In any case in which an informal fact-finding conference is not held, the record shall be closed for additional information 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, only the Commissioner's decision may be added to the record.

Additional language changes needed to support the proposed change to the close of the record and reduction in supplemental material.

§ 32.1-102.10. Commencing project without certificate grounds for refusing to issue license. Commencing any project without a certificate required by this article shall constitute grounds for refusing to issue a certificate or a license for such project.

Only a fraction of projects involve a licensed facility. This change expands the available penalty for commencing a project without a certificate and establishes a penalty that will reach all potential applicants.

Code of Virginia
With Specific Proposed Changes to Improve and Shorten the Certificate of Public Need Review Process
New language is in red and underlined, language to be deleted is red with strikethrough.

§ 32.1-102.1. Definitions. - 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.

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

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

1. General hospitals.
2. Sanitariums.
3. Nursing homes.
4. Intermediate care facilities, except those intermediate care facilities established for the mentally retarded that have no more than 12 beds and are in an area identified as in need of residential services for people with mental retardation in any plan of the Department of Mental Health, Mental Retardation and Substance Abuse Services.
5. Extended care facilities.
6. Mental hospitals.
7. Mental retardation facilities.
8. Psychiatric hospitals and intermediate care facilities established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts.
9. Specialized centers or clinics or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery, cardiac catheterization, computed tomographic (CT) scanning, ~~gamma knife surgery~~stereotactic radiosurgery, ~~lithotripsy,~~ magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, radiation therapy, ~~nuclear medicine imaging, except for the~~

~~purpose of nuclear cardiac imaging~~, or such other specialty services as may be designated by the Board by regulation.

10. Rehabilitation hospitals.

11. Any facility licensed as a hospital.

The term "medical care facility" shall not include any facility of (i) the Department of Mental Health, Mental Retardation and Substance Abuse Services; (ii) any nonhospital substance abuse residential treatment program operated by or contracted primarily for the use of a community services board under the Department of Mental Health, Mental Retardation and Substance Abuse Services' Comprehensive Plan; (iii) an intermediate care facility for the mentally retarded that has no more than 12 beds and is in an area identified as in need of residential services for people with mental retardation in any plan of the Department of Mental Health, Mental Retardation and Substance Abuse Services; (iv) a physician's office, except that portion of a physician's office described above in subdivision 9 of the definition of "medical care facility"; or (v) the Woodrow Wilson Rehabilitation Center of the Department of Rehabilitative Services. "Medical care facility" shall also not include that portion of a physician's office dedicated to providing nuclear cardiac imaging.

"*Project*" means:

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;

~~3. Relocation at the same site of 10 beds or 10 percent of the beds, whichever is less, from one existing physical facility to another in any two-year period; 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;~~

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;

5. Introduction into an existing medical care facility of any new cardiac catheterization, computed tomographic (CT) scanning, ~~gamma knife surgery~~stereotactic radiosurgery, ~~lithotripsy~~, magnetic resonance imaging (MRI), magnetic source imaging (MSI), medical rehabilitation, neonatal special care, obstetrical, open heart surgery, positron emission tomographic (PET) scanning, psychiatric, organ or tissue transplant service, radiation therapy, ~~nuclear medicine imaging, except for the purpose of nuclear cardiac imaging,~~ substance abuse treatment, or such other specialty clinical services as may be designated by the Board by regulation, which the facility has never provided or has 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, ~~gamma knife surgery~~stereotactic radiosurgery, ~~lithotripsy,~~ magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, or other specialized service designated by the Board by regulation. Replacement of existing equipment shall not require a certificate of public need; or

8. Any capital expenditure of $15 million or more, not defined as reviewable in subdivisions 1 through 7 of this definition, by or in behalf of a medical care facility. However, capital expenditures between $~~1~~ 5 and $15 million not defined as reviewable in subdivisions 1 through 7 of this definition, by or in behalf of a medical care facility shall be registered with the Commissioner pursuant to regulations developed by the Board.

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

"*State Medical Facilities Plan*" means the planning document adopted by the Board of Health which 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 (iii) procedures, criteria and standards for review of applications for projects for medical care facilities and services.

~~"*Virginia Health Planning Board*" means the statewide health planning body established pursuant to § 32.1-122.02 which serves as the analytical and technical resource to the Secretary of Health and Human Resources in matters requiring health analysis and planning.~~

§ 32.1-102.1:1. Equipment registration required.

Within thirty calendar days of becoming contractually obligated to acquire any replacement medical equipment for the provision of cardiac catheterization, computed tomographic (CT) scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, or other specialized service designated by the Board by regulation, any person shall register such purchase with the Commissioner and the appropriate health planning agency.

§ 32.1-102.2. Regulations. - A. The Board shall promulgate regulations which 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~~ or nuclear imaging and radiation therapy shall be considered in the radiation therapy batch. A single application may be filed for a combination of (i) radiation therapy and (ii) any or all of the computed tomographic (CT) scanning, magnetic resonance imaging (MRI), positron 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 § 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. Shall establish specific criteria for determining need in rural areas, giving due consideration to distinct and unique geographic, socioeconomic, cultural, transportation, and

other barriers to access to care in such areas and providing for weighted calculations of need based on the barriers to health care access in such rural areas in lieu of the determinations of need used for the particular proposed project within the relevant health systems area as a whole; and

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

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.

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 care at a reduced rate to indigents or accept patients requiring specialized care. 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 care at a reduced rate to indigents or accept patients requiring specialized care.

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

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 for the project has been demonstrated. If it is determined that a public need exists for only a portion of a project, a certificate may be issued for that portion and any appeal may be limited to the part of the decision with which the appellant disagrees without affecting the remainder of the decision. Any 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 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 finding, may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to such plan.

B. In determining whether a public need for a project has been demonstrated, the Commissioner shall consider:

1. The recommendation and the reasons therefor of the appropriate health planning agency.

2. The relationship of the project to the applicable health plans of the Board and the health planning agency.

3. The relationship of the project to the long-range development plan, if any, of the person applying for a certificate.

4. The need that the population served or to be served by the project has for the project, including, but not limited to, the needs of rural populations in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

5. The extent to which the project will be accessible to all residents of the area proposed to be served and the effects on accessibility of any proposed relocation of an existing service or facility.

6. The area, population, topography, highway facilities and availability of the services to be provided by the project in the particular part of the health service area in which the project is proposed, in particular, the distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

7. Less costly or more effective alternate methods of reasonably meeting identified health service needs.

8. The immediate and long-term financial feasibility of the project.

9. The relationship of the project to the existing health care system of the area in which the project is proposed; however, for projects proposed in rural areas, the relationship of the project to the existing health care services in the specific rural locality shall be considered.

10. The availability of resources for the project.

11. The organizational relationship of the project to necessary ancillary and support services.

12. The relationship of the project to the clinical needs of health professional training programs in the area in which the project is proposed.

13. The special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multidisciplinary clinic, specialty center or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health service area in which the project is to be located.

14. The special needs and circumstances of health maintenance organizations. When considering the special needs and circumstances of health maintenance organizations, the Commissioner may grant a certificate for a project if the Commissioner finds that the project is needed by the enrolled or reasonably anticipated new members of the health maintenance organization or the beds or services to be provided are not available from providers which are not health maintenance organizations or from other health maintenance organizations in a reasonable and cost-effective manner.

15. The special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.

16. In the case of a construction project, the costs and benefits of the proposed construction.

17. The probable impact of the project on the costs of and charges for providing health services by the applicant for a certificate and on the costs and charges to the public for providing health services by other persons in the area.

18. Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.

19. In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities in the area similar to those proposed,

including, in the case of rural localities, any distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

20. The need and the availability in the health service area for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.

§ 32.1-102.3:1. Application for certificate not required of certain nursing facilities or nursing homes. - An application for a certificate that there exists a public need for a proposed project shall not be required for nursing facilities or nursing homes affiliated with facilities which, on January 1, 1982, and thereafter, meet all of the following criteria:

1. A facility which is operated as a nonprofit institution.

2. A facility which is licensed jointly by the Department of Health as a nursing facility or nursing home and by the Department of Social Services as an assisted living facility.

3. A facility which observes the following restrictions on admissions:

a. Admissions 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 are restricted to individuals defined as ambulatory by the Department of Social Services;

c. Admissions to the nursing facility or nursing home unit are restricted to those individuals who are residents of the assisted living facility unit.

4. A facility in which no resident receives federal or state public assistance funds.

§ 32.1-102.3:2. Certificates of public need; applications ~~for increases in nursing home bed supplies~~ to be filed in response to Requests For Applications (RFAs). - A. Except for applications for continuing care retirement community nursing home bed projects filed by continuing care providers registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 which comply with the requirements established in this section, the Commissioner of Health shall only approve, authorize or accept applications for the issuance of any certificate of public need pursuant to this article for any project which would result in an increase in the number of beds in which nursing facility or extended care services are provided in a planning district ~~in which nursing facility or extended care services are provided,~~ establish a new radiation therapy service and/or stereotactic radiosurgery service or increase the number of radiation therapy or stereotactic radiosurgery machines at an existing medical care facility, establish a new neonatal special care service, establish a new obstetrical service, establish a new medical rehabilitation service, establish a new psychiatric service or increase the number of psychiatric care beds or establish a new long term-acute care hospital when such applications are filed in response to Requests For Applications (RFAs).

B. The Board of Health shall adopt regulations establishing standards for the approval and issuance of Requests for Applications by the Commissioner of Health. The standards shall include, but shall not be limited to, a requirement that determinations of need take into account any limitations on access to existing ~~nursing home beds~~services in the planning districts. The RFAs, which shall be published at least annually, shall be jointly developed by the Department

of Health and the Department of Medical Assistance Services and based on analyses of the need, or lack thereof, for increases in the ~~nursing home bed~~relevant service supply in each of the Commonwealth's planning districts in accordance with standards adopted by the Board of Health by regulation. The Commissioner shall only accept for review applications in response to such RFAs which conform with the geographic and ~~bed~~ need determinations of the specific RFA.

C. Sixty days prior to the Commissioner's approval and issuance of any Request For Applications, the Board of Health shall publish the proposed RFA in the Virginia Register for public comment together with an explanation of (i) the regulatory basis for the planning district ~~bed~~ needs set forth in the RFA and (ii) the rationale for the RFA's planning district designations. Any person objecting to the contents of the proposed RFA may notify, within fourteen days of the publication, the Board and the Commissioner of his objection and the objection's regulatory basis. The Commissioner shall prepare, and deliver by registered mail, a written response to each such objection within two weeks of the date of receiving the objection. The objector may file a rebuttal to the Commissioner's response in writing within five days of receiving the Commissioner's response. If objections are received, the Board may, after considering the provisions of the RFA, any objections, the Commissioner's responses, and if filed, any written rebuttals of the Commissioner's responses, hold a public hearing to receive comments on the specific RFA. Prior to making a decision on the Request for Applications, the Commissioner shall consider any recommendations made by the Board.

D. Except for a continuing care retirement community applying for a certificate of public need pursuant to provisions of subsections A, B, and C above, applications for continuing care retirement community nursing home bed projects shall be accepted by the Commissioner of Health only if the following criteria are met: (i) the facility is registered with the State Corporation Commission as a continuing care provider pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2, (ii) the number of new nursing home beds requested in the initial application does not exceed the lesser of twenty percent of the continuing care retirement community's total number of beds that are not nursing home beds or sixty beds, (iii) the number of new nursing home beds requested in any subsequent application does not cause the continuing care retirement community's total number of nursing home beds to exceed twenty percent of its total number of beds that are not nursing home beds, and (iv) the continuing care retirement community has established a qualified resident assistance policy.

E. The Commissioner of Health may approve an initial certificate of public need for nursing home beds in a continuing care retirement community not to exceed the lesser of sixty beds or twenty percent of the total number of beds that are not nursing home beds which authorizes an initial one-time, three-year open admission period during which the continuing care retirement community may accept direct admissions into its nursing home beds. The Commissioner of Health may approve a certificate of public need for nursing home beds in a continuing care retirement community in addition to those nursing home beds requested for the initial one-time, three-year open admission period if (i) the number of new nursing home beds requested in any subsequent application does not cause the continuing care retirement community's total number of nursing home beds to exceed twenty percent of its total number of beds that are not nursing beds, (ii) the number of licensed nursing home beds within the continuing care retirement community does not and will not exceed twenty percent of the number of occupied beds that are

not nursing beds, and (iii) no open-admission period is allowed for these nursing home beds. Upon the expiration of any initial one-time, three-year open admission period, a continuing care retirement community which has obtained a certificate of public need for a nursing facility project pursuant to subsection D may admit into its nursing home beds (i) a standard contract holder who has been a bona fide resident of the non-nursing home portion of the continuing care retirement community for at least thirty days, or (ii) a person who is a standard contract holder who has lived in the non-nursing home portion of the continuing care retirement community for less than thirty days but who requires nursing home care due to change in health status since admission to the continuing care retirement community, or (iii) a person who is a family member of a standard contract holder residing in a non-nursing home portion of the continuing care retirement community.

F. Any continuing care retirement community applicant for a certificate of public need to increase the number of nursing home beds shall authorize the State Corporation Commission to disclose such information to the Commissioner as may be in the State Corporation Commission's possession concerning such continuing care retirement community in order to allow the Commissioner of Health to enforce the provisions of this section. The State Corporation Commission shall provide the Commissioner with the requested information when so authorized.

G. For the purposes of this section:

"*Family member*" means spouse, mother, father, son, daughter, brother, sister, aunt, uncle or cousin by blood, marriage or adoption.

"*One-time, three-year open admission period*" means the three years after the initial licensure of nursing home beds during which the continuing care retirement community may take admissions directly into its nursing home beds without the signing of a standard contract. The facility or a related facility on the same campus shall not be granted any open admissions period for any subsequent application or authorization for nursing home beds.

"*Qualified resident assistance policy*" means a procedure, consistently followed by a facility, pursuant to which the facility endeavors to avoid requiring a resident to leave the facility because of inability to pay regular charges and which complies with the requirements of the Internal Revenue Service for maintenance of status as a tax exempt charitable organization under § 501 (c) (3) of the Internal Revenue Code. This policy shall be (i) generally made known to residents through the resident contract and (ii) supported by reasonable and consistent efforts to promote the availability of funds, either through a special fund, separate foundation or access to other available funds, to assist residents who are unable to pay regular charges in whole or in part.

This policy may (i) take into account the sound financial management of the facility, including existing reserves, and the reasonable requirements of lenders and (ii) include requirements that residents seeking such assistance provide all requested financial information and abide by reasonable conditions, including seeking to qualify for other assistance and restrictions on the transfer of assets to third parties.

A qualified resident assistance policy shall not constitute the business of insurance as defined in Chapter 1 (§ 38.2-100 et seq.) of Title 38.2.

"*Standard contract*" means a contract requiring the same entrance fee, terms, and conditions as contracts executed with residents of the non-nursing home portion of the facility, if the entrance fee is no less than the amount defined in § 38.2-4900.

H. This section shall not be construed to prohibit or prevent a continuing care retirement community from discharging a resident (i) for breach of nonfinancial contract provisions, (ii) if medically appropriate care can no longer be provided to the resident, or (iii) if the resident is a danger to himself or others while in the facility.

I. The provisions of subsections D, E, and H of this section shall not affect any certificate of public need issued prior to July 1, 1998; however, any certificate of public need application for additional nursing home beds shall be subject to the provisions of this act.

§ 32.1-102.3:2.1: Repealed by Acts 1998, c. 794.

§ 32.1-102.3:2.2: Expired.

§§ 32.1-102.3:3. , 32.1-102.3:4: Repealed by Acts 1992, c. 612.

§ 32.1-102.4. Conditions of certificates; monitoring; revocation of certificates. - A. A certificate shall be issued with a schedule for the completion of the project and a maximum capital expenditure amount for the project. The 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.

1. All facilities, whether licensed or not and whether or not required to be licensed, holding, or seeking, certificate of public need authorization for one or more projects will report their patient volume, gross patient revenue, net patient revenue and charity care for all certificate of public need regulated services annually to Virginia Health Information.
2. Failure of a facility holding a certificate of public need to provide the report required by this section will;
    a. render the facility, the facility's parent organization and the facility's owners ineligible to apply for additional certificates of public need until such time as all reporting is current to the later of the start of the service or January 1, 2007
    b. cause capacity at non-reporting services to not be counted in the calculations to determine need.

B. The Commissioner shall monitor each project for which a certificate is issued to determine its progress and compliance with the schedule and with the maximum capital expenditure. The Commissioner shall also monitor all continuing care retirement communities for which a certificate is issued authorizing the establishment of a nursing home facility or an increase in the number of nursing home beds pursuant to § 32.1-102.3:2 and shall enforce compliance with the conditions for such 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 subject to a civil penalty of up to $100 per violation per day until the date the Commissioner determines that such facility is in compliance.

C. A certificate may be revoked when:

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

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

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

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

D. Further, 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.

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

F. The Commissioner may condition, pursuant to the regulations of the Board, the approval of a certificate (i) upon the agreement of the applicant to provide a level of care at a reduced rate to indigents or accept patients requiring specialized care or (ii) upon the agreement of the applicant to facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area.

Any person willfully 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. Failure to report compliance with any condition of a certificate of public need by the established deadline shall be grounds for denial of additional certificate of public need requests until full compliance is demonstrated and reported.

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

§ 32.1-102.5. Certificate not transferable. - No certificate issued for a project shall be transferable.

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

Within 10 calendar days of the date on which the document is received, the Department and the appropriate health planning agency shall determine whether the application is complete or not and the Department shall notify the applicant, if the application is complete, that the application has been accepted for review and if the application is not complete, of the information needed to complete the application, that the application will not be accepted for the current review cycle and the dates of the next available review cycle.

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 health planning agency 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.

B. The appropriate health planning agency shall review each completed application for a certificate within 60 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. The health planning agency shall 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. The 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 a project is proposed to be located at least nine calendar days prior to the public hearing. Prior to the public hearing, the health planning agency shall notify the local governing bodies in the planning district. The health planning agency shall consider the comments of such governing bodies and all other public comments in making its decision. Such comments shall be part of the record provided to the Department. In no case shall a health planning agency hold more than two meetings on any application, one of which shall be the public hearing conducted by the board of the 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 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 health planning agency staff, any information in a staff report, or comments by those voting; however, such opportunity shall not increase the 60-calendar-day period designated herein for the health planning agency's review unless the applicant or applicants request a specific extension of the health planning agency's review period.

The health planning agency shall submit its recommendations on each application and its reasons therefor to the Department within ~~10~~ 5 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 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~~ 5 calendar days after the completion of its review, the Department shall, on the ~~eleventh~~ sixth calendar day after the expiration of the health planning agency's review period, proceed as though the health planning agency has recommended project approval without conditions or revision.

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 (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 health planning agency.

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~~upon 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 of this section. 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. Once scheduled by the department the informal fact-finding conference will be held on the scheduled date unless changed by the presiding Adjudication Officer in response to special, unavoidable circumstances and with the concurrence of all parties.

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 at a necessary informal fact-finding conference shall notify the Department of his request and the basis therefor on or before the eightieth calendar day following the day which begins the appropriate batch review cycle.

4. In any case in which an informal fact-finding conference is held, the informal fact-finding conference shall not be a de novo review of the request and shall be based on the material in the record on the 60th day of the review cycle, any material submitted prior to the informal fact-finding conference by a party with good cause and any informal fact-finding conference

testimony made regarding the material in the record. ~~A~~Following the 60th day of the review cycle only the analysis and recommendation of the Regional Health Planning Agency, the analysis and recommendation of the Division of Certificate of Public Need, the transcript of the informal fact finding conference, the analysis and recommendation of the adjudication officer and the Commissioner's decision may be added to the record. The date for the close of the record shall not be more than 45 days after the date the informal fact-finding conference is concluded. ~~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 for additional information 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, only the Commissioner's decision may be added to the record.

6. The provisions of subsection D of § 2.2-4019 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 subdivision E 6 of § 32.1-102.6.

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.

G. For purposes of this section, "good cause" shall mean 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.

§ 32.1-102.7: Repealed by Acts 1984, c. 740.

§ 32.1-102.8. Enjoining project undertaken without certificate. - On petition of the Commissioner, the Board or the Attorney General, the circuit court of the county or city where a project is under construction or is intended to be constructed, located or undertaken shall have jurisdiction to enjoin any project which is constructed, undertaken or commenced without a certificate or to enjoin the admission of patients to the project or to enjoin the provision of services through the project.

§ 32.1-102.9. Designation of judge. - The judge of the court to which any appeal is taken as provided in § 32.1-102.6 and the judge of the court referred to in § 32.1-102.8 shall be designated by the Chief Justice of the Supreme Court from a circuit other than the circuit where the project is or will be under construction, located or undertaken.

§ 32.1-102.10. Commencing project without certificate grounds for refusing to issue license. Commencing any project without a certificate required by this article shall constitute grounds for refusing to issue a certificate or a license for such project.

§ 32.1-102.11. Application of article. - A. On and after July 1, 1992, every project of an existing or proposed medical care facility, as defined in § 32.1-102.1, shall be subject to all provisions of this article unless, with respect to such project, the owner or operator of an existing medical care facility or the developer of a proposed medical care facility (i) has, by February 1, 1992, purchased or leased equipment subject to registration pursuant to former § 32.1-102.3:4, (ii) has, by February 1, 1992, initiated construction requiring a capital expenditure exceeding one million dollars, or (iii) has made or contracted to make or otherwise legally obligated to make,

during the three years ending February 1, 1992, preliminary expenditures of $350,000 or more for a formal plan of construction of the specific project, including expenditures for site acquisition, designs, preliminary or working drawings, construction documents, or other items essential to the construction of the specific project.

Any project exempted pursuant to subdivisions (ii) and (iii) of this subsection shall be limited to such construction, services, and equipment as specifically identified in the formal plan of construction which shall have existed and been formally committed to by February 1, 1992. Further, the equipment to be exempted pursuant to subdivisions (ii) and (iii) shall be limited to the number of units and any types of medical equipment, in the case of medical equipment intended to provide any services included in subdivision 6 of the definition of project in § 32.1-102.1, as are specifically identified in such plan and, in the case of all other equipment, such equipment as is appropriate for the construction and services included in such plan.

None of the exemptions provided in this subsection shall be applicable to projects which required a certificate of public need pursuant to this article on January 1, 1992.

B. Any medical care facility or entity claiming to meet one of the conditions set forth in subsection A of this section shall file a completed application for an exemption from the provisions of this article with the Commissioner by August 1, 1992. Forms for such application shall be made available by the Commissioner no later than April 1, 1992. The Commissioner may deny an exemption if the application is not complete on August 1, 1992, and the medical care facility or entity has not filed a completed application within forty-five days after notice of deficiency in the filing of the completed application. After receiving a completed application, the Commissioner shall determine whether the project has met one of the criteria for an exemption and is, therefore, exempt or has not met any of the criteria for an exemption and is, therefore, subject to all provisions of this article and shall notify the medical care facility or entity of his determination within sixty days of the date of filing of the completed application. If it is determined that an exemption exists for only a portion of a project, the Commissioner may approve an exemption for that portion and any appeal may be limited to the part of the decision with which the appellant disagrees without affecting the remainder of the decision. The Commissioner's determination shall be made in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq.), except that parties to the case shall include only those parties specified in § 32.1-102.6.

C. For the purposes of this section:

"*Formal plan of construction*" means documentary evidence indicating that the facility, the owner or operator of the facility, or the developer of a proposed facility was formally committed to the project by February 1, 1992, and describing the specific project in sufficient detail to reasonably define and confirm the scope of the project including estimated cost, intended location, any clinical health services to be involved and any types of equipment to be purchased. Such documentary evidence shall include designs, preliminary or working drawings, construction documents or other documents which have been used to explicitly define and confirm the scope of the project for the purposes of seeking architectural or construction plans or capital to the extent that such capital was committed or agreed to be provided for such project prior to February 1, 1992.

"*Initiated construction*" means an owner or operator of an existing facility or the developer of a proposed facility can present evidence for a specific project that (i) a construction

contract has been executed; (ii) if applicable, short-term financing has been completed; (iii) if applicable, a commitment for long-term financing has been obtained; and (iv) if the project is for construction of a new facility or expansion of an existing facility, predevelopment site work and building foundations have been completed.

"*Leased*" means that the owner or operator of an existing medical care facility or the developer of a proposed facility has a legally binding commitment to lease the equipment pursuant to an agreement providing for fixed, periodic payments commencing no later than June 30, 1992, including a lease-purchase agreement in which the owner or operator of the facility or developer has an option to purchase the equipment for less than fair market value upon conclusion of the lease or an installment sale agreement with fixed periodic payments commencing no later than June 30, 1992.

"*Purchased*" means that the equipment has been acquired by the owner or operator of an existing medical care facility or the developer of a proposed medical care facility, or the owner or operator of the facility or the developer can present evidence of a legal obligation to acquire the equipment in the form of an executed contract or appropriately signed order or requisition and payment has been made in full by June 30, 1992.

§ 32.1-102.12. Report required. - The Commissioner shall annually report to the Governor and the General Assembly on the status of Virginia's certificate of public need program. The report shall be issued by October 1 of each year and shall include, but need not be limited to:

1. A summary of the Commissioner's actions during the previous fiscal year pursuant to this article;

2. A five-year schedule for analysis of all project categories which provides for analysis of at least three project categories per year;

3. An analysis of the appropriateness of continuing the certificate of public need program for at least three project categories in accordance with the five-year schedule for analysis of all project categories;

4. An analysis of the effectiveness of the application review procedures used by the health systems agencies and the Department required by § 32.1-102.6 which details the review time required during the past year for various project categories, the number of contested or opposed applications and the project categories of these contested or opposed projects, the number of applications upon which the health systems agencies have failed to act in accordance with the timelines of § 32.1-102.6 B, and the number of deemed approvals from the Department because of their failure to comply with the timelines required by § 32.1-102.6 E, and any other data determined by the Commissioner to be relevant to the efficient operation of the program;

5. An analysis of health care market reform in the Commonwealth and the extent, if any, to which such reform obviates the need for the certificate of public need program;

6. An analysis of the accessibility by the indigent to care provided by the medical care facilities regulated pursuant to this article and the relevance of this article to such access;

7. An analysis of the relevance of this article to the quality of care provided by medical care facilities regulated pursuant to this article; and

8. An analysis of equipment registrations required pursuant to § 32.1-102.1:1, including the type of equipment, whether an addition or replacement, and the equipment costs.

§ 32.1-102.13. Transition to elimination of medical care facilities certificate of public need.
A. Transition required. - A transition for elimination of the requirements for determination of need pursuant to Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of this title shall begin on July 1, 2001, and shall be completed by July 1, 2004, as determined by the General Assembly.

B. Plan to be developed. - The deregulation required by this section shall be accomplished in accordance with a plan to be developed by the Joint Commission on Health Care. The Joint Commission on Health Care shall work collaboratively with the Departments of Health, Medical Assistance Services, and Health Professions in conjunction with the implementation of the provisions of this section. The Departments of Health, Medical Assistance Services, and Health Professions shall provide technical assistance to the Joint Commission. All agencies of the Commonwealth shall provide assistance to the Joint Commission, upon request. The Joint Commission shall seek input from all classes of health care consumers, providers, and representatives of health care facilities in the performance of the duties of the Joint Commission hereunder. The plan shall include recommendations for legislative and administrative consideration to carry out, in accordance with subsection A of this section, the elimination of the requirements for determination of need. Such plan shall be submitted to the chairmen of the House Appropriations, Senate Finance, House Health, Welfare and Institutions, and Senate Education and Health Committees on or before December 1, 2000, for review and approval by the 2001 Session of the General Assembly.

C. Components of the plan. - The plan for deregulation to be developed by the Joint Commission on Health Care shall include, but need not be limited to, provisions for (i) meeting the health care needs of the indigent citizens of the Commonwealth, including access to care and provision for all health care providers to share in meeting such needs; (ii) meeting the health care needs of the uninsured citizens of the Commonwealth, including access to care; (iii) establishing licensure standards for the various deregulated services, including whether nationally recognized accreditation standards may be adopted, to protect the public health and safety and to promote the quality of services provided by deregulated medical facilities and projects; (iv) providing adequate oversight of the various deregulated services to protect the public health and safety; (v) providing for monitoring the effects of deregulation during the transition period and after full implementation of this section on the number and location of medical facilities and projects throughout the Commonwealth; (vi) determining the effect of deregulation of long-term care facilities and new hospitals with respect to the requirements for determination of need; (vii) determining the effect of deregulation on the unique mission of academic medical centers; (viii) determining the effect of deregulation on rural hospitals which are critical access hospitals; (ix) recommending a schedule for necessary statutory changes to implement the plan and for requiring, subject to approval of the General Assembly, that the appropriate regulatory boards promulgate regulations implementing the Commission's plan prior to any deregulation recommended in the plan.

D. Fiscal impact. - In developing the plan, the Commission shall also consider the impact of deregulation on state-funded health care financing programs and shall include an examination of the fiscal impact of such deregulation on the market rates paid by such financing programs for health care and long-term care services.