

**STATE OF VERMONT
DEPARTMENT OF BANKING, INSURANCE, SECURITIES AND HEALTH
CARE ADMINISTRATION**

Division of Health Care Administration

RULE H-2010-01

Certificate of Need Program Procedures

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SECTION ONE: POLICY

(a) Authority

The Commissioner (the “Commissioner”) of the Vermont Department of Banking, Insurance, Securities and Health Care Administration adopts this Rule pursuant to Title 18, Chapter 221 of the Vermont Statutes Annotated, 18 V.S.A. § 9433, 8 V.S.A. § 15, and other applicable law.

(b) Purpose

- (1) It is the public policy of this state that the general welfare and protection of the lives, health and property of the people of the State of Vermont require that all new health care projects be offered or developed in a manner which avoids unnecessary duplication and contains or reduces increases in the cost of delivering services, while at the same time maintaining and improving the quality of access to health care services, and promoting rational allocation of health care resources in Vermont;
- (2) The need, cost, type, level, quality and feasibility of providing any new health care project shall be subject to review and assessment through the Certificate of Need program prior to any offering or development; and
- (3) The Certificate of Need program shall be administered consistent with the above stated Legislative goals and other applicable legislatively mandated health planning goals.

SECTION TWO: DEFINITIONS

By reference, the definitions included in Title 18, Chapter 221, subchapter 5 shall apply to this Rule, unless expressly defined herein. As used in this Rule, the following terms shall have the following definitions:

- (a) “Action” means any activity, such as entering into a contract or the commencement of any work, that leads to, is intended to, or is reasonably likely to lead to the offering or development of a new health care project.
- (b) “Ambulatory surgical center” means a facility or portion of a facility that provides surgical care not requiring an overnight stay. The office of a dentist in which activities are limited to dentistry and oral or maxillofacial surgical procedures shall not be deemed an ambulatory surgical center for purposes of this subchapter. In order to be considered an ambulatory surgical center, a facility shall meet the following criteria:

- (1) Charge, or intend to charge, a facility fee in addition to professional fees for the services performed.
 - (2) Have an operating room or recovery room in the facility.
 - (3) Use an anesthesiologist or nurse anesthetist.
 - (4) Provide on or more outpatient services for which Medicare coverage is provided.
- (c) “Annual operating expense” as used in this Rule means that expense which, by generally accepted accounting principles, is incurred by a health care service during the fiscal year in which the service is in full operation for the entire fiscal year.
- (d) “Applicant” means a person who has submitted an application or proposal requesting a Certificate of Need.
- (e) “Application” means an applicant’s application for a Certificate of Need. The “application” shall include all materials submitted by the applicant as part of the application review process prior to the Application Closed Date. The application includes the Department’s questions to the applicant and the applicant’s responses to the Department’s questions concerning the application and the review process.
- (f) “Capital expenditure” means an expenditure for the plant or equipment which is not properly chargeable as an expense of operation and maintenance and includes acquisition by purchase, donation, leasehold expenditure, or lease which is treated as capital expense in accordance with the accounting standards established for lease expenditures by the Financial Accounting Standards Board calculated over the length of the lease for plant or equipment, and includes assets having an expected life of at least three years. A capital expenditure includes the cost of studies, surveys, designs, plans, working drawings, specifications and other activities essential to the acquisition, improvement, expansion or replacement of the plan and equipment.
- (g) “Cardiac catheterization laboratory” means a facility, or a portion of a facility, in which cardiac catheterization procedures, whether diagnostic or therapeutic, are conducted.
- (h) “Certificate of Need Manual” means a manual published by the Department which provides guidance and instructions for entities interested in the Certificate of Need process or seeking a Certificate of Need. The Certificate of Need manual shall not contradict applicable statutes or rules.
- (i) “Commissioner” means the Commissioner of the Vermont Department of Banking, Insurance, Securities and Health Care Administration.

- (j) “Construction” means actual commencement of any construction or fabrication of any new building, or addition to any existing facility, or any expenditure relating to the alteration, remodeling, renovation, modernization, improvement, relocation, repair, or replacement of a health care facility, including expenditures necessary for compliance with applicable building codes.
- (k) “Days” means calendar days unless otherwise specified.
- (1) If a deadline falls on a weekend or holiday, the deadline shall be extended to the next business day.
 - (2) If the total time allowed for an activity is five days or less, weekends and holidays are not included in the calculation of the deadline. If the total time allowed is more than five days, weekends and holidays are included.
 - (3) Documents shall be deemed received by the Department on the date the Department receives the document in its offices. “Receipt” in the Department’s offices shall refer to receipt of the hard copy unless the Department has specifically authorized in writing the receipt of electronic materials.
- (l) “Diagnostic imaging facility” means a facility, or portion of a facility, that performs any of the following diagnostic services: computerized tomography, fluoroscopy, nuclear medicine, angiography, magnetic resonance imaging, or positron emission tomography.
- (m) “Department” means the Vermont Department of Banking, Insurance, Securities and Health Care Administration.
- (n) “Develop” when used in connection with health services or new health care projects, means to undertake activities which on their completion will, or are intended to, result in the offering of a new health care project, including the incurring of a financial obligation in relation the offering of a health care project.
- (o) “Donation” means a gift, grant, contribution or similar conveyance of something of value, whether in whole or in part, such that the recipient benefits and receives something of value for less than fair market value.
- (p) “Expenditure” means any expenditure, whether capital or otherwise.
- (q) “Full operation” means when a health service is operating, on an annual basis, at the normal and customary level of service.

- (r) “Health care facility” as used in this Rule means that as defined in 18 V.S.A. § 9432, and shall also include any person proposing to offer or develop or offering or developing a new health care project as defined therein.
- (s) “Health services” or “services” means activities and functions of a health care facility that are directly related to care, treatment or diagnosis of patients.
- (t) “Holder” means any person who receives a Certificate of Need from the Commissioner.
- (u) “Hospital” means a hospital as defined in 18 V.S.A. § 9402.
- (v) “Independent diagnostic laboratory” means a laboratory, not owned or operated by a hospital, that holds itself out to other health care providers as available for the performance of diagnostic tests, and which accepts from, and performs for or on behalf of other health care providers, during any calendar year, diagnostic tests on at least 100 specimens in any one of the following categories: microbiology, serology, clinical chemistry, immunohematology, hematology, pathology, and radiobioassay.
- (w) “Kidney disease treatment center” means a facility or portion of a facility that is approved to furnish kidney transplantation or inpatient, outpatient, or home dialysis.
- (x) “Material change” means a change to a health care project for which a certificate of need has been issued which constitutes a new health care project as defined by law or which increases the total costs of the project by more than 10 percent of the amount approved by the issued certificate of need.
- (y) “Nonmaterial change” means a modification to a new health care project subject to a certificate of need that does not meet the definition of ‘material change’ but otherwise modifies the kind, scope or capacity of a project for which a certificate of need has been granted.
- (z) “Obligation” means an obligation for a capital or other expenditure that is deemed to have been incurred by or on behalf of a health care facility or health maintenance organization.
- (aa) “Outpatient diagnostic or therapy program” means a health care program that offers diagnostic or therapeutic procedures to patients referred from health care facilities or health care providers.
- (bb) “Party” means the applicant, including a competing applicant, and an “interested party” whose petition for interested party status has been granted by the Commissioner.

- (cc) “Public Oversight Commission” or POC means the Public Oversight Commission established by 18 V.S.A. § 9407.
- (dd) “Radiation therapy facility” means a facility or portion of a facility in which patients are treated by the use of ionizing radiation to kill cells in the region of a tumor.

SECTION THREE: JURISDICTION

- (a) **Certificate of Need required.** No health care facility shall develop, or have developed on its behalf, a new health care project without the issuance of a Certificate of Need by the Commissioner.
- (b) **“New health care project”** shall mean that as defined by 18 V.S.A. § 9434.
- (c) **New Health Care Projects by Health Care Facilities Other Than Hospitals.** New health care project for health care facilities other than hospitals shall include:
 - (1) The construction, development, purchase, renovation, or other establishment of a health care facility, or any capital expenditure by or on behalf of a health care facility, for which the capital cost exceeds \$1,500,000.
 - (2) A change from one licensing period to the next in the number of licensed beds of a health care facility through addition or conversion, or through relocation from one physical facility or site to another.
 - (3) The offering of any home health service, or the transfer or conveyance of more than 50 percent ownership interest of a home health agency.
 - (4) The purchase, lease, or other comparable arrangement of a single piece of diagnostic or therapeutic equipment for which the cost, or in the case of a donation, the value, is in excess of \$1,000,000.
 - (A) The purchase or lease of one or more articles of diagnostic or therapeutic equipment which are necessarily interdependent in the performance of their ordinary functions, or which would constitute a health care facility, shall be considered together in calculating the cost of the equipment.
 - (i) To the extent a health care facility reasonably anticipates or intends to purchase components to use with a piece of diagnostic or therapeutic equipment within two years of the

initial purchase, such components shall be included in the cost of the equipment.

- (B) In determining the cost of the equipment for jurisdictional purposes, the following shall be included:
- (i) the cost of all components which are necessary to make the equipment function as intended by the health care facility, including all electrical, mechanical and software components;
 - (ii) “fit up” costs, including the cost of specifications, site preparation, construction, related equipment, and other activities related to the operation of the equipment; and
 - (iii) the fair market value of any equipment being traded in as part of the purchase.
 - (iv) If equipment is being financed, financing costs shall be included in calculating the cost of the equipment. If such costs are not finalized prior to a jurisdictional determination, the health care facility shall make a reasonable prediction regarding the costs.
 - (v) If equipment is purchased with a maintenance or service agreement, the costs of such agreement(s) shall be included in the calculation of the cost of the equipment. Maintenance and service agreements shall not be included in the cost calculation if such agreements are with any entity wholly unrelated to the seller of equipment or if such agreements are not entered into until two years after the initial purchase of the equipment.
 - (vi) If equipment is leased, the cost of an operating lease shall be calculated based on the net present value of the lease. For purposes of this subsection ‘net present value’ means the total lease payments over the useful life of the asset as set out in the 2008 version of Estimated Useful Lives of Depreciable Hospital Assets, published by the American Hospital Association, or a more current version if such version is available. The cost of a capital lease shall be equal to the amount capitalized.

- (vii) Such other expenses as may be necessary or incident to the acquisition of the project, the financing of such acquisition, and the placing of the equipment in operation.
- (C) If the actual costs for an equipment purchase exceed the jurisdictional threshold, and no Certificate of Need was obtained, the health care facility shall submit an application for review immediately upon determination that costs will exceed jurisdictional thresholds. Depending on the totality of the circumstances, after notice and opportunity to be heard, the Commissioner may assess penalties or impose other appropriate remedies for failure to obtain a Certificate of Need.
- (D) In order to determine whether a Certificate of Need is required, the cost of diagnostic or therapeutic equipment that is acquired through a donation shall be the fair market value of the equipment.
- (5) The offering of a health care service or technology having an annual operating expense which exceeds \$500,000.
 - (A) Under subsection (c)(5) above, the service or technology must:
 - (i) not have been offered by the health care facility in the previous three fiscal years; and
 - (ii) have an annual operating expense which exceeds the monetary jurisdictional thresholds in either of the next two budgeted fiscal years following the first year the service or technology was in full operation.
 - (B) A new health care service or technology under this subsection (5) shall include that which substantially improves upon or otherwise alters the processes associated with a diagnostic or therapeutic service or technology.
 - (C) Operating expenses includes all costs associated with offering the service or technology over and above any operating expenses that would be incurred by the health care facility in the normal course of business if the service or technology were not being offered.
- (6) The construction, development, purchase, lease or other establishment of an ambulatory surgical center.
- (7) If a health care facility providing nursing home services undergoes a change in ownership, corporate structure or other organizational

modification such that a new license from the appropriate state or federal licensing entity is required, such action constitutes the creation of a new healthcare facility.

- (8) The term ‘purchase’ in this subsection (c)(1) above shall include purchase, transfer, or other acquisition of the shares or assets of the entity which owns the health care facility, including both the operating entity or the entity which owns the physical health care facility, but shall not include a similar purchase, transfer, or other acquisition of a parent company unless the Commissioner determines failing to subject the purchase to Certificate of Need review circumvents the legislatively mandated goals of the Certificate of Need review.
 - (9) The transferring of ownership interests that fundamentally changes the financial stability or legal liability of the operations shall be a new health care project for the purposes of this subsection.
- (d) New Health Care Projects by Hospitals.** New health care project for hospitals shall include:
- (1) The construction, development, purchase, renovation, or other establishment of a health care facility, or any capital expenditure by or on behalf of the health care facility, for which the capital cost exceeds \$3,000,000.
 - (2) The purchase, lease, or other comparable arrangement of a single piece of diagnostic or therapeutic equipment for which the cost, or in the case of a donation, the value, is in excess of \$1,000,000.
 - (A) The purchase or lease of one or more articles of diagnostic or therapeutic equipment which are necessarily interdependent in the performance of their ordinary functions, or which would constitute a health care facility, shall be considered together in calculating the cost of the equipment.
 - (i) To the extent a health care facility reasonably anticipates or intends to purchase components to use with a piece of diagnostic or therapeutic equipment within two years of the initial purchase, such components shall be included in the cost of the equipment.
 - (B) In determining the cost of the equipment for jurisdictional purposes, the following shall be included:

- (i) the cost of all components which are necessary to make the equipment function as intended by the health care facility, including all electrical, mechanical and software components;
 - (ii) “fit up” costs, including the cost of studies, surveys, designs, plans, working drawings, specifications, site preparation, construction, related equipment, and other activities related to the operation of the equipment; and
 - (iii) the fair market value of any equipment being traded in as part of the purchase.
 - (iv) If equipment is being financed, financing costs shall be included in calculating the cost of the equipment. If such costs are not finalized prior to a jurisdictional determination, the health care facility shall make a reasonable prediction regarding the costs.
 - (v) If equipment is purchased with a maintenance or service agreement, the costs of such agreement(s) shall be included in the calculation of the cost of the equipment. Maintenance and service agreements shall not be included in the cost calculation if such agreements are with an entity wholly unrelated to the seller of equipment or if such agreements are not entered into until two years after the initial purchase of the equipment.
 - (vi) If equipment is leased, the cost of an operating lease shall be calculated based on the net present value of the lease. For purposes of this paragraph ‘net present value’ means the total lease payments over the useful life of the asset as set out in the 2008 version of Estimated Useful Lives of Depreciable Hospital Assets, published by the American Hospital Association, or a more current version if such version is available. The cost of a capital lease shall be equal to the amount capitalized.
 - (vii) Such other expenses as may be necessary or incident to the acquisition of the project, the financing of such acquisition, and the placing of the equipment in operation.
- (C) If the actual costs for an equipment purchase exceed the jurisdictional threshold, and no Certificate of Need was obtained, the health care facility shall submit an application for review

immediately upon determination that costs will exceed jurisdictional thresholds. Depending on the totality of the circumstances, after notice and opportunity to be heard, the Commissioner may assess penalties or impose other appropriate remedies for failure to obtain a Certificate of Need.

- (D) In order to determine whether a Certificate of Need is required, the cost of diagnostic or therapeutic equipment that is acquired through a donation shall be the fair market value of the equipment.
- (3) The offering of a health care service or technology having an annual operating expense which exceeds \$500,000.
 - (A) Under subsection (3) above, the service or technology must:
 - (i) not have been offered by the health care facility in the previous three fiscal years; and
 - (ii) have an annual operating expense which exceeds the monetary jurisdictional thresholds in either of the next two budgeted fiscal years following the first year the service or technology was in full operation.
 - (B) A new health care service or technology under this subsection (3) shall include that which substantially improves upon or otherwise alters the processes associated with a diagnostic or therapeutic service or technology.
 - (C) Operating expenses includes all costs associated with offering the service or technology over and above any operating expenses that would be incurred by the health care facility in the normal course of business if the service or technology were not being offered.
- (4) A change from one licensing period to the next in the number of licensed beds of a health care facility through addition or conversion, or through relocation from one physical facility or site to another.
- (e) **Physician's Offices.** "New health care project" shall not include offices of physicians, dentists or other practitioners of the healing arts as specifically exempted by 18 V.S.A. § 9435.
 - (1) To determine whether a facility is the "office" as used in subsection (e) above, the Department shall consider at least the following: the billing procedures to be used; the structures of the ownership; the training and specialties of the staff; the procedures to be performed; the patient referral

patterns and relation to other health care institutions; the type of diagnostic, and other equipment to be purchased; the representations of the facility to the public, and the frequency with which other Vermont practitioners offer the same services.

- (2) Simple ownership of a facility by a practitioner or a group of practitioners of the healing arts does not, in and of itself, exempt such facility from the definition of new health care project.
- (3) The exemption provided for in subsection (e) above shall not apply to:
 - (A) Offices owned or operated by a hospital, its subsidiary, parent, or holding company;
 - (B) Offices leased by a physician from a hospital its subsidiary, parent, holding company or other affiliated corporate entity;
 - (C) Outpatient diagnostic or therapy programs, kidney disease treatment centers, independent diagnostic laboratories, cardiac catheterization laboratories, radiation therapy facilities, ambulatory surgical centers, diagnostic imaging facilities and similar facilities owned or operated by a physician, dentist or other practitioner of the healing arts.
- (f) **Donations.** The offering or development of a new health care project that results from a donation is a new health care project subject to the standards and procedures established by Chapter 221 of Title 18 Vermont Statutes Annotated, if the donation has a fair market value requiring a Certificate of Need, or would otherwise constitute a “new health care project” under applicable law.
- (g) **Community Mental Health Centers.** Community mental health centers or developmental disability center health care projects proposed by a designated agency and supervised by the Commissioner of the Department of Mental Health or the Commissioner of the Department of Disabilities, Aging, and Independent Living, or other appropriate agency, or both, shall not be required to obtain a Certificate of Need, provided the Commissioner of the Department of Mental Health or Commissioner of the Department of Disabilities, Aging, and Independent Living issues a written approval for the proposed health care project or otherwise processes the proposal according to his or her processes. The appropriate agency shall submit a copy of the approval with a letter of intent to the Commissioner.

- (h) **Conceptual Development Phase Certificates of Need:** If a new health care project is anticipated to be in excess of \$30,000,000, a Conceptual Development Phase Certificate of Need shall be required, unless expressly provided for elsewhere in this Rule.
- (1) A Conceptual Development Phase Certificate of Need permits the applicant to make expenditures for architectural services, engineering design services, or any other planning services related to the proposed health care project. A health care facility may not undertake such expenses without a Conceptual Development Phase Certificate of Need. A Conceptual Development Phase Certificate of Need authorizes an applicant to undertake planning expenditures only; costs associated with actual project development must not be incurred until a final Certificate of Need has been granted, if one is granted.
- (A) A Conceptual Development Phase Certificate of Need shall be granted for a specified dollar amount related to the planning activities associated with the proposed project.
- (2) Upon completion of the planning activities authorized in the Conceptual Development Phase Certificate of Need, and before offering or further developing the health care project, an applicant shall secure a final Certificate of Need in accordance with this Rule and other applicable law.
- (3) Applicants shall not be subject to sanctions for failure to comply with the provisions of this subsection if such failure is solely the result of good faith reliance on verified project cost estimates issued by qualified persons, which cost estimates would have led a reasonable person to conclude the project was not anticipated to be excess of the monetary jurisdictional threshold applicable to Conceptual Development Phase Certificates of Need.
- (A) For the purposes subsection (h)(4) above, “qualified persons” shall mean a professional person with significant, relevant expertise and experience in the development and/or construction of the proposed new health care project.
- (4) The Commissioner shall apply the following criteria to determine whether to grant a Conceptual Development Phase Certificate of Need:
- (A) The proposed concept shall appear likely to be consistent with the policy goals and standards of the Health Resources Allocation Plan;

- (B) The proposed concept shall appear to be reasonable in cost because:
 - (i) The applicant can afford the projected expense.
 - (ii) The proposed concept costs will not likely result in undue increases in the costs of health care. In making a determination under this subsection (5)(B)(ii), the Commissioner shall consider:
 - (a) The financial impact the proposed concept could have on hospitals and other clinical settings, including the impact on their services, expenditures and charges;
 - (b) Whether the proposed concept's likely impact on services, expenditures and charges appears to be outweighed by the benefit to the public; and
 - (iii) Less expensive alternatives to the proposed concept do not appear to exist, or appear unsatisfactory or not feasible or appropriate.
 - (C) The proposed concept appears to meet an identifiable, existing or reasonably anticipated need which is appropriate for the applicant to provide;
 - (D) The proposed concept appears likely to improve the quality of health care in Vermont or provide greater access to healthcare for Vermont's residents, or both;
 - (E) The proposed concept does not appear likely to have an undue adverse impact on existing services provided by the applicant; and
 - (F) The proposed concept appears likely to serve the public good.
- (5) If the Conceptual Development Phase Certificate of Need application proposes the purchase or lease of a new health care information technology, the proposal shall be consistent with the most current Vermont Health Information Technology Plan.
- (6) All procedures applicable to a Certificate of Need are applicable to a Conceptual Development Phase Certificate of Need unless expressly stated to the contrary.

- (7) Nothing in a Conceptual Development Phase Certificate of Need or in the review process associated therewith shall be construed to mean that a Certificate of Need shall be granted for the proposed project.
- (i) **Related Project Components.** If the Commissioner determines that a health care facility required to obtain a Certificate of Need has separated what would otherwise be a new health care project into separate physical, functional, or financial components in order to avoid jurisdiction under Chapter 221, of Title 18, Vermont Statutes Annotated, this Rule or other applicable law, the obligation of funds, commencement of work or other action for the entire project shall nevertheless require a Certificate of Need.
- (1) Upon a written determination by the Commissioner that two or more separate actions constitute, in fact, a single health care project, the Commissioner may order the health care facility to cease and desist all actions or expenditures related to such project.
- (2) Whether two or more actions constitute a single new health care project will be based on the totality of the circumstances, including the following:
- (A) The structural interrelationship of the actions;
 - (B) The financial interrelationship of the actions;
 - (C) Whether the actions are directed at a single overall objective; and
 - (D) The time frame in which the action are to be accomplished. Separating expenditures into two or more fiscal years does not mean the actions represent distinct separate projects.
- (3) The Commissioner's decision under this subsection shall be a final decision and is subject to appeal to the Vermont Supreme Court within 30 days of notice of the decision.
- (j) **False Statements.** Any person who knowingly makes a false statement under oath or who knowingly submits false information under oath to the Commissioner, the Department, the Public Oversight Commission, or a hearing officer appointed by the Commissioner or who knowingly testifies falsely in any proceeding before the Commissioner or Public Oversight Commission may be prosecuted for perjury and subject to punishment pursuant to applicable criminal or civil law.

SECTION FOUR: CERTIFICATE OF NEED APPLICATION PROCESS

(a) Letters of Intent

- (1) Subject to Section 4(a)(3) below, a letter of intent shall be filed with the Department no less than 30 days prior to the date on which the application is filed. The letter of intent shall serve as the basis for determining whether the proposed project or action requires a Certificate of Need prior to development.
 - (A) Letters of intent shall be submitted by mail and not be submitted electronically, although electronic copies may be submitted as a courtesy.
- (2) The Department shall determine if a letter of intent is adequate to make a jurisdictional determination regarding the proposed health care project. A health care facility shall answer the Department's inquiries related to its letter of intent so that a jurisdictional determination can be made. At a minimum, an adequate letter of intent shall include:
 - (A) a narrative summary of the proposed project, including the nature of the project, the persons or entities involved, and a description of the location of the project;
 - (B) the projected expenditure associated with the project, including a sufficient description of those expenditures such that the Department may determine whether applicable jurisdictional thresholds have been met;
 - (C) Any other information necessary to make a determination that the project is, or is not, subject to Certificate of Need review.
- (3) Notwithstanding Section 4(a)(1) and (2) above, if a health care facility acknowledges a Certificate of Need is required, no letter of intent shall be required.
- (4) Within 30 days after receipt of a letter of intent, the Department shall decide whether to:
 - (A) Assert jurisdiction over the proposed project and notify the entity why certificate of need review is required;
 - (B) Decline to assert jurisdiction over the project; or

- (C) Conclude that insufficient information exists in order to determine whether the Department has jurisdiction over the proposed project. In the event that insufficient information exists, a health care facility may not proceed with the proposed project until it receives a written determination from the Department that a Certificate of Need is not required.
- (5) Every health care facility that proposes expenditures or actions which may constitute a new health care project is responsible for securing in advance a determination from the Department whether such proposed expenditures or actions constitute a new health care project subject to Certificate of Need review.
- (6) A letter of intent shall become invalid if an application is not filed within six months of the date the letter of intent is received by the Department. If jurisdiction has been asserted over the new health care project, and such project has not changed in scope or type, the health care facility may submit another letter of intent referencing the previous jurisdictional determination. After re-published public notice, the health care facility may file an application for a Certificate of Need. In the event the applicant concedes jurisdiction, a new letter of intent is not required, although public notice shall be re-published at the time of filing the application.
- (7) After notice that a proposed project will require Certificate of Need review, the applicant shall publish public notice of its letter of intent in accordance with 18 V.S.A. § 9440. In the alternative, if an applicant acknowledges a Certificate of Need is required and no letter of intent is required, as described in Section 4(a)(3), the applicant shall publish public notice upon the filing of the application. Such notice shall identify the applicant, the proposed new health care project, the date by which a competing application or petition to intervene must be filed and shall be in the form as approved by the Commissioner.
 - (A) The health care facility shall send a copy of the public notice to the clerk of the municipality in which the health care facility is located and such notice shall be posted in the clerk's office and at least two other public places in the municipality.
 - (B) The health care facility shall file a statement with the Department verifying that public notice requirements have been satisfied. Such statement shall include a copy of the public notice. Public notice shall be republished if the Department determines the notice failed to meet the requirements of this subsection.

- (C) In the event jurisdiction is conceded and no letter of intent has been filed, pursuant to 18 V.S.A. §9440(c)(2)(B), public notice described in this subsection shall be filed when the application is filed.

(b) Jurisdictional Determination

- (1) If the Commissioner determines that the project described will require a Certificate of Need, a Certificate of Need shall be required before the development or offering of the proposed project.
- (2) The Commissioner may retain professional or other staff as needed to assist in a jurisdictional determination. The reasonable costs of such analysis shall be charged to the entity submitting the letter of intent. The Commissioner, on petition by the applicant and the opportunity for a hearing, may reduce the charge to the applicant upon a finding that such expenses were excessive or unnecessary.
- (3) The Commissioner's decision regarding jurisdiction is a final decision and may be appealed to the Vermont Supreme Court.
- (4) If the Commissioner determines that a Certificate of Need is not required, a health care facility may commence the proposed project without risk of penalty or sanction under 18 V.S.A. § 9445. To the extent that a project changes from that described in the letter of intent, the health care facility shall notify the Department and the Commissioner shall notify the health care facility of any further necessary process. Determinations of no jurisdiction shall be issued in writing before application of this subsection.
- (5) If the Commissioner receives information indicating that a no jurisdiction determination was based on partial, incorrect, inaccurate or misleading information, the Commissioner may rescind such determination and assert jurisdiction over the project and sanctions may be imposed.
 - (A) If the event the Commissioner asserts jurisdiction based on new information as provided in Section 4(b)(5) above, the health care facility shall have an opportunity to respond in writing to information received. The Commissioner shall consider the health care facility's written response.

(c) Applications

- (1) Applications shall be filed as directed by the Department's Certificate of Need Manual, as updated from time to time. The Certificate of Need

Manual shall require no more information than that which is required to determine whether a Certificate of Need should be granted.

- (2) An application shall not be considered filed until the appropriate application fee has been received.
- (3) A Certificate of Need application shall contain sufficient information to establish that the proposed project or action meets all the statutory criteria, or other applicable standards, or the application shall be denied. It is the applicant's burden to establish that a Certificate of Need should be granted. A Certificate of Need application shall be denied if the applicant has failed to provide all necessary information required to review the application.
- (4) Each application shall be filed under oath by the applicant's chief executive officer. Additionally, all additional written information required or permitted to be submitted in connection with an application shall be submitted under oath. As provided for in the Certificate of Need Manual, the initial oath submitted with the application may attest to the accuracy of all information submitted in connection with the application, including information submitted subsequent to the initial application.
 - (A) If an applicant does not have a chief executive officer, the Commissioner shall direct the applicant who is the most appropriate person to verify the truth of the application material. Such person shall be the most analogous to a chief executive officer.
 - (B) The Commissioner may, in his or her sole discretion, require information submitted in connection with an application to be submitted under oath by person or persons who have personal knowledge of such information.
 - (C) The oath to accompany an application shall be in the form as provided in the Certificate of Need Manual or, with written consent of the Commissioner, in such other form as is appropriate under the specific circumstances.

(d) Application Processing

- (1) Within 30 days of receipt of an application, the Department shall either notify the applicant that the application is complete or identify areas in which additional information is needed.

- (A) Receipt of the initial notice regarding necessary additional information should not be construed to mean that all other areas of the application are considered complete, unless the Department so specifically states. The Department may identify additional areas where more information is necessary either after the initial notice or upon receipt of additional information from the applicant.
- (2) Subject to Section 4(d)(2)(A) below, within 90 days of receipt of an application, the Department shall notify the applicant that the application contains all necessary information and is complete, or that the application review period is complete notwithstanding the absence of information. In its discretion, the Department may extend the 90 day application review period for an additional 60 days. With the written consent of the applicant and any competing applicants, the application review period may be extended beyond 150 days.
 - (A) The time during which the applicant is responding to the Department's notice that additional information is necessary shall not be included within the allowable review time periods identified in Section 4(d)(2) above.
- (3) If an applicant fails to respond to the Department's requests for more information under Section 4(d)(1) and (d)(2) above within six months, the application shall be considered inactive.
 - (A) An inactive application will no longer be tracked by the Department, nor reported to the Public Oversight Commission.
 - (B) An applicant may request in writing that the Commissioner reactivate an inactive application. Such request must be received by the Department within 6 months of the inactivation date of the application.
- (4) If an applicant fails to respond to the Department's requests for more information under subsections (d)(1) and (d)(2) above within twelve months, the application shall be considered invalid.
 - (A) If an application is deemed invalid, the applicant must re-file the application in order to apply for a Certificate of Need. If an application becomes invalid, it shall be considered a withdrawn application.

- (5) Notwithstanding subsections (d)(3) and (d)(4) above, the Commissioner may, in his or her sole discretion, grant an applicant's written request to extend the time for responding to the Department's questions.

(e) Application Closed Date

- (1) The date on which the Department notifies the applicant that the application is complete, or that the review period has ended notwithstanding the absence of information, is the "Application Closed Date." All subsequent deadlines established by Title 18, Chapter 221, subchapter 5 of the Vermont Statutes Annotated, and this Rule, shall be computed from this date.
- (A) The date the Department sends the notice shall be the date of notification.
- (B) If the 90 day review period as provided in Section 4(d)(2) above has ended and the Department has not sent a notice indicating the review period is complete, the Application Closed Date shall be at the expiration of the period described in Section 4(d)(2) above.
- (2) After the Application Closed Date, the Department shall provide public notice of the application in the newspapers having general circulation in the region of Vermont affected by the application. The notice shall identify:
- (A) the applicant;
- (B) the purpose and cost of the proposed project or action;
- (C) the procedure by which a person may request information about the proposed project or action;
- (D) the date by which a competing application or a petition to intervene must be filed;
- (E) the date of the hearing before the Public Oversight Commission and that public comment is allowed at Public Oversight Commission hearings; and
- (F) any other relevant information as determined by the Department.
- (3) After the Application Closed Date, the applicant shall not submit additional material in support of its application except as expressly provided for in this Rule. If the applicant fails to provide sufficient

information in the application to justify a Certificate of Need, the Department is under no obligation to seek additional information.

- (4) An amendment to an application determined by the Commissioner to be material may require a new review schedule. If a new review schedule is necessary, public notice will be provided indicating the changes in the schedule. Otherwise, new public notice is not required. For purpose of a material amendment, the Application Closed Date is the date the amendment is accepted by the Commissioner as being sufficiently detailed so as to provide adequate notice to all parties, the Public Oversight Commission and the public of the effect of the amendment.

(f) Emergency Applications

An applicant may make written request to the Commissioner for an emergency Certificate of Need process under this subsection.

- (1) Projects shall be eligible for emergency review under this subsection (f) upon a finding by the Commissioner that the circumstances require action in less time than is normally required for review. Such circumstances include:
 - (A) repair, replacement, rebuilding or reequipping of any part of the health care facility or health maintenance organization is required due to circumstances beyond the control of the applicant; or
 - (B) other emergency circumstances beyond the control of the applicant.
- (2) If the circumstances described in subsection (f)(1) above apply, an applicant shall make written request to the Commissioner for an emergency Certificate of Need process under this subsection. Such request shall explain how the proposed project satisfies the criteria of 18 V.S.A. § 9440 relating to emergency applications.
- (3) Upon a finding that an emergency Certificate of Need process is appropriate in the applicant's circumstances, the Commissioner shall notify the applicant of the process applicable to the application in question. In the Commissioner's discretion, such process shall include as much process as provided under this Rule as can be accommodated under the specific circumstances. However, the Commissioner may review the application without notice and opportunity for a public hearing or intervention by any party.

(g) Expedited Review

- (1) An applicant seeking expedited review may file a separate letter seeking expedited review simultaneously with its Certificate of Need application.
- (2) Upon receipt of a letter seeking expedited review, the Commissioner shall make a determination that the proposed project or action may be appropriate for expedited review upon a finding that the following criteria have been satisfied:
 - (A) The application is likely to be uncontested and does not substantially alter services; or
 - (i) In subsection (2)(A) above, “substantially alter services” means:
 - (a) The capital and/or operational expenditure associated with the proposed project or action are not substantial and shall have no significant impact on the services provided, the cost of health care, or on the financial strength of the applicant; and
 - (b) The proposed project raises no significant health care policy or planning concerns.
 - (B) the application relates to a health care facility affected by bankruptcy proceedings.
- (3) Upon making a determination that the proposed project may be appropriate for expedited review, or not, the Department shall notify the applicant in writing.
 - (A) Nothing in this subsection should be construed to mean that an applicant may not elect to seek regular, as opposed to expedited, review after notice from the Department that expedited review may be appropriate.
- (4) After issuing the notice in subsection (3) above, the Department shall issue public notice of the proposed application and the request for expedited review. The public notice shall include:
 - (A) the name of the health care facility proposing the new health care project;

- (B) the nature of the proposed new health care project, with sufficient detail to adequately notify the public of the nature of the proposal;
 - (C) the fact that the health care facility has requested expedited review, without Public Oversight Commission review;
 - (D) the date by which a competing application or request for interested party status must be filed; and
 - (E) appropriate contact or reference information for procedural information regarding requesting competing applicant or interested party status.
- (5) The Commissioner may declare the application is uncontested and issue written notice granting or denying the Certificate of Need without further process, or with such abbreviated process as the Commissioner deems appropriate, upon making the following findings:
- (A) No competing application was filed; and
 - (B) No person opposing the application was granted interested party status.
- (6) Subject to subsection (7) below, if a competing application is filed or a person opposing the application is granted interested party status, expedited review shall not be allowed and the applicant must follow the standard Certificate of Need review process as dictated by statute and this Rule.
- (A) If expedited review is denied, an applicant need not file a new Letter of Intent or application, even though new deadlines are applicable.
 - (B) Deadlines applicable to the application shall be those deadlines provided in this Rule, with the notice of denial of expedited review being functionally treated as the date of receipt of the application.
 - (C) The applicant shall file public notice, as directed by the Department, notifying the public in the subject service area, of the denial of the expedited review request and when the application is to be reviewed, if it is to be reviewed.
- (7) The decision to grant expedited review shall be at the Commissioner's sole discretion. If upon further review of the application, the Commissioner determines that expedited review is not appropriate despite

a previous decision to the contrary, the applicant shall be so notified. Such notification shall contain the facts and circumstances supporting the Commissioner's decision to not expedite the application.

- (A) If the standard review process applies to the application, the first day of the review for the purposes of calculating applicable deadlines shall be the date the application was initially received.
- (8) Notwithstanding the provisions of this subsection (g), if a health care facility seeks expedited review due to a bankruptcy, the Commissioner may issue a Certificate of Need with such abbreviated process as the Commissioner deems appropriate, regardless of the contested nature of the application.

(h) Health Information Technology Applications

- (1) Certificate of Need applications for health information technology may be subject to expedited review under Section 4(g).
- (2) The Commissioner may refer a health information technology Certificate of Need application to the Vermont Information Technology Leaders, or other appropriate health information advisory group created by the Legislature pursuant to Title 18, Chapter 219 (or other applicable law), for an assessment of the proposed new health care project's consistency with the current adopted Vermont Health Information Technology Plan. In the event of such a referral, the Vermont Information Technology Leaders (or other appropriate entity) shall make written findings and a recommendation to the Commissioner for or against the referred application.
 - (A) After referral from the Commissioner, the applicant and the Vermont Information Technology Leaders shall not communicate about the application unless such communication is open and accessible to the public. As such, communications shall be in writing or in a warned and open public meeting.
 - (B) If the Vermont Information Technology Leaders has additional questions for the applicant, it shall submit such questions in writing to the Department. The Department shall forward the questions to the applicant for response. Such communications shall be in the record.
- (3) Nothing in this subsection should be construed to limit the Commissioner's authority to grant, approve, in whole or in part, the application in a manner inconsistent with the recommendation of Vermont

Information Technology Leaders (or other appropriate entity), provided the Commissioner finds that such application is or is not consistent with the Vermont Health Information Technology Plan, the Health Resources Allocation Plan or other applicable law.

(i) Waiver

Consistent with applicable law, in his or her discretion, the Commissioner may waive any provision of this Rule in furtherance of purposes of this subchapter.

SECTION FIVE: APPLICABLE CRITERIA

- (a)** A Certificate of Need shall not be granted unless such proposed project is consistent with applicable statutory criteria in 18 V.S.A. § 9437.
- (b)** Each application shall be reviewed to determine whether the new health care project proposal avoids unnecessary duplication, contains or reduces the costs of delivering health services, maintains or improves the quality of, and access to, health care services, and promotes the rational allocation of health care resources in Vermont.
- (c)** As relevant to the type of project proposed, as determined by the Commissioner, the following considerations may be relevant in determining whether a project will serve the public good:
 - (1)** The project will help meet the needs of medically underserved groups and the goals of universal access to health services.
 - (2)** The project will help facilitate the implementation of the Blueprint.
 - (3)** The applicant has demonstrated it has analyzed the impact of the project on the Vermont healthcare system and the project furthers effective integration and coordination of health care services.
 - (4)** The project is consistent with current health care reform initiatives, at the state and federal level.
- (d)** Unless an application meets the criteria of 18 V.S.A. § 9440(e), the Commissioner shall consider disapproving an application if a project was not identified prospectively as needed at least two years prior to the time of filing in the hospital's four year capital plan.

SECTION SIX: APPLICATION REVIEW PROCESS

(a) Administrative Procedures Act

The Administrative Procedures Act does not apply to the Certificate of Need review process.

(b) Review Costs

The Department may retain professional or other staff as needed to assist in the review of an application or a letter of intent. The applicant shall pay for the costs of such review. The Commissioner, on petition by the applicant and the opportunity for a hearing, may reduce the charge to the applicant upon a finding that such expenses were excessive or unnecessary.

(c) Certificate of Need Application Record

- (1) Applications shall be considered on the basis of the materials in the record as designated and maintained by the Department. Subject to subsection (c)(2) below, the record shall include:
 - (A) All materials submitted by the applicant, including the letter of intent, the application and all correspondence and materials submitted relating to the application;
 - (B) All written communications, including electronic communications, between the Department and the applicant relating to the application, including correspondence from and to the applicant, interested, competing parties, or members of the public relating to the application;
 - (C) All materials submitted by or on behalf of a competing application or an interested party. The Department's communications with the competing applicants and interested parties shall also be part of the record;
 - (D) The Department's assessment of the application prepared for the Public Oversight Commission;
 - (E) The testimony of the applicant at the Public Oversight Commission hearing and any material submitted to the Public Oversight Commission before, during or after the hearing before the Public Oversight Commission;

- (F) The transcript of any Public Oversight Commission hearing related to the application;
 - (G) The Public Oversight Commission's memorandum of findings and recommendations prepared for the Commissioner's consideration;
 - (H) Any other materials relied upon by the Commissioner in rendering his or her decision regarding the application;
 - (I) The Commissioner's proposed decision, if any;
 - (J) Materials submitted or reviewed in any hearing before the Commissioner concerning an application, including testimony and public comment, if any, at such hearing;
 - (K) The Commissioner's final decision granting or denying, in whole or in part, the application; and
 - (L) All subsequent materials submitted in relation to the Certificate of Need, including implementation reports, correspondence and amendments, if any.
- (2) Subject to the exceptions enumerated in subsection (A) below, and in Sections 6(g) and 6(i) (relating to the Public Oversight Commission and Commissioners' review), an applicant may not submit additional material in support of its application after the Application Closed Date.
- (A) An applicant may submit previously unseen presentation materials in support of its application at the Public Oversight Commission hearing. Such presentation materials must not contain any new information in support of the application which was not previously submitted unless such information was expressly requested by the Department.
- (3) If the Commissioner or Public Oversight Commission receive unsolicited or otherwise improperly submitted written information from an applicant or other party or amicus curiae about a pending application that has been declared closed, such information shall become a part of the record (and all parties and amicus curiae copied) to the extent such information is relied upon by the Commissioner in his or her decision making process. Otherwise, such information shall be excluded from the record and the party or applicant shall be so notified. All such materials, whether included in the record or not, shall be provided to all interested parties, competing applicants and the applicant.

- (A) If such information is accepted into the record, the applicant, interested party, competing applicant, amicus curiae or members of the Public Oversight Commission may be given an opportunity to comment on the information.
- (4) To the extent the contents of the application record are in dispute, the Commissioner shall make the final determination as to what shall be included in the application record.
- (5) All materials included in the record are public records, pursuant to 1 V.S.A. § 317. However, the following procedures shall apply for materials submitted in connection with an application which are not “public records” as defined by 1 V.S.A. § 317 and other applicable law.
 - (A) In the event an applicant or other person desires to submit materials into the record which are believed to be exempt from public inspection under Vermont or other applicable law, the person submitting the materials shall seek a written determination from the Commissioner regarding whether or not the materials constitute a public record under Vermont or other applicable law.
 - (B) Such request shall include a detailed description of the material at issue and a legal justification for the protection of the material. The person seeking to protect the material from public disclosure shall bear the burden of establishing such material is not a public record.
 - (C) Within 15 business days, or sooner or later upon cause shown, the Commissioner shall issue a decision regarding the status of the materials and whether such materials are subject to public inspection under Vermont or other applicable law.
 - (D) If the Commissioner finds that the material does not constitute a public record, such material shall be submitted in an envelope, or other enclosure, and clearly marked as confidential and not subject to public inspection.
 - (E) Nothing in this subsection should be construed to mean that the records at issue will not be subject to subpoena or other court order.

(d) Ex Parte Communication

- (1) The Commissioner and the Public Oversight Commission shall not consider information regarding an application unless such information is included in the record.
- (2) Unless required for the disposition of ex parte matters authorized by law, after the Commissioner makes his or her determination that a project is subject to Certificate of Need review, the Commissioner and each member of the Public Oversight Commission shall not communicate concerning the application, except as provided for below, with any party to the Certificate of Need proceeding, or with any person on behalf of a party, or with any person with a material interest in the outcome of a proceeding.
 - (A) Notwithstanding subsection (d)(2) above, prior to the Public Oversight Commission hearing, the Commissioner's staff may communicate with any party, competing applicant, amicus curiae, member of the public or any other person for the purpose of answering questions about the technical requirements of the Certificate of Need program.
 - (B) If there are no interested parties or competing applicants, prior to the Public Oversight Commission hearing on a subject application, the Commissioner's staff may answer questions regarding the quality of a subject application and whether such application is consistent with the Department's expectations. The substance of any such verbal conversations should be reduced to writing and included in the record. If there are interested parties or competing applicants, the Commissioner's staff may answer general questions regarding the quality of an application, but all interested parties or competing applicants must be a party to the communications.
 - (C) The Public Oversight Commission may communicate with the Commissioner's staff about the Public Oversight Commission's expectations regarding a specific application prior to the Application Closed Date. The Commissioner's staff may communicate such information to the applicant as part of the application process.
 - (D) Subject to Sections 6(g)(4)(B), 6(i)(5) and 6(i)(6), relating to the Public Oversight Commission's request for additional information and hearings associated with the Commissioner's proposed decision, and in addition to the prohibition on non-public communication with the Public Oversight Commission about a pending application in Section 6(d)(2), the applicant, interested

parties, amicus curiae, competing applicants, and the public may not communicate with the Commissioner's staff or the Public Oversight Commission after the Public Oversight Commission has heard an application. An applicant, interested parties, amicus curiae, competing applicants and the public may contact Department counsel, but only for technical questions and not to discuss the merits of the pending application.

- (E) Nothing in this subsection shall be construed to mean that the Commissioner cannot engage in consultations with, and rely on information provided by, Department staff for the purpose of considering, reviewing and making decisions relating to the proceedings under Title 18, Chapter 221, Subchapter 5, and this Rule. Such communications are exempt from public disclosure pursuant to 1 V.S.A. § 317(c)(24).
 - (F) The Commissioner, and his or her staff, may communicate with third party consultants in assessing applications under this Rule. To the extent such materials are relied upon by the Commissioner in his or her decision-making, such communications shall be a part of the record.
 - (i) Upon good cause and only with the written permission of the Department, an applicant's third party consultant may communicate directly to the Department's consultants about technical aspects of questions pending.
- (3) The Commissioner may require a person who appears to have violated the provisions in this subsection to show cause why his or her application or claim should not be adversely affected on account of the violation, or a penalty imposed pursuant to 18 V.S.A. § 9445 or other applicable law.

(e) Competing Applications

- (1) Any person wishing to offer or develop a new health care project that is substantially similar to a pending application may submit a letter of intent to compete, indicating that a competing application shall be forthcoming.
 - (A) The letter of intent to compete shall be filed no later than 15 days following public notice that the final application has been received by the Department.
 - (B) Within ten business days of receipt of a letter of intent to compete, the Department shall issue a written response acknowledging the letter of intent and, based on the information contained in the letter

of intent to compete, confirming jurisdiction and that the applications are in competition, if appropriate.

- (C) Within ten business days following the Department's notice in subsection (B) above, the competing applicant shall publish public notice of the competing application in a form and manner as directed by the Department.
- (2) The competing application shall be filed within 30 days of receipt of the acknowledgement in Section 6(e)(1)(B) above.
- (3) The same timelines applicable to other Certificate of Need applications shall apply to the competing application, except that the competing application shall be ruled closed no later than 55 days after the original application's Application Closed Date, or sooner, if a complete competing application is received prior to that date.
- (4) The Certificate of Need timelines for the original application shall be suspended while the competing application is being processed.
- (5) In the event that a person filing a letter of intent to compete with an existing applicant expands the scope of the proposed project or action to encompass components not included in the original application, opportunity shall be afforded to additional parties to enter the competition and for the existing applicant to respond to the expanded scope. Under such circumstances, the Department shall suspend all applicable timelines and publish a revised schedule for the competition. Such schedule shall ensure the timely, effective and efficient processing of applications.
- (6) Upon receipt of the complete competing application(s) or expiration of the 55 days provided for in subsection (e)(3) above, all competing applications shall proceed simultaneously.
 - (A) If a Public Oversight Commission hearing is required, the Public Oversight Commission shall hear all competing applications on the same day, except upon good cause shown as determined by the Commissioner.
- (7) The Commissioner may make an independent finding that two or more potential applicants should be considered competing applicants. In the foregoing sentence, "potential" applicant refers to an entity with a pending application or pending letter of intent. This finding shall serve as notice of intent to compete. Under such circumstances, the Department shall notify each party of the Commissioner's determination and give notice to each of the applicants of the date upon which applications must be ruled closed.

- (A) If an applicant elects not to pursue the project which is the subject of the competing application, or withdraws from the process, such applicant shall not seek to develop the same or similar new health care project for a period of one year following the notice of competing applications.
- (8) Nothing in this section shall be construed to restrict the Commissioner from granting a Certificate of Need to one, all, or none of the applicants.

(f) Intervention

- (1) A person or organization may seek to intervene in a Certificate of Need review process by requesting interested party status from the Commissioner by filing a written request, not in electronic form, to the Department. Such request shall be under oath, contain an original signature and must be received in the Department's offices no later than the time provided for in this Rule.
 - (A) A request to intervene as an interested party shall be made within 20 days of the public notice regarding the applicant's letter of intent (or application if no letter of intent is required) or within 20 days of the public notice regarding the Application Closed Date. Upon good cause shown, the Commissioner may accept a request to intervene which is not filed within 20 days. However, under no circumstances shall the Commissioner accept requests filed more than 5 days late.
 - (B) A request for interested party status should provide a detailed statement of the requesting person's interest in the Certificate of Need proceeding. A request should illustrate how relevant Certificate of Need criteria, including applicable health care policy goals, relate to the request to intervene and how the requestor's interests relate to the specific application under review.
 - (i) Failure to sufficiently explain why interested party status should be granted will result in a denial of the request.
- (2) The Commissioner shall grant interested party status to persons or organizations representing interests of persons who demonstrate that they will be substantially and directly affected by the new health care project under review. In this context, a substantial and direct impact shall include a direct financial or other business interest in the proposed project. A general interest in a project as a function of being in the subject service area or otherwise being generally concerned with the health care system

shall not be sufficient, although people with such an interest shall be afforded the opportunity to speak at the Public Oversight Commission hearing during the public comment portion of the hearing.

- (A) A person or organization granted interested party status shall be considered a party in the Certificate of Need application review process.
 - (B) Once interested party status has been granted, the Department shall provide the information necessary to enable the party to participate in the Certificate of Need review process. Such information shall include relevant information about procedures and copies of all materials in the record.
 - (C) After interested party status has been granted, interested parties may file pre-hearing information, may participate in the review process, and may file an appeal of the Commissioner's decision or other ruling regarding the application eligible for appeal to the Vermont Supreme Court within 30 days of the date of the Commissioner's decision or ruling.
 - (D) After interested party status has been granted, interested parties shall be copied on all materials in the record.
 - (E) Prior to the Application Closed Date, interested parties may submit proposed questions for the applicant to the Commissioner. In his or her discretion, the Commissioner may ask the applicant to respond to such questions. Such proposed questions shall be in the record and copies of such questions, whether asked by the Commissioner or not, shall be provided to the Public Oversight Commission with the application materials.
 - (F) Interested parties are interested parties for the duration of the Certificate of Need and the applicant shall supply them with copies of implementation reports and other public reporting and information required by the Certificate of Need process, if any.
- (3) **Amicus Curiae.** The Commissioner may allow persons or organizations to be admitted to the Certificate of Need process in an amicus curiae capacity upon a finding that the person or organization shall be able to render material assistance to the Commissioner by providing nonduplicative evidence relevant to the Certificate of Need application decision.

- (A) A person or organization seeking amicus curiae status shall file a request with the Commissioner no later than:
 - (i) 20 days following public notice of the filing of the letter of intent (or the filing of the application if no letter of intent is required); or
 - (ii) 20 days following public notice of receipt of the final application.
 - (B) Amicus curiae shall not be considered parties to an action, but shall be entitled to be copied on all materials in the record upon written request. Amicus curiae shall be copied on all materials in the same manner as an interested party, including reporting during the duration of the Certificate of Need.
 - (C) Materials submitted by amicus curiae shall be admitted into the record and copied to all parties.
- (4) The Commissioner shall grant or deny a request to intervene, either as an interested party or as amicus curiae, within 15 days after the petition has been received by the Department.
- (A) Upon a finding that good cause exists for an extension, the Commissioner may grant the request for intervention within 45 days after receipt.
 - (B) The Commissioner may grant a party intervention based on a status other than that which was requested.
- (5) The Health Care Ombudsman's office established under subchapter 1A of Chapter 107, Title 8, of the Vermont Statutes Annotated, or as amended if amended, is authorized to participate in any Certificate of Need review proceeding and shall be considered an interested party in such proceeding upon filing a written, not electronic, notice to intervene with the Department.
- (A) Upon receipt of such notice, the Health Care Ombudsman shall be an interested party, consistent with this Rule.
- (6) If a Certificate of Need application review proceeding involves a nursing home, the Long-Term Care Ombudsman, established under Title 33 of the Vermont Statutes Annotated, is authorized to participate in a Certificate of Need review proceeding and shall be considered an interested party in

such proceeding upon filing a written, not electronic, notice to intervene with the Department.

- (A) Upon receipt of such notice, the Long-Term Care Ombudsman shall be an interested party, consistent with this Rule.

(g) Public Oversight Commission

- (1) Unless specifically excepted under this Rule or other applicable law, the Public Oversight Commission shall review all Certificate of Need applications. As part of its review, the Public Oversight Commission shall review:

- (A) The application materials supplied by the applicant;
 - (i) The Commissioner's staff may not provide materials to the Public Oversight Commission upon a determination that such materials are duplicative or excessively costly to provide. The Public Oversight Commission shall be notified of such omissions and may request materials not provided.
 - (ii) If materials related to the application are confidential and not subject to public inspection, members of the Public Oversight Commission may review such materials at the Department's offices, subject to the requirement that the member keep the information confidential. A Public Oversight Commission member shall execute a confidentiality agreement, in a form dictated by the Department, prior to reviewing confidential materials.

- (B) The Department's assessment of the application; and

- (C) Any information, evidence, or arguments raised by competing applicants, interested parties, amicus curiae, and any other public input.

- (2) The Public Oversight Commission shall hold a public hearing during the course of its review.

- (A) Subject to the exceptions provided by subsection (2)(B) and (2)(C) and subsection (4) below, written information to be entered into the record and considered by the Public Oversight Commission must be filed with the Department prior to the Application Closed Date.

- (B) The Department's assessment of the application shall be submitted to the Public Oversight Commission no later than ten days prior to the hearing. All parties and any amicus curiae shall be copied on the assessment.
 - (C) Specific written rebuttal to the Department's assessment of the application may be provided to the Public Oversight Commission, the Department, and all other parties, three days prior to the date of the hearing. Such rebuttal shall not include any additional information, but is limited to a discussion of the information already in the record and the Department's assessment of the existing information. However, new information may be submitted by the applicant to the extent the Department's assessment of the application includes information not contained in the application, but only to the extent necessary to rebut the new information included in the assessment.
- (3) All Public Oversight Commission hearings shall allow a time for public comment. Further, after jurisdiction has been asserted over a project until ten days after a Public Oversight Commission hearing, the public may submit written comments to the Public Oversight Commission regarding an application. Such communication shall be provided to the Department and all participants in the Certificate of Need proceeding, as well as made available to the public. Verbal nonpublic communication with the Public Oversight Commission or any of its members is prohibited.
- (A) Unless such comments are submitted under oath, the Commissioner shall not consider such comments for the truth of the matter asserted therein. If information is submitted under oath, the applicant, competing applicant or interested parties shall have an opportunity to respond to the comments.
- (4) The Public Oversight Commission shall make written findings and a recommendation to the Commissioner in favor of or against each application.
- (A) If the Public Oversight Commission considers information in its review which is not already specifically in the record, the additional materials shall be provided to the Department and accepted into the record. To the extent the Commissioner considers this newly submitted information in his or her decision, the applicant, competing applicant, interested parties and amicus curiae shall be given an opportunity to respond.

- (B) After the Public Oversight Commission holds its hearing on an application, members of the Public Oversight Commission may request the applicant, competing applicants, interested parties and amicus curiae to provide additional information relating to the application.
- (i) Such requests may be made at the hearing and confirmed in writing after the hearing. The Department shall be copied on all requests for information and all responses to those requests.
 - (ii) Such request for information shall be made within five days of the hearing and responses to such request shall be provided no later than ten days after receipt of the request.
 - (iii) After the Public Oversight Commission hearing and prior to the Public Oversight Commission's vote on the application, the Department may provide assistance in communicating with the applicant on behalf of the Public Oversight Commission to obtain the information requested by the Public Oversight Commission, but shall not provide any assessment to the applicant or the Public Oversight Commission regarding the additional information provided or any other substantive matter regarding the application.
- (C) Any member of the Public Oversight Commission who has a conflict of interest in a specific application shall recuse him or herself from the Public Oversight Commission's review of the application. As used in this subsection, "conflict of interest" shall mean a significant interest, of a Public Oversight Commission member or such an interest, known to the Public Oversight Commission member, of his or her immediate family or household or of a business associate, in the outcome of any particular application pending before the Public Oversight Commission. "Conflict of interest" shall also include interests which may be implicated by virtue of a Public Oversight Commission member having served in a private capacity at a health care facility, such as serving on the hospital's board, when a specific project that is the subject of the application was being developed.
- (D) The Public Oversight Commission shall provide its written findings and recommendations to the Commissioner no later than 15 days after the meeting at which the Public Oversight Commission votes on its recommendation to the Commissioner.

(h) Withdrawal

An applicant may withdraw its application at any time prior to the Commissioner's decision without prejudice to any subsequent reapplication.

(i) Commissioner's Review

- (1) After receiving the recommendation of the Public Oversight Commission and before proposing or making a final decision, the Commissioner may request that the parties offer additional evidence or testimony that the Commissioner determines is necessary or desirable to adequately consider the application. If the Commissioner elects to include such additional written information or testimony in the application record, the parties shall be provided with notice and an opportunity to be heard on the additional written information or testimony.
- (2) Prior to making a final decision, the Commissioner shall review an application and supporting materials, other materials in the record and consider the recommendation of the Public Oversight Commission.
- (3) The Commissioner shall issue a final decision granting or denying an applicant's Certificate of Need application within 120 days of the Final Application Receipt Date. If it is not practicable to complete the review within 120 days, the Commissioner may extend the final decision due date by 30 days. With the written consent of the applicant the Commissioner may extend the decision due date beyond the additional 30 days.
- (4) The Commissioner's decision shall be in the form of a denial, an approval in whole or in part, and may be subject to such conditions as the Commissioner may impose in furtherance of the purposes of Title 18, Chapter 221, of the Vermont Statutes Annotated. The Commissioner's decision shall include written findings and conclusions stating the basis of the decision.
 - (A) In granting a partial or a conditional approval, the Commissioner shall not mandate a new health care project not proposed by the applicant, nor shall the Commissioner mandate the elimination of an existing service.
 - (B) Any partial approval or conditional approval must be directly within the scope of the project or action proposed by the applicant and the criteria applicable to the specific application.
 - (C) When the Commissioner determines that an application involves more than one health service or that a proposed new health care

project may reasonably be divided into component physical or functional parts and that one or more of the services or component physical or functional parts has not met the necessary criteria, the Commissioner shall issue a Certificate of Need for only those services or parts that meet the necessary criteria. In that event, the Commissioner shall issue a Certificate of Need that specifies in detail the services or parts of the proposed new health care project for which approval is given.

- (5) If the Commissioner proposes to issue a final decision denying an application, in whole or in part, or approving a contested application, the Commissioner shall serve the parties with notice of a proposed decision.
 - (A) The notice of proposed decision shall contain proposed findings of fact and conclusions of law and shall provide the parties with an opportunity to file exceptions and present briefs and oral argument to the Commissioner.
 - (B) Subject to subsection (6) below, the Commissioner may also, in his or her discretion, allow the parties to present additional evidence.
- (6) If the Commissioner proposes to issue a decision contrary to the recommendation of the Public Oversight Commission, the Commissioner shall serve the parties with notice of a proposed decision.
 - (A) The notice of the proposed decision shall contain findings of fact and conclusions of law demonstrating that the Commissioner fully considered all the findings and conclusions of the Public Oversight Commission and explaining why his or her proposed decision is contrary to the recommendation of the Public Oversight Commission and necessary to further the policies and purposes of Title 18, Chapter 221, subchapter 5; and
 - (B) The Commissioner shall permit the parties to present additional evidence.
- (7) The Commissioner's final decision may be appealed to the Vermont Supreme Court within 30 days of the date of the decision.

SECTION SEVEN: CERTIFICATE OF NEED

(a) Certificate of Need Issuance by the Commissioner

- (1) After the Commissioner issues a decision approving in whole or in part an application, the Commissioner shall issue a Certificate of Need.

- (2) A person may holding a Certificate of Need may obligate funds or commence work without risk of penalty upon issuance of the Certificate of Need, unless there are interested parties or competing applicants, in which case funds may not be obligated and work commenced until all appeals are final or the deadline for filing an appeal has passed.
- (3) The Commissioner may attach conditions to the Certificate of Need in furtherance of the purposes of Title 18, Chapter 221, so long as such conditions do not substantially alter the nature of the new health care project as proposed by the applicant.
 - (A) In the event the Commissioner imposes conditions on a Certificate of Need, an applicant may seek relief from a condition by filing a written request to the Commissioner.
 - (B) In any circumstance in which bonds are to be issued in connection with a new health care project, the Certificate of Need shall include the requirement that all information required to be provided to the bonding agency shall be provided to the Commissioner within a reasonable time. The Commissioner is authorized to obtain any information from the bonding agency deemed necessary to carry out the duties of monitoring and oversight of a Certificate of Need. The bonding agency shall consider recommendations of the Commissioner in connection with any such proposed authorization.
- (4) The Commissioner shall include the following in the Certificate of Need:
 - (A) The applicant, name, cost and scope of the new health care project authorized by the Certificate of Need, including, as appropriate, a description of the authorized service area;
 - (B) Conditions applicable to the new health care project, if any;
 - (C) A statement as to how long the Certificate of Need shall be in effect;
 - (i) A Certificate of Need shall be of limited duration such that at the date of expiration, the holder of the Certificate of Need is under no further obligation regarding the conditions set forth in the Certificate of Need. Unless specified otherwise in the Certificate of Need or subsequent amendments thereto, a Certificate of Need shall expire upon the Commissioner's acceptance of the final implementation report.

- (ii) An action or expenditure that is related to a service or expenditure that was the subject of a Certificate of Need shall not be considered a material or nonmaterial change to that project if the original Certificate of Need expired at least two years before the action or expenditure is proposed. The proposed action or expenditure shall require a Certificate of Need only if it would be considered a new health care project as defined by 18 V.S.A. § 9434.
 - (iii) If a Certificate of Need decision is appealed, the expiration date and other time limits will be extended to provide for the time required for all appeals to be completed.
 - (D) The amount of time the applicant has to implement and complete the new health care project; and
 - (E) The implementation report schedule and reporting requirements, if any. All such reports and related materials shall be submitted under oath.
 - (i) The holder shall provide implementation reports to all interested parties, unless such parties elect not to receive such reports. Upon the consent of the interested parties, such reports may be submitted electronically.
- (5) If the Commissioner has reason to believe that an applicant has violated a provision of Chapter 221, Subchapter 5 of Title 18, this Rule or the terms or conditions of a prior Certificate of Need, the Commissioner may take into consideration such violation in determining whether to approve, deny or approve the application subject to conditions.
 - (A) The applicant shall be provided an opportunity to contest whether such violation occurred, provided no such opportunity has previously been provided.
 - (B) The Commissioner may impose as a condition of approval of the application that a violation be corrected or remediated before the Certificate of Need takes effect.
- (b) **Certificate of Need Denial.** When the Commissioner denies an application, the applicant may not reapply for permission to provide an identical or substantially similar new health care project for a period of one year from the date of denial or resolution of any appeal, whichever is later, except upon good cause shown.

(c) Certificate of Need Extensions

- (1) Unless otherwise specified in the Certificate of Need, a new health care project shall be implemented within 5 years of issuance of the Certificate of Need. Subject to subsection (2) below, if a project is not completed within five years, or other time period specified in the Certificate of Need, the Certificate of Need shall become invalid and the applicant must obtain a new Certificate of Need to implement the project.
 - (2) Not later than 180 days before the expiration date of a Certificate of Need, an applicant that has not yet implemented the project approved in the Certificate of Need may petition the Commissioner for an extension of the time allowed to implement the project. The Commissioner may grant the extension in his or her discretion. The Commissioner may request such additional information, or impose such additional or revised conditions as he or she deems necessary.
- (d) Transfer.** A Certificate of Need is non-transferable.

(e) Project Changes.

- (1) In the event that after a new health care project has been authorized by the Commissioner, and the holder wishes to materially change the scope or cost of the approved project, such changes are subject to Certificate of Need review as described in this Rule, and other applicable law. A material change, as used in this Rule, means:
 - (A) The change constitutes a new health care project as defined by 18 V.S.A. § 9434 or this Rule; or
 - (B) The change in project cost is more than 10% above the total approved amount. All project costs are included to determine whether the 10% threshold has been exceeded, whether capital, operating, or any other expenses.
- (2) When a holder proposes to make a nonmaterial change, the holder shall notify the Department of the action. In the event of such notification, the Commissioner may provide for any necessary process, in his or her discretion, including:
 - (A) Notifying the holder that the Commissioner will not review the nonmaterial change. When the Commissioner elects not to review a nonmaterial change, the Certificate of Need shall be deemed to have been amended to approve the change. The Commissioner may issue an Order confirming this finding.

- (B) Electing to review the change and, after such process as determined appropriate by the Commissioner, approve, approve in part, or deny the change. Such process may, or may not, include consultation with the Public Oversight Commission or other public process. If the change is approved or approved in part, the Commissioner shall amend the Certificate of Need to that effect. If the change is denied, the original Certificate of Need shall remain valid and the holder shall not seek a Certificate of Need for the proposal for one year from the denial.
 - (C) The Commissioner's decision in this subsection shall be in furtherance of Certificate of Need policy goals, including those in the health resource allocation plan or other applicable law.
- (3) The Commissioner may, on his or her own initiative, based on information contained in the implementation reports or other relevant information, determine that a project has changed in kind, scope or capacity such that a material or non-material change has been made to a new health care project authorized under a previously issued Certificate of Need. In the event the Commissioner makes such a determination, the Commissioner may review the change as otherwise outlined in this subsection.

(f) Certificate of Need Revocation

The Commissioner may revoke a Certificate of Need for substantial noncompliance with the scope of the project as designated in the application, or for failure to comply with the conditions set forth in the Certificate of Need.

(g) Home Health Agency Certificate of Need Revisions

- (1) The Commissioner may modify the terms of a Certificate of Need relating to the boundaries of a geographic service area of a home health agency.
 - (A) Prior to modification of geographic service area boundaries, the Commissioner shall consult with the Commissioner of the Department of Disabilities, Aging and Independent Living, or other appropriate agency.
- (2) Modifications under this subsection (g) shall be made upon:
 - (A) the Commissioner's own initiative, provided notice and an opportunity to be heard shall be provided;

- (B) a written application to the Commissioner by the affected home health agency; or
 - (C) a written application to the Commissioner by affected consumers.
- (3) The Commissioner may modify home health agency service area boundaries:
- (A) to take into account natural or physical barriers that may make the provision of existing services uneconomical or impractical;
 - (B) to prevent or minimize unnecessary duplication of services; or facilities; or
 - (C) to otherwise promote the public interest.
- (4) Upon making findings as described in subsection (g)(3) above, the Commissioner shall issue an order granting such modification only upon a finding that the granting of such modification is consistent with the purposes of Title 33, Chapter 63, subchapter 1A, as amended if amended, and the Health Resource Allocation Plan.
- (5) The Commissioner shall not make modifications to a home health agency's geographic service area boundaries without notice and providing an opportunity for all interested parties or consumers to enter evidence into the record for the Commissioner's consideration. As used in this subsection, interested parties shall include affected local governments. In his or her discretion, the Commissioner may conduct a public hearing, with or without the Public Oversight Commission.
- (6) "Consumers" as used in this subsection (g) means users of home health agency services, or their duly authorized representatives.

SECTION EIGHT: ENFORCEMENT

- (a) Any person who offers or develops any new health care project without first obtaining a Certificate of Need, or who otherwise violates the provisions of Title 18, Chapter 221, Subchapter 5, the provisions of this Rule or other applicable law, may be subject to the sanctions as described in 18 V.S.A. § 9445.
- (b) In determining appropriate sanctions for violations of this Rule, Title 18, Chapter 221, or any other applicable laws, the Commissioner shall consider the following factors:
 - (1) Whether the entity filed a good faith letter of intent or letter of inquiry;

- (2) Whether the entity reasonably relied on a no jurisdiction determination from the Commissioner;
 - (3) Whether the project will cause an increase in costs to the health care system;
 - (4) Whether the project is likely to reduce or contain the cost of health care services;
 - (5) Whether the project is otherwise consistent with the Health Resources Allocation Plan and other Certificate of Need criteria;
 - (6) In the case of a facility that did not believe it was going to exceed monetary jurisdictional thresholds, but then did so, the Department shall consider the reasonableness of the assumption that thresholds would not be exceeded; and
 - (7) Any other mitigating or aggravating factors.
- (c) A health care facility, or any other person or entity, that develops, has developed on its behalf, purchases, renovates or otherwise establishes a new health care project without a Certificate of Need shall be subject to sanctions in the following circumstances:
- (1) The entity did not obtain a no jurisdiction determination from the Commissioner;
 - (2) The entity engaged in fraud, misrepresentation, or deception in its communications with the Department, the Commissioner or the Public Oversight Commission; or
 - (3) The project is likely to result in unnecessary duplication of services.
- (d) Prior to the imposition of sanctions, an entity shall have notice and an opportunity for a hearing.
- (1) Such hearing shall be scheduled and conducted pursuant to the schedule set by the Commissioner in that particular matter. The entity shall have no less than 15 days notice of a hearing, except for good cause shown.
 - (2) To the extent an application is pending and dependent on the resolution of potential violations of Title 18, Chapter 221, Subchapter 5, this Rule, a previously issued Certificate of Need or other applicable law, such hearing

shall occur with 20 days of notice of the suspected violation, except upon good cause shown or written permission from the applicant.

SECTION NINE: EFFECTIVE DATE

This rule shall take effect on August 17, 2010.