

GREEN MOUNTAIN CARE BOARD

Rule 4.000: CERTIFICATE OF NEED

4.100 GENERAL PROVISIONS

4.101 Authority

The Green Mountain Care Board adopts this Rule pursuant to 18 V.S.A. §§ 9375(b)(8), 9380, 9431(b), 9433 and other applicable law.

4.102 Purpose

The purpose of this Rule is to prevent unnecessary duplication of health care facilities and services, promote cost containment, guide the establishment of health facilities and services which will best serve public needs, ensure the provision of high quality services and resources, and ensure access to and equitable allocation of such facilities and services in this State.

4.103 Electronic Filing

Unless otherwise specified in this Rule, all documents submitted to or filed with the Board shall be transmitted to the Board electronically, except where doing so would cause undue hardship to the person submitting or filing the document or where the document cannot readily be converted to electronic form.

4.104 Definitions

The following terms shall have the same meanings as in 18 V.S.A. § 9432: “annual operating expense”; “applicant”; “capital expenditure”; “construction”; “to develop”; “health care facility”; “health care provider”; “health services”; and “to offer”.

The following definitions are in addition to those in 18 V.S.A. § 9432:

1. “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.
2. “Application” means all materials submitted to the Board by an applicant as part of the Certificate of Need application review process prior to the application closed date, and includes the Board’s questions, and the applicant’s responses to the Board’s questions, concerning the application and the review process.
3. “Board” means the Green Mountain Care Board.
4. “Certificate of Need Manual” means the manual published by the Board which provides guidance and instructions, consistent with applicable law, for entities seeking information about the Certificate of Need process or seeking a Certificate of Need.
5. “Days” means consecutive calendar days, except as follows:

(a) If a deadline falls on a weekend or holiday, the deadline shall be extended to the next business day;

(b) If the designated period is five (5) days or fewer, weekends and holidays are not included in the calculation.

6. “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.

7. “Equipment” means a single unit of medical equipment or a single system of components with related functions used in a patient care environment to support patient treatment and diagnosis or to provide medical and other health services.

8. “Expenditure” means any outlay of funds, including an annual operating expense or a capital expenditure, as those terms are defined by 18 V.S.A. §§ 9432(2) and 9432(5), respectively.

9. “Full operation” means when a health service is operating, on an annual basis, at the normal and customary level of service.

10. “Recipient” means any person who receives a Certificate of Need from the Board.

11. “Hospital” means a hospital as defined in 18 V.S.A. § 9402.

12. “Jurisdiction” means the Board’s assertion of authority over a health care project pursuant to 18 V.S.A. § 9434.

13. “New health care project” has the same meaning as in 18 V.S.A. § 9434(a)-(b).

14. “Party” means the applicant, a competing applicant, the Vermont Office of Health Care Ombudsman if it participates in the review of an application pursuant to 18 V.S.A. § 9440(c)(9), and any person whose petition for interested party status has been granted by the Board.

4.105 Applicability

This Rule shall apply to all certificate of need applications that are filed on or after January 1, 2013.

4.200 JURISDICTION

In determining whether a new health care project requires a Certificate of Need under 18 V.S.A. § 9434, the following rules apply.

4.201 Equipment

1. The following shall be included in the cost of equipment:

(a) the cost or, in the case of a donation, the fair market value, of the equipment itself and all related components necessary to make the equipment function as intended by the health care facility;

- (b) the costs of studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making the equipment operational;
- (c) the fair market value of any equipment being traded in as part of the purchase;
- (d) financing costs, or, if such costs have not been finalized prior to a jurisdictional determination, a reasonable prediction of financing costs;
- (e) costs for any maintenance or service contract or agreement, unless such contract or agreement is with any entity wholly unrelated to the seller of equipment, or entered into at least one year after the initial purchase of the equipment;
- (f) the cost of any components reasonably anticipated to be purchased for use with a piece of equipment within one year of the initial purchase;
- (g) the cost of any operating lease, calculated based on the net present value of the lease. “Net present value” means the total lease payments over the useful life of the asset as set out in the most current version of Estimated Useful Lives of Depreciable Hospital Assets, published by the American Hospital Association. The cost of a capital lease shall be equal to the amount capitalized; and
- (h) any other costs that are necessary to the acquisition of the equipment and the placing of the equipment in operation.

2. The costs, as defined above, of the purchase or lease of two or more pieces of equipment which are necessarily interdependent in the performance of their ordinary functions, or which would constitute a health care facility, shall be added together to calculate the cost of the equipment.

4.202 Health Care Service or Technology

1. In determining for jurisdictional purposes whether the offering of a health care service or technology exceeds the statutory thresholds in 18 V.S.A. § 9434(a)(5) or 18 V.S.A. § 9434(b)(3), the “annual operating expense” means all costs associated with offering the service or technology that are necessary to make the service or technology fully operational, including but not limited to hardware, software, interfaces, vendors, consultants and training.

2. The applicant shall notify the Board of any changes to a health information technology (“HIT”) system, including upgrades, supplements or add-ons, that are made as part of the implementation of a project for which a Certificate of Need has been issued and which are necessary to make the HIT system fully operational and to satisfy state and federal regulatory requirements and security compliance requirements. If the costs of such changes, including but not limited to the costs of hardware, software, interfaces, vendors, consultants and training, exceed ten percent of the amount approved for the project in the Certificate of Need, then the changes constitute a “material change” under 18 V.S.A. § 9432(11) and are subject to review pursuant to 18 V.S.A. § 9444(b)(1).

3. Changes to a HIT system, including upgrades, supplements or add-ons, that are made after implementation of a project for which a Certificate of Need was issued, shall constitute a new health care project under 18 V.S.A. § 9434(a) or (b) if the costs of such changes, including the

costs of hardware, software, interfaces, vendors, consultants and training, exceed the monetary thresholds in 18 V.S.A. § 9434(a)(5) or 18 V.S.A. § 9434(b)(3).

4.203 Change in Ownership for Health Care Facilities Other Than Hospitals

1. If a health care facility other than a hospital 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 shall be a new health care project.
2. The transfer or conveyance of an ownership interest in a health care facility other than a hospital that fundamentally changes the financial stability or legal liability of the facility shall be a new health care project.

4.204 Donations

The offering or development of a new health care project that results from a donation is a new health care project for jurisdictional purposes 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.

4.205 Exclusions from the Certificate of Need Process

1. Consistent with the provisions of 18 V.S.A. § 9435, to determine whether offices of physicians, dentists, or other practitioners of healing arts are excluded from Certificate of Need review, the Board shall consider, at minimum:

- (a) billing procedures to be used;
- (b) structure of ownership;
- (c) training and specialties of the staff;
- (d) procedures to be performed;
- (e) patient referral patterns and relation to other health care institutions;
- (f) type of diagnostic and other equipment to be purchased;
- (g) representations of the facility to the public, and
- (h) 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.

4.206 Conceptual Development Phase Certificates of Need

1. If a new health care project is anticipated to be in excess of the monetary threshold set forth in 18 V.S.A. § 9434(c), the applicant must apply for and obtain a Conceptual Development Phase Certificate of Need in accordance with the standards and procedures established in subchapter 5 of 18 V.S.A. chapter 221.

2. 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 and authorizes the applicant to undertake the planning activities and expenditures only.

3. An applicant that relies, in good faith, on verified projected cost estimates issued by a qualified person or persons which would have led a reasonable person to conclude the project's cost would not exceed the monetary threshold set forth in 18 V.S.A. § 9434(c), will not be subject to sanctions. A "qualified person" means a person with significant, relevant expertise and professional experience in the development and/or construction of the proposed new health care project.

4. The Board shall grant a Conceptual Development Phase Certificate of Need if the Board finds that:

- (a) The cost of the proposed planning activities is reasonable and the applicant can afford such cost;
- (b) The project appears to meet an identifiable, existing or reasonably anticipated need which is appropriate for the applicant to provide; and
- (c) If the project includes or comprises the purchase or lease of health care information technology, the project is consistent with the most current Vermont Health Information Technology Plan.

5. 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.

4.207 Related Project Components

1. A health care facility may not avoid the Board's jurisdiction by separating what would otherwise be a new health care project requiring a Certificate of Need into separate physical, functional, or financial components.

2. If the Board determines that a health care facility otherwise required to obtain a Certificate of Need has sought to avoid jurisdiction by separating the project into components, it shall notify the health care facility, in writing, of its determination. The Board shall base its determination on the totality of the circumstances, including the following considerations:

- (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 actions are to be accomplished. Separating expenditures into two or more fiscal years does not mean the actions represent distinct separate projects.

3. If the Board determines that a project, as discussed above, required a Certificate of Need, it may, pursuant to 18 V.S.A. § 9445(c), order the health care facility to cease and desist all actions or expenditures related to such project. The determination shall be a final decision and is subject

to appeal to the Vermont Supreme Court within thirty (30) days of notice of the decision. The Board may also impose sanctions or take other enforcement action pursuant to 18 V.S.A. § 9445 and Section 2.700 of this Rule.

4.300 APPLICATION PROCESS

4.301 Letter of Intent

1. If an applicant acknowledges that a Certificate of Need is required, then the applicant need not submit a letter of intent.
2. Unless the applicant acknowledges that a Certificate of Need is required or unless otherwise specified by statute, an applicant shall file with the Board a letter of intent prior to filing an application for a Certificate of Need. The letter shall include, at minimum:
 - (a) a narrative summary of the proposed project, including the nature of the project, the project's components, the service area impacted by the project, the persons or entities involved, a description of why the project is needed, and a description of the location of the project; and
 - (b) the projected expenditure associated with the project, including a sufficient description of those expenditures such that the Board may determine whether applicable jurisdictional thresholds have been met;
 - (c) any other information necessary to determine whether the project is subject to Certificate of Need review.
2. Upon providing public notice of a letter of intent, as required by 18 V.S.A. § 9440(c)(2)(A), the applicant shall file a statement with the Board verifying that it has provided such public notice and shall attach a copy of the public notice to the statement. Failure to provide public notice may prevent or delay a jurisdictional decision by the Board, or result in applicable sanction(s). This subsection 4.301(2) does not apply when the applicant has made a request for expedited review under 18 V.S.A. § 9440(c)(5) and Section 4.304 of this Rule.
3. Within thirty (30) days after receipt of a letter of intent, the Board 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 Board has jurisdiction over the proposed project. In such instance, the health care facility may not proceed with the proposed project until it receives a written determination from the Board that a Certificate of Need is not required.

The Board's determination under this provision shall be issued in writing and shall be delivered electronically to the applicant, competing applicants, and interested parties. If the Board determines that a Certificate of Need is required, then, as part of its written determination, the Board will identify the specific Certificate of Need Standards in the Vermont Health Resource Allocation Plan (HRAP), if any, that the applicant must show the project will satisfy.

4. If the Board determines that a Certificate of Need is not required, a health care facility may commence the proposed project without risk of penalty or sanction. To the extent that a project changes from that described in the letter of intent, the health care facility shall notify the Board, which shall notify the health care facility of any further necessary process.
5. If the Board subsequently determines that a no jurisdiction determination was based on partial, incorrect, inaccurate, or misleading information, the Board may rescind its determination, assert jurisdiction over the project, and may impose sanctions.

4.302 Application

1. Applications shall be filed electronically, on a form and in a manner as prescribed by the Board. Within ten days of receipt of the application, the Board shall post the application on its website.
2. Within thirty (30) days of receipt of an application, the Board shall review the application and notify the applicant in writing that the application is complete or identify areas in which additional information is needed, including the specific HRAP Certificate of Need Standards, if any, that the applicant must show the project will satisfy. If the Board identifies areas in which additional information is needed, then the applicant may elect to respond in writing, at a public hearing held pursuant to Section 4.407 of this Rule, or both.
3. The Board's decision to request additional information or allow an applicant to amend a deficient or incomplete application is discretionary. It is the applicant's burden to establish that a Certificate of Need should be granted.
4. An application that does not comply with the deadlines set forth in 18 V.S.A. § 9440, other applicable law, this Rule, or the Certificate of Need manual is deemed withdrawn. An applicant must re-file the withdrawn application unless the Board, in its discretion, grants the applicant's request for an extension of time.
5. The time during which the applicant is responding to the Board's request for additional information shall not be included within the allowable review time periods identified by statute, rule, or the Certificate of Need manual.
6. The date on which the Board 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" from which all subsequent time requirements of 18 V.S.A. § 9440 shall run.
7. Immediately following the application closed date, the Board shall post the application closed date on its website and provide public notice of the application in the newspapers of 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; and

(e) any other relevant information as determined by the Board.

8. After the application closed date, the applicant shall not submit additional material in support of its application or otherwise amend its application, except as expressly provided for by statute, rule, Certificate of Need manual, or as requested or otherwise authorized by the Board.

9. If the Board permits an applicant to amend or supplement its application, the Board may require a new review schedule for the application. In such instance, the Board shall provide public notice on its website indicating the revised schedule. The application closed date of an amended application is the date the amendment is accepted by the Board as being sufficiently detailed so as to provide adequate notice to all parties and to the public of the effect of the amendment on the application.

4.303 Emergency Certificates of Need

1. An applicant may request an emergency Certificate of Need in limited instances. To obtain an emergency Certificate of Need, the applicant shall (1) explain how the proposed project satisfies the criteria of 18 V.S.A. § 9440, and (2) provide sufficient information showing that circumstances require action in less time than normally required for review. Circumstances in which an emergency Certificate of Need may be issued include, but are not limited to:

(a) the repair, replacement, rebuilding, or reequipping of any part of a health care facility due to circumstances beyond the control of the applicant; or

(b) any other emergency circumstances beyond the control of the applicant that require expenditure and fall within Certificate of Need jurisdiction.

2. Upon a finding by the Board that issuance of an emergency Certificate of Need is appropriate, the Board shall notify the applicant of the process applicable to the application in question. In the Board's discretion, such process shall include as much process as provided under this Rule as can be accommodated under the specific circumstances. If the nature of the emergency requires it, the Board may review the application without notice and opportunity for a public hearing or intervention by any party.

4.304 Expedited Review

1. An applicant seeking expedited review of an application must show, and the Board must determine, that:

(a) the application is likely to be uncontested and the proposed project does not substantially alter services;

(b) the application is for the purchase or lease of information technology;

(c) the health care facility is affected by bankruptcy proceedings;

(d) the application involves only the review of planning and design expenditures for the conceptual development phase of a project covered by § 4.206 of this Rule; or

(e) the application involves any other project that is likely to be uncontested, is consistent with the policies expressed in 18 V.S.A. § 9431(a), and may be reviewed appropriately in an abbreviated process.

2. A project does not “substantially alter services” if:
 - (a) the project raises no significant health care policy or planning concerns; and
 - (b)(i) the expenditures associated with the proposed project or action do not have a significant impact on the services provided, the cost of health care, or the financial strength of the applicant; or
 - (ii) the project consists of the routine replacement of existing equipment that is depreciated, out-of-date or obsolete, or consists of the routine renovation, repair or maintenance of existing buildings and facilities.
3. An applicant seeking expedited review may submit a simplified application, which must:
 - (a) include a detailed explanation of the costs associated with the project;
 - (b) explain why the project qualifies for expedited review under § 4.304(1)-(2); and
 - (c) explain the need for the project and why the applicant is the appropriate person or entity to address the need.
4. The Board shall notify the applicant of its preliminary finding that the application may be appropriate for expedited review, and 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 date by which a competing application or request for interested party status must be filed; and
 - (d) appropriate contact or reference information for procedural information regarding requesting competing applicant or interested party status.
5. After issuing public notice, the Board may, after twenty (20) calendar days from such notice, grant or deny the expedited Certificate of Need application upon making the following findings:
 - (a) no competing application was filed; and
 - (b) no party has sought and been granted, or has a likelihood of being granted, interested party status.
6. 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 set forth in statute, rule, and the Certificate of Need manual.
 - (a) If expedited review is denied, an applicant need not file a new letter of intent or application, and the date the application was initially received shall be the first day of the review period for the purposes of calculating applicable deadlines under this Rule.

(b) Upon notice of denial of expedited review, the applicant shall file public notice in the subject service area which states that expedited review was denied, and other relevant information as determined by the Board.

7. The decision to grant expedited review shall be at the Board's sole discretion. If upon further review of the application, the Board determines that expedited review is not appropriate despite a previous decision to the contrary, the Board shall notify the applicant, in writing, of the facts and circumstances supporting its decision not to expedite review of the application.

8. In the case of a health care facility seeking expedited review due to a bankruptcy, the Board may issue a Certificate of Need with such abbreviated process as it deems appropriate, regardless of the contested nature of the application.

4.400 APPLICATION REVIEW PROCESS

4.401 In General

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

4.402 Criteria

1. The Board shall not grant a Certificate of Need unless the proposed project is consistent with the policy and purposes set forth in Chapter 221 of Title 18, the statutory purposes set forth in 18 V.S.A. § 9372, and the criteria set forth in 18 V.S.A. § 9437.

2. In order to satisfy 18 V.S.A. § 9437(1), the applicant must show that the project is generally consistent with the HRAP and that the project satisfies any HRAP that the Board has identified in a jurisdictional determination under Section 4.301(3) or 4.302(2) of this Rule.

3. The Board may consider the following factors in determining whether a project will serve the public good under 18 V.S.A. § 9437(6):

- (a) Whether the project will help meet the needs of medically underserved groups and the goals of universal access to health services.
- (b) Whether the project will help facilitate the implementation of the Blueprint.
- (c) Whether the applicant has demonstrated it has analyzed the impact of the project on the Vermont health care system and the project furthers effective integration and coordination of health care services.
- (d) Whether the project is consistent with current health care reform initiatives, at the state and federal level.
- (e) Except where circumstances support approval of an emergency Certificate of Need, whether the project was identified prospectively as needed at least two years prior to the time of filing in the hospital's four-year capital plan.
- (f) Whether, and if so to what extent, the project will have an adverse impact on the ability of existing facilities to provide medically necessary services to all in need, regardless of ability to pay or location of residence.

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

4.403 Application Record

1. The Board shall consider each application based on materials included in the record, as designated and maintained by the Board. 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 relating to the application between the Board and the applicant, competing applicants, and interested parties;
- (c) all materials submitted by or on behalf of a competing applicant or an interested party, including the Board's communications with competing applicants and interested parties;
- (d) any other materials, including communications from members of the public, relied upon by the Board in rendering its decision regarding the application;
- (e) the Board's proposed decision, if any;
- (f) materials submitted or reviewed in any hearing before the Board concerning an application, including testimony and public comment, if any;
- (g) the Board's final decision granting or denying, in whole or in part, the application;
- (h) the Certificate of Need; and
- (i) all subsequent materials submitted in relation to the Certificate of Need, including implementation reports, correspondence and amendments, if any.

2. Information submitted to the Board about a pending application after the application closed date shall be excluded from the record, unless the Board decides in its discretion to include such information in the record. If the Board decides to include such information in the record, it shall provide the information to the applicant, all competing applicants, and all interested parties, who may who may submit written comments or responses within ten days.

3. Materials included in the record are public records, pursuant to 1 V.S.A. § 317, unless specifically exempted. In the event an applicant or other person submitting materials into the record believes them to be exempt from public inspection:

- (a) Such person shall request a written determination from the Board as to whether the materials constitute a public record;
- (b) The request shall include a detailed description of the material at issue and a legal justification for the protection of the material;
- (c) The person seeking to protect the material from public disclosure shall bear the burden of establishing such material is not a public record; and
- (d) Within fifteen (15) business days, or sooner or later upon cause shown, the Board

shall issue a decision whether such materials are subject to public inspection under applicable law. If the materials are deemed not subject to disclosure, they will be treated as confidential and unavailable for public review.

4.404 Ex Parte Communication

1. The Board shall not consider information regarding an application unless such information is included in the record.
2. In proceedings in which a competing application has been filed or a person has obtained interested party or amicus curiae status, the Board shall not communicate concerning the merits of an application 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 after it determines that the application is subject to Certificate of Need review, except:
 - (a) to obtain additional information or documentation from the applicant or other parties necessary for review of the application;
 - (b) for the purpose of obtaining information about the technical requirements of the Certificate of Need program;
 - (c) to address procedural questions; or
 - (d) as authorized by law.
3. Nothing in this subsection shall be construed to mean that the Board cannot engage in consultations with and rely on information provided by its staff for the purpose of considering, reviewing, and making decisions relating to the application. Such communications are exempt from public disclosure pursuant to 1 V.S.A. § 317(c)(24).
4. The Board or its staff may communicate with third party consultants in assessing applications under this Rule. To the extent such materials are relied upon by the Board in its decision making, such communications shall be a part of the record. Upon good cause and only with the written permission of the Board, an applicant's third party consultant may communicate directly to the Board's consultants about technical aspects of questions pending.

4.405 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 no later than fifteen (15) days following public notice that an application for Certificate of Need has been received by the Board.
2. Within ten (10) business days of its receipt, the Board shall acknowledge, in writing to the competing applicant, receipt of the letter of intent to compete. Based on the information contained in the letter of intent to compete, the Board may confirm jurisdiction and that the applications are in competition, if appropriate.
3. Within ten (10) business days following the Board's acknowledgement of receipt of the letter of intent to compete, the competing applicant shall publish public notice of the competing application in a form and manner as directed by the Board.

4. Within thirty (30) business days following the Board's acknowledgement of receipt of the letter of intent to compete, the competing applicant must file its application.
5. The same timelines applicable to other Certificate of Need applications shall apply to the competing application, except that the competing application shall be deemed complete no later than 55 days after the date the original application closed date.
6. The Certificate of Need timelines for the original application shall be suspended while the competing application is being processed.
7. 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 beyond that included in the original application, the Board shall afford the opportunity to additional parties and for the existing applicant to respond to the expanded scope. Under such circumstances, the Board shall suspend all applicable timelines and publish a revised schedule to ensure the timely, effective, and efficient processing of applications.
8. Upon receipt of the competing application or expiration of 55 days, all competing applications shall proceed simultaneously.
9. The Board may make an independent finding that two or more potential applicants should be considered competing applicants. "Potential applicant" means an entity with a pending application or pending letter of intent. The Board's finding shall serve as notice of intent to compete. Under these circumstances, the Board shall notify each party of its finding and give notice to each competing applicant of the date upon which applications must be deemed complete.
10. 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.
11. Nothing in this section shall be construed to restrict the Board from granting a Certificate of Need to one, all, or none of the applicants.

4.406 Interveners

Interested Party Status

Pursuant to 18 V.S.A. § 9440(c)(9), the Vermont Office of Health Care Ombudsman may participate as an interested party in the review of an application by filing a notice of intervention with the Board.

2. Any other person or organization may seek to intervene in the review of an application by requesting, in writing, interested party status from the Board.
2. The request should:
 - (a) provide a detailed statement of the requestor's interest in the Certificate of Need proceeding;

(b) illustrate how relevant Certificate of Need criteria, including applicable health care policy goals, relate to the request to intervene; and

(c) explain how the requestor's interests relate to the specific application under review.

3. The Board 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. A substantial and direct impact shall include, but not be limited to, 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.

4. Failure to sufficiently explain why interested party status should be granted will result in a denial of the request.

5. An interested party

(a) shall be copied on all materials in the record;

(b) may, prior to the application closed date, submit to the Board proposed questions for the applicant, to which the Board may in its discretion ask the applicant to respond;

(c) may file pre-hearing information and participate in the review process; and

(d) may appeal the Board's decision or other ruling eligible for appeal to the Vermont Supreme Court within thirty (30) days of the date of the Board's decision or ruling.

Amicus Curiae

6. The Board 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 Board by providing nonduplicative evidence relevant to the Certificate of Need application decision.

(a) Amicus curiae shall not be considered parties to an action, but shall be copied on all materials in the same manner as an interested party.

(b) Materials submitted by amicus curiae shall be admitted into the record and copied to all parties.

4.407 Public Hearings

1. Except in the case of expedited or emergency review, the Board shall hold a public hearing during the course of its review which allows for public comment and input concerning the proposed health care project. The hearing shall be noticed and open to the public, and shall be conducted by the Board, the Board's Chairperson, or the Board's designee.

2. An applicant, competing applicant, interested party, or amicus may submit at the public hearing presentation materials that were not submitted to the Board prior to the application closed date, so long as those materials contain no new information or contain new information that was expressly requested by the Board.

3. The Board, Chair, or Board's designee may ask questions of any applicant, competing applicant, interested party, or amicus during the public hearing.
4. Public hearings under this Rule shall allow time for public comment.
5. Members of the public may submit written comment to the Board regarding an application after the Board has asserted jurisdiction over the project until ten days after a public hearing.
6. Public comments, whether made at a public hearing or submitted in writing, shall not be considered for the truth of the matter asserted unless they are submitted under oath.

4.500 ISSUANCE OF A CERTIFICATE OF NEED

1. Upon its decision approving an application in whole or in part, the Board shall issue a Certificate of Need.
2. Upon issuance, a holder may obligate funds or commence work without risk of penalty, 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 Certificate of Need shall include:
 - (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;
 - (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. The holder shall provide implementation reports to all interested parties, unless such parties elect not to receive such reports.
4. In the event the Board imposes conditions on a Certificate of Need, an applicant may seek relief from a condition by filing a written request to the Board. 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.
5. If, in the course of its review, the Board 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 Board shall issue a Certificate of Need for only those services or parts that meet the necessary criteria. The Certificate of Need shall specify in detail the services or parts of the proposed new health care project for which approval is given.

6. When the Board 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.

7. If the Board 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 Board 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 Board may impose as a condition of approval of the application that a violation be corrected or remediated before the Certificate of Need takes effect.

8. A Certificate of Need is non-transferable.

9. The Board's final decision to approve or deny, in whole or in part, a Certificate of Need may be appealed to the Vermont Supreme Court within thirty (30) days of the date of the decision.

10. If a Certificate of Need decision is appealed, the expiration date and other time limits shall be extended to provide for the time required for all appeals to be completed.

4.600 PROJECT CHANGES

1. The recipient of a Certificate of Need shall notify the Board of any changes in the scope or cost of an approved project.

2. A material change is subject to review under Chapter 221 of Title 18, Vermont Statutes Annotated and this Rule. A "material change" means:

1. a change that constitutes a new health care project as defined by statute or rule; or

2. a change in project cost that exceeds 10% of the total approved cost of the project.

All project costs, including capital, operating or other expenses, are included to determine whether the 10% threshold has been exceeded.

3. If a change is nonmaterial, the Board may in its discretion choose to review the change to determine what process, if any, is required before it may be approved. The Board shall notify the recipient in writing within twenty (2) days of its decision whether or not to review the nonmaterial change. If the Board elects not to review the nonmaterial change, the Certificate of Need is deemed amended to incorporate the change.

4. If the change is approved or approved in part, the Board 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 proposed change for one year from the date of the denial.

5. The Board may, on its own initiative based on information contained in the implementation reports or any 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 Board makes such a determination, the Board may review the change as otherwise outlined in this subsection.

6. The Board may, on its own initiative or upon written application by the affected home health agency or by affected consumers, modify the terms of a Certificate of Need relating to the boundaries of a geographic service area of a home health agency. "Consumers" means users of home health agency services, or their duly authorized representatives.

(a) The Board may modify such boundaries:

- (i) to take into account natural or physical barriers that may make the provision of existing services uneconomical or impractical;
- (ii) to prevent or minimize unnecessary duplication of services; or facilities; or
- (iii) to otherwise promote the public interest.

(b) The Board may in its discretion conduct a public hearing regarding the proposed boundary modification.

4.700 ENFORCEMENT

1. In determining appropriate sanctions for violations of this rule, Chapter 221 of Title 18 or any other applicable laws, the Board shall consider the following factors:

- (a) whether the entity filed a good faith letter of intent or letter of inquiry;
- (b) whether the entity reasonably relied on a no jurisdiction determination from the Board;
- (c) whether the project will cause an increase in costs to the health care system;
- (d) whether the project is likely to reduce or contain the cost of health care services;
- (e) whether the project is otherwise consistent with Certificate of Need criteria;
- (f) in the case of a facility that incorrectly projects it would not exceed monetary jurisdictional thresholds, whether the erroneous projection was reasonable based on a totality of the underlying facts and circumstances; and
- (g) any other mitigating or aggravating factors.

2. 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 any or all of the sanctions set forth in 18 V.S.A. § 9445 in the following circumstances:

- (a) the entity did not obtain a no jurisdiction determination from the Board;
- (b) the entity engaged in fraud, misrepresentation, or deception in its communications with the Board; or
- (c) the project is likely to result in unnecessary duplication of services.

3. Prior to the imposition of sanctions, an entity shall have notice and an opportunity for a hearing.

(a) An entity shall have no fewer than fifteen (15) days' notice of a hearing, except for good cause shown.

(b) To the extent an application is pending and dependent on the resolution of potential violations of statute, this Rule, a previously issued Certificate of Need or any other applicable law, such hearing shall occur with twenty (20) days of notice of the suspected violation, except upon good cause shown or written permission from the applicant.

4.800 OTHER MATTERS

1. Waiver of Rules. In order to prevent unnecessary hardship, delay, or injustice, or for other good cause, the Chair or the Board may waive the application of any provision of this Rule upon such conditions as the circumstances may require, unless precluded by law.

2. Conflict. In the event that this Rule or any section herein conflicts with Vermont statute, Vermont statute shall govern.

3. Severability. If any provision of this Rule or the application thereof to any Person or circumstance is for any reason held to be invalid, the remainder of the Rule and the application of such provisions to other Persons or circumstances shall not be affected thereby.

4. Effective date. This Rule shall become effective January 1, 2013.