

## **111-2-2-.08 Alternative Application and Review Procedures.**

### **(1) Batching Review Process.**

(a) Pursuant to O.C.G.A. § 31-6-3(e), the Department may limit the time periods during which it will accept applications for the following health care facilities and/or services: skilled nursing facilities; intermediate care facilities; home health agencies, open heart surgical services, pediatric cardiac catheterization and open heart services, perinatal services, freestanding birthing centers, psychiatric and substance abuse services, comprehensive inpatient physical rehabilitation services, ambulatory surgical services, positron emission tomography services, and megavoltage radiation therapy services. Limitation of the time periods shall be to only such times after the Department has determined there is an unmet need for such facilities and/or services, or will accept applications pursuant to any service specific need standard exceptions. The Department shall make a determination as to whether or not there is an unmet need for each type of facility at least every six months and shall notify those requesting such notification of that determination. No application for the services listed above will be accepted for review by the Department except as provided for pursuant to Rule 111-2-2-.08(1). For purposes of batching only, the applications entered into the one hundred twenty (120) day review period shall be evaluated according to the data used to publish the unmet need, or to accept applications pursuant to any service specific need standard exceptions, for the particular service at issue, for those services listed above, and not the latest available data at the time of decision, as is the case with all non-batched applications.

(b) Upon the determination of an unmet need for a particular facility/service in a given service area, the Department shall provide notice indicating which applications will be considered in that particular batching cycle to all interested parties requesting notice of that determination. It shall be the sole and exclusive responsibility of the interested party to notify the Department in writing of that party's desire to be informed of the Department's unmet need determination(s) for batching purposes. The Department's notice shall contain the unmet need for the type of facility/service in the given service area(s) and shall also contain the pertinent time frames and deadlines for submission of notices of intent to apply, for submission of applications, and the review of such applications.

(c) All parties interested in applying for the particular unmet need in a given service area must notify the Department of that party's intent to apply.

1. The notice must be in writing and must address specifically the type of unmet need and service area(s) for which the applicant intends to apply.

2. The notice of intent must be received by the Department no later than the close of business on the thirtieth (30th) calendar day following the date that the Department publishes the determination of unmet need. In the event that the thirtieth (30th) calendar day falls on either a weekend or a legal holiday, the thirtieth (30th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday.

3. Notwithstanding any other relevant provisions within this rule, the notice of intent to apply must be received by the Department either before or simultaneously with the submission of the actual application in accordance with the notice of intent deadline.

4. In the event that the Department fails to receive the notice of intent to apply by the stated deadline, the interested party shall be disqualified automatically from applying during that batching cycle.

(d) Subject to the proper submission of a notice of intent to apply, any interested party shall have in the Department's office a properly submitted application no later than 12:00 P.M. on the sixtieth (60th) calendar day following the date that the Department publishes the determination of unmet need. In the event that the sixtieth (60th) calendar day falls either on a weekend or a legal holiday, the sixtieth (60th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday. For purposes of batching only, all properly submitted applications will be deemed received on the sixtieth (60th) day, regardless of the actual date of submission.

(e) For the purposes of batching only, an application which has been deemed received according to (d) above, will be only be deemed properly submitted and complete if the following requirements, in addition to the requirements of 111-2-2-.06(5), are met:

1. The appropriate Certification Statement (an applicable service specific related checklist) is submitted simultaneously with the original application; and

2. All of the items addressed in the Certification Statement are provided, as certified, with the original application.

(f) In the event that an application is deemed in receipt by (d) above, but is not deemed to be properly submitted and complete by (e) above by 12:00 PM on the sixtieth (60th) calendar day following the date that the Department publishes the determination of unmet need (in the event that the sixtieth (60th) calendar day falls either on a weekend or a legal holiday, the sixtieth calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday), the application will be disqualified from the batching review.

(g) The batching review cycle will be conducted in the following manner:

1. The batching review cycle shall be one hundred and twenty (120) days in duration. As a result, no party participating in the batching review process, including the Department, shall either request or be granted an extension of time past the one hundred and twentieth (120th) day.

2. The first day of the batching review cycle shall be the day upon which all properly submitted applications are deemed to be received. [See Rule 111-2-2-.08(1)(d) above.]

3. On or before the sixtieth (60th) day of the batching review cycle, the Department shall provide the applicant(s) an opportunity to meet with the Department. The Department will describe any issues with the application and provide an opportunity to the applicant(s) to amend or withdraw the application or to submit additional information. Any and all additional information must be submitted on or before the seventy-fifth

(75th) day of the batching review cycle. The sixty (60) day meeting with the applicant(s) is restricted to the Department and the applicant(s). Parties opposing an application(s) may not attend or participate in an applicant sixty (60) day meeting.

4. Any party who is opposed to one or more applications submitted during a batching cycle must submit a notice of opposition, on the form provided by the Department, no later than the sixtieth (60<sup>th</sup>) day of the batching review cycle. The notice must contain the information specified by the form. The notice of opposition form submission shall also include one signed original of the written vendor lobbyist certification required by 111-1-2-.03(2). The notice of opposition must not contain the substantive arguments against a particular application.

Those parties who are opposed to an application will be given an opportunity to meet with the Department at a time and place specified by the Department after a review of the opposition notices. The opposition meeting, provided for by O.C.G.A. § 31-6-43(h), shall be held no earlier than the ninetieth (90<sup>th</sup>) day of the batching review cycle. The applicant(s) shall be entitled to attend the opposition meeting. Only one designated person on behalf of each party opposed to a particular application will be allowed to speak on behalf of the opposition to said application at the opposition meeting. The time period provided for that opposition spokesperson shall be determined in the sole discretion of the Department. The applicant(s) will not be allowed to speak in rebuttal of the opposition remarks at the opposition meeting. The Department shall make no formal substantive comments regarding the review of the application(s) at the opposition meeting. The opposition parties shall bring to the opposition meeting substantive written comments and arguments regarding the nature of their opposition to the particular project. The opposition parties must provide an original and one copy of the substantive opposition comments to the Department at the meeting, and also provide one copy of the substantive opposition comments to the applicant at the opposition meeting. In order for an opposing party to have standing to appeal an adverse decision pursuant to O.C.G.A. § 31-6-44, such party must attend and participate in an opposition meeting. Substantive opposition comments must pertain to only one application and one applicant. In no case shall the Department accept substantive opposition comments that concerns multiple applicants or applications.

Letters of support for a particular application must be submitted pursuant to and in compliance with 111-2-2-.06(6), and can be submitted no later than the one hundredth (100<sup>th</sup>) day of the batching review cycle.

5. Applicants shall be given the opportunity to respond to the substantive opposition comments made orally and submitted in writing at the opposition meeting. The last day for the applicant(s) to submit final amendments to the application and/or to respond to the opposition meeting comments, shall be the one hundred and tenth (110<sup>th</sup>) day of the batching review cycle. The Department reserves the right, but is not required to, ask the applicant(s) for information in response to the substantive opposition comments. If the Department asks the applicant for information as a result of the comments provided at the opposition meeting, the applicant must submit the information requested no later than the one hundred and tenth (110<sup>th</sup>) day of the batching review cycle.

6. No later than the one hundred and twentieth (120<sup>th</sup>) day of the batching review cycle, the Department shall provide written notification of its decision to issue or deny a Certificate of Need to the pertinent applicant(s).

(h) In evaluating batched applications, if any or all of the batched applications equally meet the statutory considerations, priority consideration will be given to a comparison of the applications with regard to:

1. The past and present records of the facility, and other existing facilities in Georgia, if any, owned by the same parent organization, regarding the provision of service to all segments of the population, particularly including Medicare, Medicaid, minority patients and those patients with limited or no ability to pay;

2. Specific services to be offered;

3. Appropriateness of the site, i.e., the accessibility to the population to be served, availability of utilities, transportation systems, adequacy of size, cost of acquisition, and cost to develop;

4. Demonstrated readiness to implement the project, including commitment of financing;

5. Patterns of past performance, if any, of the applicants in implementing previously approved projects in a timely fashion;

6. Past record, if any, of the applicant facility, and other existing facilities owned by the same parent organization, if any, in meeting licensure requirements and factors relevant to providing accessible, quality health care;

7. Evidence of attention to factors of cost containment, which do not diminish the quality of care or safety of the patient, but which demonstrate sincere efforts to avoid significant costs unrelated to patient care; and

8. Past compliance, if any, with survey and post-approval reporting requirements and indigent and charity care commitments.

(i) In the event of a favorable decision, the Department's notification letter shall serve as the Certificate of Need. The date of the decision shall be the date on the notification letter of the Department. The decision shall be to approve or deny the application(s) as submitted or as amended by the applicant(s) during the course of the batching review cycle, whichever is applicable. The effective date of the Certificate shall be the decision or approval date if not appealed. If administratively appealed in a timely fashion, the effective date of the Certificate shall be the date of final resolution of any administrative hearing. The Department may stay the effective date of a project appealed through judicial process at the request of any party to such appeal or upon the Department's own initiative. Any determination by the Department to stay the effective date will be based upon sound health planning principles. If the Department stays the effective date of a project appealed through judicial process, the effective date shall be the date of final resolution of any judicial appeal.

(j) The decision letter shall contain at least the following:

1. A detailed statement of the findings related to each applicable consideration and standard relevant to the decision to issue or deny a Certificate of Need; and
2. Information pertaining to the availability of an appeal hearing.

(k) A copy of the notification letter shall be sent to the applicant(s), to the appropriate Regional Development Center and to the chief elected official of the applicable county and municipal government, if any. The Department's decision shall be subject to the provisions of the Open Records Act.

(l) Appeals of the Decision of the Department shall be in accordance with the Rules promulgated by the Certificate of Need Appeal Panel found in Chapter 274.

**(2) Alternative Healthcare Models.**

**(a) Applicability.**

1. For Certificate of Need (CON) purposes, Alternative Healthcare Models are defined as new and/or innovative models of providing new or existing institutional health services delivered in a proposed or existing healthcare facility.

2. For Certificate of Need purposes, the applicant for an Alternative Healthcare Model CON will be as follows:

(i) If the service(s) will be provided within a single healthcare facility, the owner of that facility will be the applicant;

(ii) If the service(s) will be provided within two or more healthcare facilities that are part of a healthcare services network, the owner(s) of the facility(ies) in which the service(s) will be provided will be the co-applicant(s).

3. The Department shall evaluate the performance of the Alternative Healthcare Model according to the scope as defined by the Department decision and the standards set forth in these Rules. If after a review the Department determines that the Alternative Healthcare Model does not meet the defined scope or expected standards, the Department may either immediately revoke the Certificate of Need or grant a specified time period during which the Alternative Healthcare Model must meet the defined scope and the expected standards or lose its Certificate of Need.

**(b) Definitions.**

1. "Alternative healthcare model" means a new and/or innovative model of providing new or existing institutional health service(s) delivered in or through a healthcare facility(ies) and/or healthcare services networks.

2. "Authorized service" means a Department sanctioned Alternative Healthcare Model, which is either existing or approved. An existing service is an authorized service, which has become operational, and an approved service is an authorized service, which has not yet become operational.

3. "Board" means the Board of Community Health.

4. "Health care facility", as defined at O.C.G.A. § 31-6-2(17), means hospitals; destination cancer hospitals; other special care units, including but not limited to podiatric facilities; skilled nursing facilities; intermediate care facilities; personal care homes of at least twenty-five (25) beds; ambulatory surgical or obstetrical facilities; health maintenance organizations; home health agencies; diagnostic, treatment, or rehabilitative centers, but only to the extent that O.C.G.A. § 31-6-40(a)(3) or (7) or both are applicable thereto.

5. "Healthcare services network" means a collaborative arrangement that consists of at least one healthcare facility plus one or more physician groups and/or one or more third party payers, or a collaborative arrangement that includes at least two or more healthcare facilities.

6. "Most recent year" means the most recent calendar year prior to submission of an application.

7. "Official inventory" means the inventory of all authorized Alternative Healthcare Models maintained by the Department based on CON approval and official Department records.

8. "Official state component plan" means the most recent document(s) that is/are most closely related to those services being provided by the Alternative Healthcare Model. The most recent document(s) will have been developed by the Department and approved by the Board.

9. "State health policies" means the most recent policies developed by the Board, which provide a framework for the service-specific policies included within each component of the State Health Plan. These state health policies include health promotion, financial accessibility, least restrictive care, regionalization, cost containment, health planning and citizen participation, healthcare personnel, and healthcare data and information networks.

**(c) Requests for Proposals.**

1. Within the period of April 1 through May 31 of each year, the Board may accept abstracts describing potential Alternative Healthcare Models, based on the recommendation of the Department. The Board will review these abstracts, if any are solicited for that year, by August 31 of that year and select a list of those categories for which Alternative Healthcare Model Certificate of Need applications may be submitted.

2. Within thirty (30) days of the determination by the Board of the particular categories under which Alternative Healthcare Model Certificate of Need applications may be submitted, the Department shall provide notice of these categories to all interested parties. The notice shall contain:

(i) the listing of category(ies) related goals and desired outcomes and the probable scope of services;

(ii) the pertinent time frames and deadlines for submission of notices of intent to apply for Alternative Healthcare Model Certificate of Need;

(iii) the pertinent time frames and deadlines for submission of CON applications; and

(iv) the pertinent time frames and deadlines for the review of such applications, and any related criteria for review.

**(d) Intent to Apply.**

1. All parties wanting to apply for Alternative Healthcare Model Certificates of Need under the selected categories must notify the Department of that party's intent to apply.

2. This notice must be:

(i) in writing and must address specifically the particular category under which the applicant intends to apply;

(ii) received by the Department no later than the close of business on the sixtieth (60<sup>th</sup>) calendar day following the date that the Department publishes the notice of the selected categories. In the event that the sixtieth (60<sup>th</sup>) calendar day falls on either a weekend or a legal holiday, the sixtieth (60<sup>th</sup>) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday;

(iii) must be received by the Department either before or simultaneously with the submission of the actual application; and

(iv) in the event that the Department fails to receive the notice of intent to apply by the stated deadline, the interested party automatically shall be disqualified from applying during that particular review cycle.

**(e) Application Process.**

1. Certificate of Need applications pertaining to the selected categories will be submitted to the Department on or before 3:00 p.m. June 1 of the year following the year in which the categories were selected by the Board. (Although applications may be submitted prior to 3:00 p.m. June 1, all application will be deemed received on June 1.) In the event that June 1 falls either on a weekend or a legal holiday, the day of submission shall become automatically the next business day that is neither a weekend nor a legal holiday;

2. Alternative Healthcare Model Certificate of Need applications must comply with the requirements in Rule 111-2-2-.06(2) and (3).

3. For the purposes of Alternative Healthcare Model Certificate of Need applications, an application will be deemed properly submitted if the following requirements are met:

(i) a summary of the Certificate of Need application is included to be used as information for the Board and general public;

(ii) a Certification Statement of Completeness is included designating under which category the application is being submitted; and

(iii) all items addressed in the Certification Statement of Completeness are provided with the application.

**(f) The Review Cycle.**

1. The review cycle shall be automatically one hundred and twenty (120) days in duration. As a result, no party participating in the review process, including the Department, shall either request or be granted an extension of time past the one hundred and twentieth (120<sup>th</sup>) day;

2. The first day of the review cycle shall be the day upon which all properly submitted applications are deemed to be received as specified in Rule 111-2-2-.08(2)(e)3.

3. No later than the thirtieth (30<sup>th</sup>) day of the review cycle, the Department shall, if deemed necessary, submit a written request to any and all pertinent applicants for clarifying and/or supplemental information. This written request may be distributed within a meeting of the applicant(s). The purpose of the request for clarifying and/or supplemental information shall be to obtain information from the applicant(s) that clarifies or supplements the initial information submitted with the original application.

4. No later than the forty-fifth (45<sup>th</sup>) day of the review cycle, the applicant(s) shall, if deemed necessary by the Department, submit their clarifying and/or supplemental information. Failure to submit the required clarifying and/or supplemental information by the forty-fifth (45<sup>th</sup>) day may be grounds for denial of the application.

5. If, by the forty-fifth (45<sup>th</sup>) day, the review indicates potential for denial of the application(s), the Department, on or before the sixtieth (60<sup>th</sup>) day of the review cycle, shall provide the applicant(s) an opportunity to meet with the Department. The problems with the application(s) will be described and an opportunity offered to amend or withdraw the application or to submit additional information. Any and all additional information and amendments must be submitted on or before the seventy-fifth (75<sup>th</sup>) day of the review cycle.

6. The last day for interested parties (including, but not limited to, competing applicant(s) and/or existing competing health care facilities) to submit letters of support or opposition addressing the underlying merits, or lack thereof, of any pending application(s) shall be the eighty-fifth (85<sup>th</sup>) day of the review cycle. Any letters of support and/or opposition that are received after the eighty-fifth day of the review cycle shall not be considered by the Department in its review of the pertinent application(s) and the letter(s) shall not become part of the master file compiled for the pertinent application(s).

7. The last day for applicant(s) to submit final amendments and responses to letters of opposition shall be the one hundred and tenth (110<sup>th</sup>) day of the review cycle.

8. No later than the one hundred and twentieth (120<sup>th</sup>) day of the review cycle, the Department shall provide a written letter notifying the applicant of their decision to issue or deny a Certificate of Need to the pertinent applicant(s).

9. In the event of a favorable decision, this letter shall serve as the Certificate of Need. The date of the decision shall be the date on the notification letter from the Department. The decision shall be to approve or deny the application(s) as submitted or as amended by the applicant(s) during the course of the review cycle, whichever is applicable.

10. The decision letter shall contain at least the following:

(i) a detailed statement of the findings related to each applicable consideration and standard relevant to the decision to issue or deny a Certificate of Need; and

(ii) information pertaining to the availability of an appeal hearing.

11. A copy of the notification letter shall be sent to the applicant(s), to the appropriate Regional Development Center and to the chief elected official of the applicable county and municipal government, if any. The Department's decision shall be subject to the provisions of the Open Records Act.

12. Appeals of the decision of the Department shall be in accordance with the Rules promulgated by the Certificate of Need Appeal Panel.

**(g) Standards.**

1. An Alternative Healthcare Model must be consistent with the State Health Policies adopted by the Board.

2. An Alternative Healthcare Model must clearly define its target population/community.

3. An Alternative Healthcare Model must:

(i) include a hypothesis(es) to be tested within a time-limited period not to exceed five (5) years;

(ii) demonstrate, as applicable, how it will support research, new service development, health professional education and training, and/or affiliation with an academic center of higher learning; and

(iii) demonstrate that the community supports the Alternative Healthcare Model.

4. An applicant for an Alternative Healthcare Model CON shall demonstrate the feasibility of operating the Alternative Healthcare Model in Georgia, based on a review of the experience in other states including the impact on health professionals of other healthcare programs or facilities and how the project is impacted by payers and regulatory entities.

5. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to reduce healthcare costs to consumers, third party payors and the system as a whole.

6. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to maintain or improve the standards of healthcare quality in some measurable fashion.

7. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to provide increased choices or access for consumers to a continuum of services within the target community.

8. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to meet existing or emerging health status and/or health system needs.

9. For any applicant that meets the requirements of this rule the Department may waive all or part of otherwise applicable service-specific Rules 111-2-2-.20 et seq.

Authority O.C.G.A. Secs. 31-5A et seq., 31-6 et seq. **History.** Original Rule entitled “Alternative Application and Review Procedures” adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005. **Amended:** F. Sept. 11, 2008; eff. Oct. 1, 2008.