

SYNOPSIS

Rule 111-2-2 Health Planning Certificate of Need

Rule 111-2-2-.07 Review Procedures

STATEMENT OF PURPOSE AND MAIN FEATURES OF PROPOSED RULE

The purpose of this proposed amendment in totality is to modify existing regulations in light of changes in the Certificate of Need statute, O.C.G.A. § 31-6 et seq., due to the passage of Senate Bill (SB) 433 in the 2008 Georgia General Assembly. SB 433 necessitates extensive revision to the existing administrative rules for certificate of need. The revisions are outlined in detail below.

DIFFERENCES BETWEEN EXISTING AND PROPOSED RULES

Various grammatical and punctuation errors and omissions are corrected throughout the existing version of the regulations.

Rule 111-2-2-.07 Review Procedures

This section is renumbered to reflect additional provisions.

Rule 111-2-2-.07(1)(c) is amended to change the review period of time for joined applications from "90" to "120" days for all applications filed after July 1, 2008.

Rule 111-2-2-.07(1)(d) is amended to change the completion review period from 90 to 120 days and adds additional language to clarify the 30 day extension period advances the review period to 150 days.

Rule 111-2-2-.07(1)(d)1 is amended to remove the provision which allows the applicant to request an extension of time in order to amend or submit additional information.

Rule 111-2-2-.07(1)(e)1 is amended to change the number of resident signatures required to request a public hearing from "ten" to "fifty."

Rule 111-2-2-.07(1)(f) is deleted in its entirety and replaced in another subpart of the Rule to add new provisions regarding the process for submitting opposition concerning an application. The deleted language pertains to the submission of letter(s) of opposition and the applicant(s) deadlines for submitting a response to a letter(s) of opposition, submitting additional information, responding to opposition to additional information, submitting amendments and responding to opposition to amendments. The

deleted language also pertains to the deadlines for responses to be submitted by opposing party(ies). Subpart (f) now pertains to the sixty day meeting and adds clarifying language to require that the meeting with the applicant(s) is restricted to the applicant(s) and the Department. Subpart (f) 2 rewords the language pertaining to the deadline for an applicant to submit amendments to the Department by deleting the phrase, "ten days prior to the end of the review period," to "the 110th day of the review cycle." Subpart (g) deletes the phrase, "ten (10) days before the end of the review period," and replaces it with, "110th day of the review cycle."

Rule 111-2-2-.07(1)(h) is new language which establishes the requirements and the deadlines by which party(ies) opposed to an application must submit notice. The Rule provides that opposing party(ies) must submit notice of opposition by the 60th day of the review cycle and such notice must not contain the substantive arguments against a particular application. Subpart (1.) provides for an opposition meeting to be held no earlier than the 90th day of the review cycle; Subpart (2.) establishes the deadline for submission of letters of support at no later than the 100th day of the review cycle; Subpart (3.) establishes the deadline for the applicant's response to the opposition meeting comments, and final amendments, if any, to be submitted by the 110th day of the review cycle. This subpart also permits the Department to ask the applicant for information pursuant to comments raised at the opposition meeting and which must also be responded to by the 110th day by the applicant. Subpart (4.) restates the Department's requirement to issue a decision no later than the 120th day, or, if extended, no later than the 150th day.

Rule 111-2-2-.07(1)(i) adds a reference to additional provisions in other parts of the Rule by which special expedited consideration will be given to emergency expenditures that relate to situations which pose an immediate threat to health and safety.

Rule 111-2-2-.07(1)(j) adds clarifying language by deleting "above exemption" and replacing it with "language of this subsection," and clarifies, by reference to the Rule for Determinations and Letters of Non-Reviewability, that such expenditures require prior written authorization.

Rule 111-2-2-.07(1)(k) adds new language to establish an expedited review period of 30 days for projects deemed an emergency and for which the Governor has declared a state of emergency in a given region of the state. The previous language of this subsection, which relates to the procedure for department review of expedited capital expenditure projects not directly relating to the provision of clinical services is deleted.

Rule 111-2-2-.07(1)(l) adds clarifying language which relates the provisions of this section to emergency projects and establishes the review period to be no longer than 30 days.

Rule 111-2-2-.07(1)(m) amends the language of the Rule by deleting "expedited" and replacing with "emergency."

Rule 111-2-2-.07(1)(n) adds clarifying language which limits the review of emergency projects to only the provisions of subsections (k) – (m).

Rule 111-2-2-.07(1)(o) adds clarifying language regarding the filing fee for projects submitted for review under the provisions of subsections (k) – (n).

Rule 111-2-2-.07(2)(b)1 amends “90” days to “120” days.

Rule 111-2-2-.07(2)(f) amends “ninety-first” to one hundred twenty-first.”

Rule 111-2-2-.07(2)(g) deletes “Health Planning Review Board” and replaces with “Certificate of Need Appeal Panel.”

111-2-2-.07 Review Procedures.

(1) Beginning of Review Process.

(a) When an application is deemed by the Department to be complete, the Department shall provide written notice to the applicant of the completeness of the application and the schedule for review. The Department shall provide similar notice to a newspaper of general circulation in the county of the project, to the appropriate Regional Development Center, and to the chief elected official of the county and municipal government, if any, within whose boundaries the proposed project would be located. The date on the letter of notification shall be deemed to be the date of notification and the beginning date of the Certificate of Need review cycle.

(b) The Department will schedule reviews so that, unless joined with another application, no review shall, except as noted in (d) below, take longer than 90 one hundred and twenty (120) days from the date of notification of the beginning of review until the date the decision to issue or not to issue a Certificate of Need is postmarked to the applicant. Absent good cause, the Department generally will not issue a decision prior to the 60th day of the review cycle.

(c) In the event that, from the time an application is declared complete until thirty (30) days thereafter, one or more additional applications are declared complete which involve similar projects in the same or overlapping service areas, the Department may declare that such applications will be joined with the first application for review purposes. Following such joinder, none of the subsequent applications so joined may be considered as a first application for purposes of future joinder. The Department shall notify all applicants whose applications have been joined, and shall set a new time parameter for Department actions. The 90 one hundred and twenty (120)-day final decision deadline shall run from the latest date that any one of the joined applications was declared complete for review. Except as otherwise provided in Rule 111-2-2-.08(1), such joinder shall be the sole method of comparative review for all applications filed after July 1, ~~1994~~ 2008.

(d) Where the Department determines that conditions exist which make it impractical to complete a review in 90 one hundred and twenty (120) days, the Department may, on notification to the applicant, extend the time limit another thirty (30) days to one hundred and fifty (150) days. Conditions, including but not limited to the following, may constitute cause for extending the time:

- ~~1. The applicant requests time to amend the application or to submit additional relevant information;~~
- ~~2. The Department anticipates issuance of new demographic or utilization, data affecting the application;~~
- ~~3. The Department has received conflicting or contradictory information necessitating further investigation;~~
- ~~4. Results of impending legal action may have an effect on the application.~~

(e) For good cause shown, as shall be determined by the Department, a public hearing will be held at a time and location specified by the Department.

1. A request for a public hearing shall be signed by at least ~~ten~~ fifty (50) residents of the area where the project is located and must be received by the Department within twenty (20) days after the beginning date of the review cycle. The request shall include justification for the public hearing based on circumstances described in this paragraph.

2. To the extent possible, notification will be provided in a newspaper of general circulation in the area where the project is located approximately two weeks in advance of the hearing.

3. Any person desiring to offer testimony at the hearing will be given the opportunity to do so, but the providing of such testimony or evidence shall not confer upon the person or persons so testifying the status of "party" as that term is used in the Administrative Procedure Act.

4. Where distance and the nature of the project warrant, and within the budget constraints of the Department, the public hearing may be held by the Department in the area where the project is proposed to be located. Circumstances, which may indicate good cause for a hearing in the area, include but are not limited to:

(i) Projects, which could have significant effect on access to frequently used services by a sizable population group;

(ii) Projects generating strong conflicting viewpoints by the residents of an area;

(iii) Projects with potential for unusually significant impact on existing services.

5. A summary report of the hearing will be prepared, a copy of which will be sent to the party requesting the hearing and to the applicant. Such report will be made a part of the master record regarding the project. The Department may charge a fee for the summary report.

~~(f) Any interested person may submit information in writing to the Department concerning an application. Where information received is in opposition to the application, the Department will provide to the applicant a copy of the information and an opportunity to respond. A person wishing to file opposition with the Department must submit a separate letter of opposition for each project or application that is opposed. Opposition shall be submitted to the Department in accordance with and in compliance with 111-2-2-06(5). Such opposition shall also include one signed original of the written vendor lobbyist certification required by 111-1-2-03(2). The Department shall not consider opposition statements or letters that oppose more than one project, do not have the signed vendor lobbyist certification, or do not have the appropriate number of copies as required by these Rules.~~

~~4. Letters of opposition to the original application must be received by the Department no later than the 60th day of the review period. The Department shall not consider and will not accept into the Master File any letter of opposition to the original application received after the 60th day of the review period. For applications that have been granted an expedited review by 111-2-2-07(1)(k) or (l), letters of opposition to the original~~

application must be received by the Department no later than the 30th day of the review period.

~~2. An applicant's response(s), if any, to letter(s) of opposition to the original application must be received by the Department prior to the 75th day of the review period. The response(s) to letters of opposition to the original application may be submitted in tandem with additional information. For applications that have been granted an expedited review by 111-2-2-07(1)(k) or (l), an applicant's response(s) to letters of opposition to the original application must be received by the Department prior to the 35th day of the review period.~~

~~3. If additional information is submitted by the applicant to the Department prior to the 75th day of the review period:~~

~~(i) any interested person may submit a letter of opposition to additional information. A letter of opposition to the additional information must be received by the Department by the 83rd day of the review period. A letter of opposition to additional information may only refer to and oppose items and information that are supplemental to the original application and which appear in the applicant's additional information; and~~

~~(ii) an applicant's response(s), if any, to letter(s) of opposition to additional information must be received by the Department prior to or on the 87th day of the review period;~~

~~4. If an amendment is submitted by an applicant no later than 10 days prior to the end of the review period:~~

~~(i) any interested person may submit a letter of opposition to the amendment. A letter of opposition to the amendment must be received by the Department no later than 5 days prior to the end of the review period; and~~

~~(ii) an applicant's response(s), if any, to letter(s) of opposition to the amendment must be received by the Department no later than 3 days prior to the end of the review period;~~

~~(g f) If during the first 2 months of the review of the application the Department finds there are factors that create a potential for denial of the application, the Department shall, on or before the sixtieth (60th) day of the review period, provide the applicant an opportunity to meet with the Department. The problems with the application will be described and an opportunity offered to amend or to withdraw the application or to submit additional information. The 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 60-day meeting. Such addition information must be submitted prior to the seventy-fifth day of the review period.~~

1. "Additional information" is information and data submitted in response to a direct request from the Department at the meeting afforded an applicant after the first 2 months of the review of the application or in response to issues and concerns raised by the Department in said meeting, or in the lack of such a meeting or request by the Department, information and data submitted consistent with the scope, physical location, cost, charges, service, and owners in the originally submitted application. Additional information must be submitted to the Department prior to the seventy-fifth (75th) day of the review period;

2. "Amendment" is a revision to the additional information or application as originally submitted that is submitted to the Department no later than ~~ten days prior to the end of the review period~~ the one hundred and tenth (110th) day of the review cycle and that constitutes a change in scope, physical location, cost, charge, service, or owner. The following changes in an application will qualify as an amendment:

- (i) A reduction or increase in the proposed physical space capacity; or
- (ii) A reduction or increase in the number of proposed beds or service units (e. g. operating rooms); or
- (iii) A change in the owners of the legal applicant entity, as long as the legal applicant entity remains the same; or
- (iv) A reduction or increase in a proposal's capital or operating costs; or
- (v) A change in site within three miles of the site proposed in the original application or within the same service area as long as the population to be served and the service area to be served is not substantially different from that originally proposed as long as the proposed change does not require the application of a new need study or different rules; or
- (vi) A reduction or subtraction in the scope of the original application; or
- (vii) A change in the amount of commitment to indigent or charity care, projected utilization, financial information or patient charges that do not alter the basic financing or operations of the proposed project.

~~(h g)~~ The Department shall be notified with either a new application or written amendment to the current completed application when there are changes in the scope, physical location, cost, charges, service or owners of the applicant entity. Any revisions that constitute a total change in or addition to the scope of an application, in the location (except for the exemption in 111-2-2-.07(1)(~~g f~~)2.(v), or in the legal applicant that would require the submission of a new application. If the Department determines that the amendment constitutes a total change in either the scope, location, or legal applicant, the original application will be considered to be withdrawn and the applicant will be so notified. An application may be amended by the applicant at any time up to ~~ten (10) days before the end of the review period~~ the one hundred and tenth (110th) day of the review cycle. ~~Notification of substantial amendments will be provided to the appropriate Regional Development Center and to the chief elected official of the applicable county or municipal government, if any.~~

(h) Any party who is opposed to an application, or to an application(s) joined for review, must submit a notice of opposition, on the form provided by the Department, no later than the sixtieth (60th) day of the review cycle. The notice must contain the information specified by the form. The notice of opposition from submission shall also include one signed original of the written vendor lobbyist certification required by 111-2-2-.03(2). The notice of opposition must not contain the substantive arguments against a particular application.

1. 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 (90th) day of the 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 the 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 concern multiple applicants or applications.

2. 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 (100th) day of the review cycle.

3. 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 (110th) day of the 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 (110th) day of the review cycle.

4. The Department shall provide written notification of its decision to issue or deny a Certificate of Need no later than the one hundred and twentieth (120th) day of the review cycle, or, if the project was extended, no later than the one hundred and fiftieth (150th) day of the review cycle.

(i) The Department, in accordance with the provisions of subsections (k-m) below, will give special expedited consideration to emergency expenditures required solely to cope with a situation posing an immediate threat to the health and safety of patients, visitors, or staff. The General Counsel, or his designee, upon a showing that a proposed replacement facility is critical to the welfare, health and stability of the immediate community as evidenced by written support from the local, county and state governing bodies may, authorize an expenditure based on a request by telephone, with written documentation to be provided later. In the event that the authorized emergency

expenditure requires an application to replace an existing health care facility, the application will not be subject to joinder.

"Emergency expenditures" as set forth in this subparagraph (i) shall include but not be limited to expenditures necessitated by circumstances arising from an authorized hazardous condemnation as well as from acts of God including but not limited to earthquakes, hurricanes, tornados or floods.

(j) The Department will decline to review through Certificate of Need application capital expenditures that do not reach the dollar threshold as required under the Certificate of Need program, provided the person proposing such expenditure receives from the Department a prior written authorization for the expenditure. Where a proposal is considered to meet the language of this subsection, ~~above exemption~~ a letter describing the reasons for the expenditure, the cost and the anticipated date the expenditure is proposed to be made should be submitted to the Department, in accordance with the provisions of Rule 111-2-2-.10, prior to the obligation of such funds. If, in the opinion of the Department, the expenditure is consistent with those expenditures not subject to review the Department will issue a confirmation to the requestor, which shall serve as authorization for the expenditure;

~~(k) The Department may conduct an expedited review of applications involving either expenditures or other reviewable matters which, in the exercise of the Department's discretion, do not relate directly to either the bed capacity of a health care facility or the provision of a clinical health service and the Department may conduct an expedited review of applications for which waiver of review is expressly permitted by a service-specific rule, Rules 272-2-.20 et seq. By way of example, and without limitation, such applications which may be given an expedited review may involve replacements of health care facilities, relocations of ambulatory surgical or obstetrical facilities or diagnostic, treatment, or rehabilitation centers, the development of parking decks or medical office buildings, the renovation of physical plants of existing health care facilities, the establishment of special care units, and the construction, development, establishment, or expansion of personal care homes.~~

~~1. Upon request, the Department will provide an expedited review request form. The Department will consider a request for an expedited review when the applicable form has been completed by the applicant and submitted to the Department.~~

~~2. No later than 14 calendar days after the date that the application has been deemed complete for review pursuant to Rule 111-2-2-.06(4), the Department will notify the applicant in writing as to whether the application will be reviewed on an expedited basis.~~

~~3. In the event that the Department decides to review the application on an expedited basis, the projected decision due date will be no later than 45 calendar days after the application has been deemed complete for review. However, the Department's failure to issue a decision on the application by the 45th calendar day of the review period shall neither result in automatic approval of the application nor prohibit the Department from issuing a decision before the 90th calendar day of the review period.~~

~~4. If during the course of the Department's review of the application the Department finds that there are factors that create a potential for denial of the application, the Department will immediately discontinue its expedited review, notify the applicant in~~

writing of that decision, and review the application in accordance with the applicable non-expedited review procedures set forth in Rule 111-2-2-.07.

~~5. If within the first 30 calendar days after the application is deemed complete, an additional application is received and deemed complete by the Department which involves a similar project subject to the same Department Rules in the same or overlapping service areas and the Department determines that such application should be joined with the first application for review, the Department will immediately discontinue its expedited review, notify the first applicant in writing of that decision, and review the applications in accordance with the applicable non-expedited review procedures set forth in Rule 111-2-2-.07.~~

~~(j) Pursuant to the provisions of O.C.G.A. § 31-6-43(g), the Furthermore, and consistent with the standards of (k) above, the Department shall conduct an expedited review with a review period of no longer than forty-five (30) thirty days only for those projects deemed an emergency, involving the following: When the Governor has declared a state of emergency in a region of the state, existing health care facilities in the affected region may seek emergency approval from the Department to make expenditures in excess of the capital expenditure threshold or to offer services that may otherwise require a certificate of need. The Department shall give special expedited consideration to such requests and may authorize such requests for good cause. Once the state of emergency has been lifted, any services offered by an affected health care facility under this subsection shall cease to be offered until such time as the health care facility that received the emergency authorization has requested and received a certificate of need. For purposes of this subsection, 'good cause' means that authorization of the request shall directly resolve a situation posing an immediate threat to the health and safety of the public.~~

- ~~1. The construction of new parking decks;~~
- ~~2. The construction of additional spaces to existing parking decks;~~
- ~~3. The renovation of the physical infrastructure of health care facilities if the cost is over the Department's capital expenditure threshold, and thus not eligible for the express exclusion of 111-2-2-.03(12); the space to be renovated must not include any areas devoted to the provision of a clinical health service;~~
- ~~4. The construction of new medical office buildings if no clinical health services are to be offered in such buildings;~~
- ~~5. The addition of new space to existing medical office buildings if no clinical health services are offered in the existing building, and the new construction will not involve the offering of clinical health services in the building;~~
- ~~6. The expansion of an adult open heart service based solely on an increase in procedures as defined in 111-2-2-.22(2)(d), provided that the application for expansion is submitted pursuant to the provisions of 111-2-2-.22(3)(b)2.~~
7. (l) The Department shall issue a decision on applications for a Certificate of Need for the type of projects outlined above emergency projects as provided in subsection (k) above, no later than ~~forty-five (45)~~ thirty (30) days after the application has been deemed

complete for review; failure to issue the decision on or before the ~~forty-fifth (45th)~~ thirtieth (30th) day after it has been deemed complete for review shall result in an automatic approval of the application, subject to subsection (~~§ n~~) below; the decision issued by the Department shall be a summary statement of the findings during the review of the project;

~~8-~~ (m) If, during the course of the review period, the Department finds that there are factors that create the potential for denial of the application, the Department shall immediately discontinue its ~~expedited~~ emergency review, notify the applicant in writing of that decision, and review the application in accordance with the applicable non-~~expedited~~ emergency review procedures set forth in Rule 111-2-2-.07.

~~9-~~ (n) The review of such projects as outlined in ~~subsections 1. through 8.~~ (k) – (m) above shall be governed by the emergency provisions of ~~this~~ the referenced ~~subsections~~ and not the provisions of subsections ~~(k) (a) – (h)~~ above.

~~10-~~ (o) The filing fee for applications of the type specifically listed in subsections ~~(1) (1-6)~~ (k) – (n) above shall be \$1,000.00, notwithstanding the filing fee provisions of Rule 111-2-2-.06(~~34~~)(a).

(2) Department Review.

(a) In reviewing the application, the Department will take into consideration the review considerations and policies provided in 111-2-2-.09. The latest applicable data from official data sources will be used in the Department analysis, unless otherwise provided by a service-specific rule. Such data sources will include, but not be limited to, the State Office of Planning and Budget, Medicare/Medicaid Cost Reports, and questionnaires or surveys initiated by the Department.

(b) Upon completion of review, the Department shall provide written notification of its decision to issue or deny a Certificate of Need. In the event of a favorable decision, the letter shall serve as the Certificate.

1. Such decision will be postmarked no later than ninety (90) days from the beginning of the review period unless the total review period is extended in accordance with 111-2-2-.07(1)(d).

2. The date of the decision shall be the date on the notification letter of the Department.

(c) 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;

2. Information pertaining to the availability of an appeal hearing.

(d) The decision shall be to approve or deny the application as submitted or as amended by the applicant during the course of review.

(e) A copy of the notification will be sent to the applicant or, in the case of joined applications, to all applicants, to the appropriate Regional Development Center and to

the chief elected official of the applicable county and municipal government, if any. A copy may be made available to other interested persons on request.

(f) Should the Department fail to issue a decision letter on a Certificate of Need application within the time limits set forth in these Rules, the application shall be deemed approved as of the ~~ninety one hundred and twenty-first~~ 121st day, or the one hundred ~~twentyfifty-first~~ 151st day if the review period was extended pursuant to 111-2-2-.07(1)(d), following the date of notice from the Department that an application, or the last of any applications joined pursuant to 111-2-2-.07(1)(c) was declared complete for review.

(g) Appeals of the decision of the Department shall be processed in accordance with rules promulgated by the ~~Health Planning Review Board~~ Certificate of Need Appeal Panel found in Chapter 274.

(h) When a project undergoes judicial review, the Department may stay the effective date of the CON pending the outcome of the judicial review upon appropriate terms for good cause shown.

Authority O.C.G.A. §§ 31-5A et seq. and 31-6 et seq.