

SYNOPSIS

Rule 111-2-2 Health Planning Certificate of Need

Rule 111-2-2-.10 Determinations and Letters of Non-Reviewability

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-.10 Determinations and Letters of Non-Reviewability

This section is renumbered to reflect additional provisions.

Rule 111-2-2-.10(2) is amended to add the requirement that all exemptions will require official written confirmation from the Department that the proposed activity is exempt from review, except that requests for confirmation of the exemptions pertaining to single specialty ambulatory surgical center(s) or a joint venture ambulatory surgical center are considered requests for Letter(s) of Nonreviewability, which require a \$500 filing fee; adds the requirement that existing skilled nursing homes, intermediate care facilities, or intermingled nursing facilities seeking to relocate all or a portion of an existing facility, may be permitted by the Department to divide into two or more such facilities but may not increase the total number of beds authorized in the facility's current location.

Rule 111-2-2-.10(3)(d)(2) is amended to delete references to "first year's" warranty and replace with "for the first five years of operation."

Rule 111-2-2-.10(3)(d)(9) is amended to delete "initial year" and change to "first five years."

Rule 111-2-2-.10(3)(e) is amended to remove the provision that various build out costs must be included and defines build out costs. The deleted portions of the Rule relate to the requirements to include a separate Functional Build-Out/Finish Line Item Valuation

Sheet; a separate Associated and Simultaneous Build-Out/Finish Line Item Valuation Sheet; a separate Furnishings Line Item Valuation Sheet and a separate Aggregate Valuation Sheet.

Rule 111-2-2-.10(3)(f) is amended to eliminate duplicative language within the Rule. The language eliminated pertains to addition of an item and the remaining language pertains to the acquisition of an item, both which state the same or similar requirement under the Rule.

Rule 111-2-2-.10(3)(i) is amended to remove the requirement that separate line item valuation sheets have to be submitted following completion of the acquisition of the equipment for which a letter of non-reviewability is requested.

Rule 111-2-2-.10(4)(a) is new language under this Rule section but is inclusive of the requirements to qualify for a letter of non-reviewability for a single specialty ambulatory surgical center that previously existed at Rule 272-2-.07(5) as well as new requirements for exemption as a joint venture ambulatory surgical center. Rule 111-2-2-.10(4)(a)(1)-(18) includes all the language of Rule 272-2-.07(5)(a)-(r).

Rule 111-2-2-.10(4)(b)(1)-(6) is new language which establishes additional requirements to establish a single specialty ambulatory surgical center to show that it does not exceed the capital expenditure threshold of \$2.5 million or that it is the only single specialty ambulatory surgical center in the county owned by the group practice and has two or fewer operating rooms; has a hospital affiliation agreement with a nearby hospital or the medical staff at the center have admitting privileges to ensure necessary medical backup; provides care to Medicaid and/or Peachcare patients and uncompensated indigent and charity care of 2% or, if not a participant in Medicaid and/or Peachcare, provides 4% uncompensated indigent and charity care; provides annual reports. This provision does not apply to surgical centers owned by physicians specializing in the practice of ophthalmology; provides for assessment of monetary penalty for failure to meet indigent care commitment; gives Department authority to revoke exemption for repeated failure to pay any fines or monies due the department or for repeated failure to comply with reporting requirements, after notice and a fair hearing; further provides for exemption threshold to be adjusted annually.

Rule 111-2-2-.10(4)(c)(1)-(4) is new language which establishes additional requirements to establish a joint venture ambulatory surgical center to show that it does not exceed the capital expenditure threshold of \$5 million; provides care to Medicaid and/or Peachcare patients and uncompensated indigent and charity care of 2% or, if not a participant in Medicaid and/or Peachcare, provides 4% uncompensated indigent and charity care; provides annual reports. This provision provides for assessment of monetary penalty for failure to meet indigent care commitment; gives the Department authority to revoke exemption for repeated failure to pay any fines or monies due the department or for repeated failure to comply with reporting requirements, after notice and a fair hearing; further provides for exemption threshold to be adjusted annually.

Rule 111-2-2-.10(5) is new language which establishes requirements applicable to valid holders of ambulatory surgery or diagnostic or therapeutic equipment exemptions prior

to July 1, 2008 that they provide notice to the department and provide annual reports; provide care to Medicaid and/or Peachcare patients and 2% uncompensated indigent and charity care, or if a non participant in Medicaid and/or Peachcare, provide 4% uncompensated indigent and charity care, if they make a capital expenditure in excess of \$800,000 over a two-year period; build a new operating room or relocate. This provision provides for assessment of monetary penalty for failure to meet indigent care commitment; gives the Department authority to revoke exemption for repeated failure to pay any fines or monies due the department or for repeated failure to comply with reporting requirements, after notice and a fair hearing; further provides for exemption threshold to be adjusted annually.

Rule 111-2-2-.10(6) is amended to delete reference to "Health Planning Review Board" and change to "Certificate of Need Appeal Panel" and adds new requirements that the Department publish notice of all requests for approval of exempt activity and opposition to such requests; sets out the requirements to file such opposition with the Department; provides for a right to a hearing if opposition has been properly received by the Department; deletes in totality the previous challenge provisions.

111-2-2-.10 Determinations and Letters of Non-Reviewability.

(1) General Provisions Relating to Determinations and Letters of Non-Reviewability.

(a) Determinations and Letters of Non-Reviewability are conclusions of the Department that are based on specific facts and are limited to the specific issues addressed in the request for determination or letter of non-reviewability, as applicable. Therefore, the conclusions of a specific determination or letter of non-reviewability shall have no binding precedent in relation to parties not subject to the request and to other facts or factual situations that are not presented in the request.

(b) This rule shall not be construed as providing an administrative remedy for decisions made by the Department pursuant to O.C.G.A. § 31-6-43, which involve the approval or denial of applications for certificates of need.

(c) A person requesting a determination or letter of non-reviewability shall make such a request in writing and shall specify in detail all relevant facts, which relate to the proposed action or course of conduct. The request shall be directed to the General Counsel or his designee. The General Counsel or his designee shall respond to the request in writing. The request shall include, at a minimum, the following components:

1. a statement citing by appropriate reference the statutory provision or other authority under which the request is to be granted by the Department.

2. the exact legal name of each person whose rights are affected and who is requesting a determination or letter of non-reviewability and the address or principal place of business of each such person. A request may be submitted by an attorney or other party on behalf of such person, but the request must include the information required by this subsection relating to the person whose rights are affected;

3. The name, title, address, telephone number, facsimile telephone number and electronic mail address of the attorney or other person, if any, to whom correspondence or communications in regard to the request shall be addressed; and

4. An explanation of any unusual circumstances involved in the request which the Department will be expected to direct its particular attention, including the existence of emergency conditions.

(d) Requests for determination or letter of non-reviewability shall address only one matter per request.

(e) Requests for determination or letter of non-reviewability shall be submitted pursuant to and in compliance with 111-2-2-.06(5). Such requests shall also include one signed original of the written vendor lobbyist certification required by 111-1-2-.03(2).

(f) Requests for determination or letter of non-reviewability shall include payment of a request fee. Payment of the fee shall be by certified check or money order made payable to the State of Georgia Department of Community Health and must be received

by the Department before a determination request will be reviewed. Failure to provide payment of the appropriate fee will result in non-acceptance and return of the request.

1. The request fee for determination shall be \$250.00;
2. The request fee for letters of non-reviewability shall be \$500.00;
3. State-owned institutions shall be exempt from payment of these fees; and

4. The Department may waive payment of these fees for certain hospital authority facilities and for certain public non-profit providers when the Department determines that financial circumstances exist, which would justify such action. Such requests for waiver must be received at the time of the initial request.

(2) **Letters of Determination.** Pursuant to O.C.G.A. § 31-6-47(c), if a person believes or has reason to believe that the application of a Department Rule or statutory provision may directly affect or impair the legal rights of that person as to some proposed action or course of conduct being considered by that person, including, but not limited to, determinations regarding reviewability, grandfathering decisions, and relocation or replacement determinations, such person may request a written determination from the Department regarding the application of such Department rule or statutory provision upon that person's proposed action or course of conduct. A determination request is distinguished from a general question as a determination does not address general issues relating to policy and procedure.

Any person who believes a proposed activity is exempt from prior CON review and approval pursuant to O.C.G.A. § 31-6-47, shall be required to, pursuant to O.C.G.A. § 31-6-47.1, submit a request for a letter of determination from the Department. The Department's written response which confirms that the proposed activity is exempt from review shall act as the official confirmation of exemption provided in this Code section. A party is not authorized to commence or undertake the activity in question which it believes to fall within any one or more of the statutory exemptions in O.C.G.A. § 31-6-47 until written approval is issued by the Department in response to a request for a letter of determination as provided in this Rule.

Requests for confirmation of the exemptions at O.C.G.A. § 31-6-47(a)(18), (19) only, for a single specialty ambulatory surgical center or a joint venture ambulatory surgical center shall be considered requests for Letter(s) of Nonreviewability and submitted with a \$500.00 filing fee and in accordance with section (4) of this Rule.

In reviewing a determination request pursuant to this rule to relocate all or a portion of an existing skilled nursing facility, intermediate care facility, or intermingled nursing facility, pursuant to O.C.G.A. § 31-6-47(a)(24) and Rule 111-2-2-.03(26), the Department may allow such facility to divide into two or more such facilities if the Department determines that the proposed division is financially feasible and would be consistent with quality patient care. Under no circumstances will the Department allow, via a favorable determination, a facility as listed above to relocate as one facility, or divide into more than one facility, with more than the total number of beds authorized in the facility's location prior to any relocation and/or division.

(a) No person shall be entitled to request a determination that relates to an actual or proposed action or course of conduct which has been taken or which would be taken by a third party.; and

(b) In addition to the requirements of 111-2-2-.10(1), a determination request shall include a concise and explicit iteration of the facts on which the Department is expected to rely in granting the determination.

(3) Requests for Letters of Non-Reviewability for Below Threshold Diagnostic or Therapeutic Equipment. In addition to the requirements of 111-2-2-.10(1) and pursuant to the meaning of threshold as defined at 111-2-2-.01(44 54), the Department applies the following rules as they concern requests for determinations that the value of certain diagnostic or therapeutic equipment does not exceed the Department's equipment threshold, pursuant to O.C.G.A. § 31-6-2(14)(F), (H), or (F) and (H) and therefore that such equipment is not subject to prior CON review and approval.

(a) The party who requests the letter of non-reviewability must submit a manufacturer's or vendor's price quotation or purchase order for the diagnostic or therapeutic equipment. This requirement applies even if the equipment is to be leased.

(b) The party who requests the letter of non-reviewability must submit a sworn affidavit affirmed by a person capable of making a binding commitment on behalf of the manufacturer or vendor of the diagnostic or therapeutic equipment for which a determination containing the following affirmations:

1. that the affiant is capable of making a binding commitment on behalf of the manufacturer or vendor; and
2. that the price shown on the price quotation or purchase order is the total expense the requesting party is incurring for the equipment shown and the total dollar amount that the manufacturer or vendor is receiving for the exact unit shown on the quotation or purchase order; or
3. In the case of a lease or other means of acquisition, that the price shown is the total dollar amount that would have been expended had the equipment been purchased.

(c) A party requesting a letter of non-reviewability for the purchase of diagnostic or therapeutic equipment with a value below the equipment threshold must submit with the request a sworn affidavit from a person capable of making a binding commitment on behalf of the party containing the following affirmations:

1. that the affiant is capable of making a binding commitment on behalf of the party;
2. that no acquisition of additional items not listed on a Line Item Valuation Sheets or the Aggregate Valuation Sheet, to be added to or used with the operational configuration of the particular diagnostic or therapeutic equipment at issue to include functionally related equipment, will be made or will take place for a period of six (6) months from the date of installation of the equipment that would put the total expenditure incurred on the diagnostic or therapeutic equipment or its operational configuration over the Department's equipment threshold;

3. that no acquisition of additional equipment reasonably related to or associated with the general type of service provided by the equipment to be acquired not listed on a Line Item Valuation Sheet or the Aggregate Valuation Sheet will occur within a period of six (6) months, that is that such expenditure for associated, but not functionally related equipment, regardless of modality, shall occur simultaneously;

4. that no construction not listed on a Line Item Valuation Sheet or the Aggregate Valuation Sheet that can reasonably be determined to be associated with the equipment to be acquired will occur within a period of six (6) months;

5. that the Line Item Valuation Sheets and the Aggregate Valuation Sheet included in the request are accurate, reflect all of the expenses required by Rule 111-2-2-.10(3), and reflects the true cost of acquiring the exact same equipment and any and all associated and simultaneous items and activities; and

6. that the price shown on the price quotation(s) or purchase order(s) reflects the exact amount of the total expense that will be incurred and paid to the manufacturer or vendor for the exact same equipment listed on the price quotation or purchase order; or

7. in the case of a lease or other acquisition, that the price shown on the purchase order(s) or quote(s) is the total dollar amount that would have been expended had the equipment been purchased.

(d) The request for a letter of non-reviewability must include a, Equipment Line Item Valuation Sheet, generated by the party requesting a letter, listing all dollar amounts attributable to each category listed below of items the Department will evaluate for purposes of determining if the value of the diagnostic or therapeutic equipment is below the equipment threshold dollar amount. If an item is not applicable, the requesting party should include the item on the Line Item Valuation Sheet and indicate the dollar amount as \$0. For each simultaneous and associated unit of equipment, as outlined at 111-2-2-.10(3)(i) below, a separate line item valuation sheet must be submitted.

1. The dollar amount of the base price of the unit before adding any of the following items;

2. Any expense incurred for the purchase of a **first year's** warranty on the diagnostic or therapeutic equipment from the manufacturer or vendor **for the first five years of operation**;

3. Any expense incurred for operator training;

4. Any expense incurred for installation and assembly of the equipment;

5. Any expense incurred for transportation and insurance costs pertaining to the purchase and/or delivery of the equipment;

6. Any expense incurred for functionally related diagnostic or therapeutic equipment, such as, but not limited to, water chillers, surge protectors, laser cameras, computer workstations, etc.

7. Any expense incurred for any options, extra packages, or accessories to be used in the operation of the equipment;

8. Any expense incurred for RF shielding, lead shielding, magnetic shielding necessary to protect patients or staff in the operation of the equipment;

9. Any dollar amount attributable to service contracts for the ~~initial year~~ first five years of operation;

10. Any dollar amount attributable to volume or bulk purchase discounts given to the party requesting a letter of non-reviewability by the manufacturer or vendor of the equipment;

11. For mobile equipment, any expense incurred for a mobile coach, trailer, or van in which the equipment will be operated; and

12. The final line of the Line Item Valuation Sheet should reflect the total of the preceding eleven items.

(e) The value of diagnostic or therapeutic equipment for which a letter of non-reviewability is requested shall not include build out costs. Build out costs are defined as expenditures made for items such as electrical, plumbing, masonry such as concrete pads, construction of modular buildings, and renovation of the space that will actually house the equipment, such as the room where an MRI unit would be used. Build out costs shall also include expenditures for new construction for a building to house the equipment or to renovate a building or structure to house the equipment, or expenditures for administrative office space unrelated to the actual functionality of the equipment, related equipment, or software necessary to operate the equipment.

~~1. The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include a separate Functional Build-Out/Finish Line Item Valuation Sheet, generated by the party requesting a letter, listing all dollar amounts attributable to build-out to make the equipment functional to include, but not to be limited to, electrical and plumbing work to be performed, masonry expenses to lay a concrete pad, and construction of modular buildings. Each item of build-out shall be delineated. If functional build-out will not be necessary, i.e. because equipment was previously used in the exact same space, the requesting party should include the Functional Build-Out/Finish Line Item Valuation Sheet and indicate that no functional build-out is required.~~

~~2. The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include a separate Associated and Simultaneous Build-Out/Finish Line Item Valuation Sheet, generated by the party requesting a letter, listing all dollar amounts attributable to finishing and build-out items, activities, and expenditures, if such items are associated and simultaneously developed or proposed, including, but not limited to, clinical office space, administrative areas, waiting rooms, etc. If there will be no associated and simultaneous build-out/finish, the requesting party should include the Associated and Simultaneous Build-Out/Finish Line Item Valuation Sheet and indicate that no associated and simultaneous build-out/finish is required.~~

~~(f) The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include a separate Furnishings Line Item Valuation Sheet, generated by the party requesting a letter. Pursuant to the definition of "associate with and simultaneously developed or proposed," the Furnishings Line Item Valuation Sheet should include a description of each item of furniture, the quantity of each item, a price per item, and a~~

~~total based on the quantity multiplied by the price. A grand total should be calculated at the bottom of the Sheet. If no associated with and simultaneously developed or proposed expenditures related to furnishings will be incurred within 6 months of the operation of the equipment, submit a sheet entitled "Furnishings Line Item Valuation Sheet" and indicate that no furnishings will be acquired;~~

~~1. if items of furnishings are to be leased, the current market value of the furnishings shall be listed;~~

~~2. submit price quotes as applicable; and~~

~~3. both moveable and fixed furnishings shall be included;~~

~~(g) The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include a separate New Construction Line Item Valuation Sheet, generated by the party requesting a letter, listing all costs attributable to associated with and simultaneously developed or proposed new construction, including, but not limited to vaults, office space and waiting rooms. If the facility under construction will be leased, the cost of the new construction for the share of the building to be occupied by the facility or service, inclusive of a share of any common spaces, shall be included. Also, any costs associated with renovation of existing space shall be included. Each item of construction shall be delineated. If new construction will not be necessary or will not be associated with and simultaneously developed or proposed, the requesting party should include the New Construction Line Item Valuation Sheet and indicate that no construction is required;~~

~~(h) The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include an Aggregate Valuation Sheet, generated by the party requesting a letter, listing the following items and totals:~~

~~1. The Total of each Equipment Line Item Valuation Sheet;~~

~~2. The Total of the Functional Build-Out/Finish Line Item Valuation Sheet;~~

~~3. The Total of the Associated and Simultaneous Build-Out/Finish Line Item Valuation Sheet;~~

~~4. The Total of the Furnishings Line Item Valuation Sheet;~~

~~5. The Total of the New Construction Line Item Valuation Sheet; and~~

~~6. The grand total of the previous five items.~~

~~(i) A party adding an item, or incurring an expense of the types listed in 111-2-2-.10(3)(d) through (g), within a 6-month period following the date of installation of the equipment, which when added to the values of the items submitted for approval would exceed the threshold applicable at the time of approval, will be considered to be offering a new institutional health service without Certificate of Need authorization.~~

(f) A party acquiring functionally related equipment or items, including those items and expenses listed in 111-2-2-.10(3)(d) within a 6-month period, which when added to the values of the items submitted for approval would exceed the threshold applicable at the

time of approval, will be considered to be offering a new institutional health service without Certificate of need authorization;

(jg) All simultaneously acquired and associated diagnostic and therapeutic equipment regardless of modality shall be aggregated. See the definition of “associated with and simultaneously developed or proposed.” If additional diagnostic and therapeutic equipment is to be acquired, the party must submit price quotations for each piece of simultaneously acquired diagnostic and therapeutic equipment;

(kh) A letter of non-reviewability for the acquisition of diagnostic or therapeutic equipment shall be valid only for the defined equipment, physical location, cost, and entity or person named in the request as the acquirer and operator of equipment and only to the pertinent facts that were disclosed in the request, except that cost may exceed the amount approved by the Department as long as the actual final expenditures do not exceed the equipment threshold. Such letters are non-transferable and may not be acquired. If the facts pertinent to the letter of non-reviewability change in any way, the letter is no longer valid;

(li) Upon completion of the acquisition of the equipment, the party requesting a LNR shall submit a final statement of the total costs of the equipment, ~~including separate line item valuation sheets with the same detail and documentation as required in subsections 111-2-2-.10(3)(d) through (h) above.~~ In addition, if the if the equipment and associated activities are not completed within one hundred and eighty (180) days of the issuance of the LNR, the party requesting a LNR shall submit an interim statement within two weeks of the end of that one hundred and eighty (180) day period and within two weeks of the end of each succeeding ninety (90) day period until the final statement is submitted upon completion of the facility. Each of the interim statements shall disclose the expenses incurred to date, and any good faith estimates of the percentage of completion and the amount of costs expected to be incurred to complete. The accuracy and completeness of the interim and final statements shall be verified by sworn affidavits from an authorized owner or officer of the party requesting a LNR. Failure to comply with the provisions of this subsection may result in the rescission of the LNR issued.

(4) ~~Reserved. Requests for Letters of Non-reviewability for Exempt Single Specialty or Joint Venture Ambulatory Surgical Centers~~

(a) When the Department receives a request for a Letter of Nonreviewability (LNR) for the establishment of a physician-owned, single specialty, office-based ambulatory surgery facility, or a joint venture ambulatory surgical center, pursuant to O.C.G.A. § 31-6-2(33), (23, and O.C.G.A. § 31-6-47(a)(18), (19), the party requesting such a letter must comply with the following:

1. Identify the name and address of the proposed ambulatory surgery facility, including the principal business address of the sole physician or group practice that will own the facility.

2. Identify the individual private physician, or all owners (e.g. stockholders, partners, members) of the single group practice of private physicians who are also on the same single specialty, that will own, operate, and utilize the proposed facility. All members of the single group practice must be of the same specified surgical specialty. Physicians who perform procedures within the single specialty ambulatory surgical center must own

at least eighty-five (85) percent of the group practice and the surgery center. The Department will issue a LNR, if all other criteria are met, to a single group practice which utilized the services of employee physicians of the same specialty in the surgery center if these employee physicians are not a member or employee of any other medical practice. All employee physicians must be identified, and an affirmative statement with regard to their practice affiliation must be included. The Department will allow no more than fifteen (15) percent non-physician ownership in the physician(s) practice requesting a LNR, and/or the surgery center in a single specialty ambulatory surgical center. Evidence of non-physician ownership, including the percentage of such ownership, must be provided with the LNR request. For a joint venture ambulatory surgical center, the ownership interest of the hospital shall be no less than thirty (30) percent and the collective ownership of the physicians or group of physicians shall be no less than thirty (30) percent. Any evidence of non-hospital or non-physician or group of physicians ownership in a joint venture ambulatory surgical center must be provided with the LNR request.

3. All physicians must be licensed to practice in the state of Georgia, and must submit a copy of such license; should any physician members of a single group practice perform procedures in the ambulatory surgery facility created by the issuance of a LNR lose their license to practice medicine in Georgia, the LNR shall be revoked, unless within sixty (60) days of such physician losing their license, the group practice submits new evidence documenting that the physician ownership of the facility by the group practice does not include the physician who lost their license.

4. Submit evidence of the sole physician professional corporation or the entity comprising the single group practice of private physicians, to include authorizing and governing documents such as articles of incorporation, by-laws, operating agreements, partnership agreements, etc. Submit a sworn affidavit, signed by the owners, which lists all owners of the sole or group practice and the proposed surgery facility.

5. The physician(s) must show evidence of ownership by warranty deed or lease of the space housing the ambulatory surgery facility including the clinical office space.

6. Provide a detailed description of the proximity of the physician's or the group practice's clinical offices to the ambulatory surgery facility. The Department will only grant a LNR to those proposed ambulatory surgical facilities, which are deemed to be in reasonable proximity to the clinical offices of the sole physician or single group practice that will own the proposed facility. Reasonable proximity will be determined on a case-by-case basis. Example of reasonable proximity include those ambulatory surgical facilities on the same floor and physically attached to the clinical offices; surgical suites on a different floor of the same building as the clinical offices with one public entrance to the proposed facility.

7. State the number of operating rooms in the proposed ambulatory surgery facility.

8. State the total square footage in the proposed ambulatory surgery facility. This total includes the square footage associated with all operating suites, reception and waiting areas, business offices, pre and post-operation areas, all building common areas including a pro rata share of the common areas of buildings utilized by multiple tenants.

which are new and/or renovated and involve expenditures to be incurred in the development, construction and establishment of the proposed surgery facility.

9. List costs attributable to new construction or renovation of the total area comprising the ambulatory surgery facility. Documentation of the total costs of constructing, developing, and establishing the proposed ambulatory surgical facility, and the costs of all items associated with or simultaneously developed with the project, including, but not limited to, fixed equipment not included in the construction contract, moveable equipment, architectural and engineering fees, legal and administrative fees, interim financing (interest during construction), and underwriting costs. The documentation of construction and renovation costs must be in the form of a letter from a licensed Georgia architect verifying the estimated construction costs of the proposed ambulatory surgery facility. With regard to the construction of a new building (or a new wing including space devoted to services other than the surgery center) to house an ambulatory surgery facility, a pro-rata portion of the building shell costs, including all building common areas, must be allocated to the costs of the proposed ambulatory surgery facility. Other costs to be included are:

(i) The cost of new space (even if the space will be leased) based on the construction cost of the new space. Appropriate documentation from an architect licensed in Georgia must be submitted. A copy of all leases must be submitted;

(ii) The cost of all equipment (medical and non-medical) purchases for the ambulatory surgery facility.

(iii) The present value of any equipment to be leased for the surgery facility.

(iv) The Department must have a line item breakdown of all amounts attributable to new construction, renovation, furnishings, leases, and items of equipment in accordance with the provisions outlined above, including new expenditures for furnishings for non-patient care areas such as waiting areas, reception areas, and business offices.

The Department will require a sworn affidavit that no party associated with the practice or physicians requesting a LNR, by virtue of ownership or employment, has incurred any expenditure for equipment of any kind to be utilized in the surgery center that has been subsequently donated to the practice for use in the surgery center and the cost of that equipment, whether purchased or leased, was not included in the dollar threshold applicable to the surgery center.

10. A schematic floor plan must be provided to the Department. This documentation must be clear and readable. The floor plan must clearly show all areas of the proposed ambulatory surgery facility.

11. Pursuant to O.C.G.A. § 31-6-2(14), list the cost of all other items, regardless whether they are independently subject to Certificate of Need review, that are associated and to be simultaneously developed with the proposed ambulatory surgery facility, except for the expenditure or commitment of funds to develop studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites.

12. The Department will not issue a LNR to any sole physician or single specialty group practice of physicians proposing to bill a professional fee through a larger multi-

specialty group practice in which the single specialty group practice requesting the LNR remains a part of. For purposes of these rules, this provision does not preclude the issuance of a LNR to a physician(s), which utilizes a larger group practice for the sole purpose of billing services under the provider number of the sole physician or single group practice.

13. The Department will not issue a LNR to any physician(s) who is a member of more than one single group practice, pursuant to O.C.G.A. § 43-1B-3(5) of the Georgia Patient Self-Referral Law.

14. The Department will not issue a LNR to any group practice of physicians if any members of that group practice are also members of a multi-specialty clinical practice. For purposes of these rules a multi-specialty clinical group practice does not mean any volume purchasing association or managed care network whose function is managed care contracting in which the physician or group practice participates.

15. The Department will not issue a LNR to any party proposing to share operating rooms or common space in a proposed ambulatory surgical facility between more than one group practice of the same specialty or between more than one surgical group practice of different specialties, or between more than one sole physician of the same or different specialties who are not members of the same medical practice.

16. Provide a sworn affidavit, signed by the physician(s) owners, that the party requesting a LNR will not incur any additional capital expenditures involving new construction or renovation of physical space or the addition or replacement of equipment within three years after the issuance of the LNR, which, when coupled with prior expenditures, would exceed the threshold amount applicable to the statutory exemption for this type of facility unless it first secures a Certificate of Need. A party holding a LNR issued by the Department may request, in writing, a waiver from this provision for expenditures for equipment involving newly recognized and innovative medical technologies (FDA approved) present in the marketplace. Any such expenditure will be applied to the original threshold amount unless the written consent of the Department is obtained prior to the expenditure.

17. Upon completion of construction of the ambulatory surgery facility, the party requesting a LNR shall submit a final statement of the total costs of the facility, including a separate line item completed project cost sheet with the same detail and documentation as required in subsection (4)(a)(11) above. In addition, if the proposed ambulatory surgery facility is not completed within one hundred and eighty (180) days of the issuance of a LNR, the party requesting a LNR shall submit an interim statement within two weeks of the end of that one hundred and eighty (180) day period and within two weeks of the end of each succeeding ninety (90) day period until the final statement is submitted upon completion of the facility. Each of the interim statements shall disclose the cost of the facility incurred to date, and any good faith estimates of the percentage of completion of the facility and the amount of costs expected to be incurred to complete the facility. The accuracy and completeness of the interim and final statements shall be verified by sworn affidavits from an authorized owner or officer of the party requesting a LNR and from the general contractor. Failure to comply with the provisions of this subsection may result in the rescission of the LNR issued.

18. The LNR is not transferable to a purchaser of the sole physician or single group practice, which originally received a LNR. This provision is not intended to limit the transferability of a sole physician practice or a group practice, but is intended to put the new physician owners on notice that they must request a new LNR as new owners of that practice. Such a new request will be evaluated based on the LNR criteria applicable at the time of the new request, and the acquisition costs of the practice will not be a part of the applicable capital expenditure threshold.

(b) A single specialty ambulatory surgical center that requests a Letter of Nonreviewability shall provide documentation, in addition to the requirements outlined in section (1) of this rule above, to show that it:

1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed \$2,500,000.00; or

2. Is the only single specialty ambulatory surgical center in the county owned by the group practice and has two or fewer operating rooms; provided, however, that a center exempt pursuant to this provision shall be required to obtain a certificate of need in order to add any additional operating rooms;

3. Has a hospital affiliation agreement with a hospital within a reasonable distance from the facility or the medical staff at the center has admitting privileges or other acceptable documented arrangements with such hospital to ensure the necessary backup for the center for medical complications. The center shall have the capability to transfer a patient immediately to a hospital within a reasonable distance from the facility with adequate emergency room services. A party requesting a letter of nonreviewability must provide documentation to support an assertion that a hospital, pursuant to this requirement, has unreasonable denied a transfer agreement or affiliation agreement to the center;

4. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids™ beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than 2 percent of its adjusted gross revenue; or

5. If the center is not a participant in Medicaid or the PeachCare for Kids™ Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids™ beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than 4 percent of its adjusted gross revenue; provided, however, single specialty ambulatory surgical centers owned by physicians in the practice of ophthalmology shall not be required to comply with this subparagraph; and

6. Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and Rule 111-2-2-.04.

Noncompliance with any condition of subsections (4.) and (5.) of Section (4)(b) of this rule shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the department for repeated failure to pay any fines or moneys due to the department or for repeated failure to

produce data as required by O.C.G.A. § 31-6-70, and subsection (6.) of section (4)(b) of this rule, after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the 'Georgia Administrative Procedure Act.' The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index.

(c) Any joint venture ambulatory surgical center that requests a letter of nonreviewability shall provide documentation, in addition to the requirements outlined in section (1) of this rule above, to show that it:

1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed \$5,000,000.00;

2. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids™ beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than 2 percent of its adjusted gross revenue; or

3. If the center is not a participant in Medicaid or the PeachCare for Kids™ Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids™ beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than 4 percent of its adjusted gross revenue; and

4. Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and Rule 111-2-2-.04.

Noncompliance with any condition of subsections (2.) and (3.) of section (4)(c) of this rule shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the department for repeated failure to pay any fines or moneys due to the department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70, and subsection (4.) of section (4)(c) of this rule, after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the 'Georgia Administrative Procedure Act.' The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index.

(5) Requirements Applicable to Valid Holders of Ambulatory Surgery or Diagnostic or Therapeutic Equipment Exemptions Prior to July 1, 2008.

(a) Any facility offering ambulatory surgery pursuant to the exclusion designated on June 30, 2008, as division (14)(G)(iii) of O.C.G.A. § 31-6-2; any diagnostic, treatment, or

rehabilitation center offering diagnostic imaging or other imaging services in operation and exempt prior to July 1, 2008; or any facility operating pursuant to a letter of nonreviewability and offering diagnostic imaging services prior to July 1, 2008, shall:

1. Provide notice to the department of the name, ownership, location, single specialty, and services provided in the exempt facility in accordance with the provisions of Rule 111-2-2-.04(1)(b)(1.);

2. Beginning on January 1, 2009, provide annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and in accordance with the provisions of Rule 111-2-2-.04(1)(b)(2.).

(b) If, on or after July 1, 2008, any facility referenced in subsection (5)(a) above that, makes a capital expenditure associated with the construction, development, expansion, or other establishment of a clinical health service of the acquisition or replacement of diagnostic or therapeutic equipment with a value in excess of \$800,000.00 over a two-year period; builds a new operating room; or chooses to relocate in accordance with Rule 111-2-2-.03; it shall:

1. Provide care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids™ beneficiaries and provide uncompensated indigent and charity care in an amount equal to or greater than 2 percent of its adjusted gross revenue; or

2. If the facility is not a participant in Medicaid or the PeachCare for Kids™ Program, provide uncompensated care for Medicaid beneficiaries and, if the facility provides medical care and treatment to children, for PeachCare for Kids™ beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than 4 percent of its adjusted gross revenue.

Noncompliance with any condition of subsection (b)(1.) and (2) above shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the department for repeated failure to pay any fees or monies due to the department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70 after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the 'Georgia Administrative Procedure Act.' The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the consumer price index, or its successor or appropriate replacement index, if any, published by the United States Department of Labor for the preceding calendar year, commencing on July 1, 2009. In calculating the dollar amounts of a proposed project for the purposes of this paragraph, the costs of all items subject to review by this chapter and items not subject to review by this chapter associated with and simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop certificate of need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites. Subsections (b)(1.) and (2.) of section (5) of this rule, shall not apply to facilities offering ophthalmic ambulatory surgery pursuant to the exclusion designated on June 30, 2008, as division

(14)(G)(iii) of O.C.G.A. § 31-6-2 that are owned by physicians in the practice of ophthalmology.

(56) Administrative Remedies for Adverse Determinations. When the Department makes a determination or decision or declines to issue a letter of non-reviewability pursuant to Sections 111-2-2-.10(1) through (45) of this rule or any other determination or decision over which the ~~Health Planning Review Board Certificate of Need Appeal Panel~~ lacks subject matter jurisdiction, the person who requests and receives the determination or decision may appeal to the Commissioner or his designee for an administrative hearing pursuant to the Administrative Procedures Act if such person is aggrieved by the Department's determination or decision. Such request for a hearing must be made in writing and must be received by the Department within thirty (30) days of the date of the Department's determination or decision. If such written request is not received by the Department within thirty (30) days, the Department's determination or decision shall become final upon the thirty-first (31st) day.

The Department shall publish notice of all requests for approval of an exempt activity and opposition to such request, whether pursuant to O.C.G.A. § 31-6-47 or any other provision of Code Section 31-6 and these Rules. Persons opposing a request for approval of an exempt activity, whether pursuant to an express statutory exemption or any other provision of the health planning statute or these Rules, shall be entitled to file a written objection with the Department and the Department shall consider any filed objection when determining whether an activity is exempt. A person who wishes to file a written objection to an exemption determination request, including requests for letters of nonreviewability for a single specialty ambulatory surgical center or a joint venture ambulatory surgical center, must do so no later than thirty (30) days after the date of Department receipt of the initial request for the exemption determination. Such written opposition should be sent to the Department of Community Health, Office of General Counsel, Division of Health Planning, 2 Peachtree Street, 5th Floor, Atlanta, Georgia 30303. The opposition shall be submitted in accordance with Rule 111-2-2-.06(6). The opposing person shall submit an original and one copy of its written opposition.

After the issuance of an approval to a response to the request for an exemption determination, including requests for letters of nonreviewability for a single specialty ambulatory surgical center or a joint venture ambulatory surgical center, a person in opposition that has complied with the provisions outlined above, shall have the right to a fair hearing pursuant to Chapter 13 of Title 50, the 'Georgia Administrative Procedure Act,' and judicial review of a final decision in the same manner and under the same provisions as in O.C.G.A. § 31-6-44.1 and Rule 274-1 et. seq. A person who requested and received the exemption determination shall have automatic standing to participate in any such administrative proceeding to defend the approved exemption determination. The Department may also participate to defend its decision. A person who opposes an exemption determination request that is denied, and who has complied with the written opposition submission requirements provided above, shall have standing to participate in any administrative proceeding requested by the person denied an approved exemption determination. If the written opposition is not submitted in accordance with the provisions outlined above, the Department shall not consider the opposition, and the rights to an administrative hearing, and/or any participation in any proceeding as outlined above, will not adhere to the opposing person.

~~(6) **Persons Challenging Determinations and Letters of Non-Reviewability.**~~

~~Interested persons may challenge a request for a letter of determination or letter of non-reviewability, as applicable, either during the Department's consideration of the request or within 30 days of the Department's issuance of the determination or letter of non-reviewability, as applicable. Challenges must be in writing and mailed to the Division of Health Planning at 2 Peachtree Street, 5th Floor, Atlanta, Georgia 30303. Upon receipt of a timely challenge, the following procedures will be in effect:~~

~~(a) The Department will forward the written challenge to the requestor or holder, as applicable, of the letter of determination or letter of non-reviewability. The requestor or holder, as applicable, shall have 10 business days to respond to the Challenge, unless such time is extended in the Department's sole discretion for good cause.~~

~~(b) Upon receipt of the requestor's or holder's response, the Department will forward the response to the challenger. If the challenger wishes to respond, the challenger shall have 10 business days to respond to the requestor's or holder's response, unless such time is extended in the Department's sole discretion for good cause.~~

~~(c) Should the challenger respond to the requestor's or holder's response, the Department will forward the challenger's response to the requestor or holder, as applicable. The requestor or holder shall have 10 business days to make a final response to the challenge.~~

~~(d) Upon receipt of the final response from the requestor or holder, the Department shall make a determination as to the merits of the challenge.~~

~~(e) Challenges shall be submitted pursuant to and in compliance with 111-2-2-.06(5). Challenges shall also include one signed original of the written vendor lobbyist certification required by 111-1-2-.03(2).~~

~~(f) This rule shall not be construed as providing an administrative remedy for decisions made by the Department pursuant to O.C.G.A. § 31-6-43, which involve the approval or denial of applications for certificates of need. Furthermore, this challenge process shall not be construed as a proceeding meeting the definition of "contested case" under the Georgia Administrative Procedure Act.~~

~~(g) If a determination or letter of non-reviewability is revoked or cancelled by the Department pursuant to these challenge provisions, the requestor or holder shall have appeal rights pursuant to 111-2-2-.10(5).~~

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