RULES
OF
DEPARTMENT OF COMMUNITY HEALTH

CHAPTER 111-2
HEALTH PLANNING

111-2-2
CERTIFICATE OF NEED

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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 proposing an activity that would make it a health care facility unless exempted from prior CON review and approval

pursuant to O.C.G.A. § 31-6-47, or any other part of the CON statute at O.C.G.A. § 31-6 et. seq. 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(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 warranty on the diagnostic or therapeutic equipment from the manufacturer or vendor for the first five (5) 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 first five (5) 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 (11) 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.

(f) A party acquiring functionally related equipment or items, including those items and expenses listed in 111-2-2-.10(3)(d) within a six (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;

(g) 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;

(h) 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;

(i) 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. 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) **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 (3) 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 two (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 four (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 two (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 two (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 four (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.

(6) **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 (5) of this rule or any other determination or decision over which the 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.

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

111-2-2-.20 Specific Review Considerations for Short-Stay General Hospital Beds.

(1) **Applicability.**

(a) A Certificate of Need will be required prior to the establishment of a new hospital, replacement of an existing hospital, or expansion of an existing hospital.

(b) The provisions in these Rules do not apply to the following situations:

1. bed replacements in existing hospital facilities which do not require a capital or equipment expenditure over the applicable dollar threshold; or

2. changing the physical location of existing beds within an existing facility regardless of cost; provided, however, that any project in excess of the applicable capital expenditure or equipment dollar threshold must be reviewed in accordance with the review considerations set forth in Rule 111-2-2-.09; or

3. projects that are otherwise exempt from review pursuant to O.C.G.A. § 31-6-47(a)(15).

(c) An existing hospital seeking an expansion to be used for new institutional health services, including perinatal services, rehabilitation services, or psychiatric and substance abuse services, must meet the applicable service specific Rules found in this Chapter and, as a threshold matter, meet the need standards set forth in 111-2-2-.20(3)(b)3. but shall not be required to meet the other requirements in Rule111-2-2-.20.

(d) A hospital that has been approved through the certificate of need process to use a certain number of short-stay hospital beds for long-term acute care (LTAC) beds shall have such LTAC beds removed from the official inventory of available short-stay beds once the LTAC is certified by Medicare; provided, however, that such beds will revert to the hospital's official inventory of available short-stay beds at any point that the LTAC ceases operation or is no longer certified by Medicare. An application to use existing short-stay hospital beds for LTAC beds shall not be subject to the guidelines in Rule 111-2-2-.20.

(2) **Definitions.**

(a) "Age cohorts" for purposes of these Rules refers to the following age groups: persons zero (0) to seventeen (17); persons eighteen (18) to sixty-four (64); and persons sixty-five (65) and older.

(b) "Available beds" or "CON approved beds" means the total number of beds authorized for use by a hospital or group of hospitals based on capacity approved or authorized through the certificate of need process.

(c) “Children’s hospital” means a hospital in which ninety percent (90%) or more of the patients served by the hospital are seventeen (17) or less years of age.

(d) “Critical Access Hospital” means a hospital designated as a critical access hospital pursuant to the state’s rural health plan and the guidelines of the Medicare Rural Hospital Flexibility Program authorized by section 4201 of the Balanced Budget Act of 1997.

(e) “Destination cancer hospital” means an institution with a licensed bed capacity of fifty (50) or less which provides diagnostic, therapeutic, treatment, and rehabilitative care services to cancer inpatients and outpatients, by or under the supervision of physicians, and whose proposed annual patient base is composed of a minimum of sixty-five (65%) percent of patients who reside outside the State of Georgia.

(f) “Expansion” means the addition of available beds or CON approved beds for an existing hospital.

(g) “Health planning area” or “planning area” means the twelve (12) state service delivery regions as defined in O.C.G.A. § 50-4-7.

(h) “Horizon year” means the last year of a five (5) year projection period for need determinations.

(i) “Optimal Occupancy Rate” means a target or expected level of use of available beds as calculated based on the annual patient days divided by the available beds multiplied by 365. The optimal occupancy rate is variable based on the following:

1. for hospitals located in a rural county, sixty-five percent (65%);

2. for hospitals located in a non-rural county, seventy-five percent (75%); and

3. for teaching or children's hospitals, seventy percent (70%).

(j) "Patient days" means the number of days of inpatient services based on the most recent full year of hospital discharge data or the annual hospital questionnaire.

(k) "Replacement" means new construction to substitute another facility for an existing facility. New construction may be considered a replacement only if the replacement site is located three (3) miles or less from the facility being replaced or, in the case of the facility proposing a replacement site beyond the three mile limit, if the replacement site is located within the same county and would serve substantially the same patient population, based on patient origin by zip code and payer mix, as the existing facility.

(l) "Rural county" means a county with a population of 35,000 or less based on the most recent decennial census, as defined in O.C.G.A. § 31-7-94.1(c)(3).

(m) "Safety net hospital" is defined as a hospital that meets at least two (2) of following criteria:

1. the hospital is a children's hospital or a teaching hospital;

2. the hospital is designated by the Department of Human Resources as a trauma center;

3. Medicaid and Peach Care inpatient admissions constitute twenty percent (20%) or more of the total hospital inpatient admissions;

4. Uncompensated charges for indigent patients constitute six percent (6%) or more of hospital adjusted gross revenue; or

5. Uncompensated charges for indigent and charity patients constitute ten percent (10%) or more of hospital adjusted gross revenue

(n) “Short stay hospital” or “hospital” is defined as a facility with an average length of stay of less than thirty (30) days.

(o) “Target service area population” means the total populations of all counties, which are in part or in whole, within a ten (10) mile radius of the planned location of a new, expanded, or replacement hospital.

(p) “Teaching hospital” means a hospital designated as a teaching hospital by the Georgia Board for Physician Workforce, which serves as a sponsoring or major participating hospital for a program of graduate medical education accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) and maintains a written affiliation agreement with an accredited medical school located in Georgia or is owned and operated by an accredited medical school in Georgia.

(3) **Standards.**

(a) A new hospital must be at least fifty (50) beds in size if located in a rural county and at least one hundred (100) beds in size if located in a county other than a rural county.

(b) The need for a new, replacement or expanded hospital shall be determined through application of an appropriate numerical need methodology designed to assess need for the specific purpose sought in the application.

1. The numerical need for a new hospital shall be determined through application of a demand-based forecasting model. The model is outlined in the steps below:

(i) Calculate the use rate for current hospital services in the target service area population by dividing the patients days for each age cohort by the population for each age cohort for same year as patient days were calculated.

(ii) Project the horizon year use rate for hospital services in the target service area population by multiplying the use rate for

current hospital services by age cohort by the horizon year population by age cohort.

(iii) Divide the results of the calculations in Step (ii) by 365 and sum these numbers to determine a baseline bed need.

(iv) Adjust the baseline bed need by adding a factor to account for use of the hospital services located within the target service area population by persons from out of state. The factor shall be determined by calculating the patient days for the hospitals in the target service area that may be attributed to persons from out of state as a percentage of total patient days, and then dividing that percentage into the baseline bed need. In addition, if the target service area population includes any county or counties outside the state of Georgia, the projected bed need of the out-of-state counties should be calculated by applying the projected rate of beds needed per 1,000 for in-state counties in the target service area population to the prorated portion of population in out-of-state counties.

(v) Divide the baseline bed need by the optimal occupancy rate, as determined by the size of the proposed new facility, to project the total number of beds needed for the target service area population.

(vi) Calculate the number of available beds for the target service area population by adding all of the short stay beds located in the counties, including those outside of Georgia if applicable, which are in part or in whole within a ten (10) mile radius of the planned location of the new hospital.

(vii) Subtract the number of available beds from the total number of beds needed for the target service area population to determine the net number of beds needed.

2. A new hospital shall be approved only if the total target service area population is at least 50,000 persons.

3. The numerical need for a replacement or expanded hospital shall be determined through application of a demand-based forecasting model. The model is outlined in the steps below:

(i) Calculate the county use rate for the current hospital's services by dividing the patients days for Georgia residents by county within each age cohort by the population by county for each age cohort for the same year as patient days were calculated.

(ii) Project the horizon year use rate for the hospital's services by multiplying each county use rate by age cohort by the horizon year population of each county by age cohort.

(iii) Sum the number of patients resulting from Step (ii) and divide by three hundred and sixty five (365) to determine a baseline bed need rate.

(iv) Adjust the baseline bed need rate by adding a factor to account for use of the hospital's services by persons from out of state. The factor shall be determined by calculating the patient days for the hospital that may be attributed to persons from out of state as a percentage of total patient days, and then dividing that number into the baseline bed need.

(v) Divide by optimal occupancy rate, as determined by the size of the proposed facility, to project the total number of beds needed for the replacement or expanded hospital.

(vi) Compare the results of Step (v) with the number of beds requested for the replacement or expanded hospital and, if appropriate, the number of available beds to determine whether the proposed replacement or expanded hospital meets the need standards.

(c) The Department may allow an exception to need and adverse impact standards outlined in Rule 111-2-2-.20(3)(b) and (d) for a facility meeting any one of the following criteria:

1. The facility is an existing facility designated by the Department of Human Resources as a trauma center;

2. The facility is an existing teaching hospital;

3. The facility is a sole community provider and more than twenty percent (20%) of the capital cost of any new, replacement or expanded facility is financed by the county governing authority, as defined in O.C.G.A. § 1-3-3(7), of the home county or the county governing authorities of a group of counties; or

4. The facility is a designated critical access hospital and is seeking replacement of its existing facility at a size not to exceed twenty-five (25) CON approved beds.

(d) 1. An applicant for a new, replacement or expanded hospital shall demonstrate the expected effects of the proposed services on other hospitals within the target service area population, including how any enhanced competition will have a positive impact upon the cost, quality, and access to the services proposed; and in the case of applications for a new, replacement or expanded hospital where competition between providers will not have a favorable impact on cost, quality and access, the applicant shall be required to document that its application will not have an adverse impact.

2. An applicant for a new, replacement or expanded hospital shall document in its application that the new, replacement or expanded facility is not predicted to be detrimental to safety net hospitals within the planning area. Such demonstration shall be made by providing an analysis in the application that compares current and projected changes in market share and payer mix for the applicant and any safety net hospitals. Impact on an existing safety net hospital shall be determined to be adverse if, based on the utilization projected by the applicant, any existing safety net hospital would have a total decrease of ten percent (10%) or more in its average annual utilization, as measured by patient days for the two most recent and available preceding calendar years of data.

3. An applicant for a new, replacement or expanded hospital shall document in its application that the new, replacement or expanded facility is not predicted to be detrimental to any teaching hospitals in the state. Such demonstration shall be made by providing an analysis in the application that compares current and projected changes in market share and payer mix for the applicant and any teaching hospitals. Impact on an existing teaching hospital shall be determined to be adverse if, based on the utilization projected by the applicant, any existing teaching hospital would have a total decrease of five percent (5%) or more in its average annual utilization, as measured by patient days for the two most recent and available preceding calendar years of data.

(e) In considering applications joined for review, the Department may give favorable consideration to whichever of the applicants historically has provided the higher annual percentage of unreimbursed care to indigent and charity patients and the higher annual percentage of services to Medicare, Medicaid and Peach Care patients.

(f) An applicant for a new, replacement or expanded hospital shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability or the patient's ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard that meets or exceeds three percent (3%) of annual, adjusted gross revenues for the hospital;

3. providing a written commitment to participate in the Medicare, Medicaid and Peach Care programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the hospital is eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.

(g) 1. An applicant for a replacement or expanded hospital shall document that the hospital is fully accredited by the Joint Commission on Accreditation of Healthcare Organization (JCAHO) or another nationally recognized accrediting body, and also shall provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past three (3) years and has no outstanding licensure and Medicare and/or Medicaid certification deficiencies. In the event that the hospital is not accredited by JCAHO or another appropriate body and relies solely on state licensure, the applicant should provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past five (5) years and has no outstanding licensure and Medicare and/or Medicaid certification deficiencies.

2. An applicant for a new, replacement or expanded hospital shall:

(i) provide a written commitment that the applicant presently participates, or in the case of a new hospital, will participate, in a statewide or national external reporting and peer review process related to patient safety and control of medical errors;

(ii) provide evidence of the availability of resources, including health care providers, management personnel and funds for capital and operating needs, for the provision of the hospital services; and

(iii) document a plan for obtaining and maintaining staff and service quality standards necessary to promote effective patient care and clinical outcomes.

(h) 1. An applicant for a new, replacement or expanded hospital shall document a plan to operate an emergency room licensed by the Department of Human Resources.

2. An applicant for a new, replacement or expanded hospital shall provide a description of the proposed service area for the hospital and document a community planning process that addresses primary care relationships and the range of transfer and referral activities across the range of care levels. The descriptions and community planning process should address:

(i) Estimated geographic boundaries of primary and secondary service areas and the primary and outpatient providers in these areas;

(ii) Demographic and income characteristics of the service area by age, gender and racial compositions;

(iii) Anticipated payer sources by population totals and percentages to include public payers and indigent and charity care services;

(iv) Patient access to the full continuum of care, including discharge planning and long-term care options;

(v) The projected financial and economic impact that the project will have on the community;

(vi) Strategies related to physician recruitment and medical staffing to include the hospital's plan to ensure that the care provided by physicians and other clinicians is made available to patients without regard for ability to pay;

(vii) The manner in which the facility coordinates or will coordinate with the existing health care system;

(viii) The manner(s) in which the hospital will make available the necessary ancillary and support services; and

(ix) The manner in which the hospital will support the operation of any affiliated critical access hospitals, if applicable.

3. An applicant for a new, replacement or expanded hospital shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the hospital.

4. An applicant for a new, replacement or expanded hospital shall demonstrate that proposed charges for services shall compare favorably with charges for other similar hospital services in the planning area when adjusted for annual inflation. When determining the accuracy of an applicant's projected charges for hospital services, the Department may compare the applicant's history of charges if applicable, with other hospitals in the planning area(s) previously served by the applicant or its parent company.

(i) 1. To respond to changes in the health care delivery system and to promote improved efficiency, access and cost-containment, the Department may authorize the consolidation of two or more hospitals located in one rural county or in contiguous rural counties. A proposal to consolidate hospitals into a single, new consolidated hospital requires a Certificate of Need and must comply with the following criteria.

2. Two or more existing facilities, each of which are operational at the time of approval and each of which are located in the same rural county or in contiguous rural counties, may seek a consolidation to create a single consolidated facility at an existing site or a new site within the same rural county or one of the same rural counties. The applicant or applicants for such a consolidated facility must be able to meet the following conditions:

(i) The available beds for the proposed consolidated facility must not exceed the total number of available beds of the existing facilities proposed for consolidation;

(ii) The applicant(s) for the proposed consolidated facility must show, using patient origin data, that the proposed new facility and/or location is reasonably projected to continue to meet the utilization needs of those populations that historically utilized the existing facilities;

(iii) The applicant(s) must explain the impact of consolidation on the service area's health care delivery system and show that any negative impacts on existing and approved providers will be outweighed by the benefits of the proposal;

(iv) The applicant must submit documentation demonstrating that the consolidation will promote the most efficient handling of patient needs; improve the ability to update medical technology infrastructure; maximize efficiency for capital and physical plant needs; and improve consumer access to enhanced quality and depth of services; and

(v) The applicant(s) must comply with all other provisions of this Rule with exception of the need and adverse impact standards set forth in Rule 111-2-2-.20(3)(b) and (d).

(j) 1. To respond to changes in the health care delivery system and to promote improved efficiency, access and cost-containment, the Department may authorize the consolidation of two or more hospitals located in one non-rural county. A proposal to consolidate hospitals into a single, new consolidated hospital requires a Certificate of Need and must comply with the following criteria.

2. Two or more existing facilities, each of which are operational at the time of approval and each of which are located in the same non-rural county, may seek a consolidation to create a single consolidated facility at an existing site or a new site within the same non-rural county. The consolidating facilities must apply

as co-applicants. The applicant or applicants for such a consolidated facility must be able to meet the following conditions:

(i) The available beds sought for the proposed consolidated facility must not exceed the sum of the total number of beds for which each of the consolidating facilities would be authorized, at the time the application is filed, pursuant to the demand-based forecasting model for determining need set forth in Rule 111-2-2-.20(3)(b)3.

(ii) The applicant(s) for the proposed consolidated facility must show, using patient origin data by zip code, that the proposed new facility and/or location is reasonably projected to continue to meet the utilization needs of those populations that historically utilized the existing facilities;

(iii) The applicant(s) must explain the impact of consolidation on the facilities to be consolidated existing service area(s) health care delivery system and show that any negative impacts on existing and approved providers will be outweighed by the benefits of the proposal;

(iv) The applicant must submit documentation demonstrating that the consolidation will promote the most efficient handling of patient needs; improve the ability to update medical technology infrastructure; maximize efficiency for capital and physical plant needs; and improve consumer access to enhanced quality and depth of services; and

(v) The consolidating facilities must not seek to offer in a consolidation application any new clinical health service at the proposed new site not offered in each or all of the facilities to be consolidated.

(k) 1. A Certificate of Need will be issued to an applicant for a destination cancer hospital if it meets the following standards and under the following conditions.

2. An applicant for a destination cancer hospital must document that it meets the criteria described in the definition in Section (2)(e).

3. An applicant for a destination cancer hospital must:

(i) Document that the destination cancer hospital itself and all affiliated facilities are within twenty-five (25) miles of a commercial airport in the State of Georgia with five (5) or more runways;

(ii) Document that the services to be offered by the facility are solely related to the treatment of cancer patients;

(iii) Document the services to be offered within and by the facility that would otherwise be considered a separate new institutional health service. Such services will not be required to obtain separate Certificate of Need authorization, or be reviewed under any service specific need methodology or rules other than those for a destination cancer hospital if included in the initial Certificate of Need application reviewed under the rules outlined in section (k) of these Rules;

(iv) Document that the destination cancer hospital will not offer services that are not reasonable related to the diagnosis and treatment of cancer such as, but not limited to, open heart surgery, perinatal services, and cardiac catheterization;

(v) Document that at least sixty-five (65%) percent of its projected annual patient base will be composed of persons who reside outside of the State of Georgia;

(vi) Agree to provide uncompensated indigent and charity care for residents of the State of Georgia which meets or exceeds three (3%) percent of the applicant's adjusted gross revenue;

(vii) Agree to provide care to Medicaid beneficiaries;

(viii) Document that the applicant for a destination cancer hospital will comply with the criteria found in the General Review Considerations of these Rules at Section 111-2-2-.09(2).

4. A destination cancer hospital that does not meet an annual patient base composed of a minimum of sixty-five (65%) percent of patients who reside outside the State of Georgia in a calendar year shall be fined $2,000,000.00 for the first year of noncompliance, $4,000,000.00 for the second consecutive year of noncompliance, and $6,000,000.00 for the third consecutive year of noncompliance. Such fine amount shall reset to $2,000,000.00 after any year of compliance. In the event that a destination cancer hospital does not meet an annual patient base composed of a minimum of sixty-five (65%) percent of patients who reside outside of the State of Georgia for three (3) calendar years in a five (5) year period, such hospital shall be fined an additional amount of $8,000,000.00. All revenues collected from any such fine may be dedicated and deposited by the Department into the Indigent Care Trust Fund created pursuant to O.C.G.A. § 31-8-152. The Department, pursuant to O.C.G.A. § 31-6-45(a)(7), may revoke the Certificate of Need of a destination cancer hospital, in whole, or in part, after notice and an opportunity for a hearing, for failure to meet an annual patient base composed of a minimum of sixty-five (65%) percent of patients who reside outside of the State of Georgia for three calendar years in any five-year period.

5. After commencing operations upon receipt of a Certificate of Need pursuant to these Rules, a destination cancer hospital seeking to add an additional new institutional health service, shall apply for and obtain an additional Certificate of Need under the applicable statutory provisions and the Rules in this section. Any such application shall only be granted if the patient base of the destination cancer hospital is composed of at least sixty-five (65%) percent of patients who reside outside of the State of Georgia for two consecutive years.

6. The Department may apply the Rules in section (k) of these Rules to an application from a destination cancer hospital

for a Certificate of Need for services and equipment required for it to meet federal or state laws applicable to a hospital.

7. If a destination cancer hospital cannot show a patient base of a minimum of sixty-five (65%) percent of persons who reside outside of the State of Georgia, the application for a Certificate of Need for any new institutional health service shall be evaluated under the specific statutes and rules applicable to that particular service.

8. If a destination cancer hospital applies for a Certificate of Need to add an additional new institutional health service before commencing operations or completing two (2) consecutive years of operation, the applicant may rely on historical data from its affiliated entities.

9. The number of beds, services, and equipment used in and by a destination cancer hospital shall not be counted as part of the Department's inventory when determining the need for those beds, services, or equipment for other providers in other Certificate of Need applications not involving destination cancer hospitals.

10. No person shall be issued more than one Certificate of Need for a destination cancer hospital.

11. The Department will not accept an application for a Certificate of Need for a destination cancer hospital on or after January 1, 2010; however, an existing destination cancer hospital may avail itself of all applicable Certificate of Need provisions regarding the upgrade, purchase, or replacement of diagnostic or therapeutic equipment.

12. An applicant for a destination cancer hospital shall agree to provide information related to the operation of and services provided by the facility in the time frame and manner requested by the Department. In addition, a destination cancer hospital shall submit an annual statement, in accordance with the timeframes and format specified by the Department, affirming that the hospital

has met an annual patient based composed of a minimum of sixty-five (65%) percent of patients who reside outside the State of Georgia. The chief executive officer of the destination cancer hospital shall certify under penalty of perjury that the statement as prepared accurately reflects the composition of the annual patient base. The Department shall have the authority to inspect any books, records, papers, or other information of the destination cancer hospital to confirm the information provided on such statement or any other information required of the destination cancer hospital. The report required by this sub-section shall not be construed to require the release of any information that would violate the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191.

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