RULES
OF
DEPARTMENT OF COMMUNITY HEALTH

CHAPTER 111-2
HEALTH PLANNING

111-2-2
CERTIFICATE OF NEED

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111-2-2-.01 Definitions. As used in these Rules, the term:

(1) “Acquisition of an existing health care facility” means to come into possession or control of a health care facility by purchase, gift, merger of corporations, lease, purchase of stock, inheritance, or by any other legal means.

(2) “Acquisition of diagnostic or therapeutic equipment”:

(a) as it relates to a diagnostic, treatment, or rehabilitation center, means to come into possession, or control of, or to otherwise use diagnostic or therapeutic equipment by purchase, gift, donation, lease, transfer, or by any other legal means by or on behalf of the diagnostic, treatment, or rehabilitation center; and

(b) as it relates to a health care facility, means to come into possession or control of diagnostic or therapeutic equipment by purchase or lease by or on behalf of the health care facility.

(3) "Ambulatory surgery" means surgical procedures that include but are not limited to those recognized by the Centers for Medicare and Medicaid Services (“CMS”), by the Georgia Division of Medical Assistance (“DMA”), by the State Health Benefit Plans, or by any successor entities as reimbursable ambulatory surgery procedures. Ambulatory surgery is provided only to patients who are admitted to a facility which offers ambulatory surgery and which does not admit patients for treatment that normally requires stays that are overnight or exceed 24 hours and which does not provide accommodations for treatment of patients for periods of twenty-four hours or longer.

(4) "Ambulatory surgical or obstetrical facility", as defined at O.C.G.A. § 31-6-2(1) means a public or private facility, not a part of a hospital, which provides surgical or obstetrical treatment performed under general or regional anesthesia in an operating room environment to patients not requiring hospitalization.

(5) "Applicant" means the owner or lessee of an existing health care facility or the person who would be the owner or lessee of a proposed facility, as named in the application. An applicant may also be multiple owners or lessees of existing health care facilities who share common ownership or corporate affiliation and wish to submit an application to the Department for a single Certificate of Need for certain non-clinical health services, for example, but not limited to, parking decks, infrastructure improvement or replacement, and capital renovation expenditures.

(6) “Application”, as defined at O.C.G.A. § 31-6-2(2), means a written request for a Certificate of Need made to the

Department, containing such documentation and information as the Department may require.

(7) "Approved date" means the date that the Department issues a Certificate of Need to an applicant.

(8) "Associated with and simultaneously developed or proposed" means that if the Department determines that a single project or the substantial equivalent of a single project is divided into separate components which are associated and which are developed or planned simultaneously, so that the project or the substantial equivalent of a project or any component thereof does not require a total capital expenditure in excess of the capital expenditure or diagnostic or therapeutic equipment threshold, the Department shall combine the components for purposes of computing the amount of the total capital expenditure or expense and shall treat the combined components as a single project or substantial equivalent of a project. The Department shall include items and expenditures which are related and which occur simultaneously in computing an applicable threshold regardless of whether the items or expenditures individually may otherwise be below the threshold or may be otherwise unreviewable exclusive of the items exempted from review by 111-2-2-.03(1)-(3) and 111-2-2-.03(5)-(19);

(a) The Department may determine that activities, services, expenditures, and items are associated if they share a relationship or association based on law, regulation, definition, function, procedure, or process; and

(b) The Department shall determine that expenditures related to activities, services, and items are simultaneously developed or planned if such expenditures occur within a 6-month period. The 6-month period shall run from operation of the activity, service or item to initial capital expenditure on the second activity or item or from operation of the activity or item to operation of the second activity or item. For services, the date of operation shall be the date that the service is actually offered. If applicable, for facilities, the date of operation shall be the date a Certificate of Occupancy is issued.

(9) Reserved.

(10) “Basic perinatal services” means providing basic inpatient care for pregnant women and newborns without complications; managing perinatal emergencies; consulting with and referring to specialty and subspecialty hospitals; identifying high-risk pregnancies; providing follow-up care for new mothers and infants; and providing public/community education on perinatal health.

(11) "Bed capacity", as defined at O.C.G.A. § 31-6-2(4) means space used exclusively for inpatient care, including space designed or remodeled for inpatient beds even though temporarily not used for such purposes. The number of beds to be counted in any patient room shall be the maximum number for which adequate square footage is provided as established by Rules of the Department, except that single beds in single rooms shall be counted even if the room contains inadequate square footage.

(12) “By or on behalf of” means any expenditures made by a health care facility, a political subdivision of the State, a diagnostic, treatment, or rehabilitation center, or a hospital authority, itself as well as capital expenditures made by other persons or related entities to assist the facility, subdivision, center, or authority, directly or indirectly, to offer services to its patients or residents. Related entities include entities that are associated or affiliated with, have control over or are controlled by, or have any direct financial interest in, the health care facility, political subdivision of the State, diagnostic, treatment, or rehabilitation center, or hospital authority, including, without limitation, an underwriter, guarantor, parent organization, sister organization, subsidiary or sub-entity, foreign corporation, joint venturer, partner, general partner, or building lessor, as applicable.

(13) “Capital expenditure” in relation to a proposed modification, renovation, or addition to a health care facility or to a diagnostic, treatment, or rehabilitation center, or acquisition of equipment, means an expenditure by or on behalf of a health care facility or diagnostic, treatment, or rehabilitation center that, under generally accepted accounting principles, is not properly

chargeable as an expense of operation or maintenance. Any series of capital expenditures, each less than a threshold, but which when taken together are in excess of a threshold, directed toward the accomplishment of a single project, requires a Certificate of Need. Any series of capital expenditures, which are associated and simultaneously developed or proposed, will be presumed to be a single project. In calculating the capital expenditure for modifications, additions, or renovations “capital expenditure” is the amount per construction bid or total amount of invoices or purchase orders for the single project excluding diagnostic or therapeutic equipment.

(14) "Certificate of Need", as defined at O.C.G.A. § 31-6-2(6) means an official determination by the Department, evidenced by certification issued pursuant to an application, that the action proposed in the application satisfies and complies with the criteria contained in the Statute and Rules promulgated pursuant thereto.

(15) Reserved.

(16) "Clinical health services", as defined at O.C.G.A. § 31-6-2(8), means diagnostic, treatment, or rehabilitative services provided in a health care facility, or parts of the physical plant where such services are located in a health care facility, and includes, but is not limited to, the following: radiology and diagnostic imaging, such as magnetic resonance imaging and positron emission tomography; radiation therapy; biliary lithotripsy; surgery; intensive care; coronary care; pediatrics; gynecology; obstetrics; general medical care; medical/surgical care; inpatient nursing care, whether intermediate, skilled or extended care; cardiac catheterization; open-heart surgery; inpatient rehabilitation; and alcohol, drug abuse, and mental health services.

(17) "Consumer", as defined at O.C.G.A. § 31-6-2(10), means a person who is not employed by any health care facility or provider and who has no financial or fiduciary interest in any health care facility or provider.

(18) “Continuing care retirement community” means an organization, whether operated for profit or not, whose owner or

operator undertakes to provide shelter, food, and either nursing care or personal services, whether such nursing care or personal services are provided in the facility or in another setting, and other services, as designated by agreement, to an individual not related by consanguinity or affinity to such owner or operator providing such care pursuant to an agreement for a fixed or variable fee, or for any other remuneration of any type, whether fixed or variable, for the period of care, payable in a lump sum and monthly maintenance charges or in installments. Agreements to provide continuing care include agreements to provide care for any duration, including agreements that are terminable by either party.

(19) "Cost estimate" means an estimate of the total cost of a project's development and construction prepared by a licensed architect or engineer within sixty days prior to the date of submittal of an application.

(20) "Defined location," as it relates to the approved location of a project or substantial equivalent of a project, means the address of the project, or in the case of a health care facility or diagnostic, treatment, or rehabilitation center with multiple addresses, the campus of such health care facility or diagnostic, treatment, or rehabilitation center. However, in no case shall a campus be considered a single defined location if varying locations and facilities of such campus are more than 3 miles apart or within more than one county.

(21) "Destination cancer hospital" means an institution with a licensed bed capacity of 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 65 percent of patients who reside outside of the State of Georgia.

(22) "Develop", as defined at O.C.G.A. § 31-6-2(14), with reference to a project, means:

(a) constructing, remodeling, installing, or proceeding with a project, or any part of a project, or a capital expenditure project,

the cost estimate for which exceeds $2,500,000.00, which amount shall be adjusted annually as provided by law; or

(b) the expenditure or commitment of funds exceeding $1,000,000.00, which amount shall be adjusted annually as provided by law, for orders, purchases, leases, or acquisitions through other comparable arrangements of new or additional major medical equipment, including activities, items and services, which are associated with and simultaneously developed or proposed; provided, however, that this shall not include build out costs, as defined by the department, but shall include all functionally related equipment, software, and any warranty and services contract costs for the first five years. 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. Reviewability of acquisitions by lease or gift will be based on the value of the major medical equipment to be acquired. The value of the major medical equipment is the expenditure that would be required for purchase.

(c) Notwithstanding subparagraphs (a) and (b) above, the expenditure or commitment 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, develop, or prepare sites shall not be considered to be the developing of a project.

(23) “Diagnostic imaging” means magnetic resonance imaging, computed tomography (CT) scanning, positron emission tomography (PET) scanning, positron emission tomography/computed tomography, and other advanced imaging services as defined by the department by rule, but such term shall not include X-rays, fluoroscopy, or ultrasound services.

(24) "Diagnostic, treatment, or rehabilitation center", as defined at O.C.G.A. § 31-6-2(16), means any professional or business undertaking, whether for profit or not for profit, which offers or proposes to offer any clinical health service in a setting which is not part of a hospital; provided, however, that any such diagnostic, treatment, or rehabilitation center that offers or proposes to offer surgery in an operating room environment and to allow patients to remain more than 23 hours shall be considered a hospital for purposes of O.C.G.A. § 31-6, et. seq.

(25) “Effective date” means:

(a) for approved projects that have not been appealed pursuant to the appeal provisions of the Rules of the Health Planning Review Board, the approved date;

(b) for projects, which are appealed pursuant to the appeal provisions of the Rules of the Health Planning Review Board, the date of the final resolution of any such administrative appeal if the resolution results in the approval of the project; or

(c) for projects which undergo judicial review, the effective date shall be the date referenced in (b) above, unless the Department, pursuant to rule 111-2-2-.07(2)(h), or the reviewing court stays the effective date of the project pending the outcome of the judicial review. If the Department or the reviewing court stays the effective date, the effective date shall be the date of the final resolution of any such judicial review if the resolution results in approval of the project.

(26) “Expiration date” is the date upon which a certificate of need expires and becomes null and void.

(27) “Functionally related diagnostic or therapeutic equipment” means that pieces of diagnostic or therapeutic equipment are interdependent to the extent that one piece of equipment is unable to function in the absence of or without the functioning piece or equipment, or that pieces of equipment are normally used together in the provision of a single health care facility or diagnostic, treatment, or rehabilitation center service.

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

(29) "Health maintenance organization", as defined at O.C.G.A. § 31-6-2(18), means a public or private organization organized under the laws of this state which:

(a) provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual physicians' services, hospitalization, laboratory, X-ray, emergency and preventive services, and out-of-area coverage;

(b) is compensated, except for co-payments, for the provision of the basic health care services listed in subparagraph (a) of this paragraph to enrolled participants on a predetermined periodic rate basis; and

(c) provides physicians' services primarily:

1. directly through physicians who are either employees or partners of such organization; or

2. through arrangements with individual physicians organized on a group practice or individual practice basis.

(30) "Home health agency", as defined at O.C.G.A. § 31-6-2(20) means a public agency or private organization, or a subdivision of such an agency or organization, which is primarily engaged in providing to individuals who are under a written plan of care of a physician, on a visiting basis in the places of residence used as such individuals' homes, part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse, and one or more of the following services:

(a) physical therapy;

(b) occupational therapy;

(c) speech therapy;

(d) medical social services under the direction of a physician; or

(e) part-time or intermittent services of a home health aide.

(31) "Hospital", as defined at O.C.G.A. § 31-6-2(21), means an institution which is primarily engaged in providing to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. Such term includes public, private, psychiatric, rehabilitative, geriatric, osteopathic, and other specialty hospitals.

(32) “Incur a financial obligation”, in relation to the offering of a new institutional health service, means that, within time periods described in Section 111-2-2-.02(5) and (6) of these Rules, the applicant has fulfilled the following performance requirements.

(a) With regard to new construction or renovation:

1. has acquired title, an option to purchase or a leasehold to an appropriate site;

2. has filed with the Department the complete set of plans, drawings, and specifications for the project;

3. has obtained a firm commitment for adequate capital financing ; and

4. has entered into a construction contract that provides for a specific date for commencement, and completion of construction within a reasonable time span.

(b) With regard to equipment not associated with a construction project;

1. a purchase or lease agreement has been entered into or, if acquired by a comparable arrangement, the applicant has possession of the equipment.

(33) Reserved.

(34) "Intermediate care facility", as defined at O.C.G.A. § 31-6-2(22), means an institution which provides, on a regular basis, health related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide but who, because of their mental or physical condition, require health related care and services beyond the provision of room and board.

(35) “Joined applications” means two or more applications which involve similar projects in the same service area or overlapping service areas all of which have been declared complete within thirty days of the date the first application was declared complete, and whose time limits are scheduled to run from the latest date that any one of the joined applications was declared complete for review.

(36) “Joint venture ambulatory surgical center” means a freestanding ambulatory surgical center that is jointly owned by a hospital in the same county as the center or a hospital in a contiguous county if there is no hospital in the same county as the center and a single group of physicians practicing in the center and that provides surgery in a single specialty as defined by the department; provided, however, that general surgery, a group practice which includes one or more physiatrists who perform services that are reasonably related to the surgical procedures performed in the center, and a group practice in orthopedics which includes hand surgeons with a certificate of added qualifications in Surgery of the Hand from the American Board of Plastic and Reconstructive Surgery shall be considered a single specialty. The ownership interest of the hospital shall be no less than thirty percent (30%) and the collective ownership of the physicians or group of physicians shall be no less than thirty percent (30%).

(37) “Mobile unit" means an object with the ability by structure, function or design to move or be moved from one site to another,

such that upon arriving at a site the object is not permanently fixed but is temporarily secured for the purpose of providing a service to individuals.

(38) “New and emerging health care service” means a health care service or utilization of medical equipment which has been developed and has become acceptable or available for implementation or use but which has not yet been addressed under the rules and regulations promulgated, adopted and included within and hereto.

(39) "New institutional health service", as defined at O.C.G.A. § 31-6-40(a) means:

(a) the construction, development, or other establishment of a new health care facility;

(b) any expenditure by or on behalf of a health care facility in excess of $2,500,000.00, which amount shall be adjusted annually as provided by law, and which, under generally accepted accounting principles consistently applied, is a capital expenditure, except expenditures for acquisition of an existing health care facility not owned or operated by or on behalf of a political subdivision of this state, or any combination of such political subdivisions, or by or on behalf of a hospital authority, as defined in O.C.G.A. § 31-7-4 or certificate of need owned by such facility in connection with its acquisition. See the definition of “threshold” below for expenditures that shall be counted to calculate the threshold;

(c) any increase in the bed capacity of a health care facility, regardless of whether a capital expenditure is made, which increases the total bed capacity. An exception to this rule will be made in accordance with Rule 111-2-2-.03(4);

(d) clinical health services that are offered in or through a health care facility, which were not offered on a regular basis in or through such health care facility within the twelve (12) month period prior to the time such services would be offered;

(e) any conversion or upgrading of any general acute care hospital to a specialty hospital or of a facility such that it is converted from a type of facility not covered by these Rules to any of the types of health care facilities which are covered by these Rules;

(f) the purchase or lease by or on behalf of a health care facility of diagnostic or therapeutic equipment with a value in excess of $1,000,000.00; provided, however, that diagnostic or other imaging services that are not offered in a hospital or in the offices of an individual private physician or single group practice of physicians exclusively for use on patients of that physician or group practice shall be deemed to be a new institutional health service regardless of the costs of equipment; and provided, further, that this shall not include build out costs, as defined in Rule 111-2-2-.01(22)(b), but shall include all functionally related equipment, software, and any warranty and services contract costs for the first five years, which amount shall be adjusted annually as provided by law. See the definition of “threshold” below for expenditures that will be counted to calculate the threshold;

(g) the acquisition of an existing health care facility which is owned or operated by or on behalf of a political subdivision of this State; any combination of such political subdivisions, or by or on behalf of a hospital authority except as otherwise provided in these Rules.

(h) clinical health services which are offered in or through a diagnostic, treatment, or rehabilitation center which were not offered on a regular basis in or through that center within the twelve (12) month period to the time such services would be offered, but only if the clinical health services are any of the following:

1. Radiation therapy;

2. Biliary lithotripsy;

3. Surgery in an operating room environment, including but not limited to ambulatory surgery; and

4. Cardiac catheterization.

(40) "Nonclinical health services", as defined at O.C.G.A. § 31-6-2(25), means services or functions provided or performed by a health care facility, and the parts of the physical plant where they are located in a health care facility that are not diagnostic, therapeutic, or rehabilitative services to patients and are not clinical health services as defined in this chapter.

(41) “Offer”, as defined at O.C.G.A. § 31-6-2(26), means that the health care facility is open for the acceptance of patients or performance of services and has qualified personnel, equipment, and supplies necessary to provide specified clinical health services.

(42) “Operating room environment”, as defined at O.C.G.A. § 31-6-2(27), means an environment which meets the minimum physical plant and operational standards specified in the applicable administrative rules of the state which shall consider and use the design and construction specifications as set forth in the *Guidelines for Design and Construction of Health Care Facilities* published by the American Institute of Architects.

(43) “Pediatric cardiac catheterization” means the performance of angiographic, physiologic, and as appropriate, therapeutic cardiac catheterization on children fourteen (14) years of age or younger.

(44) “Person”, as defined at O.C.G.A. § 31-6-2(29), means any individual, trust, or estate, partnership, limited liability company or partnership, corporation (including associations, joint-stock companies and insurance companies), state, political subdivision, hospital authority, or instrumentality (including a municipal corporation) of a state as defined in the laws of this State. This term shall include all related parties, including individuals, business corporations, general partnerships, limited partnerships, limited liability companies, limited liability partnerships, joint ventures, nonprofit corporations, or any other for profit or not for profit entity that owns or controls, is owned or controlled by, or operates under common ownership or control with a person.

(45) “Personal Care Home”, as defined at O.C.G.A. § 31-6-2(30), means a residential facility that is certified as a provider of medical assistance for Medicaid purposes pursuant to Article 7 of Chapter 4 of Title 49 having at least twenty-five (25) beds and providing, for compensation, protective care and oversight of ambulatory, non-related persons who need a monitored environment but who do not have injuries or disabilities which require chronic or convalescent care, including medical, nursing, or intermediate care. Personal care homes including those facilities which monitor daily residents’ functioning and location, have the capability for crisis intervention, and provide supervision in areas of nutrition, medication, and provision of transient medical care. Such term does not include:

(a) Old age residences which are devoted to independent living units with kitchen facilities in which residents have the option of preparing and serving some or all of their own meals; or

(b) Boarding facilities that do not provide personal care.

(46) “Project”, as defined at O.C.G.A. § 31-6-2(31), means a proposal to take an action for which Certificate of Need review is required under these Rules. A project or proposed project may refer to the proposal from its earliest planning stages up through the point at which the new institutional health service is offered. In accordance with the definition of “associated with and simultaneously developed or proposed,” the Department shall consider simultaneous activities, including, but not limited to, construction, remodeling, development, and acquisitions, unless expressly not included by other provisions of these Rules, which are determined by the Department to be associated with one another, to be a single project.

(47) “Rural county” means a county having a population of less than 35,000 according to the United States decennial census of 2000 or any future such census.

(48) “Service-specific Rule” means those rules that are part of 111-2-2 that regard specific clinical health care services as outlined at 111-2-2-.20 et seq.

(49) “Single specialty ambulatory surgical center” means an ambulatory surgical center where surgery is performed in the offices of an individual private physician or single group practice of private physicians if such surgery is performed in a facility that is owned, operated, and utilized by such physicians who are also of a single specialty; provided, however, that general surgery, a group practice which includes one or more physiatrists who perform services that are reasonably related to the surgical procedures performed in the center, and a group practice in orthopedics which includes plastic hand surgeons with a certificate of added qualifications in Surgery of the Hand from the American Board of Plastic and Reconstructive Surgery shall be considered a single specialty.

(50) “Skilled nursing facility”, as defined at O.C.G.A. § 31-6-2(34), means a public or private institution or a distinct part of an institution which is primarily engaged in providing inpatient skilled nursing care and related services for patients who require medical or nursing care or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

(51) “Specialty hospital” means a hospital that is primarily or exclusively engaged in the care and treatment of one of the following: patients with a cardiac condition, patients with an orthopedic condition, patients receiving a surgical procedure, or patients receiving any other specialized category of services defined elsewhere in these Rules. A ‘specialty hospital’ does not include a destination cancer hospital.

(52) “State health plan”, as defined at O.C.G.A. § 31-6-2(36), means a comprehensive program based on recommendations by the Health Strategies Council and the board, approved by the Governor, and implemented by the State of Georgia for the purpose of providing adequate health care services and facilities throughout the State. The State Health Plan is divided into a series of component plans modified from time to time as needed.

(53) “Substantial equivalent of a project” means a proposal to take an action for which a letter of non-reviewability or determination is sought under these Rules. A substantial

equivalent of a project may refer to the proposal from its earliest planning stages up through the point at which the service is offered. In accordance with the definition of "associated with and simultaneously developed or proposed," the Department shall consider simultaneous activities, including, but not limited to, construction, remodeling, development, and acquisitions, unless expressly not included by other provisions of these Rules, which are determined by the Department to be associated with one another, to be a single substantial equivalent of a project.

(54) "Threshold" means the dollar amount of capital expenditures for which, when exceeded, a Certificate of Need is required.

(a) In calculating the dollar amounts of a proposed project for purposes of 111-2-2-.01(39)(b) and (39)(f), and 111-2-2-.01(49) and (36) of these Rules, the capital costs of all items subject to review by these Rules and items not subject to review by these Rules 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;

(b) The following threshold amounts are effective as of July 1, 2008:

1. The capital expenditure threshold of 111-2-2-.01(39(b), is $2,500,000.00;

2. The equipment threshold of 111-2-2-.01(39)(f) is $1,000,000.00;

3. The physician-owned, single-specialty, office-based ambulatory surgery center threshold of 111-2-2-.01(49) is $2,500,000.00;

4. The joint venture ambulatory surgical center threshold of 111-2-2-.01(36) is $5,000,000.00;

With respect to (b)(1), (3), and (4) above, beginning on July 1, 2009, the Department shall update or adjust this CON threshold amount by the annual percentage of change in an appropriate composite price index that, in the judgment of the Department, represents national construction prices for the preceding calendar year such as those published by the Department of Commerce of the United States government or other government agency;

With respect to (b)(2) above, beginning on July 1, 2010, the Department shall update or adjust this CON threshold amount by the annual percentage of change in an appropriate consumer price index, or its successor or appropriate replacement index, for the preceding calendar year, such as those published by the United States Department of Labor or other United States government agency. However, diagnostic or other imaging services that are not offered in a hospital or in the offices of an individual private physician or single group practice of physicians exclusively for use on patients of that physician or group practice shall be deemed to be a new institutional health service regardless of the cost of the equipment. Also, however, this amount or threshold figure shall not include build out costs, as defined in Rule 111-2-2-.01(22)(b), but shall include all functionally related equipment, software, and any warranty and services contract costs for the first five (5) years.

(c) For purposes of computing the capital expenditure threshold of 111-2-2-.01(39)(b) and 111-2-2-.01(22)(a) and the physician-owned, single specialty ambulatory surgical center threshold of 111-2-2-.03(20) and the joint venture ambulatory surgical center threshold of 111-2-2-.03(21), the Department shall include, but not be limited to, the following guidelines:

1. Pursuant to the definition of “associated with and simultaneously developed or proposed,” the total cost of all associated capital expenditures for items to be obligated for or purchased within a six month period for a single program, service, plan, or project, regardless of whether or not the cost of any individual item is in excess of the capital expenditure threshold and regardless of whether or not the expenditure or item is

otherwise reviewable under these Rules or the CON Statute, is included in the computation;

2. The cost of depreciable equipment that is not used for diagnosis or treatment, such as office equipment, usual business equipment, and office and waiting room furniture, is included in the computation, if such items are associated with and simultaneously developed or proposed with the project. If such furnishing and equipment are used, the cost that shall be used in calculating the threshold shall be the depreciated value or current market value of the furnishings or equipment, whichever is greater;

3. The cost of normal inventories of supplies, such as glassware, chemicals, drugs, linens, and paper, is exempt from the computation as an operating expense;

4. The value of the facilities to be acquired by lease, gift, donation or other means is based on a current (within six months) appraisal of the facility, except that the value of newly constructed facilities shall be based on the actual square footage cost to construct the facility;

5. For facilities that are acquired by lease, the computation of value shall be based on the rentable square footage of the facility and not the useable square footage. Notwithstanding this Rule, lease payments shall be considered to be operating expenses for leases other than capital leases;

6. For facilities that are only partly occupied by a person, the computation shall include a pro-rata share of the value of the common space, unless the rentable square footage is provided as required by (5) above and that rentable square footage already includes an allocation for common space, as documented by the lease agreement; and

7. In the case of a gift or donation, the value of equipment, furnishings or facilities is the fair market value of the equipment, furnishings, or facilities;

(d) For purposes of computing the equipment threshold of 111-2-2-.01(22)(b), 111-2-2-.01(39)(f), the Department shall include, but not be limited to, the following guidelines:

1. The cost of diagnostic or therapeutic equipment includes all capital costs, expenditures, charges, fees and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended, including but not limited to the following expenses:

(i) Any expense incurred for the purchase of a warranty on the diagnostic or therapeutic equipment from the manufacturer or vendor for the first five years of operation;

(ii) Any expense incurred for operator training;

(iii) Any expense incurred for installation and assembly of the equipment;

(iv) Any expense incurred for transportation and insurance costs pertaining to the purchase and/or delivery of the equipment;

(v) 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.

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

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

(viii) Any dollar amount attributable to service contracts for the first five (5) years of operation;

(ix) 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;

(x) For mobile units of equipment, expenditures and values associated with the motor coach, trailer, van, rig, or other form of

modular or transitional housing shall be included in the computation of the threshold;

2. The acquisition by whatever means of one or more items of functionally related diagnostic or therapeutic equipment shall be considered as one project. The acquisition of functionally related accessories shall also be counted. Pursuant to the definition of "functionally related diagnostic or therapeutic equipment," any individual components or pieces of diagnostic or therapeutic equipment, which depend on one another in order to function and that are purchased within a six (6) month period, shall be considered in the aggregate in calculating the threshold;

3. Diagnostic or therapeutic equipment shall include single and multiple units of equipment, if such units are associated with and simultaneously developed or proposed with one another. Pursuant to the definition of "associated with and simultaneously developed or proposed, the Department may determine that individual pieces or units of diagnostic or therapeutic equipment are associated with one another if such pieces or units of equipment are used for the same or similar health services and if such pieces or units of equipment are developed, proposed, or acquired simultaneously. Such associated and simultaneous units purchased within a 6-month period shall be aggregated to calculate the threshold;

4. Purchase or lease shall include purchases, contracts, encumbrances of funds, lease arrangements, conditional sales or a comparable arrangements that purport to be a transfer of ownership in whole or in part;

5. In the case of a lease, loan, or gift, the value of the diagnostic or therapeutic equipment is the fair market value of the diagnostic or therapeutic equipment, as evidenced by documentation from a reputable vendor or manufacturer; and

(55) "Uncompensated indigent or charity care" means the dollar amount of 'net uncompensated indigent or charity care after direct and indirect (all) compensation' as defined by, and calculated in accordance with, the Department's Hospital Financial Survey and related instructions.

(56) “Urban county” means a county having a population equal to or greater than 35,000 according to the United States decennial census of 2000 or any future such census.

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

111-2-2-.03 Exemptions from Review.

The following shall not be subject to Certificate of Need review and shall be exempted from the provisions of these Rules regarding Certificate of Need Review except as otherwise provided:

(1) infirmaries operated by educational institutions for the sole and exclusive benefit of students, faculty members, officers, or employees thereof;

(2) infirmaries or facilities operated by businesses for the sole and exclusive benefit of officers or employees thereof, provided that such infirmaries or facilities make no provision for overnight stay by persons receiving their services;

(3) institutions operated exclusively by the federal government or by any of its agencies;

(4) offices of private physicians or dentists, as determined in the sole discretion of the Department, whether for individual or group practice except as otherwise provided in 111-2-2-.01(49) and 111-2-2-.01(39)(f). Simple ownership of a facility by a practitioner or a group of practitioners of the healing arts does not, in and of itself, exempt such facility from the scope of these Rules. Seeking licensure of a place, building, or facility as a health care institution is inconsistent with an assertion that such place, building, or facility is being occupied exclusively as the office of private physicians or dentists. Therefore, any person who seeks licensure as a health care facility must secure a certificate of need if a new institutional health service is being offered or developed;

(5) Religious, nonmedical health care institutions as defined in 42 U.S.C. § 1395x(ss)(1), listed and certified by a national accrediting organization;

(6) site acquisitions for health care facilities or preparation or development costs for such sites prior to filing a Certificate of Need application;

(7) expenditures related to adequate preparation and development of an application for a Certificate of Need;

(8) the commitment of funds conditioned upon the obtaining of a Certificate of Need;

(9) transfers from one health care facility to another such facility of major medical equipment previously approved under or exempted from Certificate of Need review, except where such transfer results in the institution of a new clinical health service for which a Certificate of Need is required in the facility acquiring said equipment, provided that such transfers are recorded at net book value of the medical equipment as recorded on the books of the transferring facility;

(10) expenditures for the acquisition of existing health care facilities by stock or asset purchase, merger, consolidation, or other lawful means, unless the facilities are owned or operated by or on behalf of a:

(a) Political subdivision of this state;

(b) Combination of such political subdivision; or

(c) Hospital authority, as defined in Article 4 of Chapter 7 of Title 31.

(11) expenditures for the restructuring of or for the acquisition by stock or asset purchase, merger, consolidation, or other lawful means of an existing health care facility which is owned or operated by or on behalf of any entity described in 111-2-2-.03(10) only if such restructuring or acquisition is made by any entity described in 111-2-2-.03(10);

(12) capital expenditures otherwise covered by this Chapter required solely to eliminate or prevent safety hazards as defined by federal, state or local fire, building, environmental occupational health, or life safety codes of regulations, to comply with licensing requirements of the Department of Human Resources, or to comply with accreditation standards of the Joint Commission on Accreditation of Health Care Organizations;

(13) except as otherwise provided in this subsection, all cost overruns are excluded from prior Certificate of Need review and approval. For purposes of this subsection, a cost overrun that is subject to prior Certificate of Need review and approval (i.e., a reviewable cost overrun) is defined as meaning any cost overrun which is in excess of the current capital or diagnostic or therapeutic equipment threshold, or in excess of ten percent (10%) of the approved capital expenditure amount, whichever is less. However, in no event shall an additional expenditure of less than $300,000 be deemed a reviewable cost overrun. Reviewable cost overruns will be reviewed by the Department in accordance with the following provisions:

(a) A reviewable cost overrun associated with ongoing construction or renovation activity which has not been incurred prior to a Certificate of Need approval and is solely related to an unanticipated engineering, major fixed equipment or other construction problem, or federal, state or local fire requirements which were adopted or became effective after the issuance of the Certificate of Need but prior to the completion of construction or renovation, will receive favorable review consideration if the applicant demonstrates that the overrun will have no impact or a minimal impact on costs and/or charges per patient day or procedure; and

(b) A reviewable cost overrun which is the result of subsequent project bidding prior to any contractual obligation for construction and/or renovation work will not receive favorable review consideration by the Department but will require the entire project to be reviewed as an entirely new project subject to all the applicable criteria, standards and plans; and

(c) A reviewable cost overrun which is due to delays of project construction and/or renovation activity resulting from an appeal proceeding, when such delay has been in excess of one year, and where the Department has suspended the time periods until the issues are resolved, will be given favorable consideration as long as the project has not changed in scope, square footage, services or number of new beds proposed.

(d) For projects involving either construction or renovation, but not both, a reviewable cost overrun which increases the square footage beyond 5 percent of the originally approved project's total new square footage will require the entire project to be submitted as a new application and the new application will be subject to all the applicable criteria, standards and plans.

(e) For projects involving construction and renovation, a reviewable cost overrun which increases the square footage beyond 5 percent of the sum of the new construction square footage and renovated square footage will require the entire project to be submitted as a new application and the new application will be subject to all the applicable criteria, standards and plans.

(f) Regardless of cost, during implementation of the project, any increase in the scope of the original project or any change in the number of beds (i.e., the subtraction, addition, replacement or conversion of different number of beds than authorized in the original Certificate of Need) will invalidate the original project and the Department will deem the original project to have been withdrawn unless prior written approval is obtained from the Department.

(14) increases in the bed capacity of a hospital up to ten beds or ten percent of capacity, whichever is greater, in any consecutive two-year period, in a hospital that has maintained an overall occupancy rate greater than 75 percent (exclusive of any skilled nursing units or comprehensive inpatient rehabilitation units) for the previous twelve (12) month period;

(15) expenditures of less than $870,000.00 for any minor or major repair or replacement of equipment by a health care facility

that is not owned by a group practice of physicians or a hospital and that provides diagnostic imaging services if such facility received a letter of nonreviewability from the department prior to July 1, 2008. This paragraph shall not apply to such facilities in rural counties.

(15.1) except as provided in paragraph (15) of this subsection, expenditures for the minor or major repair of a health care facility or a facility that is exempt from the requirements of these rules, parts thereof or services provided or equipment used therein; or the replacement of equipment, including but not limited to CT scanners previously approved for a certificate of need.

(a) To qualify for this exemption, the replaced equipment must have received prior CON review and approval, or have been grandfathered, and the replaced equipment must be removed entirely from the premises and not be used in tandem with the replacement equipment, unless authorized in writing by the Department. Replacement equipment must be placed in the same defined location as the replaced equipment.

1. The Department may authorize in writing the retention of certain functionality of the equipment to be replaced if such retained functionality is not used in tandem with the replacement equipment and if the retained functionality would not otherwise result in the provision of a new institutional health service. The fair market value of the retained functionality must not exceed the applicable equipment threshold at the time of replacement.

(b) Expenditures associated with activities essential to acquiring and making operational the replacement equipment shall also be exempted from review. “Activities essential to acquiring and making operational the replacement equipment" means those activities that are indispensable and requisite, absent which the replacement equipment could not be acquired or made operational.

(c) Replacement equipment shall be comparable diagnostic or therapeutic equipment in relation to the replaced equipment. “Comparable diagnostic or therapeutic equipment” means equipment which is functionally similar and which is used for the

same or similar diagnostic or treatment purposes. Replacement equipment is comparable to the equipment being replaced if it is functionally similar and is used for the same or similar diagnostic, therapeutic, or treatment purposes as the equipment currently in use and is not used to provide a new health service;

(16) new institutional health services offered by or on behalf of a Health Maintenance Organization, or a health facility controlled, directly or indirectly, by a Health Maintenance Organization or a combination of Health Maintenance Organizations, provided specific and detailed documentation is provided to the Department that one of the following conditions are met:

(a) that seventy-five percent (75%) of the patients who can reasonably be expected to use the service will be individuals enrolled in a Health Maintenance Organization certified by the State of Georgia;

(b) that the service is needed by the Health Maintenance Organization in order to operate efficiently and economically and that it is not otherwise readily accessible to the Health Maintenance Organization because:

1. existing similar services are not available under a contract of reasonable duration;

2. full and equal staff privileges are not available in existing facilities; or

3. arrangements with existing facilities are not administratively feasible;

(17) capital expenditures for a project otherwise requiring a Certificate of Need if those expenditures are for a project to remodel, renovate, replace, or any combination thereof, a medical-surgical hospital and all the following conditions are met:

(a) the hospital has a bed capacity of not more than fifty (50) beds;

(b) the hospital is located in a county in which no other medical-surgical hospital is located;

(c) the hospital has at any time been designated as a disproportionate share hospital by the Department;

(d) the hospital has at least forty-five percent (45%) of its patient revenues derived from Medicare, Medicaid, or any combination thereof, for the immediately preceding three years;

(e) the project has at least eighty percent (80%) of its capital expenditures financed by proceeds of a special purpose county sales and use tax imposed pursuant to Article 3 of Chapter 8 of Title 48;

(f) the proposed replacement hospital is located within a three (3) mile radius of and within the same county as the hospital's existing facility; and

(g) the project does not result in any of the following:

1. the offering of any new clinical health services;

2. any increase in bed capacity;

3. any redistribution of existing beds among existing clinical health services; and

4. any increase in the capacity of existing clinical health services.

(18) Expenditures for nonclinical projects, including parking lots, parking decks, and other parking facilities; computer systems, software, and other information technology; medical office buildings; and state mental health facilities;

(19) Continuing care retirement communities, provided that the skilled nursing component of the facility is for the exclusive use of residents of the continuing care retirement community and that a written exemption is obtained from the Department; provided, however, that new sheltered nursing home beds may be used on a limited basis by persons who are not residents of the continuing care retirement community for a period up to five years after the date of issuance of the initial nursing home license, but such beds shall not be eligible for Medicaid reimbursement. For

the first year, the continuing care retirement community sheltered nursing facility may utilize not more than fifty percent (50%) of its licensed beds for patients who are not residents of the continuing care retirement community. In the second year of operation, the continuing care retirement community shall allow not more than forty percent (40%) of its licensed beds for new patients who are not residents of the continuing care retirement community. In the third year of operation, the continuing care retirement community shall allow not more than thirty percent (30%) of its licensed beds for new patients who are not residents of the continuing care retirement community. In the fourth year of operation, the continuing care retirement community shall allow not more than twenty percent (20%) of its licensed beds for new patients who are not residents of the continuing care retirement community. In the fifth year of operation, the continuing care retirement community shall allow not more than ten percent (10%) of its licensed beds for new patients who are not residents of the continuing care retirement community. At no time during the first five (5) years shall the continuing care retirement community sheltered nursing facility occupy more than fifty percent (50%) of its licensed beds with patients who are not residents under contract with the continuing care retirement community. At the end of the five (5) year period, the continuing care retirement community sheltered nursing facility shall be utilized exclusively by residents of the continuing care retirement community and at no time shall a resident of a continuing care retirement community be denied access to the sheltered nursing facility. At no time shall any existing patient be forced to leave the continuing care retirement community to comply with this paragraph. The Department is authorized to promulgate rules and regulations regarding the use and definition of 'sheltered nursing facility' in a manner consistent with this Code section. Agreements to provide continuing care include agreements to provide care for any duration, including agreements that are terminable by either party;

(20) Any single specialty ambulatory surgical center that:

(a) 1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health services 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 (2) or fewer operating rooms; provided, however, that a center exempt pursuant to this paragraph shall be required to obtain a certificated of need in order to add any additional operating rooms;

(b) 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. Hospitals shall not unreasonably deny a transfer agreement or affiliation agreement to the center;

(c) 1. 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 percent (2%) of its adjusted gross revenue; or

2. 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™ benficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) 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

(d) Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70.

Noncompliance with any condition of this paragraph 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 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. In calculating the dollar amounts of a proposed project for 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 an 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;

(21) Any joint venture ambulatory surgical center that:

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

(b) 1. 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 percent (2%) of its adjusted gross revenue; or

2. 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 percent (4%) of its adjusted gross revenue; and

(c) Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70.

Noncompliance with any condition of this paragraph 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 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. In calculating the dollar amounts of a proposed project for 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;

(22) Expansion of services by an imaging center based on a population needs methodology taking into consideration whether the population residing in the area served by the imaging center has a need for expanded services, as determined by the Department in accordance with its rules and regulations, if such imaging center:

(a) Was in existence and operational in this state on January 1, 2008;

(b) Is owned by a hospital or by a physician or a group of physicians comprising at least eighty percent (80%) ownership who are currently board certified in radiology;

(c) Provides three (3) or more diagnostic and other imaging services;

(d) Accepts all patients regardless of ability to pay; and

(e) Provides uncompensated indigent and charity care in an amount equal to or greater than the amount of such care provided by the geographically closest general acute care hospital; provided, however, this paragraph shall not apply to an imaging center in a rural county;

(23) Diagnostic cardiac catheterization in a hospital setting on patients fifteen (15) years of age and older;

(24) Therapeutic cardiac catheterization in hospitals selected by the Department prior to July 1, 2008, to participate in the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Study and therapeutic cardiac catheterization in hospitals that, as determined by the Department on an annual basis, meet the criteria to participate in the C-PORT Study but have not been selected for participation; provided, however, that if the criteria requires a transfer agreement to another hospital, no hospital shall unreasonably deny a transfer agreement to another hospital;

(25) Infirmaries of facilities operated by, on behalf of, or under contract with the Department of Corrections or the Department of Juvenile Justice for the sole and exclusive purpose of providing health care services in a secure environment to prisoners within a penal institution, penitentiary, prison, detention center, or other secure correctional institution, including correctional institutions operated by private entities in this state which house inmates under the Department of Corrections or the Department of Juvenile Justice;

(26) The relocation of any skilled nursing facility or intermediate care facility within the same county, any other health care facility in a rural county within the same county, and any

other health care facility in an urban county within a three-mile radius of the existing facility so long as the facility does not propose to offer any new or expanded clinical health services at the new location;

(27) Facilities which are devoted to the provision of treatment and rehabilitative care for periods continuing for twenty-four (24) hours or longer for persons who have traumatic brain injury, as defined in O.C.G.A. § 37-3-1.

Pursuant to O.C.G.A. § 31-6-40(c)(1), any person who had a valid exemption granted or approved by the former Health Planning Agency or the Department of Community Health prior to July 1, 2008, shall not be required to obtain a certificate of need in order to continue to offer those previously offered services.

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

111-2-2-.04 Periodic Reports.

The availability of accurate, current data is critical for adequate health planning and for the review process. Therefore, all inpatient and outpatient health care facilities and services subject to Certificate of Need review will be required to provide complete and accurate data, in a timely manner, as required by the Department. Pursuant to O.C.G.A. § 31-6-70(a), this reporting requirement shall also apply, beginning July 1, 2008, to all ambulatory surgical centers and imaging centers, whether or not exempt from obtaining a certificate of need under O.C.G.A. § 31-6 et. seq. and these Rules.

(1) **Annual and Special Questionnaires.**

(a) All CON-regulated facilities and services, as well as all ambulatory surgical centers and imaging centers, whether or not exempt from obtaining a certificate of need under these Rules, shall complete and submit certain surveys annually and periodically to the Department, as deemed necessary by the Department.

(b) 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; and

2. Beginning on January 1, 2009, provide annual reports in the same manner and in accordance with the provisions of this Rule.

(c) The Department shall publish a notice giving a date when the information responsive to subsection (b)(1) of this Rule by December 30, 2008, or the Department does not receive the annual report referenced in subsection (a), and subsection (b)(2), of this Rule from a health care facility requiring a certificate of need or an ambulatory surgical center or imaging center, whether or not exempt from obtaining a certificate of need under these Rules, on or before the date such report is due or receives a timely but incomplete report, the Department shall notify the health care facility or center regarding the deficiencies and shall be authorized to fine such health care facility or center an amount not to exceed $500.00 per day for every day up to thirty (30) days and $1,000.00 per day for every day over thirty (30) days for every day the Department has not received a report or an incomplete report has not been sufficiently corrected based on the Department's notice of deficiencies.

(d) Survey notices will be mailed or electronically transmitted by the Department to each such facility. The accurately and fully completed survey, covering the report period indicated, shall be filed with the Department within the time frame specific in the notice. The Survey shall be filed with the Department in the electronic format designated by the Department in the Survey Notice or on the Department's website. The survey shall include

an electronic signature as authorized by law, of the chief executive officer or principal administrator of the facility, who shall attest to the accuracy and completeness of the information provided.

(e) Reporting requirements shall also apply to new health facilities and services approved through Certificate of Need review. Generally, new facilities and services will be required to report if approved for operation or occupancy for sixty (60) days or more of the report period.

(f) Surveys submitted to the Department pursuant to these Rules and any service-specific Rules shall not be available for public review until after the deadline for submission for all surveys of that type;

(g) Required surveys submitted for a given period of time may not be revised by the facility or service after the survey filing deadline unless the request for revision is approved by the Department at its sole discretion.

(h) If the Department does not receive an annual report from a health care facility within one hundred eighty (180) days following the date such report was due or receives a timely but incomplete report which is not sufficiently completed within such one hundred eighty (180) days, the Department shall be authorized to revoke the certificate of need of the health care facility in accordance with O.C.G.A. § 31-6-45 and Rule 111-2-2-.05.

(2) **Post-Approval Reporting.**

(a) All entities receiving a Certificate of Need shall maintain a valid and accurate mailing address with the Department. Any notification, notice, or letter required by these Rules is deemed to be received by the certificate holder when the Department mails such notification, notice, or letter to the mailing address on file with the Department.

(b) Persons holding Certificates for construction projects shall, within twelve (12) months of the effective date of the Certificate, i.e. at the end of the implementation period, provide a

progress report to the Department including documentation of the following:

1. that the construction plans have been approved by the Department;

2. that a construction contract has been signed, specifically indicating beginning and completion dates;

3. that construction materials and equipment are on the site and construction of the project has actually begun.

(c) The Department shall monitor the certificate of need holder's progress in completing the project and phases thereof, as applicable, within the effective period as specified at 111-2-2-.02(5). Each Certificate of Need issued requires a regular reporting of the different stages of development to completion. All projects approved as presented with phases shall submit a progress report within forty-five (45) days of the completion of each phase. All Certificate of Need projects must satisfy the pertinent reporting requirements or the Certificate shall be subject to revocation. These reports shall include information as to the total dollar amount of capital expenditures that have been obligated under the certificate, and any changes in amounts of proposed or previously obligated capital expenditures or changes to the timing of phases, if approved by the Department in advance. These reports will be made on a form provided by the Department on its website and will be due on the date or dates indicated by the Department on attachments to the Certificate of Need and in subsequent correspondence.

(d) The Department may also request additional reports as often as necessary in order to determine:

1. if the timetable specified in the certificate is being met;

2. if the scope of the project is being completed as described on the certificate and in the application for the certificate of need;

3. if the amount of the capital expenditure or expenditures obligated under the certificate has exceeded or can be expected to exceed the maximum under the certificate; and

4. if the condition(s) of approval, if any, have been satisfactorily met.

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

111-2-2-.05 Enforcement.

(1) **Revocation.**

(a) In the event that the Department has cause to consider revocation of a Certificate, in whole or in part, the Department shall provide notice to the holder of the Certificate and shall hold a hearing to determine whether the holder has:

1. Intentionally provided false information to the Department;

2. Failed to incur a financial obligation in accordance with the Certificate as granted;

3. Failed to implement the project in accordance with the specific purpose(s) for which the certificate was granted or failed to meet the initial twelve-month performance standards or failed to request an extension of such standards. For certificates issued on or after July 1, 2008, failed to implement the services or units of services for which the certificate of need was issued, and that were outlines in or on the certificate granted, in a timely manner as also outlines in or on the certificate granted, as provided by O.C.G.A. § 31-6-45(a.1);

4. Transferred controlling ownership in the facility before completion of the project without prior written approval of the Department, except as authorized by 111-2-2-.02(4);

5. Changed the defined location of the project except as allowed by O.C.G.A. § 31-6-45(a) authorizing change in location under certain conditions;

6. Failed to comply with any and all requirements or conditions of the Certificate; or

7. Failed to submit a timely or complete periodic report within 180 days following the date the report is due pursuant to O.C.G.A. § 31-6-70 and as otherwise required by 111-2-2-.04;

8. Failed repeatedly to pay any fines or moneys due to the Department;

9. Failed to maintain minimum quality of care standards that are outlined within the Certificate as granted; or

10. Failed to participate as a provider of medical assistance for Medicaid purposes if made a condition of the Certificate as granted pursuant to O.C.G.A. § 31-6-45.2(a).

(b) In the event that there is sufficient evidence to justify revocation of a Certificate, the Department shall provide written notification to the holder, which shall be effective as of the postmark date on the notification letter. Notice shall also be provided to the public, to the county or municipal authority and to the appropriate Regional Development Center. Any person whose Certificate is revoked under this rule is entitled to judicial review, pursuant to O.C.G.A. § 50-13 et seq.

(c) A person whose Certificate of Need has been revoked or denied may not reapply for a Certificate of Need for the same or substantially similar project for at least one hundred twenty (120) days from the date that the revocation or denial becomes final, at which time the person may submit a new application. For purposes of this subparagraph, a decision revoking or denying a Certificate of Need shall become final when the time for appealing that decision expires without an appeal of such decision having been timely filed. If an appeal is timely filed, the decision is not final until the resolution of the administrative appeal, if any.

(d) A person holding a Certificate of Need may voluntarily request revocation of the Certificate without prejudice by submitting such request to the Department in writing.

(e) A health care facility which has a certificate of need or is otherwise authorized to operate pursuant to this chapter shall have such Certificates of Need or authority to operate automatically revoked by operation of law without any action by the Department when that facility's permit to operate pursuant to O.C.G.A. § 31-7-4 is finally revoked by order of the Department of Human Resources. For purposes of this subsection, the date of such final revocation shall be as follows:

1. When there is no appeal of the order pursuant to O.C.G.A. § 31-5, the one hundred and eightieth (180^{th}) day after the date upon which expires the time for appealing the revocation order without such an appeal being filed; or

2. When there is an appeal of the order pursuant to O.C.G.A. § 31-5, the date upon which expires the time to appeal the last administrative or judicial order affirming or approving the revocation or revocation order without such appeal being filed.

The Department may become a party to any judicial proceeding to review a decision by the Department of Human Resources to revoke such a permit.

(f) A certificate shall be subject to revocation for the following failures, without limitation:

1. Failure to incur a project-specific capital expenditure, within the initial twelve (12) month implementation period specified at 111-2-2-.02(6) and in the Certificate itself or within an extension implementation period granted by the Department, through initiation of substantial project above-ground construction or lease or purchase of the proposed equipment;

2. Failure to file the required Progress Report(s);

3. Failure to meet the conditions on the face of the Certificate; or

4. Failure to pay any penalty assessed pursuant to O.C.G.A. § 31-6-40.1.

(2) **Sanctions.**

(a) Any health care facility offering a new institutional health service without having obtained a Certificate of Need and which has not been previously licensed as a health care facility shall be denied a license to operate by the Department of Human Resources.

(b) In the event that a new institutional health service is knowingly offered or developed without having obtained a Certificate of Need as required by O.C.G.A. § 31-6 et. seq., or by these Rules, or the Certificate of Need for such service is revoked according to the provisions of 111-2-2-.05(1), a facility or person may be fined an amount not to exceed $5,000.00 per day up to thirty (30) days, $10,000.00 per day from thirty-one (31) days through sixty (60) days, and $25,000.00 per day after sixty (60) days for each day that the violation of these Rules and O.C.G.A. § 31-6 has existed and knowingly and willingly continues; provided however, that the expenditure or commitment of or incurring an obligation for the expenditure of funds to take or perform actions not subject to this chapter or to acquire, develop or prepare a health care facility site for which a Certificate of Need application is denied, shall not be a violation of this Chapter and shall not be subject to such a fine. The Commissioner or his designee shall determine, after notice and a hearing if requested, whether the fines provided in the Code section shall be levied.

(c) Any person who acquires a health care facility by stock or asset purchase, merger, consolidation, or other lawful means shall notify the Department of such acquisition, the date thereof, and the names and address of the acquiring person. Such notification shall be made in writing to the Commissioner or his designee within forty-five (45) days following the acquisition and the acquiring person may be fined by the Department in the amount of $500.00 for each day that such notification is late.

(d) The Department may require that any applicant for a certificate of need commit to provide a specified amount of clinical health services to indigent or charity, Medicare, Medicaid, PeachCare, and similar patients as a condition for the grant of a Certificate of Need. A grantee or successor in interest of a Certificate of Need or authorization to operate under O.C.G.A. §

31-6 which violates such an agreement, whether made before or after July 1, 1991, shall be liable to the Department for a monetary penalty in the amount of the difference between the amount of services so agreed to be provided and the amount actually provided. Penalties authorized under this Code section shall be subject to the same notices and hearing for the levy of fines under 111-2-2-.05(2)(b).

(e) All hearings under this Section shall be in accordance with the "Georgia Administrative Procedure Act". Any person so penalized under this rule is entitled to judicial review, pursuant to O.C.G. A.§. 50-13 et seq.

(f) If the person assessed fails to pay the amount of the assessment to the Department within thirty (30) days after notice of assessment is postmarked to him, or within such longer period, not to exceed ninety (90) days, as the Department may specify, the Department may institute a civil action to recover the amount of the assessment or may revoke the certificate of need. The Department may add reasonable interest to the assessment.

(g) For purposes of this Rule, the State of Georgia, acting by and through the Department or any other interested person, shall have standing in any court of competent jurisdiction to maintain an action for injunctive or other appropriate relief to enforce the provisions of this rule.

(3) **Department's Right to Inspect and Audit.** The Department or an authorized representative or employee designated by the Department shall have the right to inspect and audit any facility, site, location, book, document, paper, files, or other record of the holder of the certificate of need or letter of non-reviewability or other determination that is related to any project authorized by the certificate of need or letter of non-reviewability or other determination, in order to monitor and evaluate the person's compliance with the terms of issuance of the certificate of need or the letter of non-reviewability or other determination. The Department shall have the authority to make public or private investigations or examinations inside or outside of the state of Georgia to determine whether all provisions of O.C.G.A. § 31-6-2

et. seq. or any other law, rule, regulation, or formal order relating to the provisions of O.C.G.A. § 31-6-40 in particular, has been violated. Such investigations may be initiated at any time in the discretion of the Department and may continue during the pendency of any action initiated by the Department pursuant to section (1)(a) of this rule. For the purpose of conducting any investigation or inspection pursuant to this subsection, the Department shall have the authority, upon providing reasonable notice, to require the production of any books, records, or other information related to any certificate of need issue.

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

111-2-2-.06 Application for Certificate of Need.

(1) Letter of Intent. Beginning July 15, 2008, all persons who wish to submit an application for a certificate of need for a new institutional health service or health care facility, as provided in O.C.G.A. § 31-6-40(a)(b), must submit a letter of intent notifying the Department of their intent to do so at least thirty (30) days prior to submission of the certificate of need application. The notice must be in writing and must contain the following information:

(a) Name and address of the legal applicant;

(b) Person to whom inquiries must be addressed;

(c) Name, address of facility, if different from legal applicant;

(d) Proposed project site location with specificity;

(e) Brief summary description of proposal;

(f) Proposed service area; and

(g) Cost of the project.

The Department will not accept any notices of intent submitted by either telephone, facsimile, or electronic mail, pursuant to Rule

111-2-2-.06(6). Beginning with the date referenced above, no certificate of need application will be accepted without a previously filed letter of intent. The certificate of need application must be submitted no later than thirty (30) calendar days after the letter of intent has been received by the Department. In the event that the thirtieth (30^{th}) calendar day falls either on a weekend or a legal holiday, the thirtieth (30^{th}) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday. If a certificate of need application is not submitted as provided herein, it will not be accepted and an applicant filing an application beyond the time period specified will be required to submit a new notice of intent in the manner specified above.

(2) **Contents of Application.** Applications shall contain all relevant data, information and assurances required by the Department. The Department will provide application forms on request, and all applications must be on the form supplied by the Department or a copy thereof, and comply with the content requirements specified thereon. Applications shall provide information including, but not necessarily limited to, the following categories as they relate to the proposed projects:

(a) identification of the applicant;

(b) ownership;

(c) site identification;

(d) compliance with State and local codes and ordinances, including flood hazards;

(e) a detailed and complete description of proposed project;

(f) project justification, including specific documentation of the need (utilizing the Department's data and methodology) that the population to be served has for the project;

(g) staffing and operation;

(h) financial information, which shall include positive evidence of ability to obtain financing, the source of financing, and maximum interest rates, which will be paid to the lender.

Applications submitted for or on behalf of a health care institution shall include one copy of the latest audit report (or internal financial statement for investor-owned facilities). Also submitted shall be all pro forma financial data requested in the application;

(i) cost containment and quality of care considerations;

(j) project design and construction schedule including as applicable

1. Schematic Design Documents meeting the standards defined by the American Institute of Architects in section 2.4.2 of the Standard AIA Contract Language. These Schematic Design Documents shall establish the conceptual design of the Project illustrating the scale and relationship of the Project components. The Schematic Design Documents shall also include a conceptual site plan, if appropriate, and preliminary building plans, sections and elevations. Preliminary selections of major building systems and construction materials shall be noted on the drawings or described in writing;

2. A written summary of the Architect’s evaluation and planning findings and recommendations meeting the standards defined by the American Institute of Architects in section 2.3 of the Standard AIA Contract Language. This summary shall include, as applicable, an evaluation of the Applicant’s program and schedule requirements and budget for the Cost of the Work, each in terms of the other, a preliminary evaluation of the Applicant's site for the Project based on the information provided by the Applicant of site conditions, and the Applicant's program, schedule and budget for the Cost of the Work, and an evaluation of the applicant's proposed method of contracting for construction services; and

3. A detailed description of the proposed timeline and phases for project completion.

(k) a cost estimate prepared by a licensed architect or engineer within the sixty (60) days immediately preceding submission of the application;

(l) documentation from the Office of Regulatory Services of the Department of Human Resources of no uncorrected licensure operational standards in the applicant's facility, if applicable.

(3) **Submittal of Applications.**

(a) Applicants should submit to the Department one (1) signed copy of the application plus the original. The original, signed by the applicant, must accompany the copy. Failure to provide a copy or an original signature of the legal representative of the applicant will result in non-acceptance and return of the application.

(b) Applications received after 3:00 p.m. on any business day will be considered to have been received on the next business day. Receipt of the application will be acknowledged in writing by the Department.

(4) **Filing Fee Required.**

(a) Each application for a Certificate of Need review shall be accompanied by a fee, except for the provisions covered in 111-2-2-.06(4)(d) and 111-2-2-.06(4)(e), the amount of which shall be determined by the following schedule:

1. for applications with a total project cost from zero to $1,000,000.00, the fee shall be $1,000.00; and

2. for applications with a total project cost greater than $1,000,000.00, the fee shall be one-tenth of one percent (.001) of the total cost but not to exceed $50,000.00; and

3. for the review of cost overruns the fee shall be computed as shown above for the amount of the overrun only.

(b) For any project, which is to be accomplished by lease, gift or other means of acquisition, the dollar value for purposes of computing the fee will be based on the value of the major medical equipment or facilities to be acquired. The value of the major medical equipment is the expenditure, which would be required for purchase. The value of the facilities to be acquired is based on a

current (within six months of the submittal of the Certificate of Need application) appraisal of the property.

(c) Payment of the fee shall be by certified check or money order made payable to the State of Georgia and must be received by the Department before an application will be accepted for review. Failure to provide payment of the appropriate fee will result in non-acceptance and return of the application. Fee payments are collected as general State revenue.

(d) State-owned institutions shall be exempt from payment of a filing fee.

(e) The Department may waive payment of a filing fee, or any portion thereof, 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. A party requesting a waiver must make such request at the time the application is submitted to the Department.

(f) Subject to the rules in (a) through (e) above, applicants shall submit an additional filing fee for additional information or amendments provided during the review period that increase the cost of the project. For such supplementary information which increases the cost of the project, the amount that shall be submitted is an amount equal to the difference between the calculation of the filing fee based on the total amended project costs as outlined in (a) and the filing fee paid at the time of application, except that in no case shall the amount submitted be less than $500.00. Should such supplementary information decrease the costs associated with a project, the filing fee shall not be reduced or refunded. The Department shall not issue decisions on applications for which such supplementary information has been provided where an applicant has not submitted the additional filing fee, as applicable.

(5) **Review for Completeness.**

(a) Upon receipt of an application, the Department shall determine whether the application is complete. No application shall be reviewed until it has been determined by the Department

to be complete in accordance with information requirements specified in this Section.

(b) An application will be determined to be incomplete if any of the following were not either provided with the application or, as may be specified in this Section, submitted previously to the Department:.

1. all the required data, information and assurances provided on the correct forms, including but not limited to the following:

(i) detailed description of the proposed project as required by 111-2-2-.06(2)(e);

(ii) financial program to meet the requirements of 111-2-2-.06(2)(h);

(iii) documentation of necessary financing for the project, such as a letter of credit, etc.;

(iv) financial pro forma to meet the requirements of 111-2-2-.06(2)(h); and

(v) most recent audited financial statements, or personal financial statements if audited statements are not available (tax returns would meet this requirement for unaudited entities and individuals);

(vi) for projects invoking service-specific Rules, as outlined in Rules 111-2-2-.20 et seq., the appropriate service-specific review considerations;

(vii) for projects involving construction, renovation, and/or expansion, schematic plans and cost estimates certified by an architect, engineer, or general contractor, as appropriate and as required by 111-2-2-.06(2)(k);

(viii) for projects involving the acquisition of equipment, purchase orders or invoices, as appropriate;

2. appropriate number of copies of the application sent to the Department, pursuant to and in compliance with 111-2-2-.06(6);

3. signatures on all copies, with an original signature of the applicant on the application determined by the applicant as the original;

4. payment of the filing fee, as described in 111-2-2-.06(4);

5. the most recent three (3) years of all required surveys, as may be previously submitted to the Department, including the Annual Hospital Questionnaire, Annual Nursing Home Questionnaire, survey of home health agencies, or other data-gathering instruments required by the Department for any health care facilities and services owned or operated by the applicant, to include data requested pursuant to O.C.G.A. § 31-6-70. In order for an application to be deemed complete, such surveys and data-gathering instruments shall be complete and accurate, as determined by the Department. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation have submitted completed questionnaires with the Department;

6. written verification certifying entitlement to any necessary real estate property or leasehold as described by the applicant in the application. Verification of entitlement shall include, but not be limited to, deeds, contracts, lease arrangements, conditional sales agreements or a comparable arrangement that purports to be a transfer of ownership in whole or in part. If an unsigned lease arrangement is submitted, the Applicant shall also submit an original letter documenting both the lessor's and lessee's commitment to participate in the lease once the CON is approved;

7. authorization to conduct business, including but not limited to, as appropriate:

(i) if the applicant is an entity requiring authorization by the Secretary of State to become a legal entity entitled to do business in the State of Georgia, such documentation;

(ii) by-laws, articles of incorporation, or articles of organization; and

(iii) if the applicant is an existing and licensed or permitted entity, a copy of such license or permit.

8. The applicant shall file one copy of the application with the office of the County Commissioner of the county in which the project exists or is proposed. The applicant shall submit with the application an exact copy of the letter addressed and submitted to the County Commission that accompanied the submittal of the application to the County Commission;

9. all post-approval reporting requirements as mandated at 111-2-2-.04(2) for all previously approved projects, as may be previously submitted to the Department. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation have met the said post-approval reporting requirements for all previously approved projects with the Department;

10. the written vendor lobbyist certification required by 111-1-2-.03(2);

11. In order to be determined complete, an applicant must be current will all indigent and charity care commitments, if any, made to the Department as a condition or requirement for past approval of a project. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation are current with any and all indigent and charity care commitments made to the Department; and

12. In order to be determined complete, an applicant must be current with any and all fines, if any, levied by the Department for violation of these Rules.

(c) The Department shall notify the applicant within ten (10) business days following receipt of the application that the

application is complete as submitted or that additional information is required to complete the application. If additional information is required, the notice shall include a statement of the specific additional information required. Notice shall be effective the date it is postmarked by the Department.

(d) The Department shall notify the applicant no later than ten business days following receipt of the additional information whether such information is sufficient to complete the application. If it is not sufficient, the notice shall include a specific statement of the information which needs clarification or which does not adequately respond to the original request.

(e) The Department will deem an application to be withdrawn if the applicant fails to provide the Department with information requested on a notice of incompleteness within two calendar months after the date of the original letter notifying the applicant of the information necessary for completeness.

(f) In addition to the provisions of a paragraph (b) above, additional requirements shall be in effect where the application involves the acquisition of a hospital owned or operated by or on behalf of a political subdivision, any combination of such subdivisions, or by or on behalf of a hospital authority. These requirements shall be as follows:

1. in the event that a health care facility, which has been assisted at any time during the past twenty years through a grant of State funds, is proposed to be acquired by a non-grant-eligible entity, the Department, in accordance with O.C.G.A. §§ 31-7-53(c) and 31-7-57(d), is required to recover the funds granted by the State. A commitment regarding return to the State of such monies consistent with the Code should be forwarded to the Department no later than the end of the review period.

2. there shall be submitted a written agreement between the parties containing the following commitments:

(i) that the purchaser or lessee will annually allocate funds for the purpose of providing indigent/charity care. The funds allocated will be no less than three percent (3%) of the gross

revenues of the hospital after provisions for bad debt and Medicaid and Medicare contractual adjustments have been deducted. The funds allocated will be based on the previous year's financial records, except the first year of operation following an acquisition the three percent will be based on the gross revenues of the hospital after provisions for bad debt and Medicaid and Medicare adjustments have been deducted. For purposes of this rule; gross revenues will include all income derived from all sources;

(ii) that the purchaser will agree that no resident of the county in which the hospital resides will be denied emergency care (including emergency obstetrical care) due to inability to pay;

(iii) that the purchaser will participate in the Medicaid and Medicare programs and the State Health Benefit Plan, if authorized by the Department.

(6) **Submission of Information and Documents.** For the purposes of meeting any deadlines imposed by either these Rules or O.C.G.A. § 31-6, the Department will not accept any information or documents that are submitted either via telephone or facsimile. In order to meet any of the above referenced deadlines, it will be necessary to submit the information or documents either via the postal service or hand delivery, as the term hand delivery is commonly known and used. For the purposes of this rule, the use of a common carrier or a courier service shall meet the requirement of hand delivery. At all times, the interested party shall submit either the original document or a certified copy thereof. Except as otherwise provided, information and documents received after 5:00 p.m. on any business day will be considered to have been received on the next business day. Except as otherwise provided by these Rules, all documents required and described in these Rules, except for the periodic reports described in 111-2-2-.04, including, but not limited to, applications, opposition letters, supplementary information, requests for determinations, opposition to determinations, and requests for letters of non-reviewability shall be submitted with a signed original and one (1) copy.

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

111-2-2-.07 Review Procedures.

(1) **Beginning of Review Process.**

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

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

(c) In the event that, from the time an application is declared complete until thirty (30) days thereafter, one or more additional applications are declared complete which involve similar projects in the same or overlapping service areas, the Department may declare that such applications will be joined with the first application for review purposes. Following such joinder, none of the subsequent applications so joined may be considered as a first application for purposes of future joinder. The Department shall notify all applicants whose applications have been joined, and shall set a new time parameter for Department actions. The one hundred and twenty (120) day final decision deadline shall run

from the latest date that any one of the joined applications was declared complete for review. Except as otherwise provided in Rule 111-2-2-.08(1), such joinder shall be the sole method of comparative review for all applications filed after July 1, 2008.

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

1. The Department anticipates issuance of new demographic or utilization, data affecting the application;

2. The Department has received conflicting or contradictory information necessitating further investigation;

3. Results of impending legal action may have an effect on the application.

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

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

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

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

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

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

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

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

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

(f) If during the first two (2) months of the review of the application the Department finds there are factors that create a potential for denial of the application, the Department shall, on or before the sixtieth (60^{th}) day of the review period, provide the applicant an opportunity to meet with the Department. The problems with the application will be described and an opportunity offered to amend or to withdraw the application or to submit additional information. The sixty (60) day meeting with the applicant(s) is restricted to the Department and the applicant(s). Parties opposing an application(s) may not attend or participate in an applicant sixty (60) day meeting. Such addition information must be submitted prior to the seventy-fifth (75^{th}) day of the review period.

1. “Additional information” is information and data submitted in response to a direct request from the Department at the meeting afforded an applicant after the first two (2) months of the review of the application or in response to issues and concerns raised by the Department in said meeting, or in the lack of such a

meeting or request by the Department, information and data submitted consistent with the scope, physical location, cost, charges, service, and owners in the originally submitted application. Additional information must be submitted to the Department prior to the seventy-fifth (75^{th}) day of the review period;

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

(i) A reduction or increase in the proposed physical space capacity; or

(ii) A reduction or increase in the number of proposed beds or service units (e. g. operating rooms); or

(iii) A change in the owners of the legal applicant entity, as long as the legal applicant entity remains the same; or

(iv) A reduction or increase in a proposal's capital or operating costs; or

(v) A change in site within three (3) miles of the site proposed in the original application or within the same service area as long as the population to be served and the service area to be served is not substantially different from that originally proposed as long as the proposed change does not require the application of a new need study or different rules; or

(vi) A reduction or subtraction in the scope of the original application; or

(vii) A change in the amount of commitment to indigent or charity care, projected utilization, financial information or patient charges that do not alter the basic financing or operations of the proposed project.

(g) The Department shall be notified with either a new application or written amendment to the current completed application when there are changes in the scope, physical location, cost, charges, service or owners of the applicant entity. Any revisions that constitute a total change in or addition to the scope of an application, in the location (except for the exemption in 111-2-2-.07(1)(f)2.(v), or in the legal applicant that would require the submission of a new application. If the Department determines that the amendment constitutes a total change in either the scope, location, or legal applicant, the original application will be considered to be withdrawn and the applicant will be so notified. An application may be amended by the applicant at any time up to the one hundred and tenth (110^{th}) day of the review cycle.

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

1. Those parties who are opposed to an application will be given an opportunity to meet with the Department at a time and place specified by the Department after a review of the opposition notices. The opposition meeting provided for by O.C.G.A. § 31-6-43(h), shall be held no earlier than the ninetieth (90^{th}) day of the review cycle. The applicant(s) shall be entitled to attend the opposition meeting. Only one designated person on behalf of each party opposed to a particular application will be allowed to speak on behalf of the opposition to said application at the opposition meeting. The time period provided for the opposition spokesperson shall be determined in the sole discretion of the Department. The applicant(s) will not be allowed to speak in rebuttal of the opposition remarks at the opposition meeting. The Department shall make no formal substantive comments regarding the review of the application(s) at the opposition

meeting. The opposition parties shall bring to the opposition meeting substantive written comments and arguments regarding the nature of their opposition to the particular project. The opposition parties must provide an original and one copy of the substantive opposition comments to the Department at the meeting, and also provide one copy of the substantive opposition comments to the applicant at the opposition meeting. In order for an opposing party to have standing to appeal an adverse decision pursuant to O.C.G.A. § 31-6-44, such party must attend and participate in an opposition meeting. Substantive opposition comments must pertain to only one application and one applicant. In no case shall the Department accept substantive opposition comments that concern multiple applicants or applications.

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

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

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

(i) The Department, in accordance with the provisions of subsections (k-m) below, will give special expedited consideration to emergency expenditures required solely to cope with a situation posing an immediate threat to the health and safety of patients, visitors, or staff. The General Counsel, or his designee, upon a showing that a proposed replacement facility is critical to the welfare, health and stability of the immediate community as evidenced by written support from the local, county and state governing bodies may, authorize an expenditure based on a request by telephone, with written documentation to be provided later. In the event that the authorized emergency expenditure requires an application to replace an existing health care facility, the application will not be subject to joinder.

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

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

(k) Pursuant to the provisions of O.C.G.A. § 31-6-43(g), the Department shall conduct an expedited review with a review period of no longer than (30) thirty days for those projects deemed an emergency. When the Governor has declared a state of emergency in a region of the state, existing health care facilities in

the affected region may seek emergency approval from the Department to make expenditures in excess of the capital expenditure threshold or to offer services that may otherwise require a certificate of need. The Department shall give special expedited consideration to such requests and may authorize such requests for good cause. Once the state of emergency has been lifted, any services offered by an affected health care facility under this subsection shall cease to be offered until such time as the health care facility that received the emergency authorization has requested and received a certificate of need. For purposes of this subsection, 'good cause' means that authorization of the request shall directly resolve a situation posing an immediate threat to the health and safety of the public.

(l) The Department shall issue a decision on applications for a Certificate of Need for emergency projects as provided in subsection (k) above, no later than thirty (30) days after the application has been deemed complete for review; failure to issue the decision on or before the thirtieth (30^{th}) day after it has been deemed complete for review shall result in an automatic approval of the application, subject to subsection (n) below; the decision issued by the Department shall be a summary statement of the findings during the review of the project;

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

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

(o) The filing fee for applications of the type specifically listed in subsections (k) – (n) above shall be $1,000.00, notwithstanding the filing fee provisions of Rule 111-2-2-.06(4)(a).

(2) **Department Review.**

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

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

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

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

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

1. A detailed statement of the findings related to each applicable consideration and standard relevant to the decision to issue or deny a Certificate of Need;

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

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

(e) A copy of the notification will be sent to the applicant or, in the case of joined applications, to all applicants, to the appropriate Regional Development Center and to the chief elected official of the applicable county and municipal government, if any. A copy may be made available to other interested persons on request.

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

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

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

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

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

(1) **Batching Review Process.**

(a) Pursuant to O.C.G.A. § 31-6-3(e), the Department may limit the time periods during which it will accept applications for the following health care facilities and/or services: skilled nursing facilities; intermediate care facilities; home health agencies, open heart surgical services, pediatric cardiac catheterization and open heart services, perinatal services, freestanding birthing centers, psychiatric and substance abuse services, comprehensive inpatient physical rehabilitation services, ambulatory surgical services, positron emission tomography services, and megavoltage radiation therapy services. Limitation of the time periods shall be to only such times after the Department has determined there is an unmet need for such facilities and/or services, or will accept applications pursuant to any service specific need standard exceptions. The Department shall make a

determination as to whether or not there is an unmet need for each type of facility at least every six months and shall notify those requesting such notification of that determination. No application for the services listed above will be accepted for review by the Department except as provided for pursuant to Rule 111-2-2-.08(1). For purposes of batching only, the applications entered into the one hundred twenty (120) day review period shall be evaluated according to the data used to publish the unmet need, or to accept applications pursuant to any service specific need standard exceptions, for the particular service at issue, for those services listed above, and not the latest available data at the time of decision, as is the case with all non-batched applications.

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

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

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

2. The notice of intent must be received by the Department no later than the close of business on the thirtieth (30th) calendar day following the date that the Department publishes the determination of unmet need. In the event that the thirtieth (30th)

calendar day falls on either a weekend or a legal holiday, the thirtieth (30th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday.

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

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

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

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

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

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

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

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

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

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

3. On or before the sixtieth (60th) day of the batching review cycle, the Department shall provide the applicant(s) an opportunity to meet with the Department. The Department will describe any issues with the application and provide an opportunity to the applicant(s) to amend or withdraw the application or to submit additional information. Any and all additional information must be submitted on or before the seventy-fifth (75th) day of the batching review cycle. The sixty (60) day meeting with the applicant(s) is restricted to the Department and the applicant(s). Parties opposing an application(s) may not attend or participate in an applicant sixty (60) day meeting.

4. Any party who is opposed to one or more applications submitted during a batching cycle must submit a notice of opposition, on the form provided by the Department, no later than the sixtieth (60^{th}) day of the batching review cycle. The notice must contain the information specified by the form. The notice of opposition form submission shall also include one signed original

of the written vendor lobbyist certification required by 111-1-2-.03(2). The notice of opposition must not contain the substantive arguments against a particular application.

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

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

5. Applicants shall be given the opportunity to respond to the substantive opposition comments made orally and submitted

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

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

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

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

2. Specific services to be offered;

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

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

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

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

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

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

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

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

1. A detailed statement of the findings related to each applicable consideration and standard relevant to the decision to issue or deny a Certificate of Need; and

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

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

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

(2) **Alternative Healthcare Models.**

(a) **Applicability.**

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

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

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

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

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

(b) **Definitions.**

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

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

3. “Board” means the Board of Community Health.

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

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

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

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

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

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

(c) **Requests for Proposals.**

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

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

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

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

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

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

(d) **Intent to Apply.**

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

2. This notice must be:

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

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

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

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

(e) **Application Process.**

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

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

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

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

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

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

(f) **The Review Cycle.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(g) **Standards.**

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

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

3. An Alternative Healthcare Model must:

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

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

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

4. An applicant for an Alternative Healthcare Model CON shall demonstrate the feasibility of operating the Alternative Healthcare Model in Georgia, based on a review of the experience in other states including the impact on health professionals of

other healthcare programs or facilities and how the project is impacted by payers and regulatory entities.

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

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

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

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

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

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

111-2-2-.09 General Review Considerations.

(1) **General Considerations.** The burden of proof for producing information and evidence that an application is consistent with the applicable considerations and review policies, which follow, shall be on the applicant. In conducting review and making findings for Certificates of Need, the Department will consider whether:

(a) the proposed new institutional health services is reasonably consistent with the relevant general goals and

objectives of the State Health Plan. The goals and objectives related to issues and addressed in the State Health Plan, which are relevant to the Certificate of Need proposal, will be considered in the review. It should be recognized that the goals of the State Health Plan express the ideal and in some respects may be incompatible with the concept of cost containment. The statutes and Rules represent the final authority for review decisions and the content of the Plan or any component thereof shall not supersede the Rules in such determination;

(b) the population residing in the area served, or to be served, by the new institutional health service has a need for such services;

1. Population projections used by the Department will be resident population figures prepared or approved by the Office of Planning and Budget or other official figures that may be applicable as determined by the Department.

2. Updated resident population projections will be utilized upon the official effective date as stated by the Department, pursuant to these Rules, replacing and superseding the older data.

3. The projection period or horizon year for need determinations will be five years for hospital services and three years for all other services, unless otherwise provided by the Rules for the specified service. The projection period or horizon year will be advanced to the next projection year or horizon year on or about April 1 of each year.

4. Inpatient facilities will be inventoried on the basis of bed capacity approved, grandfathered, or authorized through the certificate of need process regardless of the number of beds in operation at any given time or which may be licensed by the Office of Regulatory Services, Department of Human Resources.

5. Data sources to be utilized by the Department to evaluate need, population characteristics, referral patterns, seasonal variations, utilization patterns, financial feasibility, and future trends will include, but not be limited to, the following:

(i) any surveys required by the Department, including but not limited to those for hospitals, nursing facilities, home health agencies, specialized services, and ambulatory surgery facilities;

(ii) Cost reports submitted to fiscal intermediaries and the Department;

(iii) periodic special studies or surveys, as produced or formally adopted or used by the Department;

(iv) the United States Census and other studies conducted by the Census and other Federal and State agencies and bureaus, including but not limited to, the Department of Labor; and

(v) such other data sources utilized by the Department for measurement of community health status. Such data may include information submitted by the applicant pursuant to 111-2-2-.06(1)(f), which may be necessary for the Department to ensure that the project is consistent with applicable general consideration provisions.

6. All data used by the Department in a Certificate of Need review will be available to the applicant on request, in accordance with Department policies on requested information. The most recent data reported and validated will be used in the analysis of a proposal.

(c) existing alternatives for providing services in the service area the same as the new institutional health service proposed are neither currently available, implemented, similarly utilized, nor capable of providing a less costly alternative, or no Certificate of Need to provide such alternative services has been issued by the Department and is currently valid

1. The Department supports the concept of regionalization of those services for which a service-specific rule exists.

2. The Department shall consider economies of scale where need exists for additional services or facilities.

3. Utilization of existing facilities and services similar to a proposal to initiate services shall be evaluated to assure that

unnecessary duplication of services is avoided. Where there exists significant unused capacity, initiating a similar service in another health care facility would require strong justification under other criteria.

(d) the project can be financed adequately and is in the immediate and long term, financially feasible;

(e) the effects of the new institutional health service on payors for health services, including governmental payors, are reasonable;

(f) the costs and methods of a proposed construction project, including the costs and methods of energy provision and conservation, are reasonable and adequate for quality health care. Construction plans will be reviewed in detail to assure that space is designed economically. Space shelled-in for some future use will not be accepted unless the applicant demonstrates that the shelled-in space will not be directly related to the provision of any clinical health service;

(g) the new institutional health service proposed is reasonably financially and physically accessible to the residents of the proposed service area and will not discriminate by virtue of race, age, sex, handicap, color, creed or ethnic affiliation;

1. In accordance with the provision found in O.C.G.A. § 31-6-42(7), the Department will evaluate the extent to which each applicant applying for a Certificate of Need participates in a reasonable share of the total community burden of care for those unable to pay. This provision shall not apply to applicants for continuing care retirement communities, skilled nursing facilities or units, and to projects that are reviewed by the Department on an emergency basis in accordance with 111-2-2-.07(1)(k). In all other instances, the following indicators will be evaluated:

(i) administrative policies and directives related to acceptance of indigent, medically indigent, and Medicaid patients;

(ii) policies relating medical staff privileges, if applicable, to reasonable acceptance of emergency referrals of Medicaid and

PeachCare patients and all other patients who are unable to pay all or a portion of the cost of care;

(iii) evidence of specific informational efforts targeted toward patients regarding arrangements for satisfying charges;

(iv) documented records of refunds, if any, received from the Federal, State, county, city, philanthropic agencies, donations, and any other source of funds other than from direct operations, such as indigent care trust fund distributions and disproportionate share payments, if applicable;

(v) the applicant's commitment to participate in the Medicare/Medicaid and PeachCare programs; to provide legitimate emergency care, if applicable, regardless of ability to pay; and to provide indigent and charity care;

(vi) documented records of care provided to patients unable to pay, Medicare and Medicaid contractual adjustment, Hill-Burton payments (if applicable), other indigent care, and other itemized deductions from revenue including bad debt. Such records shall demonstrate that the levels of care provided correspond to a reasonable proportion of those persons who are medically or financially indigent and those who are eligible for Medicare or Medicaid within the service area.

2. The evaluation in 1. above is in addition to satisfaction of a minimum indigent and charity care commitment required by prior CON(s), if any.

(h) the proposed new institutional health service has a positive relationship to the existing health care delivery system in the service area;

(i) the proposed new institutional health service encourages more efficient utilization of the health care facility proposing such service;

(j) the proposed new institutional health service provides, or would provide a substantial portion of its services to individuals not residing in its defined service area or the adjacent service area;

(k) the proposed new institutional health service conducts biomedical or behavioral research projects or new service development that is designed to meet a national, regional, or statewide need;

(l) the proposed new institutional health service meets the clinical needs of health professional training programs;

(m) the proposed new institutional health service fosters improvements or innovations in the financing or delivery of health services; promotes health care quality assurance that can be documented with outcomes greater than those which are generally in keeping with accepted clinical guidelines, peer review programs and comparable state rates for similar populations; promotes cost effectiveness; or fosters improvements or innovations in the financing or delivery of health services; or fosters competition that is shown to result in lower patient costs without a significant deterioration in the quality of care; and

(n) the proposed new institutional health service fosters the special needs and circumstances of Health Maintenance Organizations.

(o) the proposed new institutional health service meets the department's minimum quality standards, including, but not limited to, standards relating to accreditation, minimum volumes, quality improvements, assurance practices, and utilization review procedures;

(p) the proposed new institutional health service can obtain the necessary resources, including health care management personnel; and

(q) the proposed new institutional health service is an underrepresented health service, as determined annually by the department. The department shall, by rule, provide for an advantage to equally qualified applicants that agree to provide an underrepresented service in addition to the services for which the application was originally submitted.

(2) Destination Cancer Hospitals. In the case of Certificate of Need applications for the construction, development, or establishment of a destination cancer hospital, the applicable general considerations as to the need for such service shall not include paragraphs (a), (b), (c), (g), (h), (j), (k), and (n) of Section (1) of Rule 111-2-2-.09, but shall include:

(a) Paragraphs (d), (e), (f), (i), (l), (m), (o), (p), and (q) of Section 1 of Rule 111-2-2-.09;

(b) That the proposed new destination cancer hospital can demonstrate, based on historical data from the applicant or its affiliated entities, that its annual patient base shall be composed of a minimum of sixty-five percent (65%) of patients who reside outside of the State of Georgia;

(c) The the proposed new destination cancer hospital states its intent to provide uncompensated indigent and charity care which shall meet or exceed three percent (3%) of its adjusted gross revenues and provide care to Medicaid beneficiaries;

(d) That the proposed new destination cancer hospital shall conduct biomedical or behavioral research projects or service development which is designed to meet a national or regional need;

(e) That the proposed new destination cancer hospital shall be reasonable financially and physically accessible;

(f) That the proposed new destination cancer hospital shall have a positive relationship to the existing health care delivery system on a regional basis;

1. That the proposed new destination cancer hospital shall enter into a hospital transfer agreement with one or more hospitals within a reasonable distance from the destination cancer hospital or the medical staff at the destination cancer hospital has admitting privileges or other acceptable documented arrangements with such hospital or hospitals to ensure necessary backup for the destination cancer hospital for medical complications. The destination cancer hospital shall have the

capability to transfer a patient immediately to a hospital within a reasonable distance from the destination cancer hospital with adequate emergency room services. Hospitals shall not unreasonable deny a transfer agreement with the destination cancer hospital. In the event that a destination cancer hospital and another hospital cannot agree to the terms of a transfer agreement as required by this paragraph, the Department shall mediate between such parties for a period of no more than forty-five (45) days. If an agreement is still not reached within such forty-five (45) day period, the parties shall enter into binding arbitration conducted by the Department.

(g) That an applicant for a new destination cancer hospital shall document in its application that the new facility is not predicted to be detrimental to existing hospitals within the planning area. Such demonstration shall be made by providing an analysis in such application that compares current and projected changes in market share and payor mix for such applicant and such existing hospitals within the planning area. Impact on an existing hospital shall be determined to be adverse if, based on the utilization projected by the applicant, such existing 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; and

(h) That the destination cancer hospital shall express its intent to participate in medical staffing work force development activities.

(3) In the case of applications for basic perinatal services in counties where:

(a) Only one civilian health care facility or health system is currently providing basic perinatal services; and

(b) There are not at least three (3) different health care facilities in a contiguous county providing basic perinatal services, the Department shall not apply the consideration contained in paragraph (b) of section (1) of this rule.

(4) **Osteopathic Considerations.** When an application is made for a Certificate of Need to develop or offer a new institutional health service or health care facility for osteopathic medicine, the need for such facility shall be determined on the basis of the need and availability in the community for osteopathic services and facilities. Nothing in this Chapter shall, however, be construed as recognizing any distinction between allopathic and osteopathic medicine.

(5) **Minority-Administered Hospital Considerations.** If the denial of an application for a Certificate of Need for a new institutional health service proposed to be offered or developed by a minority-administered hospital serving a socially and economically disadvantaged minority population in an urban setting, or by a minority-administered hospital utilized for the training of minority medical practitioners, would adversely impact upon the facility and population served by said facility, the special needs of such hospital facility and the population to be served by said facility for the new institutional health service shall be given extraordinary consideration by the Department in making its determination of need. The term "minority-administered" means a hospital controlled or operated by a governing body or administrative staff composed predominantly of members of a minority race. The Department shall have the authority to vary or modify strict adherence to the provisions of Code Chapter 31-6-42(c) and this Chapter in considering the special needs of said facility and its population served and to avoid an adverse impact on the facility and the population served thereby.

(6) **Considerations for Joined Applications.**

(a) In evaluating joined applications, if the services proposed are found to be needed, and if both applications equally meet the statutory considerations, priority consideration will be given to a comparison of the applications with regard to:

1. the past and present records of the facility, and other existing facilities in Georgia, if any, owned by the same parent organization, regarding the provision of service to all segments of

the population, particularly including Medicare, Medicaid, minority patients and those patients with limited or no ability to pay;

2. specific services to be offered;

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

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

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

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

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

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

9. hospital and physician collaborations that promote greater cost efficiency to patients, ensure greater quality assurance outcomes and foster positive relationships within the existing healthcare delivery network which benefits both providers and members within the impacted service area population; and

10. proposed services that include or involve a clinical healthcare service that is or has been underrepresented in the proposed service area for more than 12 months as evidenced by geographical barriers to the service, insufficient staffing to provide the service and/or recent termination of the service in the proposed planning area.

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

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.

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 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 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.

(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 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 percent (2%) 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 percent (4%) 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 percent (2%) 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 four percent (4%) 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 (2) 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 four percent (4%) 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-.11 Service Specific Review Considerations Generally.

(1) The Department has adopted the following service-specific requirements and review considerations:

(a) Acute Care and Acute Care-Related Rules:

1. Short-Stay General Hospital Services, 111-2-2-.20;

2. Adult Cardiac Catheterization Services, 111-2-2-.21;

3. Open Heart Surgical Services, 111-2-2-.22;

4. Pediatric Cardiac Catheterization and Open Heart Services, 111-2-2-.23;

5. Perinatal Services, 111-2-2-.24;

6. Freestanding Birthing Center Services, 111-2-2-.25; and

7. Psychiatric and Substance Abuse Inpatient Services, 111-2-2-.26;

(b) Long-Term Care Rules:

1. Skilled Nursing and Intermediate Care Facility Services, 111-2-2-.30;

2. Personal Care Home Services, 111-2-2-.31;

3. Home Health Services, 111-2-2-.32;

4. Continuing Care Retirement Communities (“CCRC”), 111-2-2-.33;

5. Traumatic Brain Injury Services, 111-2-2-.34; and

6. Comprehensive Inpatient Physical Rehabilitation Services, 111-2-2-.35;

(c) Special and Other Health Services:

1. Ambulatory Surgical Services, 111-2-2-.40;

2. Positron Emission Tomography, 111-2-2-.41; and

3. Radiation Therapy Services, 111-2-2-.42.

(2) The review considerations and standards that are promulgated in service-specific rules are considerations and standards that apply to specific services in addition to the general considerations in 111-2-2-.09. Any conflict between the meaning or application of a service-specific requirement and the general

considerations shall be interpreted in favor of the service-specific consideration, unless a general consideration specifically indicates that it supersedes any and all service-specific considerations.

(3) The meaning of words as they are defined in a particular service-specific rule only applies to that service-specific rule, unless a specific citation is made to another service-specific rule.

(4) Numerical Need Calculations.

(a) The numerical need calculations, which shall apply to an application for a clinical health service for which service-specific rules exist, shall be the calculated need in effect on the date the application is deemed complete for review less any subsequently approved units and services during the review period. This provision does not apply to batching reviews as the need applicable to batching decisions is the need stated in the batching notice.

(b) In the instance of joined projects where one project is reviewed as an exception based on utilization and the other is reviewed as need-based, the approval of the utilization exception shall not preclude an approval based on a numerical need projection should, prior to the approval of any of the joined projects, the numerical need projection indicates a need for the clinical health service.

(c) Approved projects that affect service-specific numerical need calculations shall be added to the Department's service-specific inventories and the numerical need projections shall be adjusted as of the approved date of the project.

(d) Approved projects that are reversed through administrative and/or judicial appeal final resolution shall be subtracted from the Department's service-specific inventories and the numerical need projections shall be adjusted as of the date of such final resolution.

(5) Service-specific component plans provide general background on specific considerations that were undertaken in

developing service-specific rules. The service-specific rules shall supersede a component plan.

(6) If any provision of these service-specific rules, or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the particular service-specific rule in question or of the service-specific rules in general which can be given effect without the invalid provision or application, and to this end the provisions of these service-specific rules are severable.

(7) The commissioner shall be authorized, with the approval of the board, to place a temporary moratorium of up to six (6) months on the issuance of certificates of need for new and emerging health care services. Any such moratorium placed shall be for the purpose of promulgating service-specific rules and regulations regarding such new and emerging health care services. A moratorium may be extended one time for an additional three (3) months if circumstances warrant, as approved by the board. In the event that final service-specific rules and regulations are not promulgated within the time period allowed by the moratorium, any applications received by the department for a new and emerging health care service shall be reviewed under existing general statutes and regulations relating to certificates of need. Upon the identification by the Department of a new and emerging health care service as defined by 111-2-2-.01(38), and the request for and receipt of approval by the board of a moratorium as provided in this subsection, the Department shall publish notice of the moratorium and the identified service in a manner used in the normal course for other certificate of need information and announcements.

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 0 to 17; persons 18 to 64; and persons 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 90% or more of the patients served by the hospital are 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, 65%;

2. for hospitals located in a non-rural county, 75%; and

3. for teaching or children's hospitals, 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 20% or more of the total hospital inpatient admissions;

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

5. Uncompensated charges for indigent and charity patients constitute 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 (2) 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 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) Reserved.

(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 (3) calendar years in any five (5) 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.

111-2-2-.21 Specific Review Considerations for Adult Cardiac Catheterization Services.

(1) **Applicability.**

(a) For Certificate of Need (CON) purposes, Adult Cardiac Catheterization Services is classified as a specialized service and is defined as a new institutional health service which must be delivered in a permanently fixed location in either an acute care hospital or in a diagnostic, treatment, or rehabilitation center (DTRC). A certificate of need will be required prior to the establishment of a new or expanded adult cardiac catheterization service, if not exempt as provided by O.C.G.A. § 31-6-47(a)(21) and Rule 111-2-2-.03(23).

(b) If the service will be provided within a licensed acute care hospital, the hospital shall be the applicant.

(c) If cardiac catheterization services will be provided in a DTRC, the organizational entity that develops the service shall be the applicant.

(d) Seeking and receiving approval from the Department under the provisions of 111-2-2-.21 (3)(f)3 shall neither be considered a new adult cardiac catheterization service nor an expanded service. Additionally, the issuance of such an approval shall not be construed to be anything other than a time-limited approval to participate in the particular medical research trial specified in 111-2-2-.21(3)(f)(3).

(2) **Definitions.**

(a) "Adjacent acute care hospital" means an acute care hospital which is physically connected to another acute care hospital in a manner that emergency transport of a patient by a stretcher or gurney can be achieved rapidly, conveniently, and effectively without the use of motorized vehicles.

(b) "Adult" means a person fifteen (15) years of age and over.

(c) "Authorized service" means an adult cardiac catheterization service that is either existing or approved. An existing service is an authorized service that has become operational, and an approved service is an authorized service that has not yet become operational.

(d) "Capacity" means 1300 adult cardiac catheterization procedure equivalents per dedicated and multipurpose room per year. In the computation of the use rate (percent of capacity) of authorized adult cardiac catheterization rooms, each adult diagnostic cardiac catheterization and other cardiac catheterizations of similar complexity shall equal a 1.0 procedure equivalent, each coronary angioplasty procedure shall equal 1.5 procedure equivalents, and each electrophysiological (EP) study shall equal 2.0 procedure equivalents. If pediatric catheterizations are performed in a room in which adult cardiac catheterizations are performed, each pediatric procedure shall equal 2.0 procedure equivalents.

(e) “Cardiac catheterization” means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient; subsequently, the free end of the catheter is manipulated by the physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aids in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures on the heart or its vessels.

(f) “Cardiac catheterization service” means an organized program which serves inpatients and/or outpatients of an acute care hospital or diagnostic, treatment and rehabilitation center (DTRC) with a room or a suite of rooms, with equipment to perform angiographic, physiologic, and as appropriate, therapeutic cardiac catheterization procedures. An authorized adult cardiac catheterization service is prohibited from performing coronary angioplasty procedures unless the acute care hospital where the service is located meets the requirements identified in 111-2-2-.21(3)(f).

(g) “Coronary angioplasty” means a cardiac catheterization procedure to treat coronary artery disease by utilizing a catheter with a balloon, laser, laser-assisted device, rotational device, stent placement or other mechanical means to unblock an occluded coronary artery.

(h) “Diagnostic cardiac catheterization” means the performance of cardiac catheterization for the purpose of detecting and identifying defects in the great arteries or veins of the heart, or abnormalities in the heart structure, whether congenital or acquired. Post-operative evaluation of the effectiveness of prostheses (e.g. heart valves or vein grafts) also can be accomplished through use of diagnostic cardiac catheterization.

(i) “Diagnostic, treatment, or rehabilitation center (DTRC)” means any professional or business undertaking, whether for profit or not for profit, which offers or proposes to offer any clinical health service in a setting that is not part of a hospital.

(j) “Expanded Service” or “Expansion” means an adult cardiac catheterization service that undertakes any capital renovation or construction project in and to the physical space within the hospital where the cardiac catheterization services are or will be offered, the cost of which exceeds the capital expenditure threshold at that time; or that acquires a piece of diagnostic or therapeutic equipment with a value above the equipment threshold at that time which is to be utilized in the provision of cardiac catheterization services; or that seeks the addition of a new catheterization laboratory or room regardless of cost. Replacement or repair of existing diagnostic or therapeutic equipment utilized in the provision of such services is not an expansion for purposes of these Rules.

(k) “Horizon year” means the last year of a five-year projection period for need determinations for any adult cardiac catheterization services.

(l) “Official inventory” means the Department’s inventory of all authorized hospital-based and diagnostic, treatment, or rehabilitation center (DTRC) adult cardiac catheterization laboratories or any other authorized laboratory approved for operation at the time of adoption of these Rules.

(m) “Official state component plan” means the document related to specialized cardiovascular services developed by the Department adopted by the Health Strategies Council and approved by the Board of Community Health.

(n) “Procedure” means a cardiac catheterization study or treatment or combination of studies and/or treatments performed in a single session on a single patient who appears for cardiac catheterization.

(o) “Planning area” means each of the planning areas designated in the official State Component Plan.

(p) “Therapeutic cardiac catheterization” means the performance of cardiac catheterization for the purpose of ameliorating certain conditions that have been determined to exist in the heart or great arteries or veins of the heart.

(3) **Standards.**

(a) The need for new or expanded adult cardiac catheterization services shall be determined through application of a numerical need method and an analysis of service demand based on an assessment of the aggregate utilization rate of existing services;

1. the numerical need for new or expanded adult cardiac catheterization services shall be determined by a population-based formula which includes current usage patterns and projected population as follows:

(i) calculate the current state adult cardiac catheterization rate for the most recent year of reported survey or hospital and outpatient discharge data by dividing the total number of adult cardiac catheterizations performed on Georgia residents by the total state adult Resident population;

(ii) determine the projected adult cardiac catheterization procedures for the horizon year by multiplying the state rate by the adult Resident population for the planning area for the horizon year;

(iii) adjust the projected adult cardiac catheterization procedures for the planning area by adding the out-of-state hospital-based catheterizations for the most recent year based on the percentage of total procedures performed on out-of-state patients by hospitals in each planning area;

(iv) convert projected adult cardiac catheterization procedures to procedure equivalents by multiplying the projected procedures by the statewide rate of equivalents per catheterization; and

(v) determine the projected net surplus or deficit for adult cardiac catheterization capacity, expressed in terms of rooms/laboratories, in the planning area by subtracting the rooms/laboratories needed for the total projected procedure equivalents calculated in steps (i) through (iv) from the total

capacity (1300 procedure equivalents per room/laboratory) based on the official inventory.

2. before a new or expanded adult cardiac catheterization service will be approved in any planning area, the aggregate utilization rate of all adult cardiac catheterization services in that planning area shall be eighty-five (85) percent or more during the most recent year;

(b)1. The Department may allow an exception to 111-2-2-.21(3)(a) in the following circumstances:

(i) actual utilization in the applicant's existing service has exceeded ninety (90) percent of capacity over the past two years;

(ii) to remedy an atypical barrier to adult cardiac catheterization services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.

(I) An atypical barrier to services based on cost may include the failure of existing providers of adult cardiac catheterization services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state and/or planning area.

(II) An atypical barrier to services based on quality may include the failure of existing providers of adult cardiac catheterization services to provide services with outcomes generally in keeping with accepted clinical guidelines of the American College of Cardiology, peer review programs and comparable state rates for similar populations.

(III) An atypical barrier to services based on financial access may include the repeated failure, as exhibited by a documented pattern over two or more years prior to the submission of the application, of existing providers of services within the community to provide services to indigent, charity and Medicaid patients.

(IV) An atypical barrier to services based on geographic accessibility may include a planning area which has an adult cardiac catheterization rate significantly less than the state rate (two or more standard deviations from the mean), a cardiovascular disease rate as projected through death and hospital discharge data which is significantly higher than the state rate (two or more standard deviations from the mean), and other demographic risk factors which can be documented through research and clinical studies.

(V) An applicant seeking approval for a new or expanded adult cardiac catheterization service solely for the purpose of providing cardiac electrophysiological studies may apply for consideration under the terms of an atypical barrier; provided, however, that any such applicant if approved shall be restricted to the provision of electrophysiological studies.

2. The Department may allow an exception to 111-2-2-.21(3)(a) and (3)(c) for any cardiac catheterization service seeking an expansion, other than the addition of another laboratory or room; provided the applicant complies with the general considerations and policies of 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with 111-2-2-.21(3)(d), (e), (f), (g), (h), (j), (k) and (l).

(c) An applicant for a new or expanded adult cardiac catheterization service shall document that authorized cardiac catheterization services which could be adversely impacted by the establishment of the new or expanded service are not predicted to perform less than eighty (80%) percent of capacity as a result of the establishment of the new or expanded service. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application.

(d) An applicant for a new or expanded adult catheterization service shall demonstrate a plan whereby the service and its medical staff agree to provide a full array of cardiovascular services to the community, including, but not limited to, education

and outreach, prevention and screening, diagnosis and treatment, and rehabilitation.

(e) An applicant for a new or expanded adult cardiac catheterization services shall:

1. demonstrate the ability to meet the optimal clinical and physical environment standards established in the most recent American College of Cardiology/American Heart Association's Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories. These standards include, but are not limited to, physical facility requirements, staffing, training, quality assurance, patient safety, screening patients for appropriate settings, and linkages with supporting emergency services;

2. document the availability of, or shall present a plan for recruiting, at least two board-certified cardiologists with training and qualification in cardiac catheterization, and, if applicable with training and qualification in coronary intervention, who will reside within one hour drive of the service site; and

3. document a plan for obtaining a sufficient number of clinical, professional and technical staff to safely and effectively operate the service.

(f) An authorized adult cardiac catheterization service shall not perform catheterization procedures requiring open heart surgery backup as part of its service unless the acute care hospital where the service is located:

1. operates an existing adult open heart surgery service;

2. has a Department approved written agreement for open heart surgery backup with an adjacent acute care hospital as defined by these Rules; or

3. has been accepted as a participant in a randomized medical research trial comparing patient outcomes after non-primary Percutaneous Coronary Intervention (PCI) in hospitals with and without cardiac surgery on-site, which also requires the performance of Primary PCI and has a parallel Primary PCI

Registry, and which is coordinated by the Atlantic Cardiovascular-Patient Outcomes Research Team (Atlantic C-PORT). The authorized adult cardiac catheterization service must receive such Atlantic C-PORT acceptance and also must obtain written approval from the Department to perform such procedures, except that the Department may approve no more than ten (10) existing and authorized hospital services for participation, regardless of the number of such services that are accepted by Atlantic C-PORT.

(i) Any request for such Departmental approval must be submitted to the Department no later than June 30, 2005 in writing on a form developed by the Department for such purposes. Prior to final approval to participate by the Department, the requesting authorized service must provide written proof it has been accepted by Atlantic C-PORT as a participant in said trial under all applicable protocols;

(ii) In reviewing and approving such requests, the Department shall take into consideration such factors including, but not limited to, rural, suburban or urban location of the service, mix of patients to be treated, whether the service has the capability of performing a minimum of 100 PCIs (elective and primary combined) during the first year of such approval, 200 PCIs (elective and primary combined) during the second year of such approval unless a lower number, but not below 150 PCIs, is approved for specific reasons by both the Department and the trial chairperson, and 200 PCIs (elective and primary combined) during the third year of such approval, and whether the service has on its staff physicians and support staff with training and experience in both therapeutic and diagnostic cardiac catheterizations;

(iii) The selection of an authorized service for participation pursuant to this rule will be made at the sole discretion of the Department; however, the Department shall consult with medical experts in the fields of cardiology and percutaneous coronary intervention when making the decision to approve or not approve a particular service for participation in such trial;

(iv) Any approval obtained from the Department in this regard shall only be valid for as long as the health care facility receiving

such approval is an active participant in the trial; however, in no case shall such approval continue to be valid upon Atlantic C-PORT declaring the trial concluded, or under no circumstance for a period in excess of three (3) years from the time the authorized service's first procedure is conducted under the authority of the Department's approval and Atlantic C-PORT's acceptance to begin active participation in the trial; whichever event occurs first; and

(v) As any such Departmental approval is conditioned on being an active participant in the trial, should an authorized service which has received approval under the provisions of this rule be expelled or otherwise lose the approval of Atlantic C-PORT to continue participation, the Department's approval will be simultaneously withdrawn without said service's or facility's right to an appeal of the Department's withdrawal of its approval to participate in such trial.

(g) Catheterization procedures requiring open heart surgery backup include coronary angioplasty and the following:

1. catheter atherectomy;

2. catheter endomyocardial biopsy;

3. left ventricular puncture;

4. percutaneous transluminal coronary angioplasty;

5. percutaneous catheter balloon valvuloplasty; and

6. transeptal catheterization.

(h) An applicant for a new or expanded adult cardiac catheterization service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to cardiac catheterization services for all segments of the population in the documented and proposed service area of the applicant. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred

between facilities and shall promote planning for a continuum of cardiac services within the service area; and

2. propose a heart disease prevention and clinical intervention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

(i) A clinical intervention program for all catheterization patients that shall provide for the following in a comprehensive, systematic way:

(I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

(II) Assessment of risk factors and referral for appropriate care in first-degree relatives; and

(III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended including preventive therapies.

(ii) The program, if not operated by a facility with an existing Open Heart Surgical Service, shall submit a written affiliation agreement with at least one Open Heart Surgical Service that provides, at a minimum, for:

(I) a plan to transplant and handle acute cardiac emergencies;

(II) a plan to facilitate referral of patients for whom surgery or angioplasty may be indicated without unnecessarily repeating diagnostic studies; and

(III) a plan for ongoing communications between representatives of the Open Heart Surgical Service and the proposed applicant, to allow for review of pre-operative and post-operative processes and specific cases.

(iii) The program shall provide for annual support and participation in at least three (3) professional education programs targeted to community based health professionals, related to heart disease risk assessment, diagnostic procedures, disease management in clinical settings, and case finding and referral strategies.

(iv) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources to target at-risk populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors.

3. propose a system of outcome monitoring and quality improvement and identify at least five clinical outcomes that the applicant proposes to monitor for performance on a regular basis.

(i) An applicant for a new or expanded adult cardiac catheterization service must project and, if approved, shall document that the proposed service will be performing a minimum of 1040 adult cardiac catheterization procedure equivalents within three (3) years of initiation of the service and annually thereafter within the authorized guidelines for such services. Such projections, at a minimum, shall include consideration of patient origin data for catheterization services, the use rate of existing services, referral data and market patterns for existing hospital and DTRC services in the community, and cardiovascular disease incidence rates and related health indicators. An applicant

seeking approval solely for the purpose of providing electrophysiological (EP) studies shall not be required to document a projected performance minimum but shall be required to document compliance with guidelines for EP studies issued by the American College of Cardiology.

(j) An applicant for a new or expanded adult cardiac catheterization service shall provide documentation that the service is fully accredited by the Joint Commission on Accreditation of Health Care Organizations (JCAHO) or, in the case of an applicant proposing a new facility location, shall provide a written commitment to secure full accreditation by JCAHO within eighteen (18) months of initiating operation.

(k) An applicant for a new or expanded adult cardiac catheterization service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant to include disease prevention and intervention services outlined in 111-2-2-.21(3)(h), that such services shall be provided regardless of race, age, sex, creed, religion, disability or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy; and

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent of annual, adjusted gross revenues for the adult cardiac catheterization service, or the applicant may request that the Department consider allowing the commitment for services to indigent and charity to patients to be applied to the entire facility;

3. providing a written commitment to accept any patient within the facility's service area, without regard to the patient's ability to pay, unless such patient is clinically inappropriate;

4. providing a written commitment to participate in the Medicaid, PeachCare and Medicare programs and to accept any

Medicaid-, PeachCare- and/or Medicare-eligible patient for services unless such patient is clinically inappropriate;

5. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

6. 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. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(l) An applicant for a new or expanded adult cardiac catheterization service must agree in writing to the following conditions:

1. establishment and maintenance of a system of continuity of care and coordination of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs;

2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital or DTRC as well as a national, state or multi-program system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital or DTRC;

3. development of procedures to ensure that cardiologists and any other physicians providing care in the cardiac catheterization service or related services shall be required to accept Medicaid, Peach Care and Medicare payment for services without discrimination;

4. commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;

5. provision of all required data and survey information to the Department as requested; and

6. commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.

(m) The department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.

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

111-2-2-.24 Specific Review Considerations for Perinatal Services.

(1) **Applicability.** For Certificate of Need purposes, Basic Perinatal Services, Neonatal Intermediate Care Services (Specialty/Level II), and Neonatal Intensive Care Services (Subspecialty/Level III) shall be defined as new institutional health services.

(2) **Definitions.**

(a) "Basic Perinatal Services (Level I)" means providing basic inpatient care for pregnant women and newborns without complications; managing perinatal emergencies; consulting with and referring to specialty and subspecialty hospitals; identifying high-risk pregnancies; providing follow-up care for new mothers and infants; and providing public/community education on perinatal health.

(b) "Most recent year" means the most current twelve-month period within a month of the date of completion of an application or within a month of the date of completion of the first application when applications are joined. If the Department has conducted a survey within six months of the date of completion of the first application when applications are joined, the Department may consider the most recent year to be the report period covered by the prior survey.

(c) "Neonatal Intensive Care Service (Subspecialty/Level III)" means a hospital service that meets the requirements for a Neonatal Newborn Care Service and meets the definition of a Subspecialty Perinatal Hospital Service as contained in the most recent edition of the *Recommended Guidelines for Perinatal Care in Georgia,* as published by the Council on Maternal & Infant Health.

(d) "Neonatal Intermediate Care Service (Specialty/Level II)" means a hospital service that meets the requirements for a Neonatal Newborn Care Service *and* meets the definition of a Specialty Perinatal Hospital Service as contained in the most recent edition of the *Recommended Guidelines for Perinatal Care in Georgia,* as published by the Council on Maternal & Infant Health.

(e) "Neonatal Newborn Care Service (Basic/Level I)" means a hospital service which meets the minimum standards contained in Chapter 290-9-7-.34 of the Rules of the Department of Human Resources, such chapter being entitled "Newborn Service. Amended."

(f) "Obstetric Service" means a hospital service that meets the minimum standards contained in Chapter 290-5-7-.34 of the Rules of the Department of Human Resources, such chapter being entitled "Maternity and Obstetric Service. Amended."

(g) "Official Inventory" means the inventory for each hospital of Basic Perinatal Service and Neonatal Intermediate and Intensive Care Service beds maintained by the Department based upon responses to the Annual Hospital Questionnaire (AHQ) and/or its Perinatal Addendum and any Certificate of Need

approved beds after the period covered by the AHQ and with the following provisions:

1. the official inventory for each facility will remain unchanged for the year following the last day of the report period on each hospital's completed AHQ and/or its Perinatal Addendum unless the Department approves a change of bed capacity through the Certificate of Need process; and

2. the capacity of existing freestanding birthing centers will not be counted as part of the official inventory of available services when computing unmet numerical need for Basic Perinatal Services in a planning area.

(h) "Perinatal physician training program" refers to obstetrics and gynecology, family practice and pediatrics disciplines.

(i) "Planning Areas" means fixed sub-state regions for reviewable services as defined in the State Health Component Plan for Perinatal Services.

(j) "Regional Perinatal Center" (RPC) means those hospitals designated by the Department of Human Resources to serve a defined geographic area to provide the highest level of comprehensive perinatal health care services for pregnant women, their fetuses and neonates of all risk categories. The RPC accepts patients in need of these services from its region regardless of race, creed, religion, ability to pay, or funding source. The RPC provides consultation and transport for patients requiring special services; coordination and assurance of follow-up medical care for maternal and neonatal patients requiring special care; educational support to ensure quality care in institutions involved in perinatal health care; compilation, analysis, and evaluation of perinatal data from the center and referring hospitals and coordination of perinatal health care within the region.

(k) "Urban County" means a county with a projected population for the horizon year of 100,000 or more and a population density for that year of 200 or more people per square mile. All other counties are "rural."

(3) **Standards.**

(a) The need for a new or expanded Obstetric Service, Neonatal Intermediate Care Service and Neonatal Intensive Care Service shall be determined through application of a Numerical Need method and an assessment of the aggregate occupancy rate of existing services.

1. The numerical need for a new or expanded Obstetric Service in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

(i) Calculate the average obstetric utilization rate (UR) by dividing the obstetric days (OBDays) reported by hospitals for the two most recent 12-month reporting periods of the Annual Hospital Questionnaire and/or its Perinatal Addendum by the female population ages 15 to 44 (FP) for the corresponding years:

$$UR = \frac{OBDays_1 + OBDays_2}{FP_{YR}1 + FP_{YR}2}$$

(ii) Multiply the obstetric utilization rate by the projected female population ages 15 to 44 (PFP) for the horizon year to determine the number of projected obstetric days (POBDays):

$$POBDays = URxPFP$$

(iii) Calculate the number of projected obstetric beds (POBBeds) by dividing the number of projected obstetric days by 273.75 (the result of 365 days multiplied by the occupancy standard of 75 percent) with any fraction rounded up to a whole bed:

$$POBBeds = \frac{POBDays}{273.75}$$

(iv) Determine the net numerical unmet need (UN) for new or additional obstetric beds by subtracting the number of beds in the Official Inventory (OI) from the number of projected obstetric beds:

$$UN = POBBeds - OI$$

2. The numerical need for a new or expanded Level II Neonatal Intermediate Care Service in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps below, and all data elements relate to each planning area:

(i) Calculate the average resident live-birth rate (ABR) using the sum of the resident live births (RB) for the three most recent calendar years available from the Department of Human Resources or other official source divided by the corresponding years' female population ages 15 to 44 (FP):

$$ABR = \frac{RB_1 + RB_2 + RB_3}{FP_{YR}1 + FP_{YR}2 + FP_{YR}3}$$

(ii) Determine the number of projected resident live births (PRB) for the horizon year by multiplying the average resident live-birth rate by the estimated female population ages 15 to 44 (PFP) for the horizon year:

$$PRB = ABRxPFP$$

(iii) Calculate the projected number of neonatal intermediate care patient days (PN2Days) in the horizon year by multiplying the average number of patient days (N2Days) in neonatal intermediate care beds reported by hospitals for the two most recent 12-month reporting periods of the Annual Hospital Questionnaire and/or its Perinatal Addendum by the number of projected resident live births divided by the actual number of resident live births (RB) available from the Department of Human Resources or other official source for the most recent calendar year:

$$PN2Days = N2Daysx\frac{PRB}{RB}$$

(iv) Project neonatal intermediate care bed need (N2Beds) into the horizon year by dividing the projected patient days for

neonatal intermediate care services by 292 (the result of 365 days multiplied by the occupancy rate of 80 percent) with any fraction rounded up to a whole bed:

$$N2Beds = PN2\frac{Days}{292}$$

(v) To determine unmet numerical bed need (UN), subtract the official inventory (OI) from the projected neonatal intermediate care bed need:

$$UN = N2Beds - OI$$

3. The numerical need for a new or expanded Level III Neonatal Intensive Care Service in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps below, and all data elements relate to each planning area:

(i) Calculate the average resident live-birth rate (ABR) using the sum of the resident live births (RB) for the three most recent calendar years available from the Department of Human Resources or other official source divided by the corresponding years' female population ages 15 to 44 (FP):

$$ABR = \frac{RB_1 + RB_2 + RB_3}{FP_{YR}1 + FP_{YR}2 + FP_{YR}3}$$

(ii) Determine the number of projected resident live births (PRB) for the horizon year by multiplying the average resident live-birth rate by the estimated female population ages 15 to 44 (PFP) for the horizon year:

$$PRB = ABRxPFP$$

(iii) Calculate the projected number of neonatal intensive care patient days (PN2Days) in the horizon year by multiplying the average number of patient days (N2Days) in neonatal intensive care beds reported by hospitals for the two most recent 12-month reporting periods of the Annual Hospital Questionnaire and/or its Perinatal Addendum by the number of projected resident live

births divided by the actual number of resident live births (RB) available from the Department of Human Resources or other official source for the most recent calendar year:

$$PN2Days = N2Days x \frac{PRB}{RB}$$

(iv) Project neonatal intensive care bed need (N2Beds) into the horizon year by dividing the projected patient days for neonatal intensive care services by 292 (the result of 365 days multiplied by the occupancy rate of 80 percent) with any fraction rounded up to a whole bed:

$$N2Beds = PN2 \frac{Days}{292}$$

(v) To determine unmet numerical bed need (UN), subtract the official inventory (OI) from the projected neonatal intensive care bed need:

$$UN = N2Beds - OI$$

4. Prior to approval of a new or expanded Obstetric Service, Neonatal Intermediate Care Service or Neonatal Intensive Care Service in a planning area, the aggregate occupancy rate for all similar services in that planning area shall equal or exceed 75% for an Obstetric Service and 80% for a Neonatal Intermediate Care Service or Neonatal Intensive Care Service for each of the two most recent years.

(b) Exceptions to need may be considered by the Department as follows:

1. To provide that an applicant for new basic perinatal services shall not be subject to the need standard of section (3)(a)(1) or the aggregate occupancy standard of section (3)(a)(4) of this Rule if:

(i) The proposed new service would be located in a county where only one civilian health care facility or health system is currently providing basic perinatal services; and

(ii) There are not at least three (3) different health care facilities in a contiguous county providing basic perinatal services.

2. To allow expansion of an existing Level I or Level II or Level III service, if the actual utilization of that service has exceeded 80 percent occupancy over the most recent two years; or

3. To remedy an atypical barrier to perinatal services based on cost, quality, financial access, or geographic accessibility. An applicant seeking such an exception shall have the burden of proving to the Department that the cost, quality, financial access, or geographic accessibility of current services, or some combination thereof, result in a barrier to services that should typically be available to citizens in the planning area and/or the communities under review. In approving an applicant through the exception process, the Department shall document the bases for granting the exception and the barrier or barriers that the successful applicant would be expected to remedy.

(c) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care or Neonatal Intensive Care Service shall document the impact on existing and approved services in the planning area with the goal of minimizing adverse impact on the delivery system and as follows:

1. An existing perinatal physician training program shall not be adversely impacted by the establishment of a new or expanded perinatal service to the extent that the existing service could not sustain a sufficient number and variety of patients to maintain an appropriate number of providers and provider competencies and the training program's accreditation and funding status;

2. An existing nurse midwifery training program shall not be adversely impacted by the establishment of a new or expanded perinatal service to the extent that the existing service could not sustain an appropriate number of providers and provider competencies to sustain a sufficient number and variety of patients to maintain the training program's accreditation; and

3. An existing regional perinatal center shall not be adversely impacted by the establishment of a new or expanded perinatal service to the extent that the existing service could not sustain a sufficient volume and case mix of patients including both low risk and high risk deliveries to maintain its regional center status.

(d) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall foster an environment that assures access to services to individuals unable to pay and regardless of payment source or circumstances by the following:

1. providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;

2. providing a written commitment that unreimbursed services for indigent and charity patients will be offered at a standard which meets or exceeds three percent of annual gross revenues for the entire facility after Medicare and Medicaid contractual adjustments and bad debt have been deducted;

3. providing a written commitment to participate in the Medicaid program;

4. providing a written commitment to participate in any other public reimbursement programs available for perinatal services for which the hospital is eligible; and

5. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to individuals unable to pay based on the past record of service to Medicare, Medicaid, and indigent and charity patients, including the level of unreimbursed indigent and charity care.

(e) The desired minimum bed size for a Basic Perinatal Service, Neonatal Intermediate Care Service or Neonatal Intensive Care Service is as follows:

1. at least four beds for a new Basic Perinatal, Neonatal Intermediate Care, or Neonatal Intensive Care Service

2. the Department may grant an exception to these standards when the Department determines that unusual circumstances exist that justify such action.

(f) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall provide evidence of ability to meet the following continuity of care standards:

1. Document a plan whereby the hospital and its medical staff agree to provide a full array of perinatal services to the community, including but not limited to community education and outreach, prenatal, intrapartum, postpartum, newborn, and postnatal services; and

2. As appropriate, provide a formal transfer agreement with at least one hospital within reasonable proximity that provides services to high-risk mothers and babies.

(g) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall provide evidence of the ability to meet the following quality of care standards:

1. evidence that qualified personnel will be available to ensure a quality service to meet licensure, certification and/or accreditation requirements;

2. written policies and procedures for utilization review consistent with state, federal and other accreditation standards. This review shall include assessment of medical necessity for the service, quality of patient care, and rates of utilization;

3. written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Office of Regulatory Services of the Georgia Department of Human Resources; and

4. evidence that there are no uncorrected operational standards in any existing Georgia hospitals owned and/or operated by the applicant or the applicant's parent organization. Plans of correction in the applying facility must be included in the application.

(h) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall document an agreement to provide Department requested information and statistical data related to the operation and provision of services and to report that data to the Department in the time frame and format requested by the Department.

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

111-2-2-.31 Specific Review Considerations for Personal Care Homes.

(1) **Applicability.** A Certificate of Need for a personal care home will be required prior to the establishment of a new personal care home, of twenty-five beds or more, and the expansion of any personal care home which is or will be twenty-five beds or more.

(2) **Definitions.**

(a) “Health planning area” for all personal care homes, means the geographic regions in Georgia defined in the State Health Plan or Component Plan.

(b) “Horizon Year” means the last year of a three-year projection period for need determinations for a personal care home.

(c) “Official State Health Component Plan” means the document related to personal care homes developed by the Department adopted by the State Health Strategies Council, and approved by the Board of Community Health.

(d) “Personal care home” means a residential facility that is certified as a provider of medical assistance for Medicaid purposes pursuant to Article 7 of Chapter 4 of Title 49 having at least twenty-five (25) beds and providing, for compensation, protective care and oversight of ambulatory, non-related persons who need a monitored environment but who do not have injuries or disabilities which require chronic or convalescent care, including medical, nursing, or intermediate care. Personal care homes include those facilities which monitor daily residents' functioning and location, have the capability for crisis intervention, and provide supervision in areas of nutrition, medication, and provision of transient medical care. Such term does not include:

1. old age residences which are devoted to independent living units with kitchen facilities in which residents have the option of preparing and serving some or all of their own meals; or

2. boarding facilities that do not provide personal care.

(3) **Standards.**

(a)1. The numerical need for a new or expanded personal care home in a health planning area shall be determined by a population-based formula which is used to project the number of personal care home beds needed in the horizon year and which is a sum of the following:

(i) a ratio of 18.00 beds per 1,000 projected horizon year Resident population age 65 through 74;

(ii) a ratio of 40.00 beds per 1,000 projected horizon year Resident population age 75 through 84; and

(iii) a ratio of 60.00 beds per 1,000 projected horizon year Resident population age 85 and older.

2. The net numerical unmet need for personal care home beds in each health planning area shall be determined by subtracting the number of existing and approved personal care home beds in the health planning area from the projected number of personal care home beds needed in the horizon year; provided, however, that if the net numerical unmet need exceeds fifty

percent (50%) of the current existing and approved beds in the planning area, the net numerical unmet need shall be limited to fifty percent (50%) of the existing and approved beds at the time the calculation is made.

(b) The Department may allow an exception to111-2-2-.31(3)(a) as follows:

1. to allow expansion of an existing personal care home if actual utilization has exceeded ninety (90%) percent average annual occupancy based on number of licensed beds for the two year period immediately preceding application;

2. to allow expansion of an existing personal care home if the applicant has substantial occupancy by out-of-state residents. “Substantial occupancy by out-of-state residents” shall be defined as having at least thirty-three percent (33%) of the available licensed beds in the personal care home utilized by individuals who resided out side of the State of Georgia immediately prior to moving into the personal care home; or

3. to remedy an atypical barrier to personal care home services based on cost, quality, financial access, or geographic accessibility.

(c) In competing applications, favorable consideration may be given to any applicant for a new or expanded personal care home which historically has provided and/or provides sufficient documentation of plans to provide a higher percentage of un-reimbursed services to indigent and charity residents than requirement by the indigent and charity standard of 111-2-2-.31(3)(j). Favorable consideration also may be given to any applicant for a new or expanded personal care home which historically has provided and/or provides sufficient documentation of plans to provide personal care home residential services at monthly and/or annual rates that are affordable to the greatest number of individuals based on analysis of the national rate for services and the income ranges of individuals at or above age 65 and in the applicant’s market area(s).

(d) A new or expanded personal care home shall be approved in a health planning area only if the applicant complies with the following physical standards:

1. the physical plant design and the program design shall support the concept of a non-institutional, home-like setting; and

2. the proposed physical plant design is in compliance with the Rules and licensure standards of the Department of Human Resources and the applicant stipulates that the services required by such Rules and licensure standards will be provided and any services prohibited by such Rules and licensure standards will not be provided and will not be implied to be provided either through advertising or other means; and

3. there shall be a designated area for staff on duty in each personal care home and on each floor in the case of a multistory facility; and

4. the facility has the option of building kitchens or kitchenettes in the living units as long as the facility intends to provide three meals per day to residents. The kitchens or kitchenettes must comply with the Fire Marshall's and Department of Human Resources' minimum licensure standards; and

5. the facility provides assurance that it will not lease or contract space within the personal care home to an outside entity to provide services that the personal care home would otherwise not be allowed to provide.

(e) An applicant for a new or expanded personal care home must document provision of continuity of care by providing a community linkage plan which demonstrates factors such as, but not limited to, referral arrangements with appropriate services of the healthcare system and working agreements with other related community services assuring continuity of care.

(f) An applicant for a new or expanded personal care home shall provide evidence of intent to comply with all appropriate licensure requirements, resident life safety standards and

operational procedures required by the Georgia Department of Human Resources.

(g) An applicant for a new or expanded personal care home shall provide evidence of the intent and ability to recruit, hire, and retain qualified personnel and that such personnel are available in the proposed geographic service area.

(h) An applicant for a new or expanded personal care home shall provide evidence that no existing Georgia personal care home of any size owned and/or operated by the applicant, a related entity or by the applicant's parent organization has had a permit or license revoked, denied or otherwise sanctioned through formal licensure enforcement action by the Georgia Department of Human Resources within the two years immediately preceding application.

(i) An applicant for a new or expanded personal care home shall provide a plan for assuring quality of care which includes, but is not limited to, procedures and plans for staff training and a program to monitor specific quality indicators.

(j) An applicant for a new or expanded personal care home shall foster an environment which assures access to services to individuals by providing a written commitment that un-reimbursed services to residents who are indigent or meet the guidelines of a charity policy of the personal care home will be offered at a standard which meets or exceeds one percent of annual gross revenues for the personal care home after bad debt has been deducted.

(k) An applicant for a new or expanded personal care home shall agree to provide the Department with requested information and statistical data related to the operation and provision of personal care homes and to report that data to the Department in the time frame and format requested.

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

111-2-2-.33 Specific Review Considerations for Continuing Care Retirement Community (“CCRC”) Sheltered Nursing Facilities.

(1) **Applicability.** A Certificate of Need will be required prior to the establishment of a new or expanded CCRC Sheltered Nursing Facility, if not exempt as provided by O.C.G.A. § 31-6-47(a)(17) and Rule 111-2-2-.03(19). These Rules apply to sheltered nursing facilities located in CCRC facilities defined herein as Type A and Type B Continuing Care Retirement Communities. A CCRC that has obtained nursing facility beds approved under the standards contained in Rule 111-2-2-.30 does not qualify for sheltered nursing facility beds, and to convert existing nursing facility beds to sheltered nursing facility beds, such a CCRC must apply for a new Certificate of Need. Conversely, a CCRC that obtains sheltered nursing facility beds under these Rules may not qualify for beds under Rule 111-2-2-.30, and is therefore only required to complete these specific review considerations for the sheltered nursing facility beds.

(2) **Duration.** Notwithstanding 111-2-2-.02(6), the initial implementation period of a Certificate of Need granted for a new or expanded CCRC Sheltered Nursing Facility pursuant to these Rules shall be twenty-four (24) months from the effective date.

(3) **Definitions.**

(a) "A Continuing Care Retirement Community" (CCRC) is an organization which offers a contract to provide an individual of retirement status, other than an individual related by consanguinity or affinity to the provider furnishing the care, with board and lodging, licensed nursing facility care and medical or other health related services, or both. These services are provided for a minimum period of more than one (1) year and may be for as long as the lifetime of the resident.

(b) "Type A Continuing Care Retirement Community" (Type A CCRC) provides CCRC services at the same location for the life of an individual, including mutually terminable contracts, and in consideration of the payment of an entrance fee with or without

other periodic charges. A Type A CCRC offers nursing facility care for a little or no substantial increase in monthly payments, except normal operating costs and inflation adjustments.

(c) "Type B Continuing Care Retirement Community" (Type B CCRC) provides CCRC services at the same location for a period in excess of one year, including mutually terminable contracts, and in consideration of the payment of an entrance fee with other periodic charges. A Type B CCRC offers a specified amount of nursing facility care for little or no substantial increase in monthly payments except normal operating costs and inflation adjustments. After the specified amount of nursing care is received, residents pay either a discounted rate or the full per diem rate for nursing care required.

(d) "A Continuing Care Contract" means furnishing pursuant to an agreement shelter, food, and either nursing care or personal services, whether such nursing care or personal services are provided in the facility or in another setting designated by the agreement for continuing care, to an individual not related by consanguinity or affinity to the provider furnishing such care upon payment of an entrance fee. Other personal services provided shall be designated in the continuing care agreement. Agreements to provide continuing care include agreements to provide care for any duration, including agreements that are terminable by either party.

(e) "CCRC Sheltered Nursing Facility", for purposes of these Rules, is a nursing facility that meets the definition of a nursing facility as defined by section 111-2-2-.30 of the Rules of the Department. A CCRC Sheltered Nursing Facility shall be for the exclusive use of residents of a Type A or Type B CCRC.

(f) "Official State Health Component Plan" means the document related to the above-named services developed by the Department, established by the Georgia Health Strategies Council, and signed by the Governor of Georgia.

(g) "Resident" is an individual entitled to receive continuing care in a Type A or Type B Continuing Care Retirement Community.

(4) **Standards.**

(a) The numerical need for a new CCRC sheltered nursing facility shall be based on a ratio of one nursing facility bed for each five independent living units. The applicant for a CCRC Sheltered Nursing Facility shall demonstrate to the Department that the potential market for CCRC Independent Living Units in the proposed service area is based on a valid feasibility study which takes into account factors such as, but not limited to, the age and annual household income of the target population and the geographic area to be served.

(b) The numerical need for an expanded CCRC sheltered nursing facility shall be based on a ratio of one nursing facility bed for each four independent living units provided that the CCRC's existing nursing facility has experienced an occupancy rate of at least eighty percent during the most recent year.

(c) Sheltered nursing facility beds approved under these Rules shall be used exclusively for persons who are residents of the CCRC, and who are a party to a continuing care contract with the facility or the parent organization and who have lived in a non-nursing unit of the CCRC for a period of at least ninety (90) days. Exceptions shall be allowed when one spouse or sibling is admitted to the nursing unit at the time the other spouse or sibling moves into a non-nursing unit, or when the medical condition requiring nursing care was not known to exist or be imminent when the individual became a party to the continuing care contract.

(d) The applicant shall provide evidence of intent that at no time will the nursing facility be certified for participation in the Medicaid Program.

(e) A CCRC which is the applicant for a new or expanded CCRC sheltered nursing facility shall provide evidence of the intent and ability to meet all appropriate authorization and disclosure requirements of the Georgia State Department of Insurance and of any appropriate accrediting agency(ies). The CCRC shall furnish reports in such form and at such times as may

be specified, which accurately and fully disclose it has met specified requirements.

(f) A new or expanded CCRC sheltered nursing facility shall provide evidence of the intent and ability to meet all appropriate requirements regarding licensure and accreditation of the nursing facility as follows:

1. Compliance with all appropriate licensure requirements and operational procedures required by the Office of Regulatory Services of the Georgia Department of Human Resources;

2. No uncorrected operational standards in any existing Georgia general or CCRC sheltered nursing facilities owned and/or operated by the entity, its affiliates, or its principals. Plans to correct physical plant deficiencies must be provided;

3. No previous conviction of Medicaid and/or Medicare fraud by the entity, its affiliates, or its principals;

4. Provision of a plan for a comprehensive quality improvement program which includes, but is not limited to, procedures and plans for staff training and a program to monitor specific quality indicators and measure the facility's performance and patient outcomes accordingly; and

5. Intent to meet accreditation requirements of the appropriate accrediting agency(ies).

(g) A CCRC which is the applicant for a new or expanded CCRC sheltered nursing facility shall demonstrate the existence of a Health Care Fund whose liability is documented by a relevant Actuarial Study and certified by a qualified actuary; or the existence of a Long Term Care Insurance Policy issued to individual residents; or a Group Long Term Care Insurance Policy issued to the CCRC for the coverage of all residents. An Individual or Group Insurance Policy must conform to all the requirements of Chapter 120-20-16 of the Rules and Regulations of the State of Georgia Insurance Department entitled "Long Term Care Insurance Regulation". The period and scope of coverage

must be identical to the period and scope of coverage in the continuing care contract.

(h) A CCRC in which a new or expanded sheltered nursing facility is to be located shall provide the Department with requested information and statistical data related to the operation and programmatic elements of the CCRC and the Sheltered Nursing Facility. Analyses are predicated upon accurate, consistent and systematically obtained information.

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

111-2-2-.34 Specific Review Considerations for Traumatic Brain Injury Facilities.

(1) **Applicability.** The following Rules apply to Traumatic Brain Injury Facilities defined herein as providing transitional living programs and/or life long living programs.

(a) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Transitional Living Program, if not exempt as provided by O.C.G.A. § 31-6-47(a)(25) and Rule 111-2-2-.03(27). An application for Certificate of Need for a new or expanded Transitional Living Program shall be reviewed under the General Review Considerations of Rule 111-2-2-.09 and the service-specific review considerations of this Rule.

(b) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Life Long Living Program, if not exempt as provided by O.C.G.A. § 31-6-47(a)(25) and Rule 111-2-2-.03(27). An application for Certificate of Need for a new or expanded Life Long Living Program shall be reviewed under the General Review Considerations of Rule 111-2-2-.09 and the service-specific review considerations of this Rule.

(2) **Definitions.**

(a) ‘Expansion’ or ‘Expanded Service’ means increasing the number of beds in an existing Traumatic Brain Injury Facility or program; or an existing Traumatic Brain Injury Facility or program which makes expenditures which exceed the capital expenditure threshold; or an existing Traumatic Brain Injury Facility or program which seeks to add a program which it currently does not offer.

(b) "Life Long Living Program" means such treatment and rehabilitative care as shall be delivered to traumatic brain injury clients who have been discharged from a more intense level of rehabilitation, but who cannot live at home independently, and who require on-going lifetime support. Such clients are medically stable, may have special needs, but need less than 24 hour per day medical support.

(c) ‘New’ means a facility that has not operated as a Traumatic Brain Injury Facility in the previous twelve months. For purposes of these rules, an existing Traumatic Brain Injury Facility or program which proposes to be relocated to a location more than three miles from its present location shall be considered “new”.

(d) "Official State Health Component Plan" means the document related to Traumatic Brain Injury Facilities developed by the Department, established by the Georgia State Health Strategies Council and signed by the Governor of Georgia.

(e) "Planning Region" means one of the twelve state service delivery regions established by O.C.G.A. § 50-4-7.

(f) "Transitional Living Program" means such treatment and rehabilitative care as shall be delivered to traumatic brain injury clients who require education and training for independent living with a focus on compensation for skills which cannot be restored. Such care prepares clients for maximum independence, teaches necessary skills for community interaction, works with clients on pre-vocational and vocational training and stresses cognitive, speech, and behavioral therapies structured to the individual needs of clients. Such clients are medically stable, may have special needs, but need less than twenty-four (24) hour per day medical support.

(g) "Traumatic Brain Injury" means a traumatic insult to the brain and its related parts resulting in organic damage thereto that may cause physical, intellectual, emotional, social, or vocational changes in a person. It shall also be recognized that a person having a traumatic brain injury may have organic damage or physical or social disorders, but shall not be considered mentally ill.

(h) "Traumatic Brain Injury Facility" means a building or place which is devoted to the provision of residential treatment and rehabilitative care in a transitional living program or a life long living program for periods continuing for twenty-four (24) hours or longer for persons who have traumatic brain injury. Such a facility is not classified by the Office of Regulatory Services of the Georgia Department of Human Resources or the Department as a hospital, nursing home, intermediate care facility or personal care home.

(3) **Standards.**

(a) An application for a new or expanded Traumatic Brain Injury Facility or program shall provide sufficient documentation of the need for such a program in the Planning Region. In the case of an application for an expanded program, the applicant shall justify the need for the expansion by, at a minimum, documenting that the expansion program has achieved an occupancy rate of 80 percent or more for the most recent twelve (12) months prior to submitting application.

(b) An applicant for a new or expanded Traumatic Brain Injury Facility or program shall document that the establishment or expansion of its Facility or program will not have an adverse impact on existing and approved programs of the same type in its Planning Region. An applicant for a new or expanded Traumatic Brain Injury Facility or program shall have an adverse impact on existing and approved facilities or programs of the same type if it will:

1. decrease annual utilization of an existing facility or program, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than

seventy-five percent (75%) within the first twelve (12) months following the acceptance of the applicant's first patient; or

2. decrease annual utilization of an existing facility or program, whose current utilization is below eight-five percent (85%), by ten percent (10%) over the twelve (12) months following the acceptance of the applicant's first patient.

The applicant shall provide evidence of projected impact by taking into account existing planning region market share of facilities or programs of the same type and future population growth or by providing sufficient evidence that the current population is underserved by the existing Traumatic Brain Injury facility or program of the same type within the planning region.

(c) The Department may grant an exception to the need methodologies of 111-2-2-.34(3)(a) and (3)(b) to remedy an atypical barrier to the services of a Traumatic Brain Injury Facility or program based on cost, quality, financial access or geographic accessibility.

(d) Minimum bed size for a Traumatic Brain Injury Facility or program is six beds; A Life Long Living Program may not exceed thirty beds, except that an applicant for a new or expanded Life Long Living Program may be approved for total beds to exceed thirty (30) beds only if the applicant provides documentation satisfactory to the Department that the program design, including staffing patterns and the physical plant, are such as to promote services which are of high quality, are cost-effective and are consistent with client needs.

(e) An applicant for a new or expanded Traumatic Brain Injury Facility shall demonstrate the intent to meet the standards of the Commission on Accreditation of Rehabilitation Facilities (CARF) which apply to post acute brain injury programs and residential services within twenty-four (24) months of accepting its first patient. An applicant for an expanded Traumatic Brain Injury Facility or program shall be CARF-certified as of the date of its application and shall furnish proof of the certification as a part of the Certificate of Need application process.

(f) An applicant for a new or expanded Traumatic Brain Injury Facility shall demonstrate the intent to meet the licensure Rules of the Georgia Department of Human Resources for such facilities. An applicant for an expanded Traumatic Brain Injury Facility or program shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Georgia Department of Human Resources.

(g) An applicant for a new or expanded Traumatic Brain Injury Facility shall have written policies and procedures for utilization review. Such review shall consider the rehabilitation necessity for the service, quality of client care, rates of utilization and other considerations generally accepted as appropriate for review.

(h) An applicant for a new or expanded Traumatic Brain Injury Facility shall document the existence of referral arrangements, including transfer agreements, with an acute care hospital within the planning region to provide emergency medical treatment to any patient who requires such care. If the nearest acute-care hospital is in an adjacent planning region, the applicant may document the existence of transfer agreements with that hospital in lieu of such agreements with a hospital located within the planning region.

(i) An applicant for a new or expanded Traumatic Brain Injury Facility shall document that the Facility will be financially accessible by:

1. providing sufficient documentation that un-reimbursed services for indigent and charity patients in a new or expanded Facility shall be offered at a standard which meets or exceeds three (3) percent of annual gross revenues for the Facility after provisions have been made for bad debt and Medicaid/Medicare contractual adjustments have been deducted. If an applicant, or any facility owned or operated by the applicant's parent organization, received a Certificate of Need (CON) for a Traumatic Brain Injury Facility and the CON included an expectation that a certain level of un-reimbursed indigent and/or charity care would be provided in the Facility(ies), the applicant shall provide

sufficient documentation of the Facility's provision of such care. An applicant's history, or the history of any facility owned or operated by the applicant's parent organization, of not following through with a CON expectation of providing indigent and/or charity care at or above the level agreed to will constitute sufficient justification to deny an application; and

2. agreeing to participate in the Medicare and Medicaid programs, whenever these programs are available to the Facility.

(j) **Reserved.**

(k) An applicant for a new or expanded Traumatic Brain Injury Facility shall document an agreement to provide the Department requested information and statistical data related to the operation of such a Facility and to report that information and statistical data to the Department on a yearly basis, and as needed, in a format requested by the Department and in a timely manner.

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

111-2-2-.40 Specific Review Considerations for Ambulatory Surgery Services.

(1) **Applicability.** For Certificate of Need purposes, an Ambulatory Surgery Service is considered a new institutional health service if it is to be offered in an ambulatory surgery facility (ASF) or in a diagnostic, treatment, or rehabilitation center (DTRC).

(a) If the ambulatory surgery service is or will be provided as "part of a hospital", the hospital's provision of such service is not subject to Certificate of Need (CON) review under this rule. For purposes of this rule, the following are always considered to be "part of a hospital": a) if the service is located within a hospital; or, b) if the service is located in a building on the hospital's primary campus and that building, or relevant portion thereof, is included within the hospital's permit issued by the State's licensing agency,

subject to determination by the Department. The Department also will make a determination of reviewability on a case-by-case basis in other situations involving hospitals.

(b) The entity that develops any ambulatory surgery service shall be the applicant.

(c) A single specialty ambulatory surgery service will be issued a single specialty CON. A new CON will be required to become a multi-specialty service.

(d) These Rules do not apply to adult open-heart surgery, adult cardiac catheterization, pediatric cardiac catheterization, pediatric open-heart surgery, and obstetrical services because these services are covered under other CON Rules. If an ambulatory surgery service, which is part of a hospital, expands the number of ambulatory surgery operating rooms and the capital expenditure exceeds the CON threshold, the project will be reviewed under these Rules 111-2-2-.40. If an ambulatory surgery service, which is part of a hospital, involves a capital expenditure, which exceeds the CON threshold and does not increase the number of ambulatory surgery operating rooms, the project will be reviewed under the General Review Considerations (111-2-2-.09).

(2) **Definitions.**

(a) "Ambulatory surgery" means surgical procedures that include but are not limited to those recognized by the Centers for Medicare and Medicaid Services (“CMS”), the Department’s Division of Medical Assistance (“DMA”), the State Health Benefit Plans, or by any successor entities, as reimbursable ambulatory surgery procedures. Ambulatory surgery is provided only to patients who are admitted to a facility which offers ambulatory surgery and which does not admit patients for treatment that normally requires stays that are overnight or exceed twenty-four (24) hours and which does not provide accommodations for treatment of patients for periods of twenty-four hours or longer.

(b) "Ambulatory surgery facility" means a public or private facility, not part of a hospital, which provides surgical treatment

performed under general or regional anesthesia in an operating room environment to patients not requiring hospitalization. In addition to operating rooms, an ambulatory surgery facility includes all components of pre and post-operative ambulatory surgery care.

(c) "Ambulatory surgery operating room" means an operating room located either in a hospital, in an ambulatory surgery facility, or in a DTRC facility that is equipped to perform surgery and is constructed to meet the specifications and standards of the Office of Regulatory Services of the Department of Human Resources.

(d) "Ambulatory surgery service" means the provision of ambulatory surgery including pre and post-operative care to patients not requiring hospitalization. An ambulatory surgery service may be provided within any of the following types of healthcare facilities: hospitals, ambulatory surgery facilities, or DTRCs.

(e) "Ambulatory surgery services patient" means a person who makes a single visit to an operating room during which one or more surgical procedures are performed.

(f) "Authorized ambulatory surgery service" means a Department sanctioned ambulatory surgery service, which is either existing or approved prior to the date on which the Department renders a decision on a proposed project. An existing ambulatory surgery service is an authorized service, which has become operational, and an approved ambulatory surgery service is an authorized service, which has not yet become operational, including any approvals under appeal.

(g) "Diagnostic, treatment, or rehabilitation center (DTRC) facility" means, for purposes of this rule, any professional or business undertaking, whether for profit or not-for-profit, which offers or proposes to offer an ambulatory surgery service in a setting that is not part of a hospital.

(h) "Most recent year" means the most current twelve-month period within a month of the date of completion of an application or within a month of the date of completion of the first application

when applications are joined. If the Department has received an annual or ad hoc survey within six (6) months of the date of completion of the application (or first application when applications are joined), the Department may consider the report period covered in such a survey as the most recent year.

(i) "Multi-specialty ambulatory surgery service" means an ambulatory surgery service offering surgery in more than one of, but not limited to, the following specialties; dentistry/oral surgery, gastroenterology, general surgery, obstetrics/gynecology, ophthalmology, orthopedics, otolaryngology, pain management/anesthesiology, plastic surgery, podiatry, pulmonary medicine, or urology.

(j) "Not requiring hospitalization" means patients who do not require an inpatient admission to an acute care general hospital prior to receiving ambulatory surgery services, who normally would not require a stay that is overnight or exceeds twenty-four (24) hours, and who are not expected to require an inpatient admission after receiving such services.

(k) "Official inventory" means the inventory of all facilities authorized to perform ambulatory surgery services maintained by the Department based on responses to the most recent Annual Hospital Questionnaire (AHQ) Surgical Services Addendum and Freestanding Ambulatory Surgery Center Survey and/or the most recent appropriate surveys and questionnaires.

(l) "Official state component plan" means the document related to ambulatory surgery services adopted by the State Health Strategies Council, approved by the Board of Community Health, and implemented by the State of Georgia for the purpose of providing adequate health care services and facilities throughout the state.

(m) "Operating room environment" means an environment, which meets the minimum physical plant and operation standards specified on January 1, 1991, for ambulatory surgical treatment centers in Rule 290-5-33-.10 of the Rules of the Department of Human Resources.

(n) "Planning Area" means fixed sub-state regions for reviewable services as defined in the State Health Component Plan for Ambulatory Surgery Services.

(o) “Single specialty ambulatory surgery service” means an ambulatory surgery service providing surgery in only one of the specialty areas as defined in Rule 111-2-2-.40(2)(i).

(3) **Standards.**

(a) The need for an ambulatory surgery service shall be determined through application of a numerical need method and an assessment of the aggregate utilization rate of existing services.

1. The numerical need for a ambulatory surgery service shall be determined by a demographic formula which includes the number of ambulatory surgery services cases in a planning area. The following need calculation applies to each planning area:

(i) determine the projected ambulatory surgery services patients for the horizon year by multiplying the planning area ambulatory surgery patients’ rate by the total Resident population for the planning area for the horizon year;

(ii) determine the number of operating rooms needed by dividing the number of projected ambulatory surgery services patients (step i) by the capacity per operating room. Capacity per operating room per year is 1000 patients. (This is based on 250 operating room days per year (50 weeks x 5 days/weeks) x 5 patients per room per day x 80% utilization.);

(iii) determine the existing and approved inventory of ambulatory surgery operating rooms by adding:

(I) The pro-rata portion of hospital shared inpatient/ambulatory surgery operating rooms devoted to ambulatory surgery services. This portion is determined as follows:

(# ambulatory surgery patients x 90 min.)
{(ambulatory surgery patients x 90 min)+(inpatient patients x 145 min.)} x # shared rooms

(II) # of hospital dedicated ambulatory surgery operating rooms; and

(III) # of freestanding ambulatory surgery operating rooms.

(iv) determine the projected net surplus or deficit for ambulatory surgery services by subtracting the total ambulatory surgery operating rooms needed (step iii) from the inventory of existing and approved ambulatory surgery services operating rooms in the planning area.

2. Prior to approval of a new or expanded ambulatory surgery service in any planning area, the aggregate utilization rate of all existing and approved ambulatory surgery service in that planning area shall equal or exceed eighty percent (80%) during the most recent year; and

3. A proposed multi-specialty ambulatory surgery service shall have a minimum of three operating rooms and a single specialty ambulatory surgery service shall have a minimum of two operating rooms.

(b) The Department may allow an exception to the need standard referenced in (3)(a), in order to remedy an atypical barrier to ambulatory surgery services based on cost, quality, financial access, or geographic accessibility. An applicant seeking such an exception shall have the burden of proving to the Department that the cost, quality, financial access, or geographic accessibility of current services, or some combination thereof, result in a barrier to services that should typically be available to citizens in the planning area and/or the communities under review. In approving an applicant through the exception process, the Department shall document the bases for granting the exception and the barrier or barriers that the successful applicant would be expected to remedy.

(c) Each applicant shall have a hospital affiliation agreement and/or the medical director must have admitting privileges and other acceptable documented arrangements to insure the necessary backup for medical complications. The applicant must document the capability to transfer a patient immediately to a hospital with adequate emergency room services.

(d) An applicant shall submit written policies and procedures regarding discharge planning. These policies should include, where appropriate, designation of responsible personnel, participation by the patient, family, guardian or significant other, documentation of any follow-up services provided and evaluation of their effectiveness.

(e) An applicant shall provide evidence of a credentialing process that provides that surgical procedures will be performed only by licensed physicians who have been granted privileges to perform these procedures by the organization's governing body.

(f) An applicant shall assure that an anesthesiologist, a physician qualified to administer anesthesia, an oral surgeon, or a nurse anesthetist trained and currently certified in emergency resuscitation procedures is present on the premises at all times a surgical patient is present.

(g) An applicant shall submit evidence that qualified personnel will be available to insure a quality service to meet licensure, certification and/or accreditation requirements.

(h) An applicant shall submit a policy and plan for reviewing patient care, including a stated set of criteria for identifying those patients to be reviewed and a mechanism for evaluating the patient review process.

(i) An applicant shall submit written policies and procedures for utilization review consistent with state federal and accreditation standards. This review shall include review of the medical necessity for the service, quality of patient care, and rates of utilization.

(j) An applicant shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Office of Regulatory Services of the Georgia Department of Human Resources.

(k) An applicant for a new ambulatory surgery service shall provide a statement for the intent to meet, within 12 months of obtaining state licensure, the appropriate accreditation requirements of the Joint Commission for Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory surgery Facilities, Inc. (ASF) and/or other appropriate accrediting agency.

(l) An applicant for an expanded ambulatory surgery service shall provide documentation that they fully meet the appropriate accreditation requirements of the Joint Commission for Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (ASF) and/or other appropriate accrediting agency.

(m) An applicant shall provide documentation that charges are reasonable compared to other similar surgery services serving the same planning area.

(n) An applicant shall foster an environment that assures access to services to individual's unable to pay and regardless of payment source or circumstances by the following:

1. providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;

2. providing a written commitment that unreimbursed services for indigent and charity patients in the service will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the service after Medicare and Medicaid contractual adjustments and bad debt have been deducted; and

3. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant or the applicant's parent organization, of providing services to individuals unable to pay based on the past record of service to Medicare, Medicaid, and indigent and charity patients, including the level of unreimbursed indigent and charity care.

(o) An applicant for an ambulatory surgery service shall document an agreement to provide Department requested information and statistical data related to the operation and provision of ambulatory surgery and to report that data to the Department in the time frame and format requested by the Department. This information shall include, but not be limited to, any changes in number of ambulatory surgery operating rooms that may occur as a result of service expansion.

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