RULES OF
GEORGIA DEPARTMENT OF COMMUNITY HEALTH

CHAPTER 111-2
HEALTH PLANNING

CHAPTER 111-2-2
CERTIFICATE OF NEED

TABLE OF CONTENTS

Rule 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, therapeutic, or other imaging 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, therapeutic, or other imaging equipment by purchase, gift, donation, lease, transfer, or by any other legal means by or on behalf of diagnostic, treatment, or rehabilitation center; and

(b) as it relates to a health care facility, means to come into possession or control of diagnostic, therapeutic, or other imaging 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, therapeutic, or other imaging equipment threshold as applicable, 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 Ga. Comp. R. & Regs. r. 111-2-2-.03(1)-(3) and Ga. Comp. R. & Regs. r. 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, which are associated and simultaneously developed or proposed, will be presumed to be a single project.

(14) "Certificate of Need" or "CON", as defined at O.C.G.A. § 31-6-2(6), means an official finding 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 and includes, but is not limited to, the following: radiology and diagnostic imaging, such as magnetic resonance imaging and positron emission tomography (PET); 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) "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.

(19) "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.

(20) "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 percent (65%) of patients who reside outside of the State of Georgia.

(21) "Develop", as defined at O.C.G.A. § 31-6-2(14), with reference to a project, means constructing, remodeling, installing, or proceeding with a project, or any part of a project. Notwithstanding the provisions of this paragraph, 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.

(22) "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.

(23) "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 twenty-three (23) hours shall be considered a hospital for purposes of O.C.G.A. §31-6 et seq.

(24) "Effective date" means:

(a) for approved projects that have not been appealed pursuant to the appeal provisions of the Rules of the Certificate of Need Appeal Panel, the approved date;

(b) for projects, which are appealed pursuant to the appeal provisions of the Rules of the Certificate of Need Appeal Panel, 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 Ga. Comp. R. & Regs. r. 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.

(25) "Expiration date" is the date upon which a Certificate of Need expires and becomes null and void.

(26) "Functionally related diagnostic, therapeutic, or other imaging equipment" means that pieces of diagnostic, therapeutic, or other imaging 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.

(27) "General cancer hospital" means an institution which was an existing and approved destination cancer hospital as of January 1, 2019; has obtained final Certificate of Need approval for conversion from a destination cancer hospital to a general cancer hospital in accordance with O.C.G.A. § 31-6-40.3; and offers inpatient and outpatient diagnostic, therapeutic, treatments, and rehabilitative cancer care service or other services to diagnose or treat co-morbid medical conditions or diseases of cancer patients so long as such services do not result in the

offering of any new or expanded clinical health service that would require a Certificate of Need under this chapter unless a Certificate of Need or letter of determination has been obtained for such new or expanded services.

(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; freestanding emergency departments or facilities not located on a hospital's primary campus; 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, micro-hospitals, general cancer hospitals, 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 Ga. Comp. R. & Regs. r. 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 in the electronic format designated by the Department;

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.

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 by the twenty-fifth (25^{th}) calendar days of the review cycle of the first application, and whose time limits are scheduled to run from the latest date that any one of the joined applications was received.

(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. Such ambulatory surgical center shall only be utilized by physicians who are of the same single specialty, who may include physicians who are not owners or employees of the single group practice of physicians that own and operate the center; 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%). Nothing in this paragraph shall prohibit the owners of the center from entering into an arrangement with an outside entity for practice management, administrative services, or both.

(37) "Life plan 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, 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.

(38) "Medical use rights" means rights or interests in real property in which the owner of the property has agreed not to sell

or lease such real property for identified medical uses or purposes.

(a) It shall be unlawful for any health care facility to purchase, renew, extend, lease, maintain, or hold medical use rights.

(39) "Micro-hospital" means a hospital in a rural county which has at least two and not more than seven inpatient beds and which provides emergency services seven days per week and 24 hours per day.

(40) "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.

(41) "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.

(42) "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, expanded, or relocated health care facility, except as otherwise provided in O.C.G.A. § 31-6-47;

(b) **Reserved**;

(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 Ga. Comp. R. & Regs. r. 111-2-2-.03(14);

(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 except as otherwise provided in O.C.G.A. § 31-6-47 and Ga. Comp. R. & Regs. r. 111-2-2-.03 and Ga. Comp. R. & Regs. r. 111-2-2-.10;

(g) 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.

(h) The conversion of a destination cancer hospital to a general cancer hospital.

(43) "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.

(44) "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.

(45) "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.

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

(47) "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.

(48) "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.

(49) "Primary campus" means the building at which the majority of a hospital's or a remote location of a hospital's licensed and operational inpatient hospital beds are located, and includes the health care facilities of such hospital within 1,000 yards of such building. Any health care facility operated under a hospital's license prior to July 1, 2019, but not on the hospital's primary campus shall remain part of such hospital but shall not constitute such hospital's primary campus unless otherwise meeting the requirements of this paragraph.

(50) “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.

(51) “Remote location of a hospital" means a hospital facility or organization that is either created by, or acquired by, a hospital that is the main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider.

(52) "Rural county" means a county having a population of less than 50,000 according to the United States decennial census of 2010 or any future such census.

(53) "Service-specific Rule" means those rules that are part of Ga. Comp. R. & Regs. r. 111-2-2 that regard specific clinical health care services as outlined at Ga. Comp. R. & Regs. r. 111-2-2-.20 et seq.

(54) "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 and operated by the individual private physician or single group practice of private physicians who are also of a single specialty; such ambulatory surgical center shall only be utilized by physicians who are of the same single specialty, who may include physicians who are not owners or employees of the individual private physician or single group practice of private physicians that own and operate the center; 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. Nothing in this paragraph shall prohibit an individual private physician or a single group practice of private

physicians from entering into an arrangement with an outside entity for practice management, administrative services, or both.

(55) "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.

(56) "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 or a general cancer hospital.

(57) "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 The Department shall review and update the state health plan at least every five years beginning no later than January 1, 2025, to ensure the plan meets the evolving needs of the state.

(58) "Substantial equivalent of a project" means a proposal to take an action for which a letter of 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.

(59) "Threshold" means the dollar amount of capital expenditures.

(a) In calculating the dollar amounts of a proposed project for purposes of 111-2-2-.01(54) 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;

(b) The following threshold amounts are effective as of July 1, 2024:

1. **Reserved**;

2. **Reserved**;

3. The physician-owned, single-specialty, office-based ambulatory surgery center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(54) is $2.5 million;

4. The joint venture ambulatory surgical center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(36) is $5 million;

With respect to (b)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;

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 except as provided in O.C.G.A. § 31-6-47 AND Ga. Comp. R. & Regs. 111-2-2-.03 and exclusive of 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 sties.

(c) For purposes of computing the capital expenditure threshold of the physician-owned, single specialty ambulatory surgical center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.03(21) and the joint venture ambulatory surgical center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.03(22), 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 (6) 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 (6) 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 Ga. Comp. R. & Regs. r. 111-2-2-.01(42)(f), the Department shall include, but not be limited to, the following guidelines:

1. The cost of diagnostic, therapeutic, or other imaging 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, therapeutic, or other imaging 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, therapeutic or other imaging 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 determination 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, therapeutic, other imaging 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, therapeutic, or other imaging equipment", any individual components or pieces of diagnostic, therapeutic, or other imaging 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, therapeutic, or other imaging 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, therapeutic, or other imaging 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 six (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, therapeutic, or other imaging equipment is the fair market value of the diagnostic, therapeutic, or other imaging equipment, as evidenced by documentation from a reputable vendor or manufacturer.

(60) "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.

(61) "Urban county" means a county having a population equal to or greater than 50,000 according to the United States decennial census of 2010 or any future such census.

Authority: O.C.G.A. §§ 31-2 et seq., 31-6 et seq.

Rule 111-2-2-.02. Nature of Certificate of Need

(1) **Purpose**. The purpose of the Certificate of Need evaluation process is to ensure that adequate health care services and facilities are developed in an orderly and economical manner and are made available to all Georgians and that only those health care services that are found to be in the public interest shall be provided in the State. The goals are to:

(a) Review proposed health care services;

(b) Contain health costs;

(c) Promote economic value;

(d) Ensure compatibility of health care services with the needs of various areas and populations of Georgia; and

(e) Prevent unnecessary duplication or services.

(1.1) Any new institutional health service shall be required to obtain a certificate of need pursuant to O.C.G.A. 31-6 and Ga. Comp. R. & Regs. r. 111-2-2.

(2) **Contents.** The certificate, or attachments, shall specify, but not be limited to:

(a) the scope of the project;

(b) the defined location of the project;

(c) the person to whom the certificate was issued;

(d) the maximum capital expenditure, if any, which may be obligated under the certificate;

(e) the service area of the project;

(f) the valid dates;

(g) the schedule of time periods to be followed in making the service or equipment available or in completing the project;

(h) the services or units of services, which have been approved; and

(i) when the progress reporting requirements under Ga. Comp. R. & Regs. r. 111-2-2-.04(2) and Ga. Comp. R. & Regs. r. 111-2-2-.02(5) are due.

(3) **Validity.** A Certificate of Need shall be valid only for the defined scope, physical location, cost, service area, and person named in the application as the applicant.

(4) **Non-transferability.** A Certificate of Need shall not be transferable or assignable, nor shall a project for which a Certificate of Need has been issued be transferred from or assigned by one person to another, except under the following circumstances:

(a) the death of the holder of the Certificate, provided the transfer is solely from the estate of the holder to his or her heirs; or

(b) an existing licensed health care facility to which a Certificate has been issued is acquired by another person, in which instance the Certificate shall be valid for the person who acquires the facility and for the scope, location, cost, and service area previously approved by the Department.

(5) **Effective Period.** Unless otherwise provided by a service-specific rule, or unless the Department in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.02(7) has extended the effective period, the effective period of a Certificate of Need shall be as follows:

(a) Certificates involving neither construction nor equipment acquisition shall be effective for twelve (12) months;

(b) Certificates solely involving acquisition of equipment shall be effective for twelve (12) months, by which date the applicant must be in possession of the equipment; and

(c) Certificates for projects involving construction shall be effective based on a reasonable, phased timetable presented in the application, which may be amended during the review cycle, as planned, developed, proposed, and submitted by the applicant. In determining the reasonableness of the proposed phases and time periods, the Department will be guided by the applicable horizon year for the project. However, in appropriate circumstance, the Department may approve an effective period in excess of the applicable horizon year. The approved and valid phases and effective period shall be included in the Certificate of Need. When the Department extends the effective period pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.02(7) or when, due to an appeal of a project, a project's effective date is not the approved date, the Department will update the effective period, including the horizon year, of the project accordingly.

(6) **Initial 12-month Implementation Period for Projects Involving Construction.** Unless otherwise provided in a service-specific rule or unless the Department in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.02(7) has extended the initial 12-month implementation period, all projects involving construction regardless of the dollar amount must, within twelve (12) months of the effective date of the certificate, demonstrate, as evidenced by a progress report (as described at Ga. Comp. R. & Regs. r. 111-2-2-.04(2) and supporting documentation, substantial performance in beginning the project. Substantial performance shall be demonstrated by the following:

(a) The construction plans have been approved by the Department's Architect;

(b) The construction contract has been signed and specifically indicates beginning and completion dates; and

(c) Construction materials and equipment are on site.

(7) Extension of Time Periods. The Department may, upon written request of the certificate holder, grant an extension of the effective period of a Certificate of Need or of the initial 12-month

implementation period if the applicant's request is received by the Department 30 days prior to expiration of the Certificate of Need or of the initial 12-month implementation period, as applicable.

(a) A request for an extension of the initial 12-month implementation period, or any extension thereof, shall demonstrate:

1. that failure to perform as required is caused by circumstances beyond the control of the certificate holder. Occurrences that may justify an extension of the initial 12-month implementation period may include, without limitation, fire, flood, explosion, catastrophic weather conditions, riots or other civil disturbances, work stoppages or strikes, zoning or permitting changes, and similar occurrences. Ordinarily, lack of adequate or accurate planning, uncertainty as to reimbursement and/or financial difficulties will not justify an extension of the implementation period;

2. that the certificate holder has made substantial and timely progress in implementing the project. In order to show substantial and timely progress in implementing the project, the certificate holder must show that the project was on schedule and could reasonably have been implemented during the initial 12-month implementation period or extension thereof, but for the occurrence or circumstance beyond the certificate holder's control;

(b) A request for an extension of the effective period of a Certificate of Need, or any phase or extension thereof, shall:

1. demonstrate that failure to perform as required is caused by circumstances beyond the control of the certificate holder. Occurrences that may justify an extension of the effective period, or any phase or extension thereof, may include, without limitation, fire, flood, explosion, catastrophic weather conditions, riots or other civil disturbances, work stoppages or strikes, zoning or permitting changes, and similar occurrences.

2. demonstrate that but for the circumstance beyond the control of the certificate holder, the project, or phase thereof, would have been completed within the effective period;

3. demonstrate that the certificate holder has made substantial and timely progress in completing the project, or phase thereof;

4. indicate the expected completion date of the project, or phase thereof, as applicable; and

5. affirm that the project, or phase thereof, will be completed within the requested extension period.

(c) The length of an extension of the effective period or of the initial 12-month implementation period of a Certificate of Need shall be determined by the Department and shall be reasonable and consistent with the circumstances. In no case, shall the Department extend the initial 12-month implementation period of a Certificate of Need beyond an additional 12 months.

(d) In circumstances where the certificate holder is precluded from normal progression due to litigation involving the Certificate or where the method of financing is precluded by litigation, the Department may, at its discretion, suspend any or all of the time periods specified herein until the litigation has been resolved.

(8) **Expiration and Cancellation**. If, within the effective period specified in Ga. Comp. R. & Regs. r. 111-2-2-.02(5) and initial 12-month implementation period specified in Ga. Comp. R. & Regs. r. 111-2-2-.02(6), as applicable, the required performance standards are not met, the Certificate will be deemed to have expired unless an extension has been obtained from the Department pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.02(7). Unless the certificate holder demonstrated good cause not to deem the Certificate to have expired, which shall be determined by the Department, the Certificate will be canceled and notifications of same issued to the applicant, local governing authorities, Regional Development Center, and a newspaper of

general circulation in the area where the application originated. An applicant whose Certificate has expired may not resubmit an application for the same or a substantially similar project until at least 120 days after expiration of the Certificate.

(9) **Modification by Operation of Law of Certificate for Failure to Complete**. Upon expiration of the effective period, if a certificate holder has not completed all activities or has not implemented all services or units of services granted in the Certificate of Need issued on the approved date (or if appealed, the effective date), the Certificate shall be modified upon such expiration to include and be valid for only those activities, services, or units of services, which have been completed and implemented as of the date of expiration.

Authority: O.C.G.A. §§31-2 et seq., 31-6 et seq.

Rule 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 Ga. Comp. R. & Regs. r. 111-2-2-.01(54) and Ga. Comp. R. & Regs. r. 111-2-2-.01(42)(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. Section 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 restructuring or acquisition of existing health care facilities by stock or asset purchase, merger, consolidation, or other lawful means;

(11) the purchase of a closing hospital or of a hospital that has been closed for no more than twelve (12) months by a hospital in a contiguous county to repurpose the facility as a micro-hospital;

(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 Healthcare Facility Regulation Division, or to comply with accreditation standards of the Joint Commission or another nationally recognized health care accreditation body;

(13) all cost overruns are excluded from prior Certificate of Need review and approval

(14) increases in the bed capacity of a hospital up to ten beds or twenty percent (20%) of capacity, whichever is greater, in any consecutive three-year period, in a hospital that has maintained an overall occupancy rate greater than sixty percent (60%) (exclusive of any skilled nursing units or comprehensive inpatient rehabilitation units) for the previous twelve (12) month period;

(15) The acquisition, replacement, or repair of diagnostic therapeutic, or other imaging equipment by any health care facility in existence prior to July 1, 2024, that is not owned by a group practice of physicians or a hospital and that provides diagnostic imaging services so long as it does not result in the offering of any new clinical health services;

(16) An 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 therein;

(17) 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;

(18) 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 five (5)-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;

(19) Expenditures for nonclinical projects, including parking lots, parking decks, and other parking facilities; computer systems, software, and other information technology; medical office buildings; administrative office space; conference rooms; education facilities; lobbies; common spaces; clinical staff lounges and sleep areas; waiting rooms; bathrooms; cafeterias; hallways; engineering facilities; mechanical systems; roofs; grounds; signage; family meeting or lounge areas; other nonclinical physical plant renovations or upgrades that do not result in new or expanded clinical health services; and state mental health facilities;

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

(21) 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 $2.5 million; 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, and on or after January 1, 2026, in an amount equal to or greater than the minimum amount established by the Department shall be reviewed by the Department every 12 months; 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 on or after January 1, 2026, in an amount equal to or greater than the minimum amount established by the

Department which shall be reviewed by the Department every 12 months; 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;

(22) 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 million;

(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, and on or after January 1, 2026, in the amount equal to or greater than the minimum amount established by the Department, which shall be reviewed by the Department every 12 months; 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 on and after January 1, 2026, in an amount equal to or greater than the minimum amount established by the Department which shall be reviewed by the Department every 12 months; 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;

(23) 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;

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

(25) Therapeutic cardiac catheterization in hospitals meeting the following criteria:

A hospital that wishes to receive authorization to perform therapeutic cardiac catheterization procedures must:

1. submit a request for a letter of determination on the required form with the proper filing fee between May 1 and May 15 of each year, beginning with calendar year 2009; the sufficiency of the information submitted in the request shall be determined within the administrative discretion of the Department;

2. provide documentation which demonstrates it can perform a minimum of two hundred (200) percutaneous cardiac interventions (PCI) per year by the beginning of the third year of operation of a program, including both elective and primary PCI, with a minimum of thirty-six (36) primary PCI per year beginning the third year of operation;

3. provide documentation to support the criteria referenced in subsection 2 above that includes substantive information on the number of diagnostic cardiac catheterization procedures performed at the hospital, or referred to existing PCI providers by the hospital, in or out of the state of Georgia, in the two (2) calendar years immediately preceding the request;

4. provide documentation that it will have, prior to beginning a PCI program, on active medical staff, at least one (1) interventional cardiologist who will meet the American College of Cardiology (ACC) and American Heart Association (AHA) competency standards, including the performance of at least seventy-five (75) PCI procedures per year;

5. provide documentation that the interventional cardiologist is board certified, or is in the process at the time of the request, of obtaining board certification in Interventional Cardiology from the American Board of Internal Medicine;

6. provide documentation of access to at least one (1) other interventional cardiologist who meets the criteria of subsections 4. and 5. above, to participate in its program on an as-needed basis as determined by the hospital;

7. agree to report annually the data on number of PCI procedures, type, and outcomes to the National Cardiovascular Data Registry Cath/PCI registry;

8. provide documentation to show that one (1) or more interventional cardiologist(s), as qualified in subsections 4., 5. and 6. above, are available to perform primary PCI procedures twenty-four (24) hours a day, seven (7) days a week, three hundred sixty-five (365) days a year;

9. provide documentation one (1) or more interventional cardiologist(s) are required to respond to a call, within the calendar availability specified in subsection 8. above, within sixty (60) minutes;

10. provide documentation that competent and trained nursing and technical cardiac catheterization staff are available at all times and are required to respond in a manner determined by the hospital in conjunction with the interventional cardiologists;

11. provide documentation of a transfer agreement with a tertiary medical facility that has an open heart surgery service to which a patient can be transferred when necessary within a period of sixty (60) minutes, by any means of transportation as chosen by the hospital, from the time the need for transfer is identified;

(i) if the provider of an open heart surgery service within the travel time parameters of this subsection refuses to enter into a transfer agreement with the requesting hospital, the hospital may

submit documentation on the reasons given for the denial, and the Department may consider these reasons;

(ii) the Department may allow a requesting hospital to submit a transfer agreement with a provider of an open heart surgery service that is beyond the travel time parameters in this subsection if the reasons given for the denial of a transfer agreement by the tertiary provider are determined by the Department to be unreasonable;

(iii) if the Department determines the reasons for the denial of a transfer agreement by the tertiary provider within the time travel parameters in this subsection are reasonable, the Department may require the requesting hospital to address the reasons for the denial and enter into further negotiations for a transfer agreement prior to receiving a favorable determination from the Department;

12. provide documentation of an agreement with an ambulance service capable of advanced life support and intra aortic balloon pump services and that guarantees a thirty (30) minute or less response time;

13. agree to provide accurate and timely data, including outcomes analysis and formal periodic external and internal case review as required by the Department;

14. provide documentation to show that guidelines for determining patients appropriate for PCI procedures in a setting without on-site open heart backup consistent with C-PORT and ACC standards will be developed and maintained;

15. provide documentation to show the cardiac catheterization laboratory(s) at the requesting hospital is equipped in a manner consistent with C-PORT and ACC guidelines;

16. agree to participate in an elective and primary PCI Development Program at its expense, the successful completion of which will be verified by the Department through the use of an identified third-party; and

17. affirmatively agree authorization to begin a therapeutic cardiac catheterization program is expressly contingent upon successful completion of the development program as referenced in subsection 16. above.

18. no hospital shall unreasonably deny a transfer agreement with another hospital.

(b) Any hospital approved to perform therapeutic cardiac catheterization procedures as a result of a request submitted between May 1 and May 15 of any calendar year after the adoption of this rule, must, between May 1 and May 15, of each subsequent year, submit a request which documents its compliance with the standards of this Rule, and the Department must re-affirm the hospital's current compliance in writing in order for the hospital to continue its therapeutic cardiac catheterization program.

(c) Any administrative proceeding held pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.10(6), in opposition to a Department approval of a request from a hospital to perform therapeutic cardiac catheterization procedures in accordance with the standards established in this section, or in opposition to a Department decision to deny a hospital request to perform therapeutic cardiac catheterization procedures, shall not conduct a de novo review of the Department decision, and such decision shall only be reversed by an administrative hearing officer upon a showing the Department's action was without reason, arbitrary, or capricious;

(26) Infirmaries for 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;

(27) The relocation of any skilled nursing facility, intermediate care facility, or micro-hospital 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 five-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;

(28) 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;

(29) The renovation, remodeling, refurbishment, or upgrading of a health care facility, so long as the project does not result in any of the following:

(a) The offering of any new or expanded clinical health services;

(b) Any increase in inpatient bed capacity;

(c) Any redistribution of existing beds among existing clinical health services; or

(30) The acquisition of diagnostic, therapeutic, or other imaging equipment, by or on behalf of:

(a) A hospital; or

(b) An individual private physician or single group practice of physicians exclusively for use on patients of such private physician or single group practice of physicians and such private physician or member of such single group practice of physicians is physically present at the practice location where the diagnostic or other imaging equipment is located at least seventy-five percent (75%) of the time that the equipment is in use.

(31) Any capital expenditures by a hospital at such hospital's primary campus for:

(a) The expansion or addition of the following clinical health services: operating rooms, other than dedicated outpatient operating rooms; medical-surgical services; gynecology; procedure rooms; intensive care; pharmaceutical services; pediatrics; cardiac care or other general hospital services; provided, however, that such expenditure does not include the expansion or addition of inpatient beds or the conversion of one type of inpatient bed to another type of inpatient bed; or

(b) The movement of clinical health services from one location on the hospital's primary campus to another location on such hospital's primary campus.

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.

(32) New or expanded psychiatric or substance abuse inpatient programs or state funded beds that serve Medicaid and uninsured patients that:

(a) Are open 365 days per year, seven days per week, and 24 hours per day;

(b) Provide uncompensated indigent and charity care in an amount equal to or greater than 3 percent of its adjusted gross revenue, and on and after January 1, 2026, in an amount equal to or greater than the minimum amount established by the department by rule which shall be at least 3 percent, and which shall be reviewed by the department every 12 months;

(c) Participate as providers of medical assistance for Medicaid purposes;

(d) Have hospital affiliation agreements with acute care hospitals within a reasonable distance from the programs or state funded beds or the medical staffs at the programs or state funded beds have admitting privileges or other acceptable documented arrangements with such hospitals to ensure the necessary backup for the programs or state funded beds for medical complications. The programs or state funded beds shall have the capability to transfer a patient immediately to a hospital within a reasonable distance from the programs or state funded beds with adequate emergency room services. Acute care hospitals shall not unreasonably deny a transfer agreement or affiliation agreement with the programs or state funded beds;

(e) Provide annual reports in the same manner as in accordance with Code Section 31-6-70

Noncompliance with any condition of this subsection shall result in a monetary penalty in the amount of the difference between the services which the exemption holder is required to provide and the amount actually provided and shall be subject to revocation of its exemption status by the Department for repeated failure to meet any one or more requirements for exemption, for repeated failure to pay any fines or moneys due to the Department, or for repeated failure to produce data as required by Code Section 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." "Expanded" means exceeding a health car facility's total approved inpatient bed capacity through the addition of beds to an existing CON-authorized or exempt or grandfathered freestanding psychiatric and/or substance abuse hospital.

(33) The offering of new or expanded basic perinatal services, as defined in Ga. Comp. R. & Regs. r. 111-2-2-.24(2)(a), by a hospital in a rural county, as defined at Ga. Comp. R. & Regs. r. 111-2-2-.24(2)(k) provided that:

(a) Such services are available 365 days per year, seven days per week, and 24 hours per day;

(b) The hospital participates as a provider of medical assistance for Medicaid purposes;

(c) The hospital has a hospital affiliation agreement with an acute care hospital with at least Level III perinatal services, as defined in Ga. Comp. R. & Regs. r. 111-2-2-.24(2)(c), within a reasonable distance from the hospital providing the perinatal services or the medical staff at the hospital providing the perinatal services has admitting privileges or other acceptable documented arrangements with such acute care hospital to ensure the necessary backup for the hospital providing the perinatal services for medical complications. The hospital providing the perinatal services shall have the capability to transfer a patient immediately to the acute care hospital within a reasonable distance from the hospital providing the perinatal services with adequate emergency room services. Acute care hospitals shall not unreasonably deny a transfer agreement or affiliation agreement with the hospital providing the perinatal services. This subparagraph shall not apply if the hospital providing the basic perinatal services is itself an acute care hospital with at least Level III perinatal services; and

(d) Provides annual reports in the same manner and in accordance with Code Section 31-6-70;

Noncompliance with any condition of this subsection shall result in a monetary penalty in the amount of the difference between the services which the exemption holder is required to provide and the amount actually provided and shall be subject to revocation of its exemption status by the Department for repeated failure to meet any one or more requirements for the exemption, for repeated failure to pay any fines or moneys due to the Department, or for repeated failure to produce data as required by ode Section 31-6-70 after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the “Georgia Administrative Procedures Act.”

(33.1) Any new or expanded building or facility where human births occur on a regular and ongoing basis and which is classified

as a birthing center pursuant to Ga. Comp. R. & Regs. r. 111-8-7 *et seq.*, provided that:

(a) Services are available 365 days per year, seven days per week, and 24 hours per day;

(b) The birthing center participates as a provider of medical assistance for Medicaid purposes;

(c) The birthing center has a hospital affiliation agreement with an acute care hospital with at least Level III perinatal services within a reasonable distance from the birthing center or the medical staff at the birthing center has admitting privileges or other acceptable documented or medical arrangements with such acute care hospital to ensure the necessary backup for the birthing center for medical complications. The birthing center shall have the capability to transfer a patient immediately to the acute care hospital within a reasonable distance from the birthing center. Acute care hospitals shall not unreasonably deny a transfer agreement or affiliation agreement with the birthing center;

(d) The birthing center:

1. Provides basic perinatal services, as defined at Ga. Comp. R. & Regs. r. 111-2-2-.24(2)(a), which shall include but not be limited to a combination of such services as determined by the department;

2. Meets the standards for certification established by the American Association of Birthing Centers, or equivalent or higher standards as determined by the department;

3. Schedules routine visits and visits with other appropriate providers, as necessary, and tracks patients to verify that services have been received;

4. Prior to 20 weeks gestation, certifies that a patient has been deemed to be a low risk patient, as defined by the department for purposes of this paragraph;

5. Admits and provided services only to patients certified as low risk; and

6. Refers patients to other appropriate providers if, at any point between the 20 weeks gestation certification and antepartum, the birthing center determines that a patient no longer qualifies as a low risk patient for any reason; and

(e) The birthing center provides annual reports in the same manner and in accordance with Code Section 3-6-70;

(f) For purposes of this exemption, “expanded” means any capital renovation or construction project which results in the addition of a birth room as defined at Ga. Comp. R. & Regs. r. 111-8-7-.01(c). Noncompliance with any condition of this subsection shall result in a monetary penalty in the amount of the difference between the services which the exemption holder is required to provide and the amount actually provided and shall be subject to revocation of its exemption status by the Department for repeated failure to meet any one or more requirements for the exemption, for repeated failure to pay any fines or moneys due to the Department, or for repeated failure to produce data as required by Code Section 31-6-70 after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of the Title 50, the “Georgia Administrative Procedure Act.”

(34) A new general acute care hospital in a rural county, as defined at Ga. Comp. R. & Regs. r. 111-2-2-.20(2)(l) that:

(a)

1. Attains status as a teaching hospital, as defined in Ga. Comp. R. & Regs. r. 111-2-2-.20(2)(p) withing 36 months of opening, and maintains such status thereafter; or

2. Obtains verification as a Level I, II, III, or IV trauma center from the American College of Surgeons within 36 months of opening, and maintains such verification thereafter;

(b) Provides emergency, inpatient, and outpatient psychiatric and behavioral health services;

(c) Has an emergency department that is open 365 days per year, seven days per week, and 24 hours per day;

(d) Provides uncompensated indigent and charity care in an amount equal to or greater than 3 percent of its adjusted gross revenue, and on and after January 1, 2026, in an amount equal to or greater than the minimum amount established by the department by rule which shall be no less than 3 percent and which shall be reviewed by the department every 12 months;

(e) Participates as a provider of medical assistance for Medicaid purposes; and

(f) Provides annual reports in the same manner and in accordance with Code Section 31-6-70;

Noncompliance with any condition if this subsection shall result in a monetary penalty in the amount of the difference between the services which the exemption holder is required to provide and the amount actually provided and ball be subject to revocation of its exemption status by the Department for repeated failure to meet any one or more requirements for the exemption, for repeated failure to pay any fines or moneys due to the Department, or for repeated failure to produce data as required by Code Section 3-6-70 after the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the “Georgia Administrative Procedure Act.”

(35) A new acute care hospital where a short-stay general hospital in a rural county, as defined at Ga. Comp. R. & Regs., R. 111-2-2-.20(2)(i), has been closed for more than 12 months and a new replacement hospital has not opened that:

(a) Is locates in the same rural county where the short-stay general hospital was closed;

(b) Has no more than the number of licensed beds that were previously licensed in the closed hospital;

(c) Has an emergency department that is open 365 days per year, seven days per week, and 24 hours per day;

(d) Providers all required clinical health services as generally offered by a short-stay general hospital to meet licensure requirements pursuant to Ga. Comp. R. & Regs. r. 111-8-40 *et seq*.; and

(e) Providers uncompensated indigent and charity care in an amount equal to or greater than 3 percent of its adjusted gross revenue, and on and after January 1, 2026, in an amount equal to or greater than the minimum amount established by the department by rule which shall be no less than 3 percent and which shall be reviewed by the department every 12 months.

Such acute care hospital may provide basic perinatal services as defined at Ga. Comp. R. & Regs. 111-2-2-.24(2)(a);

(36) A new short-stay general hospital to address the underserved population previously served by a short-stay general hospital that was closed within the 48 months preceding the filing of a request for a letter of determination that:

1. Is located within a county with a population of more than 1 million according to the United States decennial census of 2020 or any future such census:

2. Is located within five miles of and in the same county as the main campus of a medical school that is accredited by the Liaison Committee on Medical Education to confer Doctor of Medicine (M.D.) degrees;

3. Has in place at the time of filing of a request for a letter of determination a written agreement to serve as a teaching hospital, as defined at Ga. Comp. R. & Regs. r. 111-2-2-.20(2)(p), for students of the medical school described in division (ii) of this paragraph;

4. Has a maximum number of short-stay general hospital beds not greater that 50 percent of the maximum number of short-stay general hospital beds for which the closed short-stay general hospital had previously been licensed at any time during the 12 months prior to its closure;

5. Has an emergency Department that is open 365 days per year, seven days per week, and 24 hours per day; and

6. Provides uncompensated indigent and charity care in an amount equal to or greater than 3 percent of its adjusted gross revenue, and on and after January 1, 2026, in an amount equal to or greater than the minimum amount established by the department by rule which shall be no less than 3 percent and which shall be reviewed by the Department every 12 months;

(b) An exemption for a new short-stay general hospital under this subsection shall include an exemption for all clinical services and equipment generally utilized at an acute care short-stay general hospital and required for licensure, including, but not limited to, an emergency department; Level II perinatal/neonatal services, including labor, delivery, recovery, and Level II neonatal intermediate care services; diagnostic imaging services; and surgical services; and

(c) For a period of ten years following the issuance of its original license, a new short-stay general hospital approved for an exemption pursuant to this subsection shall be entitled to one or more determinations from the department to add additional short-stay general hospital beds, so long as the total licensed capacity of such hospital does not exceed the maximum number of short-stay general hospital beds for which the closed short-stay general had previously been licensed at any time during the 12 months prior to its closure; and

(37) Transfer of existing beds from one general acute care hospital's primary campus to another general acute care hospital's primary campus within the same hospital system within a 15-mile

radius of the original campus, provided that all of the following are satisfied:

(a) Both hospitals involved in the transfer are general acute care hospitals and neither is a specialty hospital;

(b) Both hospitals involved in the transfer are under common ownership or control;

(c) The transferring hospital may not, for a period of 12 months after the transfer is effective, seek to expand the bed type which was transferred; and

(d) The transferring hospital is open and operational at the time of transfer and shall not close within 12 months after the transfer is effective.

(e)Written notice is provided to the Department within thirty (30) calendar days of the transfer confirming the number and types of beds transferred and that the transfer complies with all the requirements of this subsection.

Authority: O.C.G.A. §§31-2 et seq., 31-6 et seq.

Rule 11-2-2-.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. §3 1-6 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 non-reviewability 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 $2,000.00 per day for every day up to thirty (30) days and $5,000.00 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 Ga. Comp. R. & Regs. r. 111-2-2-.05.

(i) The Department shall make publicly available all annual reports submitted pursuant to O.C.G.A. § 31-6-70 on the Department website. The Department shall also provide a copy of such annual reports to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the chairpersons of the House Committee on Health and Human Services and the Senate Health and Human Services Committee.

(j) All health care facilities, ambulatory surgical centers, and imaging centers required to submit an annual report pursuant to O.C.G.A. § 31-6-70(a) shall make such annual reports publicly available on their websites.

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

(a) All entities receiving a Certificate of Need shall maintain a valid and accurate mailing and electronic mail 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 sends such notification, notice, or letter to the mailing or electronic mail 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 Ga. Comp. R.

& Regs. r. 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 condition(s) of approval, if any, have been satisfactorily met.

Authority: O.C.G.A. §§31-2 et seq., 31-6 et seq.

Rule 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 (12) 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 outlined in or on the certificate granted, in a timely manner as also outlined 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 Ga. Comp. R. & Regs. r. 111-2-2-.02(4);

6. 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;

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

8. 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 Ga. Comp. R. & Regs. r. 111-2-2-.04;

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

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

11. 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 date it is sent electronically by the Department. 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 Healthcare Facility Regulation Division. 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 (180th) 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.

(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 Ga. Comp. R. & Regs. r. 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 Healthcare Facility Regulation Division.

(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 Ga. Comp. R. & Regs. r. 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 et seq. 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 et seq. 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 Ga. Comp. R. & Regs. r. 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. §§31-2 et seq., 31-6 et seq.

Rule 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 ca re facility, as provided in O.C.G.A. § 31-6-40(a) and (b), must submit a letter of intent notifying the Department of their intent to do so at least twenty-five (25) days prior to submission of the Certificate of Need application. The notice must be in writing, must be submitted via the Department's web portal, 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 Ga. Comp. R. & Regs. r. 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 twenty-five (25) calendar days after the letter of intent has been received by the Department. In the event that the twenty-fifth (25th) calendar day falls either on a weekend or a legal holiday, the twenty-fifth (25th) 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 letter 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 Healthcare Facility Regulation Division of no uncorrected licensure operational standards in the applicant's facility, if applicable.

(3) **Submittal of Applications.**

(a) Using the Department's web portal, Applicants should submit one (1) copy of the application signed by the applicant or the legal representative of the applicant. Failure to do so will result in non-acceptance 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 Ga. Comp. R. & Regs. r. 111-2-2-.06(4)(d) and Ga. Comp. R. & Regs. r. 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. **Reserved**.

(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 (6) months of the submittal of the Certificate of Need application) appraisal of the property.

(c) Payment of the fee shall be by credit/debit card via the Department's website, 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 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) The Department will have 120 days to review an application, beginning on the day the application is received.

(b) The Department shall notify the applicant with seven (7) calendar 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 sent electronically by the Department.

(c) The Department shall notify the applicant no later than seven (7) calendar days following receipt of the additional information whether such additional information is sufficient to complete the application.

(d) The Department will deem an application to be withdrawn if the applicant fails to provide the Department with information sufficient to complete the application, as requested on a notice of incompleteness, by the 15th calendar of the review cycle.

(e) 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 Ga. Comp. R. & Regs. r. 111-2-2-.06(2)(e);

(ii) financial program to meet the requirements of Ga. Comp. R. & Regs. r. 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 Ga. Comp. R. & Regs. r. 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 Ga. Comp. R. & Regs. r. 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 Ga. Comp. R. & Regs. r. 111-2-2-.06(2)(j) and (k);

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

2. signature of the applicant;

3. payment of the filing fee, as described in Ga. Comp. R. & Regs. r. 111-2-2-.06(4);

4. 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 to Department;

5. 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;

6. 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.

7. 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;

8. all post-approval reporting requirements as mandated at Ga. Comp. R. & Regs. r. 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;

9. the written vendor lobbyist certification required by Ga. Comp. R. & Regs. r. 111-1-2-.03(2);

10. 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

11. 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.

12. No applicant for a new Certificate of Need, a modification to an existing Certificate of Need, or a conversion of a Certificate of Need that has any outstanding amounts owed to the state including fines, penalties, fees, or other payments for noncompliance with any requirements contained in O.C.G.A. §§ 31-6-40.1, 31-6-45.2, 31-6-70, 31-7-280, or 31-8-179.2 shall be eligible to receive a new Certificate of Need or a modification to an existing Certificate of Need unless such applicant pays such outstanding amounts to the state. Any such fines, penalties, fees, or other payments for noncompliance shall be subject to the same notices and hearing for the levy of fines under O.C.G.A. § 31-6-45.

(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 (3%) 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. §31-6-1 *et seq*, all information and documents shall be submitted electronically through the Department’s designated web portal. 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.

Rule 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.

(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 beginning on the day the Department receives the application until the date the decision to issue or not to issue a Certificate of Need is sent electronically to the applicant. Absent good cause, the Department generally will not issue a decision prior to the sixtieth (60th) day of the review cycle.

(c) In the event that, from the time an application is received until the twenty-fifth (25th) calendar day of the review cycle, 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 received. Except as otherwise provided in Ga. Comp. R. & Regs. r. 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 thirty (30) days 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 thirtieth (30th) 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 thirty (30) 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 thirty (30) day meeting. Such addition information must be submitted on or before the forty-fifth (45th) 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 on or before the thirtieth day 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 on or before the forty-fifth (45th) 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 ninetieth (90th) 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 five 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 Ga. Comp. R. & Regs. r. 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 ninetieth (90th) day of the review cycle.

(g.1) No party may oppose an application for a Certificate of Need for a proposed project unless:

1. Such party offers substantially similar services as proposed within a 35 mile radius, in Georgia, of the proposed project or has a service area in Georgia that overlaps the applicant's proposed service area; or

2. Such party has submitted a competing application in the same batching cycle and is proposing to establish in Georgia the same type of facility proposed or offers, in Georgia, substantially similar services as proposed and has a service area located in Georgia that overlaps the applicant's proposed service area.

(h) Any party, pursuant to O.C.G.A. § 31-6-43(d)(2), who is permitted to oppose an application, or an application(s) joined for review, must submit a notice of opposition, on the form provided by the Department, no later than the thirtieth (30th) day of the 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 Ga. Comp. R. & Regs. r. 111-1-2-.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 sixtieth (60th) 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 submit via the Department's web portal, substantive written comments and arguments regarding the nature of their opposition to the particular project. The opposition parties must 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. Applicants shall be given the opportunity to submit final amendments and/or letters of support for a particular application pursuant to and in compliance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6) via the Department's web portal no later than the ninetieth (90^{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 respond to the opposition meeting comments shall be the seventy-fifth (75th) 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 seventy-fifth (75th) day of the review cycle.

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

(i) The Department, in accordance with the provisions of subsections (k)-(m) below, will give special expedited consideration to the emergency offering of services 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 approval based on a request by telephone, with written documentation to be provided later. In the event that the approval 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) Reserved;

(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 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, the term "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 received; failure to issue the decision on or before the thirtieth (30th) day after it has been received 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 Ga. Comp. R. & Regs. r. 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 Ga. Comp. R. & Regs. r. 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 Ga. Comp. R. & Regs. r. 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 Governor's 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 issued no later than one hundred twenty (120) days beginning on the day the Department receives the application unless the total review period is extended in accordance with Ga. Comp. R. & Regs. r. 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; and

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 Ga. Comp. R. & Regs. r. 111-2-2-.07(1)(d), beginning on the day the Department receives the application, or the last of any applications joined pursuant to Ga. Comp. R. & Regs. r. 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 Ga. Comp. R. & Regs. 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. §§31-2 et seq., 31-6 et seq.

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

(1) **Batching Review Process**

(a) Pursuant to O.C.G.A. § 31-6-43(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 (6) 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 Ga. Comp. R. & Regs. r. 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, submitted via the Department's web portal, 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 twenty-fifth (25th) calendar day following the date that the Department publishes the determination of unmet need. In the event that the twenty-fifth (25th) calendar day falls on either a weekend or a legal holiday, the twenty-fifth (25th) 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 use the Department's web portal to submit an 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 only be deemed properly submitted and complete if the following requirements, in addition to the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.06(5)(b), are met:

1. The appropriate Certification Statement of Completeness is submitted simultaneously with the original application; and

2. All of the items addressed in the Certification Statement of Completeness 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 twenty-fifth (25th) calendar day following the date that the Department receives the notice of intent (in the event that the twenty-fifth (25th) calendar day falls either on a weekend or a legal holiday, the twenty-fifth (25th) 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 Ga. Comp. R. & Regs. r. 111-2-2-.08(1)(d) above.]

3. On or before the thirtieth (30th) 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 forty-fifth (45th) day of the batching review cycle. The thirty (30) 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 thirty (30) day meeting.

4. Any party who is opposed to one or more applications submitted during a batching cycle must submit a notice of opposition via the Department's web portal, on the form provided by the Department, no later than thirty (30) days of receipt by the Department of such application. 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 Ga. Comp. R. & Regs. r. 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 sixtieth (60th) 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 submit via the Department's web portal, substantive written comments and arguments regarding the nature of their opposition to the particular project. The opposition parties must 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.

Applicants shall be given the opportunity to submit final amendments and/or letters of support for a particular application pursuant to and in compliance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6) via the Department's web portal no later than the ninetieth (90th) 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 respond to the opposition meeting comments, shall be the seventy-fifth (75th) 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 seventy-fifth (75th) 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 Ga. Comp. R. & Regs. Chapter 274.

(2) **Alternative Healthcare Models**

(a) **Applicability.**

1. For Certificate of Need 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; freestanding emergency departments or facilities not located on a hospital's primary campus; 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, submitted via the Department's web portal, 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 (60th) calendar day falls on either 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; and

(iii) 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 via the Department's web portal 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 Ga. Comp. R. & Regs. r. 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 (120th) 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 Ga. Comp. R. & Regs. r. 111-2-2-.08(2)(e)3.

3. No later than the tenth (10th) 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 shall be effective the date it is sent electronically by the Department. 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 twenty-fifth (25th) 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 twenty-fifth (25th) day may be grounds for denial of the application.

5. If, by the twenty-fifth (25th) day, the review indicates potential for denial of the application(s), the Department, on or before the thirtieth (30th) 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 must be submitted on or before the forty-fifth (45th) 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 sixtieth (60th) day of the review cycle and must be submitted via the Department's web portal. Any letters of support and/or opposition that are received after the fifty-fifth (55th) 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 eightieth (80th) 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 Ga. Comp. R. & Regs. r. 111-2-2-.20 et seq.

Authority: O.C.G.A. §§ 31-2 et seq., 31-6 et seq.

Rule 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 Healthcare Facility Regulation Division.

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 Ga. Comp. R. & Regs. 111-2-2-.06(2)(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 life plan communities, skilled nursing facilities or units, and to projects that are reviewed by the Department on an emergency basis in accordance with Ga. Comp. R. & Regs. r. 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; and

(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 or cost effectiveness; or fosters competition that is shown to result in lower patient costs without a significant result in lower patient costs without a significant deterioration in the quality of care;

(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.

(3) **General Cancer Hospital**

(a) On and after July 1, 2019, a destination cancer hospital may apply for a letter of determination in accordance with O.C.G.A. § 31-6-40(a)(8).

(b) Upon its receipt of a complete application for a destination cancer hospital to convert to a general cancer hospital, the Department shall issue such determination within 60 days.

(c) Upon the conversion of a destination cancer hospital to a general cancer hospital:

1. The general cancer hospital may continue to provide all institutional health care services and other services it provided as of the date of such conversion, including but not limited to inpatient beds, outpatient services, surgery, radiation therapy, imaging, and positron emission tomography (PET) scanning, without any further approval from the Department;

2. The destination cancer hospital shall be classified as a general cancer hospital under this chapter and shall be subject to all requirements and conditions applicable to hospitals under this

article, including but not limited to, indigent and charity care and inventories and methodologies to determine need for additional providers or services; and

3. The hospital's inpatient beds, operating rooms, radiation therapy equipment, and imaging equipment existing on the date of conversion shall not be counted in the inventory by the Department for purposes of determining need for additional providers or services, except that any inpatient beds, operating rooms, radiation therapy equipment, and imaging equipment added after the date of conversion shall be counted in accordance with the Department's rules and regulations.

(d) In the event that a destination cancer hospital does not convert to a general cancer hospital, it shall remain subject to all requirements and conditions applicable to destination cancer hospitals under this article.

(4) 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.

(5) **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.

(6) **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.

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

(a) In evaluating joined applications, if the services proposed are found to be needed, and if any or all 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;

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 twelve (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. §§31-2 et seq., 31-6 et seq.

Rule 111-2-2-.10. Determinations

(1) General Provisions Relating to Determinations

(a) Determinations are conclusions of the Department that are based on specific facts and are limited to the specific issues addressed in the request for determination, as applicable. Therefore, the conclusions of a specific determination 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 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 submitted via the Department's web portal. The Department 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 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 shall address only one matter per request.

(e) Requests for determination shall be submitted pursuant to and in compliance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6). Such requests shall also include one signed original of the written vendor lobbyist certification required by Ga. Comp. R. & Regs. r. 111-1-2-.03(2).

(f) Requests for determination shall include payment of a request fee. Payment of the fee shall be by credit/debit card via the Department's website, 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 of the request.

1. The request fee for determination shall be $500.00;

2. State-owned institutions shall be exempt from payment of these fees; and

3. 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, if a person believes or has reason to believe that the application of a Department Rule or statutory provision may directly affect or impair the legal rights of that person as to some proposed action or course of conduct being considered by that

person, including, but not limited to, determinations regarding reviewability, grandfathering decisions, and relocation or replacement determinations, such person may request a written determination from the Department regarding the application of such Department Rule or statutory provision upon that person's proposed action or course of conduct. A determination request is distinguished from a general question as a determination does not address general issues relating to policy and procedure.

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

The Department requires prior notice and approval of any activity which is believed to be exempt pursuant to paragraphs (10), (10.1), (15), (17), (18), (19), (20), (21), (26), (27), (28), (29), (30), (31), (31.1), (32), (33), and (34) of subsection (a) of Code Section 31-6-47 and Ga. Comp. R. & Regs. r. 111-2-2-.03 (14), (15), (16), (17), (18), (20), (21), (22), (23), (24), (29), (30), (31), (32), (33), (33.1), (34), (35), and (36).

The Department requires prior notice and approval of any activity which is believed to be exempt pursuant to paragraph (25) of subsection (a) of Code Section 31-6-47 and Ga. Comp. R. & Regs. r. 111-2-2-.03 (28), which establish a new health care facility.

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 Ga. Comp. R. & Regs. r. 111-2-2-.03(27), 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 Ga. Comp. R. & Regs. r. 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.

(c) The Department shall establish timeframes, forms, and criteria to request a letter of determination that an activity is properly exempt or excluded under this chapter prior to its implementation.

1. If no objection to a request for determination is filed within 30 days of the Department's receipt of such request for Determination, the Department shall have 60 days from the date of the Department's receipt of such request to review the request and issue a letter of determination.

2. Where conditions exist which make it impractical to complete a review in 60 days, the Department may, on notification to the requester, extend the time limit another 30 days to 90 days.

(d) The Department shall publish notice of all requests for letters of determination regarding exempt activity and opposition to such request.

(e) **Reserved.**

(3) **Requests for Letters of Determination for Below Threshold Diagnostic, Therapeutic, or Other Imaging Equipment.** A party requesting a letter of determination for the acquisition of diagnostic, therapeutic, or other imaging equipment 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:

(a) that the affiant is:

1. a hospital; or

2. an individual private physician or single group practice of physicians and is

(i) acquiring the equipment exclusively for use on patients of such private physician or single group practice of physicians; and

(ii) such private physician or member of such single group practice of physicians is physically present at the practice location where the diagnostic or other imaging equipment is located at least seventy-five percent (75%) of the time that the equipment is in use.

3. that the affiant is capable of making a binding commitment on behalf of the party;

4. **Reserved**.

5. **Reserved**.

6. **Reserved.**

7. **Reserved**.

8. **Reserved**.

9. **Reserved**.

(b). **Reserved**.

1. **Reserved**.

2. **Reserved**.

3. **Reserved**.

4. **Reserved**.

5. **Reserved**.

6. **Reserved**.

7. **Reserved**.

8. **Reserved**.

9. **Reserved**.

10. **Reserved**.

11. **Reserved**.

12. **Reserved**.

(c) **Reserved**.

(d) **Reserved**.

(e) **Reserved**.

(f) A letter of determination for the acquisition of diagnostic, therapeutic, or other imaging 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 the equipment and only to the pertinent facts that were disclosed in the request. Such letters are non-transferable and may not be acquired. If the facts pertinent to the letter of determination change in any way, the letter is no longer valid;

(g) If the equipment and associated activities are not completed within one hundred and eighty (180) days of the issuance of the determination, the party requesting a determination 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 any good faith estimates of the percentage of completion. 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 determination. Failure to comply with the provisions of this subsection may result in the rescission of the determination issued.

(4) **Requests for Letters of Determination for Exempt Single Specialty or Joint Venture Ambulatory Surgical Centers.**

(a) When the Department receives a request for a letter of determination 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 percent (85%) of the group practice and the surgery center. The

Department will issue a determination, 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. Such ambulatory surgical center shall only be utilized by physicians who are of the same single specialty, who may include physicians who are not owners or employees of the individual private physician or single group practice of private physicians that own and operate the center. The Department will allow no more than fifteen percent (15%) non-physician ownership in the physician(s) practice requesting a determination, 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 determination request. For a joint venture ambulatory surgical center, 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%). Any evidence of non-hospital or non-physician or group of physician's ownership in a joint venture ambulatory surgical center must be provided with the determination request.

3. All physicians who utilize the surgery center 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 determination lose their license to practice medicine in Georgia, the determination 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 determination 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, no party who will utilize the surgery center, and none of the physicians requesting a determination, 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 determination 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 determination remains a part of. For purposes of these Rules, this provision does not preclude the issuance of a determination 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. Nothing in this section shall prohibit an individual private physician or a single group practice of private physicians from entering into an arrangement with an outside entity for practice management, administrative services, or both.

13. The Department will not issue a determination 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 determination 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 determination to any party proposing to share operating rooms or common space in a proposed ambulatory surgical facility between more than one surgical group practice of different specialties, or between more than one sole physician of different specialties.

16. Provide a sworn affidavit, signed by the physician(s) owners, that the party requesting a determination will not incur any additional capital expenditures involving new construction or renovation of physical space or the addition or replacement of equipment within three (3) years after the issuance of the determination, 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 determination 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 determination 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 determination, the party requesting a determination

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 determination and from the general contractor. Failure to comply with the provisions of this subsection may result in the rescission of the determination issued.

18. The determination is not transferable to a purchaser of the sole physician or single group practice, which originally received a determination. 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 determination as new owners of that practice. Such a new request will be evaluated based on the determination 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 determination shall provide documentation, in addition to the requirements outlined in section (a) 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 determination 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 and or after January 1, 2026, in an amount equal to or greater than the minimum amount established by the Department which shall be reviewed by the Department every 12 months; 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 and on after January 1, 2026, in an amount equal to or greater than the minimum amount established by the Department which shall be reviewed by the Department every 12 months; 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 Ga. Comp. R. & Regs. r. 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 determination 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 and on and after January 1, 2026, in an amount equal to or greater than the minimum amount

established by the Department which shall be reviewed by the Department every 12 months; 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 on and after January 1, 2026, in an amount equal to or greater than the minimum amount established by the Department which shall be reviewed by the Department every 12 months; and

4. Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and Ga. Comp. R. & Regs. r. 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 annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and in accordance with the provisions of Ga. Comp. R. & Regs. r. 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 or the acquisition or replacement of diagnostic or therapeutic equipment with a value in excess of $800,000.00 over a two-year period; builds a new operating room; or chooses to relocate in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.03, it shall:

1. Provide care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries and provide uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue, and on and after January 1, 2026, in an amount equal to or greater than the minimum amount established by the Department which shall be reviewed by the Department every 12 months; 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 and on and after January 1, 2026, in an amount equal to or greater than the minimum amount established by the Department which shall be reviewed by the Department every 12 months.

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 pursuant to Ga. Comp. R. & Regs. r. 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 letters of determination regarding 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 determination 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 submitted via the Department's web portal. The opposition shall be submitted in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6).

If no objection to a request for determination is filed within 30 days of the Department's receipt of such request for Determination, the Department shall have 60 days from the date

of the Department's receipt of such request to review the request and issue a letter of determination. The Department may adopt rules for deciding when it is not practicable to provide a determination in 60 days and may extend the review period upon written notice to the requestor but only for an extended period of no longer than an additional 30 days.

After the issuance of an approval to a response to the request for an exemption determination, including requests for letters of determination 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. 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. §§. 31-2 *et seq*., 31-6 *et seq*.

Rule 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, Ga. Comp. R. & Regs. r. 111-2-2-.20;

2. Adult Cardiac Catheterization Services, Ga. Comp. R. & Regs. r. 111-2-2-.21;

3. Open Heart Surgical Services, Ga. Comp. R. & Regs. r. 111-2-2-.22;

4. Pediatric Cardiac Catheterization and Open Heart Services, Ga. Comp. R. & Regs. r. 111-2-2-.23;

5. Perinatal Services, Ga. Comp. R. & Regs. r. 111-2-2-.24;

6. Freestanding Birthing Center Services, Ga. Comp. R. & Regs. r. 111-2-2-.25; and

7. Psychiatric and Substance Abuse Inpatient Services, Ga. Comp. R. & Regs. r. 111-2-2-.26;

(b) **Long-Term Care Rules**:

1. Skilled Nursing and Intermediate Care Facility Services, Ga. Comp. R. & Regs. r. 111-2-2-.30;

2. Personal Care Home Services, Ga. Comp. R. & Regs. r. 111-2-2-.31;

3. Home Health Services, Ga. Comp. R. & Regs. r. 111-2-2-.32;

4. Life Plan Community ("LPC") Sheltered Nursing Facilities, Ga. Comp. R. & Regs. r. 111-2-2-.33;

5. Traumatic Brain Injury Services, Ga. Comp. R. & Regs. r. 111-2-2-.34; and

6. Comprehensive Inpatient Physical Rehabilitation Services, Ga. Comp. R. & Regs. r. 111-2-2-.35;

7. Long Term Care Hospitals, Ga. Comp. R. & Reg. R. 111-2-2-.36

(c) **Special and Other Health Services**:

1. Ambulatory Surgical Services, Ga. Comp. R. & Regs. r. 111-2-2-.40;

2. Positron Emission Tomography Units, Ga. Comp. R. & Regs. r. 111-2-2-.41; and

3. Radiation Therapy Services, Ga. Comp. R. & Regs. r. 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 Ga. Comp. R. & Regs. r. 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 Ga. Comp. R. & Regs. r. 111-2-2-.01(41), 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. §§31-2 et seq., 31-6 et seq.

Rule 111-2-2-.12. Reserved

Rule 111-2-2-.13. Reserved

Rule 111-2-2-.14. Reserved

Rule 111-2-2-.15. Reserved

Rule 111-2-2-.16. Reserved

Rule 111-2-2-.17. Reserved

Rule 111-2-2-.18. Reserved

Rule 111-2-2-.19. Reserved

Rule 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; or

2. changing the physical location of existing beds within an existing facility; or

3. projects that are otherwise exempt from review pursuant to O.C.G.A. § 31-6-47(a) and GA. Comp. R. & Regs. r. 111-2-2-.03.

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

(2) **Definitions**.

(a) "Age cohorts" for purposes of these Rules refers to the following age groups: persons zero (0) to seventeen (17); persons

eighteen (18) to sixty-four (64); and persons sixty-five (65) and older.

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

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

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

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

hundred sixty-five (365). The optimal occupancy rate is variable based on the following:

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

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

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

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

(k) "Replacement" means new construction to substitute another facility for an existing facility. New construction may be considered a replacement only if the replacement site is located three (3) miles or less from the facility being replaced or, in the case of the facility proposing a replacement site beyond the three (3) 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 having a population of less than 50,000 according to the United States decennial census of 2010 or any future such censes , as defined in O.C.G.A. § 31-7-94.1(c)(2).

(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 Healthcare Facility Regulation Division as a trauma center;

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

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

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

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

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

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

(3) **Standards.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the proposed replacement or expanded hospital meets the need standards.

(c) The Department may allow an exception to need and adverse impact standards outlined in Ga. Comp. R. & Regs. r. 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 Public Health 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; or

5. The facility is an existing short-stay general hospital meeting one of the following conditions:

(i) A facility in an urban county or rural county seeking to add short-stay general hospital beds in response to the closure of a short-stay general hospital located within a five (5) mile radius;

(ii) A facility in a rural county seeking to add short-stay general hospital beds in response to the closure of a short-stay general hospital located in the same rural county or a contiguous county; or

(iii) A facility in an urban county seeking to add short-stay general hospital beds in response to the closure of a short-stay general hospital located in a contiguous rural county.

To qualify for an exception under Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(c)5, the existing hospital must demonstrate that it

will serve substantially the same patient population based on patient origin and payor mix data as the closed hospital, to be determined in the sole discretion of the Department. The expansion under Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(c)5 may be for up to twenty percent (20%) of capacity of the applicant hospital and the application for a certificate of need under this exception shall be filed no more than eighteen (18) months after the closure of the short-stay general hospital. Notwithstanding the foregoing, the exception set forth in Comp. R. & Regs. r. 111-2-2-.20(3)(c)5 may be requested by an applicant only one (1) time in response to the closure of a particular short-stay general hospital unless such applicant provides written justification in support of a second request that is granted by the department in its sole discretion, if such justification was submitted within no more than eighteen (18) months after closure of that hospital.

(d)

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

2. An applicant for a new, replacement or expanded hospital shall document in its application that the new, replacement or expanded facility is not predicted to be detrimental to safety net hospitals within the planning area. Such demonstration shall be made by providing an analysis in the application that compares current and projected changes in market share and payer mix for the applicant and any safety net hospitals. Impact on an existing safety net hospital shall be determined to be adverse if, based on the utilization projected by the applicant, any existing safety net

hospital would have a total decrease of ten percent (10%) or more in its average annual utilization, as measured by patient days for the two most recent and available preceding calendar years of data.

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

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

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

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

2. providing a written commitment that services for indigent and charity patients will be offered at a standard that meets or

exceeds three percent (3%) of annual, adjusted gross revenues for the hospital;

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

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

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

(g)

1. An applicant for a replacement or expanded hospital shall document that the hospital is fully accredited by the Joint Commission 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 the Joint Commission or another nationally recognized health care accreditation 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 Healthcare Facility Regulation Division.

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 Ga. Comp. R. & Regs. r. 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 Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(b)3.

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

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

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

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

(k)

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

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

3. An applicant for a destination cancer hospital must:

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

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

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

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

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

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

(vii) Agree to provide care to Medicaid beneficiaries;

(viii) Document that the applicant for a destination cancer hospital will comply with the criteria found in the General Review Considerations of these Ga. Comp. R. & Regs. r. 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 percent (65%) 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 percent (65%) 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 percent (65%) of patients who reside outside of the State of Georgia for three calendar years in any five-year period.

5. After commencing operations upon receipt of a Certificate of Need pursuant to these Rules, a destination cancer hospital

seeking to add an additional new institutional health service, shall apply for and obtain an additional Certificate of Need under the applicable statutory provisions and the Rules in this section. Any such application shall only be granted if the patient base of the destination cancer hospital is composed of at least sixty-five percent (65%) 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 percent (65%) 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 percent (65%) 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. §§ 31-2-8, 31-7-2.2, 31-7-4, 31-7-3.5.

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

(1) **Applicability.**

(a) For Certificate of Need 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 Ga. Comp. R. & Regs. r. 111-2-2-.03(24).

(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 Ga. Comp. R. & Regs. r. 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 Ga. Comp. R. & Regs. r. 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 Ga. Comp. R. & Regs. r. 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; or that acquires a piece of diagnostic or therapeutic equipment 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 percent (85%) or more during the most recent year;

(b)

1. The Department may allow an exception to Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(a) in the following circumstances:

(i) actual utilization in the applicant's existing service has exceeded ninety percent (90%) of capacity over the past two (2) 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.

(II) 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 Ga. Comp. R. & Regs. r. 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 Ga. Comp. R. & Regs. r. 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with Ga. Comp. R. & Regs. r. 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 percent (80%) 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

(II) 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 or another nationally recognized health care accreditation body, in the case of an applicant proposing a new facility location, shall provide a written commitment to secure full accreditation by the Joint Commission or another nationally recognized health care accreditation body 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 Ga. Comp. R. & Regs. r. 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;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) 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, PeachCare 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. §§31-2 et seq., 31-6 et seq.

Rule 111-2-2-.22. Specific Review Considerations for Adult Open Heart Surgery Services

(1) **Applicability.** A Certificate of Need will be required prior to the establishment of a new or, subject to certain stipulations, expanded adult open heart surgical service.

(2) **Definitions.**

(a) "Adult" means persons 15 years of age and over.

(b) "Authorized service" means an adult open heart surgery 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 become operational.

(c) "Coronary Angioplasty" means a cardiac catheterization procedure to treat coronary heart 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.

(d) "Expanded Service" or "Expansion" means an adult open heart surgery service that undertakes any capital renovation or construction project in and to the physical space within the hospital where the adult open heart surgery service is or will be offered; or that acquires a piece of diagnostic or therapeutic equipment which is to be utilized in the provision of open heart surgery services; or, for any service a full four (4) years or more following implementation of an approved Certificate of Need, that increases adult open heart surgery volume to a level resulting in a twenty-five percent (25%) or more increase in procedures being performed by the service over the higher annual number of procedures having been performed during the most recent prior two calendar years. Replacement or repair of existing diagnostic or therapeutic equipment utilized in the provision of such service is not an expansion for purposes of these Rules.

(e) "Official State Component Plan" means the document related to specialized cardiovascular services developed by the Department established by the Health Strategies Council, and adopted by the Board of Community Health.

(f) "Open heart surgery" means surgery performed directly on the heart or its associated veins or arteries during which a heart and lung by-pass machine (extracorporeal pump) may be used to perform the work of the heart and lungs.

(g) "Open heart surgery service" means an organized surgical program that serves inpatients of a hospital that has a

suitable operating room or suite of operating rooms, equipment, staff, intensive care unit, and all support services required to perform adult open-heart surgery. The adult open heart surgery service shall be located in an acute care hospital that has an authorized adult cardiac catheterization service.

(h) "Procedure" means an adult open heart surgery operation or combination of operations performed in a single session on a single patient who appears for open heart.

(3) **Standards.**

(a)

1. An application for new adult open heart surgery services shall be considered by the Department only if each and all of the following conditions are met:

(i) an applicant must have operated an existing adult cardiac catheterization service which is located in an acute care hospital setting for at least three (3) years prior to the date of application; and

(ii) an applicant shall document, based on actual service data of the applicant, survey data provided to the Department and other supporting research and documentation, that the hospital's existing adult cardiac catheterization service generated a minimum of 250 or more adult open heart surgery procedures in each of the two (2) calendar years immediately prior to submittal of the application; and

(iii) an applicant shall project and, if approved, shall document that the proposed adult open heart surgery service will be performing a minimum of 300 adult open heart surgery procedures per year within three years of initiation of the service. Such projections, at a minimum, shall include consideration of patient origin data for open heart and catheterization services, the use rate of existing services, and referral data and market patterns

for existing hospital services, and cardiovascular disease incidence rates and related health indicators; and

(iv) an applicant shall document that existing and approved adult open heart surgery services in the state are not predicted to be adversely impacted as a result of the establishment of the new service. Impact on an existing or approved service shall be determined to be adverse if, based on the number of cases projected to be performed by the applicant, any of the existing or approved services would have either a decrease in volume equal to or greater than ten percent (10%) of the average annual service volume in the preceding two calendar years or a decrease of less than ten percent (10%) of the annual service volume in the preceding two calendar years but which would result in such service falling below a minimum of 200 open heart surgical procedures annually. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application. An existing service that has been operational for four or more years and has not performed a minimum of 200 open heart surgical procedures in at least one of the past four years shall be excluded from a determination of adverse impact; and

(v) if multiple applications are joined or comparatively reviewed, the Department shall determine whether the individual impact of the establishment of each proposed service or the cumulative impact of the establishment of two or more proposed services would adversely impact an existing or approved service or any of the proposed services if established.

2. The Department may allow an exception to the need standard and adverse impact requirements in Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(a)1. of this paragraph to remedy an atypical barrier to open heart surgery 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 open-heart surgical 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.

(ii) An atypical barrier to services based on quality may include the failure of existing providers of open-heart surgical services to provide services with outcomes generally in keeping with accepted clinical guidelines, 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 an existing provider or group of providers of open-heart surgical services within the community to provide services to indigent, charity and Medicaid patients.

(b)

1. An existing adult open heart surgery service seeking an expansion or expanded service due to a capital or equipment expenditure shall be approved if the applicant complies with the general considerations and policies of Ga. Comp. R. & Regs. r. 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c),(d),(e),(g),(h) and (j).

2. Any existing service seeking an expansion or expanded service based on an increase in procedures pursuant to the definition in Ga. Comp. R. & Regs. r. 111-2-2-.22(2)(d) may request a determination from the Department that the service is fully in compliance with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c),(d),(e),(g),(h) and (j). The Department may issue a determination that the service is in compliance. If the Department issues such a determination, the service will not be

required to apply for a Certificate of Need. If the Department determines that the service is not in compliance with the above referenced conditions, the service will be required to submit a Certificate of Need application.

(c) An applicant requesting a new or expanded adult open heart surgery service shall comply with the following three requirements:

1. Document that the open-heart surgery service shall have the capability to implement circulatory assist devices such as intra-aortic balloon assist and prolonged cardiopulmonary procedures, including at a minimum:

(i) repair and replacement of heart valves;

(ii) cardiac revascularization;

(iii) treatment of cardiac trauma;

(iv) repair of congenital defects in adults; and

(v) repair of acute aortic dissection.

2. Document that the applicant has available to the open-heart surgery service a full range of hospital-based diagnostic, ancillary, and support services, including the following organizational departments or services:

(i) medicine: cardiology, hematology, nephrology;

(ii) radiology: diagnostic, nuclear medicine;

(iii) surgery: cardiovascular, thoracic;

(iv) pathology: anatomic, clinical, blood bank, coagulation laboratory;

(v) anesthesiology: inhalation therapy; echocardiology in the operating room;

(vi) neurology;

(vii) special laboratories: cardiac catheter/angiographic;

(viii) clinical dietary;

(ix) cardiac surgical intensive care unit;

(x) pacemaker therapy;

(xi) cardiac rehabilitation services;

(xii) renal dialysis; and

(xiii) social services.

3. Document that the service shall be available for elective procedures as needed, at least eight hours per day, five days a week, and shall document the capability to rapidly mobilize surgical and medical support teams for emergency cases 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

(d) An applicant for a new or expanded adult open heart surgery service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to cardiac surgical services for all segments of the population in the documented and proposed service area of the facility and service. 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;

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

(i) Clinical intervention for cardiac patients (any inpatient or outpatient with a principal diagnosis of ischemic heart disease). These patients are at high risk for development of adverse

cardiovascular events and the program 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;

(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; and

(IV) Establishment and maintenance of systems to assist in tracking and follow-up to determine attendance at referred services and status of risk management.

(ii) Clinical intervention for non-cardiac patients (any inpatient or outpatient whose principal diagnosis is not ischemic heart disease). For these patients, the program shall encourage the following:

(I) Assessment of risk factors including, hypertension, hypercholesterolemia, smoking, obesity, sedentary lifestyle, and history of diabetes;

(II) Provision of appropriate counseling and referral for diagnostic evaluation, treatment and risk factor modification; and

(II) Establishment and maintenance of record systems to assist in documenting risk factors identified, referrals made, and other follow-up action taken.

(iii) The program shall assure access to cardiac rehabilitation services, provided either by the hospital itself or through formal referral agreements.

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

(v) 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 for target 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; and

(3) **Standards.**

(a)

1. An application for new adult open heart surgery services shall be considered by the Department only if each and all of the following conditions are met:

(i) an applicant must have operated an existing adult cardiac catheterization service which is located in an acute care hospital setting for at least three (3) years prior to the date of application; and

(ii) an applicant shall document, based on actual service data of the applicant, survey data provided to the Department and other supporting research and documentation, that the hospital's existing adult cardiac catheterization service generated a

minimum of 250 or more adult open heart surgery procedures in each of the two (2) calendar years immediately prior to submittal of the application; and

(iii) an applicant shall project and, if approved, shall document that the proposed adult open heart surgery service will be performing a minimum of 300 adult open heart surgery procedures per year within three years of initiation of the service. Such projections, at a minimum, shall include consideration of patient origin data for open heart and catheterization services, the use rate of existing services, and referral data and market patterns for existing hospital services, and cardiovascular disease incidence rates and related health indicators; and

(iv) an applicant shall document that existing and approved adult open heart surgery services in the state are not predicted to be adversely impacted as a result of the establishment of the new service. Impact on an existing or approved service shall be determined to be adverse if, based on the number of cases projected to be performed by the applicant, any of the existing or approved services would have either a decrease in volume equal to or greater than ten percent (10%) of the average annual service volume in the preceding two calendar years or a decrease of less than ten percent (10%) of the annual service volume in the preceding two calendar years but which would result in such service falling below a minimum of 200 open heart surgical procedures annually. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application. An existing service that has been operational for four or more years and has not performed a minimum of 200 open heart surgical procedures in at least one of the past four years shall be excluded from a determination of adverse impact; and

(v) if multiple applications are joined or comparatively reviewed, the Department shall determine whether the individual impact of the establishment of each proposed service or the cumulative impact of the establishment of two or more proposed

services would adversely impact an existing or approved service or any of the proposed services if established.

2. The Department may allow an exception to the need standard and adverse impact requirements in Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(a)1. of this paragraph to remedy an atypical barrier to open heart surgery 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 open-heart surgical 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.

(ii) An atypical barrier to services based on quality may include the failure of existing providers of open-heart surgical services to provide services with outcomes generally in keeping with accepted clinical guidelines, 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 an existing provider or group of providers of open-heart surgical services within the community to provide services to indigent, charity and Medicaid patients.

(b)

1. An existing adult open heart surgery service seeking an expansion or expanded service due to a capital or equipment expenditure shall be approved if the applicant complies with the general considerations and policies of Ga. Comp. R. & Regs. r. 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement

to comply with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c),(d),(e),(g),(h) and (j).

2. Any existing service seeking an expansion or expanded service based on an increase in procedures pursuant to the definition in Ga. Comp. R. & Regs. r. 111-2-2-.22(2)(d) may request a determination from the Department that the service is fully in compliance with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c),(d),(e),(g),(h) and (j). The Department may issue a determination that the service is in compliance. If the Department issues such a determination, the service will not be required to apply for a Certificate of Need. If the Department determines that the service is not in compliance with the above referenced conditions, the service will be required to submit a Certificate of Need application.

(c) An applicant requesting a new or expanded adult open heart surgery service shall comply with the following three requirements:

1. Document that the open-heart surgery service shall have the capability to implement circulatory assist devices such as intra-aortic balloon assist and prolonged cardiopulmonary procedures, including at a minimum:

(i) repair and replacement of heart valves;

(ii) cardiac revascularization;

(iii) treatment of cardiac trauma;

(iv) repair of congenital defects in adults; and

(v) repair of acute aortic dissection.

2. Document that the applicant has available to the open-heart surgery service a full range of hospital-based diagnostic, ancillary, and support services, including the following organizational departments or services:

(i) medicine: cardiology, hematology, nephrology;

(ii) radiology: diagnostic, nuclear medicine;

(iii) surgery: cardiovascular, thoracic;

(iv) pathology: anatomic, clinical, blood bank, coagulation laboratory;

(v) anesthesiology: inhalation therapy; echocardiology in the operating room;

(vi) neurology;

(vii) special laboratories: cardiac catheter/angiographic;

(viii) clinical dietary;

(ix) cardiac surgical intensive care unit;

(x) pacemaker therapy;

(xi) cardiac rehabilitation services;

(xii) renal dialysis; and

(xiii) social services.

3. Document that the service shall be available for elective procedures as needed, at least eight hours per day, five days a week, and shall document the capability to rapidly mobilize surgical and medical support teams for emergency cases 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

(d) An applicant for a new or expanded adult open heart surgery service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to cardiac surgical services for all segments of the population in the documented and proposed service area of the facility and service. 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;

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

(i) Clinical intervention for cardiac patients (any inpatient or outpatient with a principal diagnosis of ischemic heart disease). These patients are at high risk for development of adverse cardiovascular events and the program 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;

(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; and

(IV) Establishment and maintenance of systems to assist in tracking and follow-up to determine attendance at referred services and status of risk management.

(ii) Clinical intervention for non-cardiac patients (any inpatient or outpatient whose principal diagnosis is not ischemic heart disease). For these patients, the program shall encourage the following:

(I) Assessment of risk factors including, hypertension, hypercholesterolemia, smoking, obesity, sedentary lifestyle, and history of diabetes;

(II) Provision of appropriate counseling and referral for diagnostic evaluation, treatment and risk factor modification; and

(III) Establishment and maintenance of record systems to assist in documenting risk factors identified, referrals made, and other follow-up action taken.

(iii) The program shall assure access to cardiac rehabilitation services, provided either by the hospital itself or through formal referral agreements.

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

(v) 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 for target 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; and

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.

(e) An applicant for a new or expanded adult open heart surgery service shall foster an environment which 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 Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(d), 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;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the adult open heart surgery service, or the applicant may request that the Department allow 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 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.

(f) In considering applications joined for review for new adult open heart surgery services, the Department may give favorable consideration to an applicant which historically has provided a higher annual percentage of unreimbursed services to indigent and charity patients and a higher annual percentage of services to Medicare and Medicaid patients.

(g) An applicant for a new or expanded adult open heart surgery service shall comply with the following three requirements:

1. Demonstrate the intent to achieve the optimal standards established by the American College of Surgeons and the Advisory Council for Cardiothoracic Surgery of the American College for evaluating the clinical and physical environments of cardiac surgical services and covering professional qualifications and responsibilities, staffing requirements, support services, physical plant, and equipment.

2. Document the availability of; or shall present a plan for recruiting, a qualified surgeon certified by the American Board of Thoracic Surgery with special qualifications in cardiac surgery.

3. Document a plan for obtaining a sufficient number of professional and technical staff; including cardiac intensive care nurses, for the size of the adult open heart surgery program proposed and document that the operating room team necessary for an adult open heart surgical procedure shall be available, including a cardiovascular surgeon who is board certified by the American Board of Thoracic Surgery; a second physician who is a cardiovascular or thoracic surgeon or surgical resident; a board-certified anesthesiologist trained in open heart surgery; a circulating nurse or scrub nurse (RN); an operating room technician or registered nurse trained in cardiac procedures; and one or two pump technicians, with one being certified and one qualified.

(h) An applicant for a new or expanded adult open heart surgery service shall provide documentation that the hospital is fully accredited by the Joint Commission or another nationally recognized health care accreditation 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 years and has no outstanding licensure and Medicare and/or Medicaid certification deficiencies.

(i) An applicant for a new adult open heart surgery service shall demonstrate that charges and/or reimbursement rates for the service shall compare favorably with charges and/or reimbursement rates in existing adult open heart surgery services in the state when adjusted for annual inflation. When determining the accuracy of an applicant's projected charges for adult open heart surgery procedures, the Department may compare the applicant's history of charges and/or reimbursement rates for cardiac catheterization procedures and other treatments and/or interventions for disorders of the circulatory system and for open heart procedures, if applicable, with such charges and/or reimbursement rates in other similar hospitals.

(j) An applicant for a new or expanded adult open heart surgery 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; and

2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital as well as a national, state or multi-hospital 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;

3. development of procedures to ensure that any surgeon authorized to perform open heart surgery for the hospital shall be required to perform at least 100 procedures on annual basis across his or her various practice settings, and shall be required to accept Medicaid or 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.

(k) 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. §§ 31-2 et seq., 31-6 et seq.

Rule 111-2-2-.23. Specific Review Considerations for Pediatric Cardiac Catheterization and Open-Heart Surgery

(1) **Definitions.**

(a) "Authorized service" means a pediatric cardiac catheterization service or pediatric cardiac surgery 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 become operational.

(b) "Capacity" means:

1. for a pediatric catheterization service:

(i) in considering applications for a new pediatric cardiac catheterization service, 750 procedures per year per authorized service regardless of the number of rooms used; or

(ii) in considering applications for expansion of an existing service, 750 pediatric cardiac catheterization procedures per dedicated room per year in the existing service (3 per day per room, 5 days per week, 50 weeks per year) and for each multipurpose room in the existing service, 750 procedures (special procedures and pediatric cardiac catheterization procedures) per year. If adult and pediatric cardiac catheterization are performed in the same room in a service seeking to expand, the capacity of the room shall be equivalent to 750 pediatric procedures with adult procedures performed in the room weighted in proportion to pediatric procedures as being 0.50 for each adult cardiac catheterization or special procedure, except for each adult coronary angioplasty, which shall be 0.75, in order to determine the service's use rate; or

2. for a pediatric cardiac surgery service, the number of pediatric cardiac surgery procedures which could be performed annually as reported by each hospital with an authorized service and based on survey and other reported data. In determining capacity, a hospital must consider factors such as available operating rooms which can be used for pediatric cardiac surgery, cardiac surgical intensive care beds and other pediatric intensive care beds available for pediatric patients, general bed capacity, and any other factors which impact the determination.

(c) "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.

(d) "Closed heart surgery" means an operation performed directly on the heart or its associated veins or arteries that does not require use of a heart and lung bypass machine (extracorporeal pump) to perform the work of the heart and lungs. Such operations often require the bypass machine to be available on standby for use if the surgery needs to be changed to open heart with the machine then performing the work of the heart and lungs.

(e) "Official State Component Plan" means the document related to specialized cardiovascular services developed by the Department, established by the Health Strategies Council, and adopted by the Board of Community Health.

(f) "Open heart surgery" means surgery performed directly on the heart or its associated veins or arteries during which a heart and lung bypass machine (extracorporeal pump) is used to perform the work of the heart and lungs.

(g) "Pediatric" refers to children 14 years of age and under.

(h) "Pediatric cardiac catheterization service" means an organized program which serves pediatric patients of a hospital which has a room or suite of rooms with the equipment, staff, and all support services required to perform angiographic, physiologic, and, as appropriate, therapeutic cardiac catheterization procedures. The pediatric cardiac catheterization service shall be located in a pediatric tertiary hospital. Procedures may be performed in a room dedicated to cardiac catheterization and/or in a special procedures or multipurpose room not exclusively used for cardiac catheterization.

(i) "Pediatric cardiac surgery" means an operation performed directly on a pediatric patient's heart or its associated veins or arteries, including open heart and closed heart surgery procedures but excluding surgical procedures for the closure of neonatal patent ductus arteriosus.

(j) "Pediatric cardiac surgery service" means an organized surgical program which serves pediatric inpatients of a hospital which has a suitable operating room or suite of operating rooms, equipment, staff, and all support services required to perform closed heart and open-heart operations for pediatric patients. The pediatric cardiac surgery service shall be located in a pediatric tertiary hospital.

(k) "Pediatric tertiary hospital" means a teaching center, specialty medical or large community hospital characterized by serving pediatric patients from a large region or the entire state with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients.

(l) "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 or a pediatric open or closed heart operation or combination of operations performed in a single session on a single patient who appears for pediatric cardiac surgery.

(m) "Service area", for pediatric cardiac catheterization and pediatric cardiac surgery means the State of Georgia.

(2) **Standards.**

(a) An applicant for new pediatric cardiac catheterization and pediatric cardiac surgery services must be a pediatric tertiary hospital. Due to the highly specialized nature of pediatric cardiac catheterization and pediatric cardiac surgery services, applicants for these services must propose to provide both pediatric cardiac catheterization and pediatric cardiac surgery. Only those projects

that meet all applicable standards for both services will be approved.

(b) New pediatric cardiac catheterization services shall be approved in the state only if each and all of the following conditions are met:

1. the combined use rate for all existing and approved pediatric cardiac catheterization services in the state has been at or above eighty percent (80%) of capacity for the past two (2) years as documented through surveys submitted to the Department;

2. an applicant must project that the proposed service will be operating at a minimum of one-hundred fifty (150) procedures per year within three (3) years of initiation of the service in order to maintain and strengthen skills. Such projection at a minimum shall include consideration of patient origin data and the use rate of existing services; and

3. an applicant must show that authorized pediatric cardiac catheterization services that would be impacted by the establishment of the new service are not predicted to perform less than the minimum quality level of one-hundred fifty (150) procedures annually as a result of the establishment of the new service.

(c) An application for expansion of an existing pediatric cardiac catheterization service shall be approved in the state only if the applicant's existing service has operated at a use rate of at least eighty percent (80%) of capacity for each of the past two (2) years and the applicant can project a minimum of one-hundred fifty (150) additional pediatric procedures per year within three (3) years of initiation of the service expansion and the applicant demonstrates compliance with or documents a plan and agreement to comply with the applicable provisions of Ga. Comp. R. & Regs. r. 111-2-2-.23(2)(f) through (o).

(d) New pediatric cardiac surgery services shall be approved in the state only if each and all of the following conditions are met:

1. the combined use rate of all authorized pediatric cardiac surgery services in the state has been at or above eighty percent of (80%) capacity for the past two (2) years as documented through surveys submitted to the Department;

2. an applicant must project that the proposed service will be operating at a minimum of one hundred (100) pediatric cardiac surgery procedures per year, of which at least fifty (50) are open heart operations, within three years of initiation of the service in order to maintain and strengthen skills. Such projections at a minimum shall include consideration of patient origin data and the use rate of existing services; and

3. an applicant must show that authorized pediatric cardiac surgery services which would be impacted by the establishment of the new services are not predicted to perform less than the minimum quality level of one hundred (100) procedures annually, of which at least fifty (50) are open heart operations, as a result of the establishment of the new service.

(e) An application for expansion of an existing pediatric cardiac surgery service which shall be approved in the state only if the applicant's existing service has operated at a use rate of at least eighty percent (80%) of capacity for each of the past two years and the applicant can project a minimum of one hundred 100 additional pediatric cardiac surgery procedures, of which at least fifty (50) are open heart operations, within three (3) years of initiation of the service expansion and the applicant demonstrates compliance with or documents a plan and agreement to comply with the applicable provisions of Ga. Comp. R. & Regs. r. 111-2-2-.23(2)(f) through (o).

(f) An applicant for a new or expanded pediatric cardiac catheterization service shall:

1. document that the applicant is a pediatric tertiary hospital, which serves pediatric patients from a large region or the entire state, with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients; and

2. document that, in addition to the basic requirements described for adult cardiac catheterization services, the hospital shall have support services and equipment necessary for the diagnosis and treatment of infants and children as specified by the American College of Cardiology and the American Academy of Pediatrics.

(g) An applicant for a new or expanded pediatric cardiac surgery service shall:

1. document that the applicant is a pediatric tertiary hospital, which serves pediatric patients from a large region or the entire state, with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients; and

2. document that, in addition to the basic requirements described for adult open-heart surgery, the hospital shall have support services and equipment necessary for surgery on infants and children as specified by the American College of Cardiology and the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers. This includes a complete pediatric cardiology unit, a neonatal intensive care unit, a pediatric intensive care unit, and a general pediatric unit with pediatric sub-specialists in hematology, endocrinology, pulmonary neurology, and radiology.

(h) An applicant for a new or expanded pediatric cardiac catheterization service or for a new or expanded pediatric cardiac surgery service shall document that the service shall be available for the performance of procedures as needed at least eight hours per day, five days per week, and shall document the capability to rapidly mobilize the surgical and medical support teams for

emergency procedures 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

(i) An applicant for a new or expanded pediatric cardiac catheterization service and/or pediatric cardiac surgery service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to 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;

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 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 shall provide for annual support and participation in at least three 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.

(iii) 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; and

3. propose a system of outcome monitoring and quality improvement and identify at least five (5) clinical outcomes that the applicant proposes to monitor for performance on a regular basis.

(j) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall foster an environment which 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 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;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the pediatric cardiac catheterization and surgical services, 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 and PeachCare programs and to accept any Medicaid- and/or PeachCare-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.

(k) An applicant for a new or expanded pediatric cardiac catheterization service shall:

1. demonstrate the intent to achieve the optimal standards established by the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers for evaluating the clinical and physical environments of cardiac

catheterization services and covering professional qualifications and responsibilities, staffing requirements, supporting services, physical plant, and equipment;

2. document the availability of, or shall present a plan for recruiting, a qualified service director who is a physician, board-certified in pediatrics, with subspecialty training and board eligibility in pediatric cardiology and who is competent to perform physiologic and angiographic procedures or both; and

3. document a plan for obtaining a sufficient number of professional and technical staff for the size of the pediatric cardiac catheterization service proposed, including a pediatric nurse, radiologic technologist, cardiopulmonary technician, and darkroom technician and document that the staff required for most procedures shall be available, including two physicians, one nurse, and two technicians, with the nurse and technicians cross trained to cover technical responsibility of the monitoring and recording technicians.

(l) An applicant for a new or expanded pediatric cardiac surgery service shall comply with the following three requirements:

1. Demonstrate the intent to achieve the optimal standards established by the Advisory Council for Cardiothoracic Surgery of the American College of Surgeons, and the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers for evaluating the clinical and physical environments of cardiac surgical services and covering professional qualifications and responsibilities, staffing requirements, supporting services, physical plant, and equipment.

2. Document the availability of, or shall present a plan for recruiting, a qualified pediatric cardiac surgery director who is a pediatric cardiovascular surgeon, board-certified in thoracic surgery, with special emphasis and experience in surgery for congenital heart disease.

3. Document a plan for obtaining a sufficient number of professional and technical staff, including pediatric cardiac intensive care nurses, for the size of the pediatric cardiac surgery service proposed, including at least two board-qualified cardiac surgeons on the staff of the hospital and a cardiovascular surgical team which includes a neonatologist, a pediatric anesthesiologist, a pediatric radiologist, a pediatric cardiologist, a nurse clinician, and backup of medical social services.

(m) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall provide documentation that the hospital is fully accredited by the Joint Commission or another nationally recognized health care accreditation 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 Medicaid certification deficiencies in the past three (3) years and has no outstanding licensure and Medicare and Medicaid certification deficiencies.

(n) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall demonstrate that the applicant's charges and/or reimbursement for pediatric cardiac catheterization and pediatric cardiac surgery services shall compare favorably with charges and/or reimbursement in existing pediatric cardiac catheterization and pediatric cardiac surgery services in the state, when adjusted for annual inflation.

(o) An applicant for new or expanded pediatric cardiac catheterization and/or pediatric cardiac surgery services 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 as well as a national, state or multi-hospital 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;

3. development of procedures to ensure that any surgeon or cardiologists authorized to perform pediatric cardiac services for the hospital shall be required to accept Medicaid and PeachCare 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.

(p) 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. §§ 31-2 et seq., 31-6 et seq.

Rule 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 (6) 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 111-8-40 of the Rules of the Healthcare Facility Regulation Division, such chapter being entitled "Newborn Service. Amended."

(f) "Obstetric Service" means a hospital service that meets the minimum standards contained in Chapter 111-8-40 of the Rules of the Healthcare Facility Regulation Division, 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 Public Health 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):

$$POBDays = UR_x PFP$$

(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 seventy-five percent (75%)) 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 Public Health 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 Public Health or other official source for the most recent calendar year:

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

(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 eighty percent (80%)) 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 Public Health or other official source divided by the corresponding years' female population ages 15 to 44 (FP):

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

(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 Public Health or other official source for the most recent calendar year:

$$PN2Days – N2Daysx \frac{PRB}{RB}$$

(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 eighty percent (80)) 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 seventy-five percent (75%) for an Obstetric Service and eighty percent (80%) for a Neonatal Intermediate Care Service or Neonatal Intensive Care Service for each of the two (2) 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 (3%) 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 Healthcare Facility Regulation Division; 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. §§31-2*et seq*., 31-6 *et seq*.

Rule 111-2-2-.25 Repealed and Reserved

Rule 111-2-2-.26. Repealed and Reserved

Rule 111-2-2-.30. Specific Review Considerations for Skilled Nursing and Intermediate Care Facilities

(1) **Applicability.** A Certificate of Need will be required prior to the establishment of a new or expanded skilled nursing facility, intermediate care facility, or an intermingled facility.

(2) **Definitions.**

(a) "Horizon year" means the last year of the three-year projection period for need determinations for a nursing facility.

(b) "Hospital-based nursing facility" means a nursing facility which meets the current definition of "Hospital-Based Nursing Facilities" as defined in the current Policies and Procedures for Nursing Facility Services by the Georgia Department of Community Health, Division of Medical Assistance. A new hospital-based nursing facility can only result from conversion of existing inpatient space on the hospital's campus.

(c) "Intermediate care facility" ("ICF") 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.

(d) "Intermingled facility" means a nursing facility that provides both skilled intermediate levels of care.

(e) "Medicare distinct part skilled nursing unit" means a unit which meets the current definition of "Distinct Part of an Institution as SNF" as defined in the current Medicare Part A Intermediary Manual by the Centers for Medicare and Medicaid Services ("CMS") of the U.S Department of Health and Human Services.

(f) "Nursing facility" means a facility classified as either a skilled nursing facility, an intermediate care facility or an intermingled facility which admits patients by medical referral and provides for continuous medical supervision via 24-hour-a-day nursing care and related services in addition to food, shelter, and personal care.

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

(h) "Planning area" for all nursing facilities, with the exception of state nursing facilities, means the geographic regions in Georgia defined in the "Official State Health Component Plan". "Planning area for a state nursing facility" means the State of Georgia.

(i) "Retirement community-based nursing facility" means a nursing facility which operates as a lesser part of a retirement community which is a planned, age-restricted, congregate living development which offers housing, recreation, security, dietary services, and shared living areas accessible to all residents.

(j) "Skilled nursing facility" ("SNF") 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 the injured, disabled or sick persons.

(k) "State nursing facility" is a facility that meets the definition of a Nursing Facility as defined above and is owned and operated by a branch or branches of government of the State of Georgia.

(l) "Urban county" means a county with a projected population for the horizon year of 100,000 or more and 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 nursing facility in a planning area in the horizon year shall be determined through application of a numerical, supply-oriented need method and an assessment of current planning area utilization designed to measure demand for services.

1. The numerical need for a new or expanded nursing facility in any planning area in the horizon year shall be determined by a population-based formula which is a sum of the following:

(i) a ratio of 0.43 beds per 1,000 projected horizon year Resident population age 64 and younger;

(ii) a ratio of 9.77 beds per 1,000 projected horizon year Resident population age 65 through 74;

(iii) a ratio of 32.5 beds per 1,000 projected horizon year Resident population age 75 through 84; and

(iv) a ratio of 120.00 beds per 1,000 projected horizon year Resident population age 85 and older.

2. The demand for services in each planning area will be measured by the cumulative facility bed utilization rate during the most recent survey year period. The utilization rate shall be

determined by dividing the actual bed days of resident care by the bed days available for resident care.

3. In order to establish need for a new or expanded nursing facility in any planning area, the utilization rate in that planning area shall have equaled or exceeded ninety-five percent (95%) during the most recent survey year.

(b) The required bed size for a new nursing facility in a rural or urban county is as follows: (Rural/urban designation shall be based on the county within which the proposed facility is to be located.)

1. A freestanding nursing facility in a rural county: a minimum of 60 beds;

2. A freestanding nursing facility in an urban county: a minimum of 100 beds;

3. A hospital-based nursing facility in a rural county: a minimum of 10 beds and a maximum of 20 beds;

4. A hospital-based nursing facility in an urban county: a minimum of 20 beds and a maximum of 40 beds;

5. A retirement community-based nursing facility: 1 nursing home bed for each 4 residential units, with a minimum of 20 beds and a maximum of 30 beds.

(c) In competing applications, favorable consideration may be given for the inclusion of services for special needs populations, such as but not limited to, persons with Alzheimer's Disease and related disorders, medically fragile children, or persons with HIV/AIDS. An applicant must document a need for the service and that it is cost effective.

(d) The Department may allow an exception to Ga. Comp. R. & Regs. r. 111-2-2-.30(3)(a) under the following circumstances:

1. the establishment of a new Medicare distinct part skilled nursing unit if the proposed unit is to be in a county that does not

have an existing Medicare unit; and if the applicant can document that there is limited access in the proposed planning area for skilled nursing services for Medicare patients. Limited access means that existing nursing facilities have not provided the proposed services in response to a demonstrated demand for the services over the three (3) most recent years. The implementation of an approved Certificate of Need will be valid only if the proposed beds will be limited to Medicare recipients. This exception is available to existing nursing facilities and hospitals; or

2. the applicant for a new or expanded nursing facility can show that there is limited access in the proposed geographic service area for special groups such as, but not limited to medically fragile children and HIV/AIDS patients. Limited access means that existing nursing facilities have not provided the proposed services in response to a demonstrated demand for the services over the three (3) most recent years.

(e) An applicant for a new or expanded facility must document provision of continuity of care by meeting each of the following:

1. An applicant shall provide 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; and

2. An applicant shall document the existence of proposed and/or existing referral agreements with a nearby hospital to provide emergency services and acute-care services to residents of the proposed or existing facility; and

3. An applicant shall provide existing or proposed rehabilitation plans for services to facility residents; and

4. An applicant shall provide existing or proposed discharge planning policies.

(f) An applicant for a new or expanded nursing facility must provide evidence of the intent to meet all appropriate requirements regarding quality of care as follows:

1. An applicant shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division;

2. An applicant shall provide evidence that there are no uncorrected operational standards in any existing Georgia nursing homes owned and/or operated by the applicant or by the applicant's parent organization. Plans to correct physical plant deficiencies in the applying facility must be included in the application;

3. An applicant and any facility owned and/or operated by the applicant or its parent organization shall have no previous conviction or Medicaid or Medicare fraud;

4. An applicant shall demonstrate the intent and ability to recruit, hire and retain qualified personnel to meet the current Medicaid certification requirements of the Department's Division of Medical Assistance for the services proposed to be provided and that such personnel are available in the proposed geographic service area;

5. An applicant shall provide a plan for a comprehensive quality improvement program that 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; accordingly, and

6. In competing applications, favorable consideration will be given to an applicant that provides evidence of the ability to meet accreditation requirements of appropriate accreditation agencies within two years after the facility becomes operational.

(g) An applicant or a new or expanded facility must provide evidence of meeting the following standards pertaining to financial accessibility:

1. An applicant shall provide a written commitment of intent to participate in the Medicaid and Medicare programs if appropriate;

2. An applicant shall demonstrate a case-mix of Medicaid, Medicare and private pay patients; and

3. Document policies and practices of nondiscrimination by past performance of the applicant or its parent organization.

(h) A new or expanded state nursing facility may be exempted from the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.30(3)(a), (b), (c), (d), and (g) when the facility meets all of the following criteria:

1. documentation that the proposed facility will meet the definition of a state nursing facility as defined in Ga. Comp. R. & Regs. r. 111-2-2-.30(1) ((k);

2. documentation that the applicant will admit patients from any of Georgia's counties with a primary focus on a pre-designated, multi-county service area or region;

3. the facility intends to become accessible to patients whose care, because of income and other limitations, would normally come under the jurisdiction of the state; and

4. such other considerations as may be considered necessary by the Department at the time of the application.

(i) An applicant for a new or expanded nursing facility shall document an agreement to provide Department requested information and statistical data related to the operation and provision of nursing facility services and to report that data to the Department in the time frame and format requested by the Department.

Authority: O.C.G.A. §§ 31-2 et seq., 31-6 et seq.

Rule 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 to Ga. Comp. R. & Regs. r. 111-2-2-.31(3)(a) as follows:

1. to allow expansion of an existing personal care home if actual utilization has exceeded ninety percent (90%) 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 outside 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 Ga. Comp. R. & Regs. r. 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;

2. the proposed physical plant design is in compliance with the Rules and licensure standards of the Healthcare Facility Regulation Division 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;

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;

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 Marshal's and the Healthcare Facility Regulation Division's 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 Healthcare Facility Regulation Division.

(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 Healthcare Facility Regulation Division 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 (1%) 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. §§ 31-2 et seq., 31-6 et seq.

Rule 111-2-2-.32. Specific Review Considerations for Home Health Services

(1) **Applicability.** A Certificate of Need for a home health agency will be required prior to the establishment of a new home health agency or the expansion of the geographic service area of an existing home health agency unless such expansion is a result of a non-reviewable acquisition of another existing home health agency.

(2) **Definitions.**

(a) "Home health agency" 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 place of residence used as such individual's home, 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: physical therapy, occupational therapy, speech therapy, medical-social services under the direction of a physician, or part-time or intermittent services of a home health aide.

(b) "Horizon year" means the last year of the three-year projection period for need determinations for a new or expanded home health agency.

(c) "Geographic service area" means a grouping of specific counties within a planning area for which the home health agency is authorized to provide services to individuals residing in the specific counties pursuant to an existing or future Certificate of Need. For purposes of establishing a service area for a new home health agency, the geographic service area shall consist of any individual county or combination of contiguous counties which have an unmet need as determined through the numerical need formula or the exception. For purposes of an expansion of an existing agency, the geographic service area shall consist of an individual county or any combination of counties which have an unmet need, and which are within any planning area in which the home health agency already provides service; however, in no case may an existing home health agency apply to provide

services outside the health planning areas in which its current geographic service area is located.

(d) "Nursing care" means such services provided by or under the supervision of a licensed registered professional nurse in accordance with a written plan of medical care by a physician. Such services shall be provided in accordance with the scope of nursing practice laws and associated rules.

(e) "Planning area" for all home agencies means the geographic regions in Georgia defined in the State Health Plan or Component Plan.

(3) **Standards.**

(a) The need for a new or expanded home health agency shall be determined through application of a numerical need method and an assessment of the projected number of patients to be served by existing agencies.

1. The numerical need for a new or expanded home health agency in any planning area in the horizon year shall be based on the estimated number of annual home health patients within each health planning area as determined by a population-based formula which is a sum of the following for each county within the health planning area:

(i) a ratio of 4 patients per 1,000 projected horizon year Resident population age 17 and younger;

(ii) a ratio of 5 patients per 1,000 projected horizon year Resident population age 18 through 64;

(iii) a ratio of 45 patients per 1,000 projected horizon year Resident population age 65 through 79; and

(iv) a ratio of 185 patients per 1,000 projected horizon year Resident population age 80 and older.

2. The net numerical unmet need for home health services shall be determined by subtracting the projected number of

patients for the current calendar year from the projected need for services as calculated in (3)(a)1. The projected number of patients for the current calendar year is determined by multiplying the number of patients having received services in each county, as reported in the most recent survey year, by the county population change factor. The county population change factor is the percent change in total population between the most recent survey year and the current calendar year.

(b)

1. The Department shall accept applications for review as enumerated below:

(i) If the net numerical unmet need in a given planning area is 250 patients or more, the Department shall authorize the submission of applications for an expanded home health agency; or

(ii) If the net numerical unmet need in a given planning area is 500 patients or more, the Department shall authorize the submission of applications for a new home health agency as well as an expanded home health agency.

2. An applicant must propose to provide service only within a county or group of counties, each of which reflects a numerical unmet need, and contained within the given planning area for which the Department has authorized the submission of applications.

3. The Department shall only approve applications in which the applicant has applied to serve all of the unmet numerical need in any one county in which need is projected. The need within counties shall not be divided or shared between any two or more applicants.

(c) The Department may authorize an exception to Ga. Comp. R. & Regs. r. 111-2-2-.32(3)(a) if:

1. the applicant for a new or expanded home health agency can show that there is limited access in the proposed geographic service area for special groups such as, but not limited to, medically fragile children, newborns and their mothers, and HIV/AIDS patients. For purposes of this exception, an applicant shall be required to document, using population, service, special needs and/or disease incidence rates, a projected need for services in the planning area of at least 200 patients within a defined geographic service area. A successful applicant applying under this section will be restricted to serving the special group or groups identified in the application within the county or counties stipulated in the application; or

2. a particular county is served by no more than two (2) home health agencies and either of the following conditions exists:

(1) less than one percent (1%) of the county's population has received home health services, or

(2) one of the two home health agencies has demonstrated a failure to adequately serve Medicaid patients as evidenced by a level of service to such individuals that is less than the statewide average within each of the past two years as reported on the Annual Home Health Services survey. For purposes of this exception, an applicant must already be approved to provide service in a contiguous county or be approved to provide service in a county that is no further than 15 miles from the county authorized through the exception. In all other aspects of the application process, the applicant shall be required to comply with provisions applicable to expanded home health agencies. For purposes of this exception, "served by" shall mean the agency(ies) are licensed to serve the county by the Healthcare Facility Regulation Division of the Georgia Department of Community Health.

(d) An applicant for a new or expanded home health agency shall provide 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 focusing on coordinated, integrated systems which promote continuity rather than acute, episodic care. Working agreements with other related community services may include the ability to streamline referrals to other appropriate services and to participate in the development of cross-continuum care plans with other providers.

(e) An applicant for a new or expanded home health agency shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division of the Georgia Department of Community Health.

(f) An applicant for a new or expanded home health agency or agency(ies) owned and/or operated by the applicant or its parent organization shall have no history of uncorrected or repeated conditional level violations or uncorrected standard deficiencies as identified by licensure inspections or equivalent deficiencies as noted from Medicare or Medicaid audits.

(g) An applicant for a new or expanded home health agency or agency(ies) owned and/or operated by the applicant or its parent organization shall have no previous conviction of Medicaid or Medicare fraud.

(h) An applicant for a new or expanded home health agency shall provide a written plan which demonstrates the intent and ability to recruit, hire and retain the appropriate numbers of qualified personnel to meet the requirements of the services proposed to be provided and that such personnel are available in the proposed geographic service area.

(i) An applicant for a new home health agency shall provide evidence of the intent to meet the appropriate accreditation requirements of The Joint Commission (TJC), the Community Health Accreditation Program, Inc. (CHAP), and/or other appropriate accrediting agencies.

(j) An applicant for an expanded home health agency shall provide documentation that they are fully accredited by The Joint Commission (TJC), the Community Health Accreditation Program, Inc. (CHAP), and/or other appropriate accrediting agency.

(k) An applicant for a new or expanded home health agency shall provide its existing or proposed plan for a comprehensive quality improvement program.

(l) An applicant for a new or expanded home health agency shall assure access to services to individuals unable to pay and to all individuals regardless of payment source or circumstances by:

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

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds one percent (1%) of annual, adjusted gross revenues for the home health agency or, in the case of an applicant providing other health services, the applicant may request that the Department allow the commitment for services to indigent and charity patients to be applied to the entire facility;

3. 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 Medicare, Medicaid, and indigent and charity patients;

4. providing a written commitment to participate in the Medicare, Medicaid and PeachCare for Kids® programs; and

5. providing a written commitment to participate in any other state health benefits insurance programs for which the home health service is eligible.

(m) An applicant for a new or expanded home health agency shall demonstrate that their proposed charges compare favorably

with the charges of existing home health agencies in the same geographic service area.

(n) An applicant for a new or expanded home health agency shall document an agreement to provide Department requested information and statistical data related to the operation and provision of home health services and to report that data to the Department in the time frame and format requested by the Department.

(o) The Department may authorize an existing home health agency to transfer one county or several counties to another existing home health agency without either agency being required to apply for a new or expanded Certificate of Need, provided the following conditions are met:

1. the two agencies agree to the transfer and submit such agreement and a joint request to transfer in writing to the Department at least thirty (30) days prior to the proposed effective date of the transfer;

2. the two agencies document within the written request that the transfer would result in increased and improved services for the residents of the county or counties including Medicare and Medicaid patients;

3. the agency to which the county or counties are being transferred currently offers services in at least one contiguous county or within the health planning area(s) in which county or counties are located; and

4. the two agencies are in compliance with all other requirements of these Rules; such compliance to be evaluated with the written transfer request.

No such transfer shall become effective without written approval from the Department.

Authority: O.C.G.A. §§ 31-2 et seq., 31-6 et seq.

Rule 111-2-2-.33. Specific Review Considerations for Life Plan Community (LPC) Sheltered Nursing Facilities

(1) **Applicability.** A Certificate of Need will be required prior to the establishment of a new or expanded LPC Sheltered Nursing Facility, if not exempt as provided by O.C.G.A. § 31-6-47(a)(17) and Ga. Comp. R. & Regs. r. 111-2-2-.03(20). These Rules apply to sheltered nursing facilities located in LPC facilities defined herein as Type A and Type B Life Plan Communities. A LPC that has obtained nursing facility beds approved under the standards contained in Ga. Comp. R. & Regs. r. 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 LPC must apply for a new Certificate of Need. Conversely, a LPC that obtains sheltered nursing facility beds under these Rules may not qualify for beds under Ga. Comp. R. & Regs. r. 111-2-2-.30, and is therefore only required to complete these specific review considerations for the sheltered nursing facility beds.

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

(3) **Definitions.**

(a) "A Life Plan Community" (LPC) 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 Life Plan Community" (Type A LPC) provides LPC 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 LPC offers nursing facility care for a little or no substantial increase in monthly payments, except normal operating costs and inflation adjustments.

(c) "Type B Life Plan Community" (Type B LPC) provides LPC 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 LPC 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) "LPC Sheltered Nursing Facility", for purposes of these Rules, is a nursing facility that meets the definition of a nursing facility as defined by Ga. Comp. R. & Regs. r. 111-2-2-.30 of the

Rules of the Department. A LPC Sheltered Nursing Facility shall be for the exclusive use of residents of a Type A or Type B LPC.

(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 Life Plan Community.

(4) **Standards.**

(a) The numerical need for a new LPC sheltered nursing facility shall be based on a ratio of one nursing facility bed for each five independent living units. The applicant for a LPC Sheltered Nursing Facility shall demonstrate to the Department that the potential market for LPC 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 LPC sheltered nursing facility shall be based on a ratio of one nursing facility bed for each four independent living units provided that the LPC's existing nursing facility has experienced an occupancy rate of at least eighty percent (80%) 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 LPC, 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 LPC 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 LPC which is the applicant for a new or expanded LPC 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 LPC 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 LPC 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 Healthcare Facility Regulation Division;

2. No uncorrected operational standards in any existing Georgia general or LPC 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 LPC which is the applicant for a new or expanded LPC 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 LPC 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 LPC 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 LPC and the Sheltered Nursing Facility. Analyses are predicated upon accurate, consistent, and systematically obtained information.

Authority: O.C.G.A. §§ 31-2 et seq., 31-6 et seq.

Rule 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 lifelong 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 Ga. Comp. R. & Regs. r. 111-2-2-.03(28). An application for Certificate of Need for a new or expanded Transitional Living Program shall be reviewed under the

General Review Considerations of Ga. Comp. R. & Regs. r. 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 Ga. Comp. R. & Regs. r. 111-2-2-.03(28). An application for Certificate of Need for a new or expanded Life Long Living Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 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; 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 (12) 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 Healthcare Facility Regulation Division 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 eighty percent (80%) 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 eighty-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 Ga. Comp. R. & Regs. r. 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 Healthcare Facility Regulation Division 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 Healthcare Facility Regulation Division.

(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 percent (3%) 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 for a Traumatic Brain Injury Facility and the Certificate of Need 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 Certificate of Need 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. §§ 31-2 et seq., 31-6 et seq.

Rule 111-2-2-.35. Specific Review Considerations for Comprehensive Inpatient Physical Rehabilitation Services

(1) **Applicability.**

(a) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Comprehensive Inpatient Physical Rehabilitation Adult Program. An application for Certificate of Need for a new or expanded Comprehensive Inpatient Physical Rehabilitation Adult Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 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 Comprehensive Inpatient Physical Rehabilitation Pediatric Program. An application for Certificate of Need for a new or expanded Comprehensive Inpatient Physical Rehabilitation Pediatric Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(2) **Definitions.**

(a) ”Adults” means persons eighteen (18) years of age and over. However, a Certificate of Need authorized or grandfathered Comprehensive Inpatient Physical Rehabilitation Adult Program will not be in violation of the Certificate of Need laws and regulations if it provides service to a patient older than fifteen years if the provider has determined that such service is medically necessary, provided that the treatment days and patient census associated with patients sixteen and seventeen years of age do not exceed ten percent (10%) of annual treatment days and

annual census, respectively. Rehabilitation programs specifically focused towards treatment of spinal cord injuries and disorders and which existed prior to the effective date of this version of Ga. Comp. R. & Regs. r. 111-2-2-.35 shall not be subject to the adult age limitations; such programs may treat any patient aged twelve (12) and over.

(b) "Comprehensive Inpatient Physical Rehabilitation Programs" means rehabilitation services, which have been classified by Medicare as an inpatient rehabilitation facility pursuant to 42 C.F.R. § 412.23(b)(2), provided to a patient who requires hospitalization, which provides coordinated and integrated services that include evaluation and treatment, and emphasizes education and training of those served. The program is applicable to those individuals who require an intensity of services which includes, as a minimum, physician coverage twenty-four (24) hours per day, seven (7) days per week, with daily (at least five (5) days per week) medical supervision, complete medical support services including consultation, 24-hour-per-day nursing, and daily (at least five (5) days per week) multidisciplinary rehabilitation programming for a minimum of three hours per day. For regulatory purposes, the definition includes a program which asserts its intent to be Medicare-classified as an inpatient rehabilitation facility no later than twenty-four (24) months after accepting its first patient. If a program, which has been awarded a CON pursuant to this Rule, has not been so classified by Medicare within the timeframe outlined above, the CON issued to that entity shall be revoked.

(c) "Expansion" and "Expanded" mean the addition of beds to an existing CON-authorized or grandfathered Comprehensive Inpatient Physical Rehabilitation Program. However, a CON-authorized or grandfathered provider of Comprehensive Inpatient Physical Rehabilitation in a freestanding rehabilitation hospital may increase the bed capacity of an existing program by the lesser of ten percent (10%) of existing capacity or ten (10) beds if it has maintained an average occupancy of eighty-five percent

(85%) for the previous twelve (12) calendar months provided that there has been no such increase in the prior two years.

(d) ”Freestanding Rehabilitation Hospital” means a specialized hospital organized and operated as a self-contained health care facility that provides one or more rehabilitation programs and which has been classified as an inpatient rehabilitation facility by the Medicare program pursuant to 42 C.F.R. § 412.23(b)(2). For regulatory purposes, the definition includes a hospital which asserts its intent to be Medicare-classified as an inpatient rehabilitation facility no later than twenty-four (24) months after accepting its first patient. If an entity, which has been awarded a CON pursuant to this Rule, has not been so classified by Medicare within the timeframe outlined above, the CON issued to that entity shall be revoked. An entity, which has had its CON revoked pursuant to this Rule, shall not have the authority to operate as a general acute care hospital.

(e) ”New” means a Program that has not been classified by the Medicare program as a rehabilitation hospital or program in the previous twelve (12) months. Adult programs described in Ga. Comp. R. & Regs. r. 111-2-2-.35(1)(a) and pediatric programs described in Ga. Comp. R. & Regs. r. 111-2-2-.35(1)(b) shall be considered independent programs such that a provider seeking to add a program not offered by that provider in the previous twelve (12) months shall be considered to be offering a new program for which a Certificate of Need must be obtained. For purposes of these Rules, an existing program which proposes to be relocated to a location more than three (3) miles from its present location shall be considered "new".

(f) ”Official State Health Component Plan” means the document related to Physical Rehabilitation Programs and Services developed by the Department, established by the Georgia Health Strategies Council and signed by the Governor of Georgia.

(g) ”Pediatric” means persons seventeen (17) years of age and under. However, a CON-authorized or grandfathered Comprehensive Inpatient Rehabilitation Pediatric Program will not be in violation of the CON laws and regulations if it provides service to a patient younger than twenty-two (22) years if the provider has determined that such service is medically necessary, provided that the treatment days and patient census associated with patients eighteen, nineteen, twenty, and twenty-one years of age do not exceed ten percent (10%) of annual treatment days and annual census, respectively. Rehabilitation programs specifically focused towards treatment of spinal cord injuries and disorders and which existed prior to the effective date of this version of Ga. Comp. R. & Regs. r. 111-2-2-.35 shall not be subject to the pediatric age limitations; such programs may treat any patient aged twelve (12) and over.

(h) ”Planning Region” means one of the four sub-state regions for Physical Rehabilitation Programs and Services as follows:

1. Rehabilitation Region 1, including the following counties: Dade, Walker, Catoosa, Whitfield, Murray, Gilmer, Fannin, Union, Towns, Rabun, Stephens, Habersham, White, Lumpkin, Dawson, Pickens, Gordon, Chattooga, Floyd, Bartow, Cherokee, Forsyth, Hall, Banks, Franklin, Hart, Elbert, Madison, Jackson, Barrow, Gwinnett, Fulton, Cobb, Paulding, Polk, Haralson, Carroll, Douglas, DeKalb, Rockdale, Walton, Oconee, Clarke, Oglethorpe, Greene, Morgan, Newton, Butts, Henry, Clayton, Fayette, Coweta, Heard, Troup, Meriwether, Pike, Spalding, Lamar, and Upson

2. Rehabilitation Region 2, including the following counties: Wilkes, Lincoln, Columbia, McDuffie, Warren, Taliaferro, Hancock, Glascock, Putnam, Jasper, Monroe, Jones, Baldwin, Washington, Jefferson, Richmond, Burke, Screven, Jenkins, Emmanuel, Johnson, Treutlen, Montgomery, Wheeler, Telfair, Wilcox, Dodge, Laurens, Pulaski, Bleckley, Houston, Peach, Twiggs, Wilkinson, Bibb, and Crawford

3. Rehabilitation Region 3, including the following counties: Harris, Talbot, Taylor, Muscogee, Chattahoochee, Marion, Schley, Macon, Dooly, Sumter, Webster, Stewart, Quitman, Randolph, Terrell, Lee, Crisp, Ben Hill, Irwin, Turner, Worth, Dougherty, Calhoun, Clay, Early, Baker, Mitchell, Colquitt, Miller, Cook, Tift, Berrien, Lanier, Echols, Lowndes, Brooks, Thomas, Grady, Decatur, and Seminole

4. Rehabilitation Region 4, including the following counties: Effingham, Bulloch, Candler, Toombs, Tattnall, Evans, Bryan, Chatham, Liberty, Long, Wayne, Appling, Jeff Davis, Coffee, Bacon, Pierce, Brantley, McIntosh, Glynn, Camden, Charlton, Ware, Atkinson, and Clinch

(3) **Service-Specific Review Standards.**

(a) The need for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program ("CIPR") shall be determined and applied as follows:

1. The need for new or expanded Comprehensive Inpatient Physical Rehabilitation Adult Program in a planning region shall be determined using the following demand-based need projection:

(i) Determine the comprehensive inpatient physical rehabilitation utilization rate per 1,000 for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharges from licensed providers of inpatient rehabilitation in the planning region for patients aged eighteen (18) and over by current year projected resident population (aged 18 and over) for the planning region and multiplying by 1,000. The source of current year discharge data for purposes of this Rule include data collected pursuant to O.C.G.A. § 31-7-280(c)(14), or in the Department's discretion, discharge data collected on the most recent Annual Hospital Questionnaire. The source for current and horizon year resident population shall be resident population projections from the Governor's Office of Planning and Budget. For the first Horizon Year projection using this Rule, and for the first horizon year projection only, the utilization rate per 1,000 for

each planning region shall be reduced by sixteen percent (16%) to account for anticipated utilization reduction after full implementation of the Center for Medicare and Medicaid Services' ("CMS") seventy-five percent (75%) rule.

(ii) Calculate the projected horizon year discharges for each planning region by multiplying the planning region utilization rate obtained in Step (i) by the horizon year resident population projection (aged 18 and over) for that planning region.

(iii) Determine the comprehensive inpatient physical rehabilitation average length of stay for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharge days of care from licensed providers of inpatient rehabilitation in the planning region for patients aged eighteen (18) and over by the current year inpatient rehabilitation discharges determined in Step (i).

(iv) Multiply the projected discharges obtained in Step (ii) by the current year's average length of stay (aged 18 and over) determined in Step (iii) to determine the horizon year projected patient days for each planning region.

(v) Divide the product obtained in Step (iv) by the number of calendar days in the horizon year to obtain the average projected daily census in each planning region.

(vi) Divide the result obtained in Step (v) by .85 to determine the number of projected beds utilizing an eighty-five percent (85%) capacity standard for each planning region.

(vii) Determine the current inventory of comprehensive inpatient physical rehabilitation beds for adults in the planning region from Departmental data. For all CIPR providers, which have been licensed as a Rehabilitation Hospital by the Healthcare Facility Regulation Division, the current inventory of CIPR beds shall reflect the number of beds reported as CON-authorized in the Facility Inventory prior to the date of adoption of these Rules augmented from that time forward only by increases in bed

capacity approved through the CON process (or by exemptions thereto) and by decreases due to a provider ceasing to provide such services for a period in excess of twelve (12) months. For purposes of this Rule, the initial inventory shall not include the beds of licensed Long Term Care Hospitals; the beds of such facilities shall be included in the applicable Long Term Care Hospital inventory.

(viii) If the projected bed need in Step (vi) is greater than the current inventory of adult CIPR beds in the planning region, the application for the Certificate of Need should reflect a number of beds equal to or lesser than the resulting unmet bed need.

2. The need for new or expanded Comprehensive Inpatient Physical Rehabilitation Pediatric Program in a planning region shall be determined using the following demand-based need projection:

(i) Determine the comprehensive inpatient physical rehabilitation utilization rate per 1,000 for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharges from licensed providers of inpatient rehabilitation in the planning region for patients aged seventeen (17) and under by current year resident population (aged 17 and under) for the planning region. The source of current year discharge data for purposes of this Rule include data collected pursuant to O.C.G.A. § 31-7-280(c)(14), or in the Department's discretion, discharge data collected on the most recent Annual Hospital Questionnaire.

(ii) Calculate the projected horizon year discharges for each planning region by multiplying the planning region utilization rate obtained in Step (i) by the horizon year resident population projection (aged 17 and under) for that planning region.

(iii) Determine the comprehensive inpatient physical rehabilitation average length of stay for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharge days of care from licensed providers of

inpatient rehabilitation in the planning region for patients aged seventeen (17) and under by the current year inpatient rehabilitation discharges determined in Step (i).

(iv) Multiply the projected discharges obtained in Step (ii) by the current year's average length of stay (aged 17 and under) determined in Step (iii) to determine the horizon year projected patient days for each planning region.

(v) Divide the product obtained in Step (iv) by the number of calendar days in the horizon year to obtain the average projected daily census in each planning region.

(vi) Divide the result obtained in Step (v) by .85 to determine the number of projected beds utilizing an eighty-five percent (85%) capacity standard for each planning region.

(vii) Determine the current inventory of comprehensive inpatient physical rehabilitation beds for pediatric patients in the planning region from Departmental data. For all CIPR providers, which have been licensed as a Rehabilitation Hospital by the Healthcare Facility Regulation Division, the current inventory of CIPR beds shall reflect the number of beds reported as CON-authorized in the Facility Inventory prior to the date of adoption of these Rules augmented from that time forward only by increases in bed capacity approved through the CON process (or by exemptions thereto) and by decreases due to a provider ceasing to provide such services for a period in excess of twelve (12) months. For purposes of this Rule, the initial inventory shall not include the beds of licensed Long Term Care Hospitals; the beds of such facilities shall be included in the applicable Long Term Care Hospital inventory.

(viii) If the projected bed need in Step (vi) is greater than the current inventory of pediatric CIPR beds in the planning region, the application for the Certificate of Need should reflect a number of beds equal to or lesser than the resulting unmet bed need.

(b) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall document that the establishment or expansion of its 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 Comprehensive Inpatient Physical Rehabilitation Program shall have an adverse impact on existing and approved programs of the same type if it will:

1. decrease annual utilization of an existing 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 program, whose current utilization is below eighty-five percent (85%), by ten percent over the twelve (12) months following the acceptance of the applicant's first patient.

(c) The Department may grant the following exceptions:

1. The Department may grant an exception to the need methodology of Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a) 1. and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(b) for an applicant proposing a program to be located in a county with a population of less than 75,000 and to be located a minimum of fifty (50) miles away from any existing program in the state.

2. The Department may grant an exception to the need methodologies of either Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a) 1. or 111-2-2-.35(3)(a) 2. and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(b) to remedy an atypical barrier to Comprehensive Inpatient Physical Rehabilitation Programs based on cost, quality, financial access or geographic accessibility or if the applicant's annual census demonstrates thirty percent (30%) out of state utilization for the previous two years.

3. The Department may grant an exception to the need methodologies of Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a) 1. or Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a) 2. in a planning area which has no existing provider provided that the applicant demonstrates a need for the service based on patient origin data.

(d) A new Comprehensive Inpatient Physical Rehabilitation Program shall have the following minimum bed sizes based on type of program offered:

1. A new Comprehensive Inpatient Physical Rehabilitation Adult Program shall have a minimum bed size of twenty (20) beds in a freestanding rehabilitation hospital already offering another Comprehensive Inpatient Physical Rehabilitation Program, twenty (20) beds or in an acute-care hospital, and forty (40) beds for a new freestanding rehabilitation hospital not already offering another Comprehensive Inpatient Physical Rehabilitation Program.

2. A new Comprehensive Inpatient Physical Rehabilitation Pediatric Program shall have a minimum of 10 beds in a freestanding rehabilitation hospital already offering another Comprehensive Inpatient Physical Rehabilitation Program, 10 beds in an acute-care hospital, and forty (40) beds for a new freestanding rehabilitation hospital not already offering another Comprehensive Inpatient Physical Rehabilitation Program.

(e) An applicant for a new Comprehensive Inpatient Physical Rehabilitation Program shall demonstrate the intent to meet the standards of the Commission on Accreditation of Rehabilitation Facilities ("CARF") applicable to the type of Program to be offered within eighteen (18) months of offering the new service.

(f) An applicant for an expanded Comprehensive Inpatient Physical Rehabilitation Program shall be accredited by the CARF for the type of Program which the applicant seeks to expand prior to application. The applicant must provide proof of such accreditation.

(g) An applicant for a new freestanding rehabilitation hospital shall demonstrate the intent to meet the licensure Rules of the Healthcare Facility Regulation Division for such hospitals.

(h) An applicant for an expanded freestanding rehabilitation hospital shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Healthcare Facility Regulation Division.

(i) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall have written policies and procedures for utilization review. Such review shall consider, but is not limited to, factors such as medical necessity, appropriateness and efficiency of services, quality of patient care, and rates of utilization.

(j) An applicant for a new or expanded freestanding rehabilitation hospital shall document the existence of referral arrangements, including transfer agreements with an acute-care hospital(s) 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.

(k) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program 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 un-reimbursed 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'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 un-reimbursed indigent and charity care.

(l) **Reserved.**

(m) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall agree to provide the State Health Department with requested information and statistical data related to the operation of such a Program on a yearly basis, or as needed, and in a format requested by the Department.

Authority: O.C.G.A. §§31-2*et seq*., 31-6 *et seq*.

Rule 111-2-2-.36. Specific Review Considerations for Long Term Care Hospitals

(1) **Applicability.** A Certificate of Need ("CON") shall be required prior to the establishment of a new or the expansion of an existing Long Term Care Hospital. An application for Certificate of Need for a new or expanded Long Term Care Hospital shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(2) **Definitions.**

(a) “Expansion” or “Expanded” means the addition of beds to an existing CON-authorized or grandfathered Long Term Care Hospital. A CON-authorized or grandfathered Long Term Care Hospital may increase the bed capacity of an existing hospital by the lesser of ten percent (10%) of existing capacity or 10 beds if it has maintained an average occupancy of eighty-five percent (85%) for the previous twelve (12) calendar months provided that there has been no such increase in the prior two years and provided that the capital expenditures associated with the increase do not exceed the Capital Expenditure Threshold. If such an increase exceeds the Capital Expenditure Threshold, the increase will be considered an expansion for which a Certificate of Need shall be required under these Rules.

(b) “Free-standing LTCH” or “Free-standing LTACH” means a Long Term Care Hospital organized and operated as a self-contained health care facility.

(c) “Hospital-within-a-Hospital LTCH” or “Hospital-within-a-Hospital LTACH” means a Long Term Care Hospital co-located within the same building or the same campus as another CON-Authorized hospital.

(d) “Long Term Care Hospital” or “LTCH” or “Long Term Acute Care Hospital” or “LTACH” means a hospital that is classified as a long term hospital by the Medicare program pursuant to 42 CFR 412.23(e). These hospitals typically provide extended medical and rehabilitative care for patients who are clinically complex and may suffer from multiple acute or chronic conditions. Services typically include comprehensive rehabilitation, respiratory therapy, head trauma treatment, and pain management. For regulatory purposes, the definition includes a hospital which asserts its intent to be Medicare-classified as a long term hospital within twenty-four (24) months of accepting its first patient. If an entity, which has been awarded a CON pursuant to this Rule, has not been so classified by Medicare within this timeframe, the CON issued to that entity shall be revoked. An entity, which has had its CON revoked pursuant to this Rule, shall not have the authority to

operate as a general acute care hospital. However, an acute care hospital, which has been awarded a CON to convert acute care beds for use as a long term care hospital, may again use such beds for acute care if such beds have not been Medicare-classified as a long term care hospital within twenty-four (24) months of accepting its first patient. Furthermore, a hospital that has been approved through the Certificate Of Need process to use all of its short-stay beds for a Freestanding LTCH shall have such beds removed from the official inventory of available short-stay beds when the LTCH is certified by Medicare; provided, however, that the hospital's beds will revert to the official inventory of available short-stay beds at any point that the facility ceases to be certified by Medicare as an LTCH.

(e) “New” means a hospital that has not been classified by the Medicare program as a long term hospital in the previous twelve (12) months. For purposes of these Rules, an existing hospital which proposes to be relocated to a location more than three miles from its present location shall be considered "new".

(f) “Occupancy Rate” means the ratio of beds occupied by inpatients as reported on the most recent Annual Hospital Questionnaire divided by the total licensed beds.

(g) “Official State Health Component Plan” means the document related to Long Term Care Hospitals developed by the Department, established by the Georgia Health Strategies Council and signed by the Governor of Georgia.

(h) “Planning Region” means one of the four sub-state regions for Long Term Care Hospitals, as follows:

1. LTCH Region 1, including the following counties: Dade, Walker, Catoosa, Whitfield, Murray, Gilmer, Fannin, Union, Towns, Rabun, Stephens, Habersham, White, Lumpkin, Dawson, Pickens, Gordon, Chattooga, Floyd, Bartow, Cherokee, Forsyth, Hall, Banks, Franklin, Hart, Elbert, Madison, Jackson, Barrow, Gwinnett, Fulton, Cobb, Paulding, Polk, Haralson, Carroll, Douglas, DeKalb, Rockdale, Walton, Oconee, Clarke, Oglethorpe,

Greene, Morgan, Newton, Butts, Henry, Clayton, Fayette, Coweta, Heard, Troup, Meriwether, Pike, Spalding, Lamar, and Upson

2. LTCH Region 2, including the following counties: Wilkes, Lincoln, Columbia, McDuffie, Warren, Taliaferro, Hancock, Glascock, Putnam, Jasper, Monroe, Jones, Baldwin, Washington, Jefferson, Richmond, Burke, Screven, Jenkins, Emmanuel, Johnson, Treutlen, Montgomery, Wheeler, Telfair, Wilcox, Dodge, Laurens, Pulaski, Bleckley, Houston, Peach, Twiggs, Wilkinson, Bibb, and Crawford

3. LTCH Region 3, including the following counties: Harris, Talbot, Taylor, Muscogee, Chattahoochee, Marion, Schley, Macon, Dooly, Sumter, Webster, Stewart, Quitman, Randolph, Terrell, Lee, Crisp, Ben Hill, Irwin, Turner, Worth, Dougherty, Calhoun, Clay, Early, Baker, Mitchell, Colquitt, Miller, Cook, Tift, Berrien, Lanier, Echols, Lowndes, Brooks, Thomas, Grady, Decatur, and Seminole

4. LTCH Region 4, including the following counties: Effingham, Bulloch, Candler, Toombs, Tattnall, Evans, Bryan, Chatham, Liberty, Long, Wayne, Appling, Jeff Davis, Coffee, Bacon, Pierce, Brantley, McIntosh, Glynn, Camden, Charlton, Ware, Atkinson, and Clinch

(3) **Service-Specific Review Standards.**

(a) The need for new or expanded Long Term Care Hospital in a LTCH planning region shall be determined using the following need projection:

1. Determine the total discharges from general acute care hospitals less LTCH discharges, and less perinatal and neonatal discharges, and less psychiatric and substance abuse discharges, and less comprehensive inpatient physical rehabilitation discharges for the planning region in which the Long Term Care Hospital is or will be located. The source of discharge data for purposes of this Rule include data collected pursuant to O.C.G.A. § 31-7-280(c)(14), or in the Department's discretion, discharge data collected on the most recent Annual Hospital Questionnaire.

2. Calculate the discharge rate for each planning region by dividing the number of current acute care discharges obtained in Step 1 in each planning region by the corresponding year's resident population projection from the Governor's Office of Planning and Budget in each planning region.

3. Calculate the projected discharges for each planning region by multiplying the discharge rate obtained in Step 2 by the horizon year resident population projection for that planning region and then reduce that figure by six percent (6%) to account for overlap with rehabilitation facilities.

4. Calculate gross beds needed in the horizon year as follows:

(i) Multiply the projected discharges obtained in Step 3 by a utilization factor of 1.3% to determine the projected number of acute care discharge who may benefit from services at a LTCH.

(ii) Multiply the product obtained in Step 4(i) by the average LTCH length of stay for the most recent previous three-year period. Beginning with the first need calculation and continuing until the third complete year of survey data collected pursuant to this Rule, the Department shall use 28.1 as a proxy for the average LTCH length of stay for the previous three years.

(iii) Divide the product obtained in Step 4(ii) by 365 to determine the projected daily LTCH census.

(iv) Divide the result obtained in Step 4(iii) by .85 to determine the number of projected LTCH beds utilizing an eighty-five percent (85%) capacity standard.

5. Determine the current inventory of LTCH beds in the planning region from Departmental data. For all long term care hospital providers, which have been licensed as a Long Term Care Hospital by the Healthcare Facility Regulation Division, the current inventory of LTCH beds shall reflect the number of beds reported as CON-authorized in the Facility Inventory prior to the date of

adoption of these Rules augmented from that time forward only by increases in bed capacity approved through the CON process (or by exemptions thereto) and by decreases due to a provider ceasing to provide such services for a period in excess of twelve (12) months. For purposes of this Rule, the initial inventory shall not include the beds of licensed rehabilitation hospitals even if such hospitals have a reported average length of stay of greater than twenty-five (25) days for Medicare patients; the beds of such facilities shall continue to be included in the applicable Comprehensive Inpatient Physical Rehabilitation inventory.

6. If the projected LTCH bed need in Step 4(iv) is greater than the current inventory of LTCH beds in the planning region, the application for the Certificate of Need should reflect a number of beds equal to or lesser than the resulting unmet bed need.

(b) An applicant for a new or expanded Long Term Care Hospital shall document that the establishment or expansion of its hospital will not have an adverse impact on an existing and approved long term care hospital in its planning region. An applicant for a new or expanded Long Term Care Hospital shall have an adverse impact on existing and approved hospitals of the same type if it will:

1. decrease annual utilization of an existing hospital, 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 hospital, whose current utilization is below eighty-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 hospitals of the same type and future population growth or by providing sufficient evidence that the current population is

underserved by the existing Long Term Care Hospitals within the planning region.

(c) The Department may grant an exception to the need methodology of Ga. Comp. R. & Regs. r. 111-2-2-.36(3)(a) and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-2-2-.36(3)(b) for an applicant proposing a program to be located in a county with a population of less than 75,000 and to be located a minimum of fifty (50) miles away from any existing program in the state; or to remedy an atypical barrier to the services of a Long Term Care Hospital based on cost, quality, financial access or geographic accessibility. The Department may grant an exception to the need methodologies of either Ga. Comp. R. & Regs. r. 111-2-2-.36(3)(a) and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-2-2-.36(3)(b) if the applicant's annual census demonstrates thirty percent (30%) out of state utilization for the previous two years.

(d) A new or expanded Long Term Care Hospital shall have the following minimum bed sizes:

1. A new freestanding LTCH shall have a minimum bed size of forty (40) beds.

2. A new Hospital-within-a-Hospital LTCH shall have a minimum bed size of twenty (20) beds.

3. The minimum number of beds for the expansion of an existing Long Term Care Hospital, including satellite locations, shall be ten (10) beds or ten percent (10%) of the total current authorized bed capacity of the Long Term Care Hospital, whichever is less.

(e) An applicant for a new Long Term Care Hospital shall demonstrate the intent to meet the standards of the Joint Commission or another nationally recognized health care accreditation body within twenty-four (24) months of accepting its first patient. An applicant for an expanded Long Term Care Hospital shall be Joint Commission-certified or certified by another

nationally recognized health care accreditation body 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 Long Term Care Hospital shall demonstrate the intent to meet the Licensure Rules of the Healthcare Facility Regulation Division for such hospitals. An applicant for an expanded Long Term Care Hospital shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Healthcare Facility Regulation Division.

(g) An applicant for a new or expanded Long Term Care Hospital shall have written policies and procedures for utilization review. Such review shall consider, but is not limited to, factors such as medical necessity, appropriateness and efficiency of services, quality of patient care, and rates of utilization.

(h) An applicant for a new or expanded Long Term Care Hospital shall document the existence of referral arrangements, including transfer agreements, with an acute-care hospital(s) 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 Long Term Care Hospital 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 un-reimbursed 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;

3. 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 un-reimbursed indigent and charity care;

4. providing documentation of current or proposed charges and policies, if any, regarding the amount or percentage of charges that charity patients, self pay patients, and the uninsured will be expected to pay; and

5. agreeing to participate in the Medicare and Medicaid programs if such programs reimburse for such services.

(j) **Reserved**.

(k) An applicant for a new or expanded Long Term Care Hospital shall agree to provide the Department with requested information and statistical data related to the operation of such a Program on a yearly basis, or as needed, and in a format requested by the Department.

Authority: O.C.G.A. §§ 31-2 et seq., 31-6 et seq.

Rule 111-2-2-.37. Reserved

Rule 111-2-2-.38. Reserved

Rule 111-2-2-.39. Reserved

Rule 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 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, the project will be reviewed under Ga. Comp. R. & Regs. r. 111-2-2-.40.

(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 Healthcare Facility Regulation Division.

(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 by Chapter 111-8-4 of the Rules of the Healthcare Facility Regulation Division or such substantially equivalent standards as determined by the Department. Such acceptable standards shall be maintained on the Department's website.

(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 Ga. Comp. R. & Regs. r. 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 an 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 Healthcare Facility Regulation Division.

(k) An applicant for a new ambulatory surgery service shall provide a statement for the intent to meet, within twelve (12) months of obtaining state licensure, the appropriate accreditation requirements of the Joint Commission or another nationally recognized health care accreditation body, 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 or another nationally recognized health care accreditation body, 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. §§ 31-2 et seq., 31-6 et seq.

Rule 111-2-2-.41. Specific Review Considerations for Positron Emission Tomography Units

(1) Applicability.

(a) A Certificate of Need shall be required for a new or expanded positron emission tomography ("PET") unit except as otherwise provided in O.C.G.A. § 31-6-47 and Ga. Comp. R. & Regs. r. 111-2-2-03.

(b) On or after January 1, 2008, the Department shall only consider and approve applications for dual modality PET units; stand-alone PET units shall not be approved.

(c) On or after July 1, 2024, an applicant for a mobile unit site shall be DTRC which has entered into an agreement to receive mobile services. The actual mobile service provider shall not be the applicant. The hospital or DTRC that is serviced by the mobile provider shall be responsible for the provision of annual surveys and the provision of information to the Department.

(d) **Reserved**.

(e) A Certificate of Need obtained by a hospital or DTRC to offer mobile PET services shall be valid for the provision of mobile PET services only. A DTRC approved to offer mobile PET services must obtain a separate CON prior to offering fixed PET services.

(2) **Definitions.**

(a) "Health Planning Area" or "planning area" means the thirteen (13) geographic regions in Georgia as defined in the

official State Health Component Plan for use in planning for PET Scan services.

(b) "Horizon Year" means the last year of a five-year projection period for need determinations.

(c) "Expansion" or "expanded service" means the addition of a fixed or mobile unit at a DTRC. The addition of a component or components, such as computer tomography (CT) imaging, to an existing fixed or mobile unit or the upgrade of an existing fixed or mobile unit shall not be considered an expansion and shall not be subject to the need standards.

(d) "Fixed Unit" means a unit that is stationary within one approved facility.

(e) "Mobile Unit" means a unit that is operated by one or shared by two or more health care facilities and which has a data acquisition system and a computer. In order to meet the definition of mobile unit, the applicant must provide proof of the following:

1. The unit must not be on site at any Facility more than three (3) consecutive operating days per week or sixteen (16) total days per month.

2. The facilities involved with the mobile unit are fully informed and participating in the service as evidenced by written agreements or correspondence provided in the application.

3. For applications approved prior to January 1, 2008, a mobile provider is limited to providing service only to those facilities approved in the mobile provider's application for CON. On or after January 1, 2008, a mobile provider may serve any DTRC that receives a Certificate of Need for mobile PET services, provided that no DTRC may be serviced by more than one mobile provider at a time.

4. The applicant shall project scans per facility on a pro-rated basis for the first year of operation, and such projections shall be used in any need determinations during that first year of operation.

Thereafter, in annual surveys, the applicant, if successful, must document scans by each service facility for use in need determinations.

(f) "Optimal Utilization" refers to scans per year and shall be defined as 2,750 PET scans per year. A PET Scan or Study means the gathering of data during a single patient visit from which one or more images may be constructed.

(g) "PET Scan Service" or "Service" means a facility that owns one or more units and provides diagnostic imaging through positron emission tomography exclusively or as a dedicated PET/CT or dual modality unit.

(h) "Positron Emission Tomography" or "PET" means a noninvasive diagnostic technology, which enables the body's physiological and biological processes to be observed through the use of positron emitting radiopharmaceuticals.

(i) "Unit" means a single piece of equipment that performs PET scans.

(3) **Standards.**

(a) The need for a new or expanded service shall be determined through the application of a Numerical Need method and an assessment of the aggregate utilization rate of existing and approved units.

1. The numerical need for a new unit 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 projected incidence of cancer for each county by multiplying the most recent Cancer Incidence Rate, as published by the State Cancer Registry, for each county by the horizon year population for the county;

(ii) Multiply the projected incidence of cancer by fifty percent (50%) to determine the projected number of patients diagnosed with cancer who might benefit from a scan.

(iii) Add the number of cancer cases that might benefit from a scan for each county within a Health Planning Area to determine the estimated need for services within a Health Planning Area for persons diagnosed with cancer.

(iv) Multiply the number of cancer cases for each Health Planning Area from subsection (iii) by 1.4 to accommodate for non-oncology patients and for follow-up scans for oncology patients in the projected need for services. On or after January 1, 2010, in lieu of multiplying by 1.4 each year, the Department shall use actual data from the previous 2 survey years to determine the multiplication factor by adding 1 to the ratio of cardiology, neurology and follow up oncology scans to the number of initial oncology scans.

(v) Calculate the number of needed units by dividing the number of individuals who might receive scanning services as determined from subsection (iv) by 2,750, which represents the optimal utilization of a unit.

(vi) Determine the net numerical unmet need for PET scan unit(s) by subtracting the total number of PET/CT or dual modality units currently existing or approved for use from the number of needed units. Mobile units shall be subtracted based on the number of days providing service to sites within a planning area in the most recent survey year divided by 365. Stand-alone PET units shall not be included in the inventory and shall not be subtracted to determine the net numerical unmet need.

(vii) If the net numerical unmet need in any Health Planning Area is at or above seventy-five percent (75%) of a unit (approximately 2,062 individuals needing scans), the needed units shall be rounded up by one unit. If the balance net numerical need in any Health Planning Area is at or above 3.2875% of a unit (approximately (90) individuals needing scans), a mobile unit may

be approved to serve the planning area. The maximum number of days a mobile unit may be approved to provide services in the planning area shall be determined using the following formula:

APPROVED DAYS PER YEAR

< NET NUMERICAL UNMET NEED

365

2. Prior to the approval of a new or expanded unit in a planning area, the aggregate utilization rate for all units in that planning area that existed during the most recent survey year and that provided data to the Department for the most recent survey year shall equal or exceed eighty percent (80%) of optimal utilization for the most recent survey year.

(b) Exceptions to the need standards and requirements in (3)(a) may be granted by the Department:

1. to an applicant seeking to remedy an atypical barrier to services based on cost, quality, financial access, or geographic accessibility when the applicant has documented such a barrier;

2. to an applicant seeking the addition of a fixed unit who has been served solely by a mobile PET when the applicant demonstrates that 850 studies have been performed on the mobile unit at the applicant's facility in the most recent survey year; and

3. **Reserved**.

(c) In considering applications joined for review, the Department may give favorable consideration to an applicant that

has historically provided a higher annual percentage of un-reimbursed services to indigent and charity patients.

(d) An applicant for a new or expanded 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 that stipulates that any 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 five percent (5%) of annual, adjusted gross revenues of the PET scan service; or

3. providing a written commitment to participate in Medicaid, Peach Care and Medicare programs, to the extent such programs reimburse for PET scan services, and to accept any Medicaid-, Peach Care- and/or Medicare-eligible patient for services;

4. 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

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. 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.

(e) An applicant for a new or expanded service shall provide evidence of the ability to meet the following quality of care standards:

1. Document certification or a plan for securing certification for operation of a unit from the Georgia Department of Natural Resources.

2. Document that the unit proposed for purchase is approved for use by the U.S. Food and Drug Administration and for reimbursement by the Center for Medicare and Medicaid Services.

3. Document that the service will function as a component of a comprehensive diagnostic service and that appropriate referral to treatment and follow-up will be provided. The applicant must have accessible the following modalities and capabilities on site or through agreements, as evidenced by documentation provided at the time of application: computed tomography, magnetic resonance imaging, nuclear medicine, and conventional radiography.

4. Document that the PET service shall be under the direction of a physician who is board certified in nuclear medicine or diagnostic radiology; and is licensed as an authorized user of radioactive materials in accordance with the Rules of the Georgia Department of Natural Resources.

5. Document that the PET services has arrangements with board-certified interpreting physician(s) that are licensed in the State of Georgia.

6. Document the training and experience in PET scan services of the physician, nuclear medicine technologist, and radiology technologist. Such personnel shall be certified by appropriate national accreditation bodies.

7. Document fully the safe and timely access to radiopharmaceuticals.

(f) An applicant for a new or expanded service shall provide evidence of the ability to meet the following continuity of care standards:

1. Document that the applicant provides or has signed emergency transfer agreements and arrangements with one or more acute care hospital(s) located within the applicant's health planning area or in the case where the nearest acute care hospital is located in an adjacent health planning area, the nearest acute care hospital.

2. Document a referral system that includes a feedback mechanism for communicating scan results and any other pertinent patient information to the referring physician.

3. Document that the applicant will maintain current listings of appropriate clinical indications for PET procedures and will provide such listings to referring physicians and patients.

4. Document how medical emergencies will be managed in conformity with accepted medical practice.

(g) An applicant for a new or expanded service shall agree to provide the Department with all requested information and statistical data related to the operation and provision of services and to report that data to the Department in the time and format requested by the Department.

Authority: O.C.G.A. §§ 31-2 et seq., 31-6 et seq.

Rule 111-2-2-.42. Specific Review Considerations for MegaVoltage Radiation Therapy Services/Units

(1) **Applicability.**

(a) A Certificate of Need will be required for the establishment of any new or expanded MegaVoltage Radiation Therapy Service.

(b) MegaVoltage Radiation Therapy, including Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) may be conducted on non-special units or on special purpose units.

(c) A Certificate of Need will be required for the addition of a non-special MRT unit. An application for the addition of a non-special MRT unit shall address the standards contained in Ga. Comp. R. & Regs. r. 111-2-2-.42(3) in addition to the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1). A certificate holder who has been authorized to provide MRT service solely on a non-special unit may not provide service on a special purpose unit without obtaining a special purpose MRT Certificate of Need.

(d) A Certificate of Need will be required for the addition of a special purpose MRT unit. An application for the addition of a special purpose MRT unit shall address the standards contained in Ga. Comp. R. & Regs. r. 111-2-2-.42(4) in addition to the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1). A certificate holder who has been authorized to provide MRT service solely on a special purpose unit may not provide service on a non-special unit without obtaining a non-special MRT Certificate of Need.

(e) An application for the establishment of a new or expanded MegaVoltage Radiation Therapy Service with the addition of both non-special and special purpose MRT units shall address the standards of Ga. Comp. R. & Regs. r. 111-2-2-.42(3), 111-2-2-.42(4) and the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1).

(2) **Definitions.**

(a) "Brachytherapy" means the administration of radiation therapy by applying a radioactive material inside or in close

proximity to the patient. The material may be contained in various types of apparatus; may be on the surface of plaques; or may be enclosed in tubes, needles, wire, seeds, or other small containers. Common materials that are or have been used for the administration of brachytherapy include but are not limited to radium, Cobalt-60, Cesium-137, Iodine-125, Palladium-103 and Iridium-192.

(b) "Complex treatment visit" means a treatment visit involving three or more treatment sites, tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom blocking.

(c) "Course of treatment" means the planned series of visits that compose a plan for treatment of one or more cancer sites for a single patient.

(d) "Gamma knife" means a special stereotactic radiosurgery unit consisting of multiple cobalt sources all simultaneously focused to irradiate cancer or other neoplasms in the brain or cerebrovascular system abnormalities.

(e) "Health Planning Area" or "Planning Area" means the geographic regions in Georgia for use in planning for MRT services.

1. The Health Planning Areas or Planning Areas for non-special MRT services are the twelve state service delivery regions established by O.C.G.A. § 50-4-7.

2. The Health Planning Areas or Planning Areas for special purpose MRT services are five sub-state regions comprised as follows:

(i) Special Purpose MRT Region 1, including the following counties: Dade, Walker, Catoosa, Whitfield, Murray, Gilmer, Fannin, Union, Towns, Rabun, Stephens, Habersham, White, Lumpkin, Dawson, Pickens, Gordon, Chattooga, Floyd, Bartow, Cherokee, Forsyth, Hall, Banks, Franklin, Hart, Gwinnett, Fulton,

Cobb, Paulding, Polk, Haralson, Douglas, DeKalb, Rockdale, Newton, Henry, Clayton, and Fayette;

(ii) Special Purpose MRT Region 2, including the following counties: Elbert, Madison, Jackson, Barrow, Oconee, Clarke, Oglethorpe, Greene, Morgan, Walton, Wilkes, Lincoln, Columbia, McDuffie, Warren, Taliaferro, Glascock, Jefferson, Richmond, Burke, Screven, Jenkins, and Emmanuel;

(iii) Special Purpose MRT Region 3, including the following counties: Carroll, Coweta, Heard, Troup, Meriwether, Pike, Spalding, Lamar, Upson, Harris, Talbot, Taylor, Muscogee, Chattahoochee, Marion, Schley, Macon, Sumter, Webster, Stewart, Quitman, Randolph, Terrell, Lee, Worth, Dougherty, Calhoun, Clay, Early, Baker, Mitchell, Colquitt, Miller, Brooks, Thomas, Grady, Decatur, and Seminole;

(iv) Special Purpose MRT Region 4, including the following counties: Hancock, Putnam, Jasper, Butts, Monroe, Jones, Baldwin, Washington, Johnson, Treutlen, Montgomery, Wheeler, Telfair, Wilcox, Dodge, Laurens, Pulaski, Bleckley, Houston, Peach, Twiggs, Wilkinson, Bibb, Crawford, Dooly, Crisp, Ben Hill, Irwin, Turner, Cook, Tift, Berrien, Lanier, Echols, and Lowndes; and

(v) Special Purpose MRT Region 5, including the following counties: Effingham, Bulloch, Candler, Toombs, Tattnall, Evans, Bryan, Chatham, Liberty, Long, McIntosh, Wayne, Appling, Jeff Davis, Coffee, Bacon, Pierce, Brantley, Glynn, Camden, Charlton, Ware, Atkinson, and Clinch.

(f) "Heavy particle accelerator" means a machine such as a cyclotron, which produces beams of high-energy particles such as protons, neutrons, pions, or heavy ions with rest masses greater than that of an electron (mc2 = 0.511 MeV).

(g) "Horizon Year" means the last year of a five-year projection period for need determinations for MRT services.

(h) "Intensity modulated radiation therapy" or "IMRT" means a treatment delivery utilizing a radiotherapy treatment plan optimized using an inverse or forward planning technique to modulate the particle or energy fluence to create a highly conformal dose distribution. This beam modulated treatment delivery can be accomplished either by the use of the computer controlled multi-leaf collimator or high resolution milled or cast compensators.

(i) "Intermediate treatment visit" means a treatment visit involving two separate treatment sites, three or more fields to a single treatment site, or the use of special blocking.

(j) "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer, other neoplasms, or cerebrovascular system abnormalities are treated with radiation which is delivered by an MRT unit.

(k) "MRT service" means the CON approved MRT utilization of a MRT unit(s) at one geographic location.

(l) "MRT unit" or "unit" means a CON approved linear accelerator; cobalt unit; or other piece of medical equipment operating at an energy level equal to or greater than 1.0 million electron volts (megavolts or MeV) for the purpose of delivering doses of radiation to patients with cancer, other neoplasms, or cerebrovascular system abnormalities.

(m) "Non-special MRT unit" or "non-special unit" means an MRT unit other than an MRT unit meeting the definition of a special purpose MRT unit.

(n) "Operating room based intraoperative MRT unit" or "OR-based IORT unit" means an MRT unit that is designed to emit only electrons, is located in an operating room in the surgical department of a licensed hospital and is available for the treatment of a patient undergoing a surgical procedure with megavoltage radiation.

(o) "Simple treatment visit" means a treatment visit involving a single treatment site, single treatment field, or parallel opposed fields with the use of no more than simple blocks.

(p) "Simulation" is the process of defining relevant normal and abnormal anatomy, acquiring the images and data necessary to develop the patient's approved radiation treatment plan. Simulation always occurs prior to treatment and may be repeated multiple times during the course of treatment depending on the type of cancer, the radiation therapy technique utilized and the patient's clinical response to treatment. Simulation is used to direct the treatment beams to the specific volume.

(q) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units:

(i) heavy particle accelerator;

(ii) gamma knife;

(iii) dedicated linear accelerator stereotactic radiosurgery unit (SRS LINAC), including CyberKnife; or

(iv) an OR-based IORT unit.

(r) "Stereotactic body radiation therapy (SBRT)" is a term used to describe extracranial stereotactic radiosurgery (SRS) or radiotherapy (SRT). SBRT is a radiotherapy treatment method to deliver a high dose of radiation to the target, utilizing either a single dose or a small number of fractions with a high degree of precision within the body.

(s) "Stereotactic treatment visit" or "SRS treatment visit" means a visit involving SRS or SBRT treatment techniques.

(t) "Stereotactic Radiosurgery (SRS)" is performed in a limited number of treatment visits (up to a maximum of five), using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic image-guidance system to treat lesions in the body (extracranial) or brain (intracranial).

Technologies that are used to perform SRS include linear accelerators, particle beam accelerators and multi source Cobalt-60 units.

(u) "SRS LINAC" is a dedicated linear accelerator stereotactic radiosurgery unit that consists of three key components:

(i) an advanced linear accelerator (linac) (this device is used to produce a high energy megavoltage of radiation),

(ii) a device which can point the linear accelerator from a wide variety of angles, and

(iii) image-guidance patient positioning system using kilovoltage x-rays for either in-room diagnostic x-rays or tomographic images. The devices obtain pictures of the patient (planar x-ray or computed tomography) before or during treatment and use this information to target the radiation beam emitted by the linear accelerator, SRS LINAC includes units such as CyberKnives.

(v) "Treatment site" means the anatomical location of the MRT treatment.

(w) "Treatment visit" means one patient encounter during which MRT is administered. One treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same patient at different times of the same day shall be counted as a separate treatment visit.

(x) "Unit" means a single machine used for MRT services.

(y) "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 for Non-Special MRT.**

(a) The need for the addition of a non-special MRT unit shall be determined through the application of a Numerical Need method and an assessment of the aggregate utilization rate of existing services not including units added through the exception in section (3)(b)(2) of this Rule.

1. The numerical need for the addition of a non-special MRT unit 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 projected incidence of cancer excluding basal, epithelial, papillary, and squamous cell carcinomas of the skin from other than a genital area for each county by multiplying the most recent Cancer Incidence Rate, as published by the State Cancer Registry, for each county by the horizon year population for the county;

(ii) Multiply the projected incidence of cancer by fifty percent (50%) to determine the number of projected cancer cases in each county that could be treated with a non-special MRT unit;

(iii) Add the number of treatable cases for each county within a Health Planning Area to determine the projected number of patients needing treatment with a non-special MRT unit within the Health Planning Area in the horizon year;

(iv) Multiply the number obtained in step (iii) above by the most recent two year average of treatment visits per patient for the respective planning area of each county to project the number of projected patient visits in the horizon year;

(v) Determine the percentage of total visits in each planning area attributable to (1) Simple treatment visits, (2) Intermediate treatment visits, (3) Complex treatment visits, (4) IMRT, and (5) SRS treatment visits performed on non-special equipment as based on a running average of the most recent two annual surveys for facilities located in each respective planning area.

Prior to the 2008 survey year, the percentage of total visits in each planning area shall be based on the most recent annual survey for facilities located in each respective planning area;

(vi) Determine the number of projected equivalent visits in the horizon year for each planning area as follows:

A. Project the number of equivalent simple visits by multiplying the percentage obtained in step (v) for simple visits by the projected patient visits in the horizon year obtained in step (iv);

B. Project the number of equivalent intermediate visits by multiplying the percentage obtained in step (v) for intermediate visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for intermediate visits, 1.1;

C. Project the number of equivalent complex visits by multiplying the percentage obtained in step (v) for complex visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for complex visits, 1.3;

D. Project the number of equivalent IMRT visits by multiplying the percentage obtained in step (v) for IMRT visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for IMRT visits, 1.8;

E. Project the number of equivalent SRS visits by multiplying the percentage obtained in step (v) for SRS visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for SRS visits, 7.0; and

F. Sum the products obtained in step (vi)A. through step (vi)E.;

(vii) Calculate the number of needed non-special MRT units by dividing the number of projected equivalent visits obtained in

step (iv)F. by 9,000, which represents the weighted equivalent capacity of a non-special MRT unit within a given year; and

(viii) Determine the net numerical unmet need for non-special MRT units by subtracting the total number of non-special MRT units currently existing or approved for use, not including units approved pursuant to the exception in section (3)(b)2. of this Rule, from the number of needed non-special MRT units obtained in step (vii).

2. Prior to approval of an additional non-special MRT unit in a planning area, the aggregate utilization rate for all existing non-special MRT units, not including units approved pursuant to the exception in section (3)(b)2. of this Rule, in that planning area shall equal or exceed eighty percent (80%) of capacity based on 9,000 weighted equivalent visits. For those existing non-special MRT units that have not reported data in the most recent survey year, the Department shall include the non-reporting unit at the statewide average utilization rate.

(b) Exceptions to the need standard referenced in (3)(a) may be granted for applicants proposing any of the following:

1. To assure geographic access to non-special MRT services in rural areas when the proposed service is:

(i) to be located in a rural county;

(ii) to be located a minimum of 45 miles away from any existing or approved non-special MRT service; and

(iii) projected to serve a minimum of 150 patients per year. For purposes of this requirement, service projections must be submitted by the applicant using, at a minimum, state cancer registry data and documented cancer treatments within the service area.

2. To allow expansion of an existing service if the actual utilization of each radiation therapy unit within that service has exceeded ninety percent (90%) of optimal utilization over the most

recent two years. Any such units approved pursuant to this exception shall not be included in the calculation of need and aggregate utilization for the applicable service delivery region but will be included in the Department non-special MRT unit inventory.

3. To allow the addition of a non-special MRT unit at the same defined location if the applicant has a substantial out-of-state patient base. 'Substantial out of state patient base' shall be defined as using at least thirty-three percent (33%) of capacity or 2,970 weighted equivalent visits at the applicant's own percentage of treatment visits weighted by treatment type using the statewide weighted equivalent factor for each non-special MRT unit over the most recent two years to treat patients who reside outside of the State of Georgia.

4. To remedy an atypical barrier to non-special MRT services based on cost, quality, financial access and geographic accessibility.

(c) An applicant for a new or expanded non-special MRT service shall document the impact on existing and approved services which already provide non-special MRT to the residents of the planning area with the goal of minimizing adverse impact on existing and approved services of the same type in its planning area. An applicant for a new or expanded non-special MRT service shall have an adverse impact on existing and approved programs if it will:

1. decrease annual utilization of an existing service, whose current utilization is at or above eighty percent (80%), to a projected utilization of less than seventy percent (70%) within the first twenty-four (24) months of the initial operation of the service or additional non-special MRT unit; or

2. decrease annual utilization of an existing service, whose current utilization is below eighty percent (80%), by ten percent (10%) or more within the first twenty-four (24) months of the initial operation of the service or additional non-special MRT unit.

An applicant shall provide evidence of projected impact by taking into account existing planning area market share of existing non-special MRT services and future population growth or by providing sufficient evidence that the current population is underserved by the existing non-special MRT services, if any, within the planning area. An applicant proposing an additional non-special MRT unit pursuant to the exceptions to need standards referenced in (3)(b)2. shall not be required to document impact on existing and approved services as required by this paragraph.

(d) An applicant for a new or expanded non-special MRT service 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, or ability to pay;

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

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

4. providing a written commitment to participate in any other state health benefits insurance programs for which the radiation therapy service 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.

(e) An applicant for a new or expanded non-special MRT service shall provide evidence of a cancer treatment program,

which shall include the provision of the following, either on-site or through written agreements with other providers:

1. Access to simulation capabilities, which may include a dedicated simulator, a radiation therapy treatment unit, a virtual-reality based three-dimensional simulation system, or other diagnostic X-ray, magnetic resonance, ultrasound, or nuclear medicine equipment that has been modified to localize volumes to define the area requiring treatment; and which must be at the defined location of the non-special MRT service;

2. Access to a computer-based treatment planning system, which shall be a computer system capable of interfacing with diagnostic patient data acquisition systems such as CT, MRI, PET-CT to obtain the patient specific anatomical data. The planning system must be able to display radiation doses and 3-D dose distributions within a patient's anatomical contour and utilize measured or modeled radiation output data from the specific unit used to treat the patient. The minimum software requirements for the treatment planning system are an external beam program, an irregular field routine, and a Brachytherapy package;

3. Non-Special MRT capability including electron beam capability;

4. Capability to fabricate treatment aids; and

5. Access to brachytherapy;

(f) The applicant must provide a written commitment that physicians providing professional radiation oncology services at the MRT facility shall at all times have privileges or be eligible for and have an active pending application for privileges and be members in good standing of the medical staff, or are eligible for and have an active pending application for privileges, of a hospital with a comprehensive cancer treatment program located within the applicant's service area which will provide those physicians with access to participate in all of the following:

1. Consultative services from all major disciplines needed to develop a comprehensive treatment plan.

2. A multi-disciplinary cancer committee, which shall be a standing committee that:

(i) includes representatives from the medical specialties or sub-specialties which refer patients to the MRT service; representatives from the specialties of diagnostic radiology, radiation oncology, and pathology; representatives from those who oversee the tumor registry; and representatives from administration, nursing, social services, pharmacy, and rehabilitation;

(ii) meets at least on a quarterly basis; and

(iii) is responsible for the following:

A. establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility;

B. monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and

C. oversight of the applicant's tumor registry for quality control, staging, and abstracting;

3. Patient care evaluation studies, which shall be a system of patient care evaluation, conducted annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient evaluation studies; facility quality assurance activities; and ongoing monitoring, evaluating, and action planning; and

4. Cancer prevention and education programs.

(g) The applicant must participate and report to the Georgia Comprehensive Cancer Registry of the Georgia Department of Public Health.

(h) An applicant shall demonstrate that the following staff, at a minimum, will be identified and available:

1. One (1) FTE board-certified or board-qualified physician trained in radiation oncology, which shall be available by continuous means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

2. One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with a special competence in radiation oncology physics; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

3. One (1) medical dosimetrist, who shall be a member of the radiation oncology team who has the knowledge of the overall characteristics and clinical relevance of radiation oncology treatment machines and equipment, is cognizant of procedures commonly used in brachytherapy and has the education and expertise necessary to generate radiation dose distributions and dose calculations in collaboration with the medical physicist and radiation oncologists; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

4. Two (2) radiation therapy technologists, who shall be registered or eligible by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT); and who shall be on-site at all times of operation of the facility; and

5. One (1) program director, who shall be a board-certified physician trained in radiation oncology who may also be the physician required under (h)1.; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

(i) An applicant for a new or expanded non-special MRT service shall agree to provide the Department with all 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.

(4) **Standards for Special Purpose MRT.**

(a) The need for the addition of a special purpose MRT unit shall be determined through analysis of the capacity and utilization of the existing units of the same type in the planning area and an applicant's reasonable and documented projection of a minimum volume as follows:

Special MRT Equipment	**Capacity**	**Minimum Aggregate Utilization**	**Minimum Projected Volume**
Gamma Knife	500	80%	300 by 3rd Year of Operation
Heavy Particle Accelerator	4,000 per Gantry	80%	2,400 per Gantry by 3r
Dedicated SRS LINAC (including CyberKnife)	850	80%	510 by 3rd Year of Operation

OR-based IORT	350	80%	150 by 3rd Year of Operation

Where capacity is measured in annual procedures; where minimum aggregate utilization is the aggregate utilization rate for all existing special purpose MRT units of the same type (Gamma Knife utilization for Gamma Knife, etc.) in the planning area, except that for those existing special purpose MRT units that have not reported data in the most recent survey year, the Department shall include the non-reporting unit at the statewide average utilization rate for special purpose equipment of the same type; and where the minimum projected volume is measured in procedures per year.

(b) Exceptions to the need standards referenced in (3)(a) may be granted for applicants proposing to remedy an atypical barrier to special purpose MRT services based on cost, quality, financial access and geographic accessibility.

(c) An applicant for a new or expanded special purpose MRT service shall document the impact on existing and approved services of the same type (Gamma Knife for Gamma Knife application, etc.) which already provide special purpose MRT to the residents of the planning area with the goal of minimizing adverse impact on existing and approved services of the same type in its planning area. An applicant for a new or expanded special purpose MRT service shall have an adverse impact on existing and approved programs if it will:

1. decrease annual utilization of an existing service of the same type, whose current utilization is at or above seventy percent (70%), to a projected utilization of less than sixty percent (60%) within the first twenty-four (24) months of the initial operation of the service or additional special purpose MRT unit; or

2. decrease annual utilization of an existing service of the same type, whose current utilization is below seventy percent (70%), by ten percent 10% or more within the first twenty-four (24) months of the initial operation of the service or additional special purpose MRT unit.

An applicant shall provide evidence of projected impact by taking into account existing planning area market share of existing special purpose MRT services and future population growth or by providing sufficient evidence that the current population is underserved by the existing special purpose MRT services, if any, within the planning area.

(d) An applicant for a new or expanded special purpose MRT service 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, or ability to pay;

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

3. providing a written commitment to participate in the Medicaid and PeachCare for Kids® programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the radiation therapy service 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.

(e) An applicant for a new or expanded special purpose MRT service shall provide evidence of a cancer treatment program, which shall include the provision of the following, either on-site or through written agreements with other providers:

1. Access to simulation capabilities, which may include a dedicated simulator, a radiation therapy treatment unit, a virtual-reality based three-dimensional simulation system, or other diagnostic X-ray, magnetic resonance, ultrasound, or nuclear medicine equipment that has been modified to localize volumes to define the area requiring treatment; and which must be at the defined location of the special purpose MRT service;

2. Access to a computer-based treatment planning system, which shall be a computer system capable of interfacing with diagnostic patient data acquisition systems such as CT, MRI, PET-CT to obtain the patient specific anatomical data. The planning system must be able to display radiation doses and 3-D dose distributions within a patient's anatomical contour and utilize measured or modeled radiation output data from the specific unit used to treat the patient; and

3. Capability to fabricate treatment aids as applicable.

(f) The applicant must provide written commitment that physicians providing professional radiation oncology services at the special purpose MRT facility shall at all times have privileges or be eligible for and have an active pending application for privileges and be members in good standing of the medical staff of a hospital with a comprehensive cancer treatment program located within the applicant's service area which will provide those physicians with access to participate in all of the following:

1. Consultative services from all major disciplines needed to develop a comprehensive treatment plan.

2. A multi-disciplinary cancer committee, which shall be a standing committee that:

(i) includes representatives from the medical specialties or sub-specialties which refer patients to the MRT service; representatives from the specialties of diagnostic radiology, radiation oncology, and pathology; representatives from those who oversee the tumor registry; and representatives from administration, nursing, social services, pharmacy, and rehabilitation;

(ii) meets at least on a quarterly basis; and

(iii) is responsible for the following:

A. establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility;

B. monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and

C. oversight of the applicant's tumor registry for quality control, staging, and abstracting;

3. Patient care evaluation studies, which shall be a system of patient care evaluation, conducted annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient care evaluation studies; facility quality assurance activities; and ongoing monitoring, evaluating, and action planning; and

4. Cancer prevention and education programs.

(g) The applicant must participate and report to the Georgia Comprehensive Cancer Registry of the Georgia Department of Public Health.

(h) An applicant shall demonstrate that the following staff, at a minimum, will be identified and available;

1. For applicants seeking the addition of a Gamma Knife:

(i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating a Gamma Knife and who shall be available on-site; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating a Gamma Knife; and who shall be available on-site;

2. For applicants seeking the addition of a Heavy Particle Accelerator, Two (2) radiation therapy technologists, who shall be registered or eligible by the American Registry of Radiological Technologists ("ARRT") or the American Registry of Clinical Radiography Technologists ("ARCRT"); who shall have received special training in operating a Heavy Particle Accelerator and who shall be on-site at all times of operation of the facility;

3. For applicants seeking the addition of a dedicated SRS LINAC:

(i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating an SRS LINAC and who shall be available on-site; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating an SRS LINAC; and who shall be available on-site;

(iii) One (1) radiation therapy technologist, who shall be registered or eligible by the American Registry of Radiological

Technologists or the American Registry of Clinical Radiography Technologists; who shall have received special training in operating an SRS LINAC; and who shall be on-site at all times of operation of the facility; and

4. For applicants seeking the addition of an OR-Based IORT unit:

(i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology; who shall have received special training in operating an OR-Based IORT unit; and who shall be available on-site; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating an OR-Based IORT unit; and who shall be available on-site.

(i) An applicant for a new or expanded special purpose MRT service shall agree to provide the Department with all 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. §§ 31-2 et seq., 31-6 et seq.