

SYNOPSIS

Rule 111-2-2- et seq. Administrative Rules for Certificate of Need

STATEMENT OF PURPOSE AND MAIN FEATURES OF PROPOSED RULE

The purpose of this proposed amendment is to modify and update existing regulations with respect to the specific Certificate of Need review considerations for ambulatory surgery services.

DIFFERENCES BETWEEN EXISTING AND PROPOSED RULES

Rule 111-2-2-.40 Specific Review Considerations for Ambulatory Surgery Services

Rule 111-2-2-.40(2)(c) is amended to update the language to reflect that the Office of Regulatory Services of the Department of Human Resources is now the Healthcare Facility Regulation Division of the Department of Community Health.

Rule 111-2-2-.40(2)(m) is amended to change text from Department of Human Resources to Georgia Department of Community Health.

Rule 111-2-2-.40(3)(b) is amended to delete the current atypical barrier need exception and to insert specific circumstances that would warrant an exception to the rule need standard.

Rule 111-2-2-.40(3)(j) is amended to update the language to reflect that the Office of Regulatory Services of the Department of Human Resources is now the Healthcare Facility Regulation Division of the Georgia Department of Community Health.

Rule 111-2-2-.40(3)(k) is amended to update the language to reflect that the Joint Commission for the Accreditation of Health Care Organizations (JHACO) is now The Joint Commission.

Rule 111-2-2-.40(3)(l) is amended to update the language to reflect that the Joint Commission for the Accreditation of Health Care Organizations (JHACO) is now The Joint Commission.

111-2-2-.40 Specific Review Considerations for Ambulatory Surgery Services.

(1) Applicability. For Certificate of Need purposes, an Ambulatory Surgery Service is considered a new institutional health service if it is to be offered in an ambulatory surgery facility (ASF) or in a diagnostic, treatment, or rehabilitation center (DTRC).

(a) If the ambulatory surgery service is or will be provided as "part of a hospital", the hospital's provision of such service is not subject to Certificate of Need (CON) review under this rule. For purposes of this rule, the following are always considered to be "part of a hospital": a) if the service is located within a hospital; or, b) if the service is located in a building on the hospital's primary campus and that building, or relevant portion thereof, is included within the hospital's permit issued by the State's licensing agency, subject to determination by the Department. The Department also will make a determination of reviewability on a case-by-case basis in other situations involving hospitals.

(b) The entity that develops any ambulatory surgery service shall be the applicant.

(c) A single specialty ambulatory surgery service will be issued a single specialty CON. A new CON will be required to become a multi-specialty service.

(d) These Rules do not apply to adult open-heart surgery, adult cardiac catheterization, pediatric cardiac catheterization, pediatric open-heart surgery, and obstetrical services because these services are covered under other CON Rules. If an ambulatory surgery service, which is part of a hospital, expands the number of ambulatory surgery operating rooms and the capital expenditure exceeds the CON threshold, the project will be reviewed under these Rules 111-2-2-.40. If an ambulatory surgery service, which is part of a hospital, involves a capital expenditure, which exceeds the CON threshold and does not increase the number of ambulatory surgery operating rooms, the project will be reviewed under the General Review Considerations (111-2-2-.09).

(2) Definitions.

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

(b) "Ambulatory surgery facility" means a public or private facility, not part of a hospital, which provides surgical treatment performed under general or regional anesthesia in an operating room environment to patients not requiring hospitalization. In addition to operating rooms, an ambulatory surgery facility includes all components of pre and post-operative ambulatory surgery care.

(c) "Ambulatory surgery operating room" means an operating room located either in a hospital, in an ambulatory surgery facility, or in a DTRC facility that is equipped to perform surgery and is constructed to meet the specifications and standards of the [Office of Regulatory Services of the Department of Human Resources Healthcare Facility Regulation Division of the Georgia Department of Community Health.](#)

(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 (12) month period within a month of the date of completion of an application or within a month of the date of completion of the first application when applications are joined. If the Department has received an annual or ad hoc survey within six (6) months of the date of completion of the application (or first application when applications are joined), the Department may consider the report period covered in such a survey as the most recent year.

(i) "Multi-specialty ambulatory surgery service" means an ambulatory surgery service offering surgery in more than one of, but not limited to, the following specialties; dentistry/oral surgery, gastroenterology, general surgery, obstetrics/gynecology, ophthalmology, orthopedics, otolaryngology, pain management/anesthesiology, plastic surgery, podiatry, pulmonary medicine, or urology.

(j) "Not requiring hospitalization" means patients who do not require an inpatient admission to an acute care general hospital prior to receiving ambulatory surgery services, who normally would not require a stay that is overnight or exceeds twenty-four (24) hours, and who are not expected to require an inpatient admission after receiving such services.

(k) "Official inventory" means the inventory of all facilities authorized to perform ambulatory surgery services maintained by the Department based on responses to the most recent Annual Hospital Questionnaire (AHQ) Surgical Services Addendum and Freestanding Ambulatory Surgery Center Survey and/or the most recent appropriate surveys and questionnaires.

(l) "Official state component plan" means the document related to ambulatory surgery services adopted by the State Health Strategies Council, approved by the Board of Community Health, and implemented by the State of Georgia for the purpose of providing adequate health care services and facilities throughout the state.

(m) "Operating room environment" means an environment, which meets the minimum physical plant and operation standards specified on January 1, 1991, for ambulatory surgical treatment centers in Rule 290-5-33-.10 of the Rules of the [Georgia Department of Human Resources Community Health](#).

(n) "Planning Area" means fixed sub-state regions for reviewable services as defined in the State Health Component Plan for Ambulatory Surgery Services.

(o) "Single specialty ambulatory surgery service" means an ambulatory surgery service providing surgery in only one of the specialty areas as defined in Rule 111-2-2-.40(2)(i).

(3) Standards.

(a) The need for an ambulatory surgery service shall be determined through application of a numerical need method and an assessment of the aggregate utilization rate of existing services.

1. The numerical need for a ambulatory surgery service shall be determined by a demographic formula which includes the number of ambulatory surgery services cases in a planning area. The following need calculation applies to each planning area:

(i) determine the projected ambulatory surgery services patients for the horizon year by multiplying the planning area ambulatory surgery patients' rate by the total Resident population for the planning area for the horizon year;

(ii) determine the number of operating rooms needed by dividing the number of projected ambulatory surgery services patients (step i) by the capacity per operating room. Capacity per operating room per year is 1000 patients. (This is based on 250

operating room days per year (50 weeks x 5 days/weeks) x 5 patients per room per day x 80% utilization.);

(iii) determine the existing and approved inventory of ambulatory surgery operating rooms by adding:

(I) The pro-rata portion of hospital shared inpatient/ambulatory surgery operating rooms devoted to ambulatory surgery services. This portion is determined as follows: (# ambulatory surgery patients x 90 min.) {(ambulatory surgery patients x 90 min)+(inpatient patients x 145 min.)} x # shared rooms

(II) # of hospital dedicated ambulatory surgery operating rooms; and

(III) # of freestanding ambulatory surgery operating rooms.

(iv) determine the projected net surplus or deficit for ambulatory surgery services by subtracting the total ambulatory surgery operating rooms needed (step iii) from the inventory of existing and approved ambulatory surgery services operating rooms in the planning area.

2. Prior to approval of a new or expanded ambulatory surgery service in any planning area, the aggregate utilization rate of all existing and approved ambulatory surgery service in that planning area shall equal or exceed eighty percent (80%) during the most recent year; and

3. A proposed multi-specialty ambulatory surgery service shall have a minimum of (3) three operating rooms and a single specialty ambulatory surgery service shall have a minimum of (2) 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. in the following circumstances:~~

~~(1) For an applicant seeking a certificate of need solely to convert an ASF previously issued a letter of nonreviewability as a statutorily exempt single specialty, physician owned, office based ASF to a single specialty ASF with no physician ownership or employee participation restrictions, and::~~

~~(i) there is no change in ownership;~~

~~(ii) there is no change in location;~~

~~(iii) there is no change in the number of operating rooms;~~

~~(iv) there is no associated capital expenditure;~~

~~(v) there is no change in surgical specialty; and,~~

~~(vi) the applicant otherwise complies with the criteria of these rules, including the indigent and charity care commitment of section (3)(n)(2).~~

~~(2) For an applicant who can provide written and empirical documentation using clinical guidelines of the American College of Surgeons, or comparable clinical ambulatory surgery entity, that the proposed ASF will offer and perform surgical procedures not currently offered in the planning area due to technological, financial, staffing, clinical capability, or licensure deficiency issues of other ambulatory surgical providers in the planning area.~~

~~(3) For an applicant who agrees to provide services to indigent and charity patients as defined by the Department in an amount no less than six percent (6.0%) of the adjusted gross revenues of the ambulatory surgery service and the proposed ASF will have no more than two operating rooms if a proposed single specialty ASF or no more than three (3) operating rooms if a proposed multi-specialty ASF. A certificate of need awarded to an applicant pursuant to this exception will be subject to revocation if, based upon a review of required annual surveys (such review not to begin until one full year after award of certificate of need for an existing ASF, or one full year after initial operation for a new ASF), the amount of indigent and charity care committed in the application is not provided through direct patient services for more than one consecutive year.~~

(4) For an applicant seeking to provide an ambulatory surgery specialty, if a proposed single specialty ASF, that would be the only one of its kind in the planning area, or to provide more than one surgical specialty not currently available in the planning area if a proposed multi-specialty ASF. Applicants would be required to provide written and empirical documentation of the lack of availability of such ambulatory surgical services within the planning area, including hospital-based services or other freestanding facilities.

(c) Each applicant shall have a hospital affiliation agreement and/or the medical director must have admitting privileges and other acceptable documented arrangements to insure the necessary backup for medical complications. The applicant must document the capability to transfer a patient immediately to a hospital with adequate emergency room services.

(d) An applicant shall submit written policies and procedures regarding discharge planning. These policies should include, where appropriate, designation of responsible personnel, participation by the patient, family, guardian or significant other, documentation of any follow-up services provided and evaluation of their effectiveness.

(e) An applicant shall provide evidence of a credentialing process that provides that surgical procedures will be performed only by licensed physicians who have been granted privileges to perform these procedures by the organization's governing body.

(f) An applicant shall assure that an anesthesiologist, a physician qualified to administer anesthesia, an oral surgeon, or a nurse anesthetist trained and currently certified in emergency resuscitation procedures is present on the premises at all times a surgical patient is present.

(g) An applicant shall submit evidence that qualified personnel will be available to insure a quality service to meet licensure, certification and/or accreditation requirements.

(h) An applicant shall submit a policy and plan for reviewing patient care, including a stated set of criteria for identifying those patients to be reviewed and a mechanism for evaluating the patient review process.

(i) An applicant shall submit written policies and procedures for utilization review consistent with state federal and accreditation standards. This review shall include review of the medical necessity for the service, quality of patient care, and rates of utilization.

(j) An applicant shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the ~~Office of Regulatory Services~~ Healthcare Facility Regulation Division of the Georgia Department of ~~Human Resources~~ Community Health.

(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 ~~(TJC) for Accreditation of Healthcare Organizations (JCAHO)~~, the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory surgery Facilities, Inc. (ASF) and/or other appropriate accrediting agency.

(l) An applicant for an expanded ambulatory surgery service shall provide documentation that they fully meet the appropriate accreditation requirements of The Joint Commission ~~(TJC) for Accreditation of Healthcare Organizations (JCAHO)~~, the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (ASF) and/or other appropriate accrediting agency.

(m) An applicant shall provide documentation that charges are reasonable compared to other similar surgery services serving the same planning area.

(n) An applicant shall foster an environment that assures access to services to individual's unable to pay and regardless of payment source or circumstances by the following:

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

2. providing a written commitment that unreimbursed services for indigent and charity patients in the service will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the service after Medicare and Medicaid contractual adjustments and bad debt have been deducted; and

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

(o) An applicant for an ambulatory surgery service shall document an agreement to provide Department requested information and statistical data related to the operation and provision of ambulatory surgery and to report that data to the Department in the time frame and format requested by the Department. This information shall include, but not be limited to, any changes in number of ambulatory surgery operating rooms that may occur as a result of service expansion.

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