

SYNOPSIS

Rule 111-2-2 Health Planning Certificate of Need

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

STATEMENT OF PURPOSE AND MAIN FEATURES OF PROPOSED RULE

The purpose of this proposed amendment in totality is to modify existing regulations in light of changes in the Certificate of Need statute, O.C.G.A. § 31-6 et seq., due to the passage of Senate Bill (SB) 433 in the 2008 Georgia General Assembly. SB 433 necessitates extensive revision to the existing administrative rules for certificate of need. The revisions are outlined in detail below.

DIFFERENCES BETWEEN EXISTING AND PROPOSED RULES

Various grammatical and punctuation errors and omissions are corrected throughout the existing version of the regulations.

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

This section is renumbered to reflect additional provisions.

Rule 111-2-2-.09(1)(g)1 is amended to delete "expedited" and replace with "emergency" and incorporate new Rule reference to subpart (k) of Rule 111-2-2-.07(1) regarding review period for emergency applications.

Rule 111-2-2-.09(1)(o)-(q) is new language which establishes additional General Review Considerations. Subpart (o) adds a requirement that the proposed project meet minimum quality standards; subpart (p) adds a requirement that the proposed project be able to obtain the necessary resources and management personnel; and subpart (q) adds a requirement that the department provide for an advantage to equally qualified applicants that agree to provide an underrepresented service in addition to the service(s) for which the application was originally submitted.

Rule 111-2-2-.09(2)(a)-(h) is new language which establishes general review considerations specific to Destination Cancer Hospitals, as defined at Rule 111-2-2-.01(21). Subpart(a) references the applicable General Review Considerations to be addressed by the applicant in the application; subpart (b) establishes the requirement to demonstrate, through data, that the a minimum of 65% of its annual patient base will reside outside Georgia; subpart (c) establishes the requirement to make a minimum 3%

uncompensated indigent or charity care commitment; subpart (d) establishes the requirement to conduct research and service development to meet a national or regional need; subpart (e) establishes the requirement to demonstrate financial and physical accessibility; subparts (f) and (f)(1) establish the requirement to demonstrate a positive relationship to the existing health care delivery system on a regional basis including documentation of transfer agreements or demonstration of admitting privileges at a hospital(s) within a reasonable distance from the proposed facility; requires the Department to mediate and/or conduct binding arbitration if the terms of a transfer agreement cannot be reached between the applicant and a nearby hospital; subpart (g) establishes the requirement to demonstrate the proposed project is not expected to be detrimental to existing hospitals within the planning area taking into consideration market share and payor mix and not resulting in the utilization of existing hospitals decreasing by more than 10% for the two most recent and available preceding calendar years of data; subpart (h) establishes the requirement to participate in medical staffing work force development activities.

Rule 111-2-2-.09(3)(a) and (b) is new language which requires the Department not to apply the need requirement established at 111-2-.09(1)(b) to applications for basic perinatal services in counties where only one civilian health care facility or health system is providing basic perinatal services and there are not at least three different health care facilities in a contiguous county providing basic perinatal services.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Utilization of existing facilities and services similar to a proposal to initiate services shall be evaluated to assure that unnecessary duplication of services is avoided. Where there exists significant unused capacity, initiating a similar service in another health care facility would require strong justification under other criteria.

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

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

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

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

1. In accordance with the provision found in O.C.G.A. § 31-6-42(7), the Department will evaluate the extent to which each applicant applying for a Certificate of Need participates in a reasonable share of the total community burden of care for those unable

to pay. This provision shall not apply to applicants for continuing care retirement communities, skilled nursing facilities or units, and to projects that are reviewed by the Department on an ~~expedited~~ emergency basis in accordance with 111-2-2-.07(1)(~~k~~). In all other instances, the following indicators will be evaluated:

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

(ii) policies relating medical staff privileges, if applicable, to reasonable acceptance of emergency referrals of Medicaid and PeachCare patients and all other patients who are unable to pay all or a portion of the cost of care;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. That the proposed new destination cancer hospital shall enter into a hospital transfer agreement with one or more hospitals within a reasonable distance from the destination cancer hospital or the medical staff at the destination cancer hospital has admitting privileges or other acceptable documented arrangements with such hospital or hospitals to ensure necessary backup for the destination cancer hospital for medical complications. The destination cancer hospital shall have the capability to transfer a patient immediately to a hospital within a reasonable distance from the destination cancer hospital with adequate emergency room services. Hospitals shall not unreasonably deny a transfer agreement with the destination cancer hospital. In the event that a destination cancer hospital and another hospital cannot agree to the terms of a transfer agreement as required by this paragraph, the Department shall mediate between such parties for a period of no more than forty-five (45) days. If an agreement is still not reached within such forty-five (45) day period, the parties shall enter into binding arbitration conducted by the Department.

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

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

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

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

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

(24) 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.

(35) 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.

(46) Considerations for Joined Applications.

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

1. the past and present records of the facility, and other existing facilities in Georgia, if any, owned by the same parent organization, regarding the provision of service to all segments of the population, particularly including Medicare, Medicaid, minority patients and those patients with limited or no ability to pay;
2. specific services to be offered;
3. appropriateness of the site, i.e., the accessibility to the population to be served, availability of utilities, transportation systems, adequacy of size, cost of acquisition, and cost to develop;
4. demonstrated readiness to implement the project, including commitment of financing;
5. patterns of past performance, if any, of the applicants in implementing previously approved projects in timely fashion;
6. past record, if any, of the applicant facility, and other existing facilities owned by the same parent organization, if any, in meeting licensure requirements and factors relevant to providing accessible, quality health care;
7. evidence of attention to factors of cost containment, which do not diminish the quality of care or safety of the patient, but which demonstrate sincere efforts to avoid significant costs unrelated to patient care; and
8. Past compliance, if any, with survey and post-approval reporting requirements and indigent and charity care commitments.
9. hospital and physician collaborations that promote greater cost efficiency to patients, ensure greater quality assurance outcomes and foster positive relationships within the existing healthcare delivery network which benefits both providers and members within the impacted service area population; and

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

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