

SYNOPSIS

Rule 111-2-2 Health Planning Certificate of Need

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

STATEMENT OF PURPOSE AND MAIN FEATURES OF PROPOSED RULE

The purpose of this proposed amendment in totality is to modify an existing regulation 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 revision is outlined in detail below.

DIFFERENCES BETWEEN EXISTING AND PROPOSED RULES

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

Section (k)(3)(vi) outlines the indigent and charity care requirement for a destination cancer hospital CON applicant, but does not include language regarding possible revocation of the CON in this specific provision.

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

(1) Applicability.

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

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

1. bed replacements in existing hospital facilities which do not require a capital or equipment expenditure over the applicable dollar threshold; or
2. changing the physical location of existing beds within an existing facility regardless of cost; provided, however, that any project in excess of the applicable capital expenditure or equipment dollar threshold must be reviewed in accordance with the review considerations set forth in Rule 111-2-2-.09; or
3. projects that are otherwise exempt from review pursuant to O.C.G.A. § 31-6-47(a)(15).

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

(2) Definitions.

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

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

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

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

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

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

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

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

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

1. for hospitals located in a rural county, sixty-five percent (65%);
2. for hospitals located in a non-rural county, seventy-five percent (75%); and
3. for teaching or children's hospitals, seventy percent (70%).

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

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

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

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

1. the hospital is a children's hospital or a teaching hospital;
2. the hospital is designated by the Department of Human Resources as a trauma center;
3. Medicaid and Peach Care inpatient admissions constitute twenty percent (20%) or more of the total hospital inpatient admissions;
4. Uncompensated charges for indigent patients constitute six percent (6%) or more of hospital adjusted gross revenue; or
5. Uncompensated charges for indigent and charity patients constitute ten percent (10%) or more of hospital adjusted gross revenue

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

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

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

(3) **Standards.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2. The facility is an existing teaching hospital;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. An applicant for a destination cancer hospital must:

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

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

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

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

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

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

(vii) Agree to provide care to Medicaid beneficiaries;

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

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

5. After commencing operations upon receipt of a Certificate of Need pursuant to these Rules, a destination cancer hospital seeking to add an additional new institutional health service, shall apply for and obtain an additional Certificate of Need under the applicable statutory provisions and the Rules in this section. Any such application shall only be granted if the patient base of the destination cancer hospital is composed of at

least sixty-five (65%) percent of patients who reside outside of the State of Georgia for two consecutive years.

6. The Department may apply the Rules in section (k) of these Rules to an application from a destination cancer hospital for a Certificate of Need for services and equipment required for it to meet federal or state laws applicable to a hospital.

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

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

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

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

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

12. An applicant for a destination cancer hospital shall agree to provide information related to the operation of and services provided by the facility in the time frame and manner requested by the Department. In addition, a destination cancer hospital shall submit an annual statement, in accordance with the timeframes and format specified by the Department, affirming that the hospital has met an annual patient base composed of a minimum of sixty-five (65%) percent of patients who reside outside the State of Georgia. The chief executive officer of the destination cancer hospital shall certify under penalty of perjury that the statement as prepared accurately reflects the composition of the annual patient base. The Department shall have the authority to inspect any books, records, papers, or other information of the destination cancer hospital to confirm the information provided on such statement or any other information required of the destination cancer hospital. The report required by this sub-section shall not be construed to require the release of any information that would violate the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191.

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