SYNOPSIS

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

STATEMENT OF PURPOSE AND MAIN FEATURES OF PROPOSED RULE

The purpose of this proposed amendment is to modify the guidelines for specific review considerations for Level I Basic Perinatal Services.

DIFFERENCES BETWEEN EXISTING AND PROPOSED RULES

Section (3)(b)(1) has been modified to provide that an applicant for a Basic Perinatal Service shall not be subject to the need standard of Section (3)(a)(1) or the aggregate occupancy standard of Section (3)(a)(4) if the service will be offered in a county with only one hospital or health system offering a Basic Perinatal Service at the time of the application.

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 Service (Level I)" means Obstetric and Neonatal Newborn Care Services.

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

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

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

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

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

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

1. the official inventory for each facility will remain unchanged for the year following the last day of the report period on each hospital's completed AHQ

and/or its Perinatal Addendum unless the Department approves a change of bed capacity through the Certificate of Need process; and

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

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

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

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

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

(3) **Standards.**

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

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

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

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

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

$$POBDays = URxPFP$$

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

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

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

$$UN = POBBeds - OI$$

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

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

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

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

$$PRB = ABRxPFP$$

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

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

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

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

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

$$UN = N2Beds - OI$$

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

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

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

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

$$PRB = ABRxPFP$$

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

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

(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 80 percent) with any fraction rounded up to a whole bed:

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

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

$$UN = N2Beds - OI$$

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

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

~~1. To assure geographic access to a new Basic Perinatal Service in rural areas when the facility is located in a rural county and is the sole provider of general hospital services in the county; or~~

1. To provide that an applicant for a new Basic Perinatal Service 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 the proposed new service would be located in a county which, at the time of the application, has only one hospital or health system offering a Basic Perinatal Service;

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

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

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

1. An existing perinatal physician training program shall not be adversely impacted by the establishment of a new or expanded perinatal service to the extent that the existing service could not sustain a sufficient number and variety

of patients to maintain an appropriate number of providers and provider competencies and the training program's accreditation and funding status;

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

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

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

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

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

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

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

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

(e) The desired minimum bed size for a Basic Perinatal, 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 Service or Neonatal Intensive Care service.

~~2. no more than four beds for a new service in a facility applying under the numerical need exception for a new service in a rural county; and~~

2~~3~~. the Department may grant an exception to these standards when the Department determines that unusual circumstances exist that justify such action.

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

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

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

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

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

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

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

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

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

Authority O.C.G.A. Secs. 31-5A et seq., 31-6 et seq. **History.** Original Rule entitled "Specific Review Considerations for Perinatal Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.