



STATE OF TENNESSEE

STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA
FOR
Neonatal Intensive Care Units

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applicants seeking to provide neonatal intensive care unit services. Rationale statements are provided for standards to explain the Division of Health Planning's underlying reasoning. Additionally, these rationale statements may assist stakeholders in responding to these Standards and may assist the HSDA in its assessment of applicants. Existing providers of neonatal nursery services are not affected by these Standards and Criteria unless they take action that requires a new certificate of need (CON) for such services.

These Standards and Criteria are effective immediately upon approval and adoption by the Governor. However, applications to provide neonatal intensive care unit services that are deemed complete by the HSDA prior to the approval and adoption of these Standards and Criteria shall be considered under the Guidelines for Growth, 2000 Edition.

The Certificate of Need Standards and Criteria serve to uphold the Five Principles for Achieving Better Health set forth by the State Health Plan. Utilizing the Five Principles for Achieving Better Health during the development of the CON Standards and Criteria ensures the protection and promotion of the health of the people of Tennessee. The State Health Plan's Five Principles for Achieving Better Health are as follows:

1. **Healthy Lives:** The purpose of the State Health Plan is to improve the health of people in Tennessee.
2. **Access:** People in Tennessee should have access to health care and the conditions to achieve optimal health.
3. **Economic Efficiencies:** Health resources in Tennessee, including health care, should be developed to address the health of people in Tennessee while

encouraging value and economic efficiencies.

4. **Quality of Care:** People in Tennessee should have confidence that the quality of care is continually monitored and standards are adhered to by providers.
5. **Workforce:** The state should support the development, recruitment, and retention of a sufficient and quality health workforce.

Definitions

Definitions for **Level I, Level II, Level III and Level IV Neonatal Services** can be found in the Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing and Facilities. These Standards and Criteria apply to Level II and higher neonatal services.

Neonatologist: A board-certified pediatrician with subspecialty certification in neonatal/perinatal medicine or who is eligible for certification in neonatal/perinatal medicine and is within five years of completion of an accredited fellowship program.

Service Area: Refers to the county or counties represented by an applicant as the reasonable area in which the applicant intends to provide neonatal nursery services and/or in which the majority of its current service recipients reside.

Standards and Criteria

1. **Determination of Need:** The need for neonatal nursery services is based upon data obtained from Tennessee Department of Health Office of Vital Records in order to determine the total number of live births which occurred within the designated service area. The need shall be based upon the current year's population projected for three years forward. The total number of neonatal intensive and intermediate care beds shall not exceed nine beds per 1,000 live births per year in a defined neonatal service area. These estimates represent gross bed need and shall be adjusted by subtracting the existing applicable staffed beds including certified beds in outstanding CONs operating in the area as counted by TDH in the Joint Annual Report (JAR).

Rationale: The number of beds per 1,000 live births utilized for the determination of need has been changed from eight to nine. Health Planning analyzed data provided by the Department of Health in order to determine if the previous need formula was adequate given current NICU utilization trends. The data show that statewide utilization rates have increased by 1,087 between 2010 and 2014. However, Health Planning believes it is not possible to determine if this increase in utilization is due to an increase in high-risk births or if it is due to overutilization. This position regarding utilization is supported by scholarly research focusing on

epidemiologic trends in neonatal intensive care. The current bed need formula was developed in consultation with the Perinatal Advisory Committee.

Research can be found at the following link:

<http://archpedi.jamanetwork.com/article.aspx?articleid=2381545>

Wade Harrison and David Goodman, "Epidemiologic Trends in Neonatal Intensive Care, 2007-2012," JAMA Pediatrics, Vol. 169, No. 9, Sept. 2015, pp. 855-862.

- 2. Minimum Bed Standard:** A single Level II neonatal special care unit shall contain a minimum of 10 beds. A single Level III neonatal special care unit shall contain a minimum of 15 beds. These numbers are considered to be the minimum ones necessary to support economical operation of these services. An adjustment in the number of beds may be justified due to geographic remoteness.
- 3. Establishment of Service Area:** The geographic service area shall be reasonable and based on an optimal balance between population density and service proximity of the applicant.
- 4. Access:** The applicant must demonstrate an ability and willingness to serve equally all of the service area in which it seeks certification. In addition to the factors set forth in HSDA Rule 0720-11-.01(1) (listing factors concerning need on which an application may be evaluated), the HSDA may choose to give special consideration to an applicant that is able to show that there is a limited access in the proposed service area.
- 5. Orderly Development of Applicant's Neonatal Nursery Services:** The applicant shall document the number of Level II, Level III, and Level IV cases that have been referred out of the hospital during the most recent three year period of available data.
- 6. Occupancy Rate Consideration:** The Agency may take into account the following suggested occupancy rates of existing facilities in the service area. The occupancy rates of an existing facility shall be 80 percent or greater in the preceding 12 months to justify expansion. The overall utilization of existing providers in the service area shall be 80 percent or greater for the approval of a new facility in a service area.
- 7. Assurance of Resources:** The applicant shall document that it will provide the resources necessary to properly support the applicable level of neonatal nursery services. These resources shall align with those set forth by the Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing and Facilities. Included in such documentation shall be a letter of support from the applicant's governing board of directors documenting the full commitment of the

applicant to develop and maintain the facility resources, equipment, and staffing to provide a full continuum of neonatal nursery services. The applicant shall also document the financial costs of maintaining these resources and its ability to sustain them to ensure quality treatment of patients in the neonatal nursery services continuum of care.

- 8. Perinatal Advisory Committee.** The Department of Health will consult with the Perinatal Advisory Committee regarding applications.
- 9. Adequate Staffing:** An applicant shall document a plan demonstrating the intent and ability to recruit, hire, train, assess competencies of, supervise, and retain the appropriate numbers of qualified personnel to provide the services described in the application and that such personnel are available in the proposed service area. The applicant shall comply with the staffing guidelines and qualifications set forth by the Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing and Facilities.

Rationale: The Division of Health Planning aligned the Criteria and Standards for staffing patterns with the Tennessee Perinatal Care System Guidelines in order to ensure consistency. Additionally, utilizing the work of experts in the field ensures the Standards are stringent and appropriate. This Standard was reviewed and deemed adequate by the Tennessee Perinatal Advisory Committee.

- 10. Staff and Service Availability for Emergent Cases:** The applicant shall document the capability to access the neonatologist rapidly for emergency cases 24 hours per day, seven days per week, 365 days per year.
- 11. Education:** The applicant shall provide details of its plan to educate physicians, other professional and technical staff, and parents. This plan shall be performed in accordance with the education guidelines set forth by Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing and Facilities.
- 12. Community Linkage Plan:** The applicant shall describe its participation, if any, in a community linkage plan, including its relationships with appropriate health care system providers/services and working agreements with other related community services assuring continuity of care. The applicant is encouraged to include primary prevention initiatives in the community linkage plan that would address risk factors leading to the increased likelihood of NICU usage.

Rationale: The 2014 Update to the State Health Plan moved from a primary emphasis of health care to an emphasis on “health protection and promotion”. The development of primary prevention initiatives for the community advances the mission of the current State Health Plan.

13. Data Requirements: Applicants shall agree to provide the Department of Health and/or the Health Services and Development Agency with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

14. Quality Control and Monitoring: The applicant shall identify and document its existing or proposed plan for data reporting, quality improvement, and outcome and process monitoring system.

Rationale: This section supports the State Health Plan's Fourth Principle for Achieving Better Health regarding quality of care.

15. Tennessee Initiative for Perinatal Quality Care (TIPQC): The applicant is encouraged to include a description of its plan to participate in the TIPQC.

Rationale: This Standard was developed under the guidance of the Perinatal Advisory Committee.