

Proposed Standard

NEONATAL INTENSIVE CARE UNITS

I. INTRODUCTION

Due to a number of factors, including the need to establish a foundation for consistent standards of service by hospitals focused on the improvement of neonatal care, it is increasingly important to deliver neonates at "risk appropriate" facilities to improve outcomes for both mothers and their babies. Whether providing nursery care or care in a neonatal intensive care unit ("NICU"), there are national guidelines that have been developed that match hospitals' capabilities with maternal and neonatal risks.

The mission of the West Virginia Health Care Authority ("Authority") is to ensure that West Virginians have appropriate access to quality, affordable health care services while protecting consumers from unnecessary duplication of services.

Recognizing the critical need for NICU services at the appropriate level to be available for neonates, these standards address the necessary criteria which must be met to obtain a Certificate of Need ("CON") to provide NICU services in West Virginia.

II. DEFINITIONS

- A. Acute Care: Inpatient hospital care provided to patients requiring immediate and continuous attention of short duration. Acute care includes, but is not limited to, medical, surgical, obstetric, pediatric, psychiatric, ICU and CCU care in a hospital.
- B. Acute Care Bed: Any licensed inpatient bed dedicated to the use of patients requiring acute care.
- C. Admission Rate: The number of patients entering into the hospital for acute care services per 1,000 population.
- D. Average Daily Census: The average number of licensed acute care beds in the hospital that are used by inpatients.
- E. Average Length of Stay: The average number of days a patient stays in the hospital.
- F. Bed: A general measure of hospital size and capacity.
- G. Capital Expenditure: Those expenditures as defined in W.Va. Code § 16-2D-2

including a series of expenditures exceeding the expenditure minimum and determined by the Health Care Authority to be a single capital expenditure subject to review.

- H. Discharge Planning: A coordinated effort to ensure that each patient to be discharged from a health care facility has a planned program of needed continuing care and follow up that seeks optimum functioning of that patient and the earliest practicable discharge.
- I. Discharge Rate: The number of patients who have received acute care services discharged per 1,000 population.
- J. Inpatient: A patient who has been admitted to the hospital for an overnight stay or longer.
- K. Intensive Care Unit (ICU): Care provided in a specially licensed unit set up for the purpose of providing maximum surveillance and support of vital functions and definitive therapy for patients suspected of having acute, or potentially reversible life-threatening impairment of single or multiple vital systems (pulmonary, cardiovascular, renal or nervous systems). Such a unit requires special equipment and specially trained staff.
- L. Levels of Care: A system of categorizing neonatal services according to complexity and sophistication. Neonatal care is divided into four levels of care including basic, specialty, subspecialty and regional subspecialty care centers as defined in the most current edition of the *Guidelines for Perinatal Care* published by the American Academy of Pediatrics ("AAP"), the American College of Obstetricians and Gynecologists ("ACOG") and the Society for Maternal-Fetal Medicine ("SMFM").
- M. Licensed Beds: The basic index of hospital capacity, consisting of the beds in each hospital which are licensed for acute care use. In the case of state-operated acute care facilities, it is the number set up and staffed.
- N. Neonatal: A term used to refer to an infant less than 29 days old.
- O. Neonatal Intensive Care Unit: An ICU specializing in the care of ill or premature newborn infants. NICUs provide extraordinary surveillance and support of vital functions and definitive therapy for infants having acute or potentially reversible life-threatening impairment of a vital system(s).
- P. Observation Services: Services ordered by a patient's physician and provided by a hospital on the hospital's premises. These services include the use of a bed and periodic monitoring by the hospital's nursing or other staff, which are reasonable and necessary for a possible admission to the hospital as an inpatient. Observation beds are not licensed acute care beds.

- Q. Observation Equivalent Days: The total observation hours divided by 24. Observation equivalent days may be added to acute care days to demonstrate peak occupancy.
- R. Occupancy Rate: The average percentage of licensed beds in a hospital or one of its units that are filled as of midnight each day. To demonstrate peak occupancy, the hospital may also document the occupancy rate at a different time of the day.
- S. Peer Review: The evaluation of health professionals and their performance by their peers. This term relates to programs such as utilization review and professional review organizations.

III. CURRENT INVENTORY

The Authority will provide each applicant with a current inventory of existing NICU beds.

IV. NEED METHODOLOGY

An applicant proposing to provide NICU services must apply for a specific NICU level, i.e. NICU Level II, Level III or Level IV.

A. Existing Level III providers - West Virginia University Hospitals, Inc., Charleston Area Medical Center and Cabell Huntington Hospital - may apply for NICU Level IV without addressing the requirements of this section, unless the proposal involves adding beds to their hospital license. If the proposal adds licensed beds, Section C below must be addressed. Applications for NICU Level IV providers will be limited to these three hospitals.

B. Applicants for NICU Level II and Level III must demonstrate that:

1. There is an unmet need for the proposed NICU service, that the proposed service will not have a negative impact on current providers of the service, and that the proposed service is the most cost-effective alternative;
2. It can delineate the service area by documenting the expected areas from which the facility is expected to draw patients. The applicant may submit testimony or documentation on the expected service area, based upon national data or statistics, or upon projections generally relied upon by professionals engaged in health planning or the development of health services;
3. It can document the expected number of days for the services to be provided by the facility for the population within the service area;
4. It can document the number of existing providers within the service area, as provided by the Authority, and the number of NICU days by existing providers in the service area based on the most recent uniform report(s) on

file with the Authority;

5. There is an unmet need by demonstrating that the total expected number of NICU days, less the number of NICU days provided by existing providers in the service area, results in a difference that requires an addition of the NICU Level being proposed by the applicant.

6. Applicants must be an existing birthing hospital as provided below:

- a. Level II NICU applicants must be an existing provider of Level I nursery care.
- b. Level III tertiary care NICU applicants must be an existing provider of Level II NICU services.

C. If an applicant is seeking to add the NICU beds to its hospital license, as opposed to converting existing licensed beds to NICU beds, the Authority will not approve the addition of beds if, after completion of the project, the number of licensed acute care beds for the hospital is equal to or exceeds 160% of the average daily census for licensed acute beds for the last twelve (12) month period. The Authority may grant an exception to the 160% average daily census requirement if the applicant has experienced significant fluctuations in its occupancy levels and (a) the applicant is the sole hospital in a county or (b) the applicant has exceeded an 85% acute care occupancy level for two consecutive months during the past twelve (12) months. In determining the average daily census, the hospital may adjust for observation equivalent days and swing bed days. The Authority, in its discretion, may also take into consideration data submitted by the hospital to demonstrate the impact of a distinct part unit on the hospital's average daily census.

V. QUALITY

A. The applicant must document that its birthing program meets the most current edition of the *Guidelines for Perinatal Care* published by the American Academy of Pediatrics ("AAP"), the American College of Obstetricians and Gynecologists ("ACOG") and the Society for Maternal-Fetal Medicine ("SMFM") for its current birthing level of care.

B. The applicant must provide a detailed plan for how it will meet the most current edition of the *Guidelines for Perinatal Care* published by the American Academy of Pediatrics ("AAP"), the American College of Obstetricians and Gynecologists ("ACOG") and the Society for Maternal-Fetal Medicine ("SMFM") for the proposed NICU level including, but not limited to, specially trained staff, equipment or other specialty services.

C. The applicant must demonstrate that the physical layout and location for the NICU is consistent with the most current edition of the *Guidelines for Perinatal Care* published by the American Academy of Pediatrics ("AAP"), the American College of Obstetricians and Gynecologists ("ACOG") and the Society for Maternal-Fetal Medicine ("SMFM").

D. Utilization review and quality assurance programs must be maintained.

E. The applicant must be accredited by The Joint Commission, Det Norske Veritas (DNV), or another accepted accreditation body.

VI. CONTINUUM OF CARE

A. The applicant must document how it currently collaborates with other birthing hospitals to coordinate maternal referrals and or transfers to ensure neonates are delivered at a "risk appropriate" facility and how it will collaborate if it moves to a higher level of birthing care.

B. The applicant must provide its current policy/procedure for interhospital transfers of neonates and its proposed policy for interhospital transfers of neonates when it begins the proposed NICU services.

C. The applicant must demonstrate that it has in place effective utilization review, quality assurance, peer review, and discharge planning processes.

D. The applicant shall ensure that it meets the criteria outlined in the current Guidelines for Perinatal Care, prior to notifying patients and the public that it provides a particular designated level of NICU care. The applicant must provide a plan for how it will ensure compliance with the criteria both initially and on an ongoing basis. This should include validation by a qualified external party.

VII. COST

Applicants shall demonstrate the financial feasibility of the proposal by providing an analysis of the cost-effectiveness of the proposed project to include:

A. A three (3) year projection of revenues and expenses for the project;

B. Evidence that sufficient capital is available to initiate and operate the proposed project;

C. Evidence that financing arrangements are reasonable and secure;

D. Documentation that all indigent persons needing the service can be served without jeopardizing the viability of the project; and,

E. That the charges and costs used in projecting financial feasibility are equitable in comparison to prevailing rates for similar services in similar hospitals.

VIII. ACCESSIBILITY

A. NICU services shall be provided based on patients' medical needs and appropriateness without regard to the source of referral or payment;

B. The applicant shall provide written policies, which are non-discriminatory in terms of race, color, creed, age, ethnicity, sex, sexual preference, financial resources, or location of residence.

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