D. Special Care Neonatal Beds

Definition

"Special Care Neonatal beds" are licensed acute care beds located in hospital neonatal units that provide care and treatment of newborn infants through the age of twenty-eight (28) days, and longer if necessary.

Review Criteria

An application for Level II special care neonatal beds shall be consistent with this Plan if the following criteria are met:

1. Approval of the application does not cause the number of Level II beds to exceed the following calculation:

Maximum number of Level II beds in the ADD= (Total annual ADD births for the plan year ÷ 1000) • 4;

2. The number of Level II beds in a facility shall be eight (8) per unit except in those cases where population distribution and access to Level II services justify a smaller unit. In no case shall a unit be smaller than four (4) beds;

3. No new Level II program shall be approved in an ADD unless the overall utilization of existing providers of Level II services in the ADD is at least seventy (70) percent as computed from the most recently published inventory and utilization data;

4. No additional beds will be approved for an existing unit unless the utilization in this unit is at least seventy (70) percent as computed from the most recently published inventory and utilization data;

5. The application documents consistency with the most recent published edition of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists *Guidelines for Perinatal Care*;

6. In addition to the above criteria, an application for Level II special care neonatal care beds must document the ability to provide:

    a. All services required of a Level I basic care neonatal bed;

    b. Care only for stable or moderately ill newborn infants who are born at ≥ 32 weeks gestation or who weigh ≥ 1500 grams at birth with problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty-level services on an urgent basis;

    c. Ventilation limited to an interim basis until the infant's condition either soon improves or the infant can be transferred to a higher-level facility. Delivery of continuous positive airway pressure shall be readily available by experienced

personnel, and mechanical ventilation can be provided for a brief duration (less than 24 hours);

d. Policies and procedures to ensure that care is provided by obstetricians and neonatologists who are continuously available on site or able to be present on the unit within 30 minutes to provide ongoing care as well as to address emergencies;

e. Policies and procedures to ensure the appropriate equipment (e.g., portable x-ray equipment, blood gas analyzer) are continuously available;

f. Policies and procedures to ensure personnel that have specialized training in neonatal care including specialized nurses, respiratory therapists, radiology technicians, and laboratory technicians shall be staffing the unit at all times; and

g. Policies and procedures, including transfer agreements, to ensure referral to a higher level of care occurs for all infants born at < 32 weeks gestation or who weigh < 1,500 grams at birth or when needed for pediatric surgical or medical subspecialty intervention;

7. Notwithstanding criteria 6b, 6c, and 6g above, an applicant for Level II special care neonatal care beds that will provide care for stable or moderately ill newborn infants who are born at ≥ 28 weeks gestation, or who weigh ≥ 1200 grams at birth, or require ventilation for > 24 hours must document the ability to:

a. Establish a collaborative relationship through a written affiliation agreement, which shall be submitted to and approved by the Cabinet, with at least one provider who is located within the Commonwealth or in a contiguous state who meets Level IV criteria in the most recent published edition of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists *Guidelines for Perinatal Care* and agrees to participate in the collaborative relationship as described in criteria i through v of this item, for the purposes of consultation, clinical expertise, education and training, and maternal and neonatal transfer. The affiliation agreement with a facility who meets Level IV criteria in the most recent published edition of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists *Guidelines for Perinatal Care* does not preclude the ability of the Level II facility to transfer a sick infant to a different facility if that facility is an appropriate higher level of care. The affiliation agreement shall specify the mutual responsibility for at least the following:

i. Provision of consultation by the facility that provides Level IV services to the applicant for any infant born or anticipated to be born at the Level II facility at < 32 weeks, < 1500 grams, or requiring ventilation for > 24 hours to determine the most appropriate level of care for that infant;

ii. Provision of education and training for perinatal health professionals of the applicant by the facility that provides Level IV services;

iii. The joint development of guidelines for the provision and receipt of consultation between the parties for perinatal, neonatal, and other specialty disciplines as necessary;

iv. The provision of consultation by the facility that provides Level IV services in the development, review, or revision of the applicant's protocols, policies, and procedures related to:

(a) Maternal and neonatal patient referral and transport, including the process used by the referring facility to identify patients requiring transfer to a higher level of care;

(b) The care of the high risk obstetric and neonatal patients;

(c) The joint review of these polices at least every two years;

(d) Joint development of guidelines for transferring a patient back to the referral facility when care needs can be adequately met by the referring facility; and

(e) Annual joint review of patient outcomes, including all deaths, complications, adverse outcomes [Very Low Birth Weight (VLBW), Bronchopulmonary Dysplasia (BPD), Retinopathy of Prematurity (ROP), Intraventricular Hemorrhage (IVH)] and patients requiring transfer to higher levels of care, with the development collaboratively of a plan of correction for areas where performance falls below expected levels; and agreement to allow technical assistance, including chart review, by the facility that provides Level IV services; and

v. Policies, which at a minimum, include the following requirements for the Level II to transfer to a higher level of care:

(a) All premature infants <28 weeks or <1200 grams;

(b) Patients needing pediatric surgery evaluation or treatment;

(c) Patients needing pediatric subspecialty evaluation or treatment, such as pediatric neurosurgery or cardiac consultation, catheterization, or cardiac surgery;

(d) Patients needing pediatric multiple subspecialty care or pediatric subspecialty care not available on site;

(e) Anticipated or possible need for high frequency ventilation, nitric oxide, or extracorporeal membrane oxygenation (ECMO); and

(f) Patients anticipated to need total body cooling or brain cooling;

b. Participate in the Vermont Oxford Network (VON), including the Kentucky State VON Report, to ensure the capability to collect data and assess outcomes within the Level II facility and to compare with other levels; and include a review of the hospital's data as part of the annual joint review of patient outcomes conducted in collaboration with the hospital's affiliated provider of Level IV services;

c. Demonstrate readily available pediatric ophthalmology services and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity; and

d. Obtain consultation, on a 24 hour basis, from a maternal-fetal medicine specialist regarding management of high risk obstetric patients; and

8. Notwithstanding criterion 1 above, if the most recently published inventory and utilization data indicates that the occupancy of the applicant's existing Level II special care neonatal beds was seventy (70) percent or greater, an application to designate up to four (4) additional acute care beds as Level II special care neonatal beds shall be consistent with this plan.

An application for Level III special care neonatal beds shall be consistent with this Plan if:

1. Approval of the application does not cause the number of Level III beds in the Commonwealth to exceed the following calculation:

(Total annual state births for the plan year ÷ 1000) ● 1 = Maximum number of Level III beds in the state;

2. The application documents consistency with the most recent published edition of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists *Guidelines for Perinatal Care*;

3. In addition to the above criteria, an application for Level III special care neonatal care beds must document its ability to provide:

a. All services required of a Level II special care neonatal care bed;

b. Neonatologists and personnel that have specialized training in neonatal care, including neonatal nurses, respiratory therapists, radiology technicians, and laboratory technicians that are on-site and available 24 hours per day;

c. Equipment that is continuously available to provide life support for as long as needed;

d. Advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition and pharmacy support with pediatric expertise;

e. Ongoing assisted ventilation for periods longer than 24 hours, which may include conventional ventilation, high-frequency ventilation, and inhaled nitric oxide;

f. Maternal-fetal medicine specialists and a broad range of pediatric medical subspecialists and pediatric surgical specialists that are readily accessible on site or by prearranged consultative agreements using telemedicine or telephonic consultation. If provided by prearranged consultative agreements, explain the details of the prearrangement;

g. Readily available pediatric ophthalmology services in the Level III facility and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity;

h. The policies and procedures in place to ensure that all complex surgical procedures performed in newborn infants are performed by pediatric surgical specialists (including anesthesiologists with pediatric expertise). The capability to perform major surgery may be on site if pediatric surgical and anesthesia specialists are available, or by arrangement with a closely related institution, ideally in close geographic proximity. If capability is at a related institution, explain in detail arrangements that ensure the availability of transport services to quickly and safely transfer infants requiring this subspecialty intervention;

i. The capability to perform advanced imaging with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging, and echocardiography;

j. Documentation of the facility's participation in the Vermont Oxford Network (VON), including the Kentucky State VON Report, to ensure the capability to collect data and assess outcomes within their facility and to compare with other levels; and include a review of the hospital's data as part of the annual joint review of patient outcomes conducted in collaboration with the hospital's affiliated provider of Level IV services; and

k. A collaborative relationship through a written affiliation agreement, which shall be submitted to and be approved by the Cabinet, with at least one provider who is located within the Commonwealth or in a contiguous state who meets Level IV criteria in the most recent published edition of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists *Guidelines for Perinatal Care* and agrees to participate in the collaborative relationship as described in criteria i through iv of this item for the purposes of consultation, clinical expertise, education and training, and maternal and neonatal transfer. The affiliation agreement with a facility who meets Level IV criteria in

the most recent published edition of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists *Guidelines for Perinatal Care* does not preclude the ability of the Level III facility to transfer a sick infant to a different facility if that facility is an appropriate higher level of care. The affiliation agreement shall specify the mutual responsibility for at least the following:

i. Detailed explanation of any prearranged consultative agreements for pediatric medical subspecialists not available on site;

ii. Assurance that, when pediatric surgeons are not available on site, infants needing surgery are transferred to a site where all complex surgical procedures performed on newborn infants are performed by pediatric surgical specialists (including anesthesiologists with pediatric expertise);

iii. Assurance that referral to a higher level of care will occur for all infants requiring subspecialty intervention or surgical repair of complex conditions (e.g., congenital cardiac malformations that require cardiopulmonary bypass with or without ECMO); and

iv. Assurance of the availability of transport services to quickly and safely transfer infants requiring these subspecialty interventions to higher level facilities or children's hospitals;

4. Notwithstanding the above criterion 1, if the most recently published inventory and utilization data indicates that the occupancy of the applicant's existing Level III special care neonatal beds was seventy (70) percent or greater, an application to designate up to two (2) additional Level II neonatal beds as Level III special care neonatal beds shall be consistent with this plan; and

5. Notwithstanding the above criteria 1 and 4, applications proposing to convert up to fifty percent (50%) of existing Level II special care neonatal beds, as published in the November 2012 Certificate of Need Inventory of Health Facilities and Services, to Level III special neonatal beds shall be consistent with the State Health Plan if the hospital:

a. Is licensed for a minimum of sixteen (16) neonatal Level II beds;

b. Has a minimum of 1,500 Medicaid neonatal Level II patient days per year;

c. Has a gestational age lower limit of twenty-seven (27) weeks; and

d. Has a full-time perinatologist on staff.

An application for Level IV special care neonatal beds shall be consistent with this Plan if the application:

1. Requests to convert a specified number of existing Level III special care neonatal beds to Level IV special care neonatal beds and the applicant is:

    a. An academic medical center with a pediatric and neonatal training program that is accredited by the American College of Graduate Medical Education, or

    b. Is a children's hospital with a pediatric and neonatal training program that is accredited by the American College of Graduate Medical Education;

2. Documents the ability to provide all services required of a Level III special care neonatal care bed;

3. Documents the ability to provide pediatric medical subspecialists and pediatric surgical services within the institution, including anesthesiologists with pediatric expertise, as well as pediatric surgical subspecialists. These pediatric surgical subspecialist services, at a minimum, must include the ability to provide surgical repair of complex conditions;

4. Documents policies and procedures to facilitate transport systems and provide outreach education in their catchment area;

5. Documents capability to collect data on long-term outcomes to evaluate both the effectiveness of delivery of perinatal health services and the safety and efficacy of new therapies;

6. Documents consent to enter into collaborative relationships through written affiliation agreements with Level II neonatal facilities caring for stable or moderately ill newborn infants who are born at ≥ 28 weeks gestation or who weigh ≥ 1,200 grams at birth. An affiliation agreement shall specify the mutual responsibility for at least the following:

    a. Provision of education and training opportunities by the Level IV facility for perinatal health professionals of the applicant;

    b. The joint development of guidelines for the provision and receipt of consultation between the parties for perinatal, neonatal, and other specialty disciplines as necessary; and

    c. The provision of consultation by the Level IV facility to the Level II facility in the development, review, or revision of the Level II facility's protocols, policies, and procedures related to:

        i. Maternal and neonatal patient referral and transport, including the process used by the Level II facility to identify patients requiring transfer to a higher level of care;

ii. The care of the high risk obstetric and neonatal patients;

iii. The joint review of these polices at least every two years; and

iv. Joint development of guidelines for transferring a patient back to the referral facility when care needs can be adequately met by the referring facility;

7. Documents consent to enter into a collaborative relationship through a written affiliation agreement with Level III neonatal facilities for the purposes of consultation, clinical expertise, education and training, and maternal and neonatal transfer; and

8. Documents commitment to:

a. Participate in the Vermont Oxford Network (VON), including the Kentucky State VON Report, to ensure the capability to collect data and assess outcomes within the Level IV facility and to compare with other levels; and to provide an annual report, which does not identify specific hospitals, to the Cabinet on aggregate statewide outcomes and trends based on the Kentucky State VON Report;

b. Establish a mortality and morbidity conference between Level III and Level IV facilities at least annually to review outcome data and identify opportunities for improvement;

c. Take the leadership role in establishing joint reviews with affiliated hospitals of patient outcomes, including all deaths, complications, adverse outcomes (VLBW, BPD, ROP, IVH) and patients requiring transfer to higher levels of care, at least annually;

d. Develop collaboratively with the affiliate facility a plan of correction for areas where performance falls below expected levels; and

e. Provide technical assistance, including chart review if needed, to assure areas of low performance show improvement.

E. Open Heart Surgery Program

Definition

Open heart surgery is any surgical procedure involving the heart, performed to correct acquired or congenital defects, to replace diseased valves, to open or bypass blocked vessels, or to graft a prosthesis or a transplant in place. In open-heart procedures, the heart chambers are open and fully visible and blood is detoured around the surgical field by a heart-lung bypass machine unless the procedure involved is a minimally invasive coronary artery bypass graft, in which case a heart-lung machine might not be used, but must still be available in the operating room on a stand-by basis.

A "case" is defined as the entire episode of treatment in the operating room regardless of the number of procedures performed.

Review Criteria

An application for an open heart surgery program shall be consistent with this Plan if the following criteria are met:

1. For adult open heart surgery, there is not an existing or approved open heart surgery program in the ADD or the following criteria are met:

    a. According to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*, every open heart surgery program in the ADD performed at least four hundred (400) adult open-heart surgeries;

    b. According to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*, every open heart surgery program within a fifty (50) mile radius of the proposed site performed at least four hundred (400) adult open-heart surgeries;

    c. Every open heart surgery program in the ADD that is not listed in the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report* performed at least three hundred (300) adult open-heart surgeries in the past twelve (12) months;

    d. Every open-heart surgery program that is within a fifty (50) mile radius of the proposed site and is not listed in the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report* performed at least three hundred (300) adult open heart surgeries in the past twelve (12) months;

    e. The applicant shall document that at least four hundred (400) adult open-heart procedures will be performed during the third year of operation. These projections must consider historical number of diagnostic cardiac catheterization procedures performed at the applicant hospital, the Kentucky statewide ratio of open heart surgeries to diagnostic catheterization procedures as calculated in the

latest published inventory and utilization data, and documentation of the number of diagnostic catheterization patients referred for open heart surgery from the applicant hospital during the most recent twelve (12) month period;

f. The applicant shall document that the approval of the proposed program will not cause any existing program in the ADD or any other open heart surgery program within a fifty (50) mile radius of the proposed site to fall below four hundred (400) cases annually when considering historical trends in utilization, referral patterns for these services to existing providers, and commonality of medical staffs;

g. The applicant shall demonstrate that the projected number of therapeutic cardiac catheterization procedures will reach at least three hundred-fifty (350) by the third year of operation of the open heart surgery program. These projections must consider historical diagnostic cardiac catheterization procedures at the applicant hospital, the Kentucky statewide ratio of therapeutic catheterizations to diagnostic catheterizations and documentation of the historical number of diagnostic cardiac catheterization patients referred from the applicant hospital for therapeutic cardiac catheterization during the most recent twelve (12) month period;

h. The applicant shall document that the most recently published *Guidelines for Coronary Artery Bypass Graft Surgery* adopted by the American College of Cardiology and the American Heart Association will be followed; and

i. The applicant must identify the surgeon who will be the primary attending surgeon in the open heart service. Further, the applicant must also provide information regarding this individual's background and experience concerning open heart surgery, and this individual's availability to care for open heart patients in the event of emergencies; and

2. For pediatric open heart surgery:

a. Only pediatric teaching facilities shall be approved for pediatric open heart surgery;

b. According to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*, every existing pediatric program in the state shall be performing, and shall be projected to continue to perform, at least one hundred-fifty (150) pediatric open-heart surgeries per year; and

c. The applicant shall document that at least one hundred (100) pediatric open-heart procedures will be performed during the third year of operation.