12 VAC 5-410-440. Obstetric and newborn services general requirements.

A. Hospitals with licensed obstetric and newborn services in operation prior to the effective date of this chapter or revisions to thereof shall comply with all of the requirements of this section within 12 months of the effective date of this chapter, with the exception of specified sections of ~~subdivision C 5 of this section~~ 12 VAC 5-410-442. Hospitals that establish and organize obstetric and newborn services after the effective date of this chapter shall comply with all requirements of this section and sections 12 VAC 5-410-441 through 12 VAC 5-410-447 of this chapter before licensure approval is granted.

B. A hospital with organized obstetric and newborn services shall comply with the following general requirements:

1. ~~Administrative management.~~ The governing body of the hospital or the chief executive officer shall appoint an administrative manager for the obstetric and newborn services. The administrative manager may serve as an administrator of another hospital service but must be available to the obstetric and newborn services. The chief executive officer shall designate, in writing, an individual to act in the administrative manager's behalf during a temporary absence of the administrative manager.

2. ~~Services plan.~~ The hospital is responsible for the development, periodic review and revision of a service management plan. The plan must include provisions to assure that the hospital complies with all state and federal regulations and guidelines applicable to obstetric and ~~neonatal~~ newborn care as well as the policies and procedures for obstetric and newborn care adopted by the hospital's governing body and medical staff. The plan is to be developed and maintained as follows:

a. The plan shall be developed in cooperation with the medical directors and nursing staffs assigned to each of the services.

b. The plan shall include the protocol, required by §32.1-127 of the Code of Virginia, for the admission or transfer of any pregnant woman who presents in labor.

c. The plan shall be the responsibility of the administrative manager who is to assure that the plan is developed, that it complies with state and federal requirements and the hospital's policies and procedures, and that it is periodically reviewed and revised.

d. A copy of the plan shall be readily available at each nursing station within the obstetric and newborn services for staff reference.

e. A copy of the plan shall be made available, upon request, to the ~~hospital~~ ~~state~~ licensing inspector for review.

3. ~~Support services.~~ The hospital shall provide the following services in support of the obstetric and newborn services units:

a. Clinical laboratory services and blood bank services shall be available in the hospital on a 24-hour basis. Laboratory and blood bank personnel shall be available on-site or on-call on a 24-hour basis. The blood bank shall have group O Rh negative blood available at all times and be able to provide correctly matched blood in 45 minutes from

request. The hospital's laboratory and blood bank personnel must be capable of performing the following tests with less than 1.0 ml of blood within one hour of request or less if specified:

(1) Blood group and Rh type determination/cross matching
(2) Arterial blood gases within 20 minutes
(3) Blood glucose within 20 minutes
(4) Complete ~~Blood Count~~ blood count
(5) Total protein
(6) Total bilirubin
(7) Direct Coombs test
(8) Electrolytes
(9) Blood ~~Urea Nitrogen~~ urea nitrogen
(10) Clotting profile (may require more than one cc of blood)

b. Portable radiological services for basic radiologic studies in each labor room, delivery room, and nursery shall be available on call on a 24-hour basis.

c. In addition to the requirements specified in 12VAC5-410-240 of this chapter, anesthesia service personnel shall be available on-site or on-call to begin anesthesia within 30 minutes of notification.

~~C.~~ 12 VAC 5-410-441. Obstetric service requirements ~~are as follows:~~ ; medical direction; physician consultation and coverage; nurse staffing and coverage; policies and procedures.

~~1. Medical direction. a.~~ A. The governing body shall appoint a physician as medical director of the organized obstetric service who meets the qualifications specified in the medical staff bylaws.

~~b.~~ 1. If the medical director is not a board certified obstetrician or board eligible in obstetrics, the hospital shall have a written agreement with one or more board-certified or board-eligible obstetricians to provide consultation on a 24-hour basis. Consultation may be by telephone.

~~c.~~ 2. The duties and responsibilities of the medical director of obstetric services shall include but not be limited to:

~~(1)~~ a. The general supervision of the quality of care provided patients admitted to the service;

~~(2)~~ b. The establishment of criteria for admission to the service;

~~(3)~~ c. The adherence to standards of professional practices and policies and procedures adopted by the medical staff and governing body;

~~(4)~~ d. The development of recommendations to the medical staff on standards of professional practice and staff privileges;

~~(5)~~ e. The identification of clinical conditions and medical or surgical procedures that require physician consultation;

~~(6)~~ f. Arranging conferences, at least quarterly, to review obstetrical surgical procedures, complications and infant and maternal mortality and morbidity. Infant

mortality and morbidity shall be discussed jointly between the obstetric and newborn service staffs.

~~2. Physician consultation and coverage.~~

~~a.~~ B. A physician with obstetrical privileges capable of arriving on-site within 30 minutes of notification shall be on a 24-hour on-call duty roster.

~~b.~~ C. A physician with obstetrical privileges shall be accessible for patient treatment within 10 minutes during the administration of an oxytocic agent to an antepartum patient.

~~c.~~ D. A physician or a certified nurse-midwife, under the supervision of a physician with obstetrical privileges, shall be in attendance for each delivery. Physician supervision of the nurse-midwife shall be in compliance with the regulations of the Boards of Nursing and Medicine.

~~d.~~ E. A physician shall be in attendance during all high-risk deliveries. High-risk deliveries shall be defined by the obstetric service medical staff.

~~e.~~ F. A physician or a nurse skilled in neonatal cardiopulmonary resuscitation (CPR) shall be available in the hospital at all times.

~~f.~~ G. A current roster of physicians, with a delineation of their obstetrical, newborn, pediatric, medical and surgical staff privileges, shall be posted at each nurses' station in the obstetric suite and in the emergency room.

~~g.~~ H. A copy of the 24-hour on-call duty schedule, including the list of on-call consulting physicians, shall be posted at each nurses' station in the obstetric suite and in the emergency room.

~~3. Nursing staff and coverage.~~

~~a.~~ I. An occupied unit of the obstetrics service shall be supervised by a registered nurse 24 hours a day.

~~b.~~ J. If the postpartum unit is organized as a separate nursing unit, staffing shall be based on a formula of one nursing personnel for every six to eight obstetric patients. Staffing shall include at least one registered nurse for the unit for each duty shift.

~~c.~~ K. If the postpartum and general care newborn units are organized as combined rooming-in or modified rooming-in units, staffing shall be based on a formula of one nursing personnel for every four mother-baby units. The rooming-in units shall be staffed at all times with no less than two nursing personnel each shift. At least one of the two nursing personnel on each shift shall be a registered nurse.

~~d.~~ L. A registered nurse shall be in attendance at all deliveries. The nurse shall be available on-site to monitor the mother's general condition and that of the fetus during labor, at least one hour after delivery, and longer if complications occur.

~~e.~~ M. Nurse staffing of the labor and delivery unit shall be scheduled to ensure that the total number of nursing personnel available on each shift is equal to one half of the average number of deliveries in the hospital during a 24-hour period.

~~f.~~ N. At least one of the personnel assigned to each shift on the obstetrics unit shall be a registered nurse. At no time when the unit is occupied shall the nursing staff on any shift be less than two staff members.

~~g.~~ O. Patients placed under analgesia or anesthesia during labor or delivery shall be under continuous observation by a registered nurse or a licensed practical nurse for at least one hour after delivery.

~~h.~~ P. To ensure adequate nursing staff for labor, delivery, and postpartum units during busy or crisis periods, duty schedules shall be developed in accordance with the following nurse/patient ratios:

~~(1)~~ 1. 1:1 to 2 Antepartum testing
~~(2)~~ 2. 1:2 Laboring patients
~~(3)~~ 3. 1:1 Patients in second stage of labor
~~(4)~~ 4. 1:1 Ill patients with complications
~~(5)~~ 5. 1:2 Oxytocin induction or augmentation of labor
~~(6)~~ 6. 1:2 Coverage of epidural anesthesia
~~(7)~~ 7. 1:1 Circulation for cesarean delivery
~~(8)~~ 8. 1:6 to 8 Antepartum/postpartum patients without complications
~~(9)~~ 9. 1:2 Postoperative recovery
~~(10)~~ 10. 1:3 Patients with complications, but in stable condition
~~(11)~~ 11. 1:4 Mother-newborn care

~~i.~~ Q. Student nurses, licensed practical nurses and nursing aides who assist in the nursing care of obstetric patients shall be under the supervision of a registered nurse.

~~j.~~ R. At least one registered nurse trained in obstetric and neonatal care shall be assigned to the care of mothers and infants at all times.

~~k.~~ S. At least one member of the nursing staff on each shift who is skilled in cardiopulmonary resuscitation of the newborn must be immediately available to the delivery suite.

~~l.~~ T. All nursing personnel assigned to the obstetric service shall have orientation to the obstetrical unit.

~~4. Policies and procedures.~~

~~a. General policies and procedures.~~ U. The governing body shall adopt written policies and procedures for the management of obstetric patients approved by the medical and nursing staff assigned to the service.

1. The policies and procedures shall include, but not be limited to, the following:

~~(1)~~ a. Criteria for the identification and referral of high-risk obstetric patients;

~~(2)~~ b. The types of birthing alternatives, if offered, by the hospital;

~~(3)~~ c. The monitoring of patients during antepartum, labor, delivery, recovery and postpartum periods with or without the use of electronic equipment;

~~(4)~~ d. The use of equipment and personnel required for high-risk deliveries, including multiple births;

~~(5)~~ e. The presence of family members or chosen companions during labor, delivery, recovery, and postpartum periods;

~~(6)~~ f. The reporting, to the Department of Health, of all congenital defects;

~~(7)~~ g. The care of patients during labor and delivery to include the administration of Rh O(D) immunoglobulin to Rh negative mothers who have met eligibility criteria. Administration of RH O(D) immunoglobulin shall be documented in the patient's medical record;

~~(8)~~ h. The provision of family planning information, to each obstetric patient at time of discharge, in accordance with §32.1-134 of the Code of Virginia;

~~(9)~~ i. The use of specially trained paramedical and nursing personnel by the obstetrics and newborn service units;

~~(10)~~ j. A protocol for hospital personnel to use to assist them in obtaining public health, nutrition, genetic and social services for patients who need those services;

~~(11)~~ k. The use of anesthesia with obstetric patients;

~~(12)~~ l. The use of radiological and electronic services, including safety precautions, for obstetric patients;

~~(13)~~ m. The management of mothers who utilize breast milk with their newborns. Breast milk shall be collected in ~~sterile~~ aseptic containers, dated, stored under refrigeration and consumed or disposed of within ~~24~~ 48 hours of collection if the breast milk has not been frozen. This policy pertains to breast milk collected while in the hospital or at home for hospital use;

~~(14)~~ n. Staff capability to perform cesarean sections within 30 minutes of notice;

~~(15)~~ o. Emergency resuscitation procedures for mothers and infants;

~~(16)~~ p. The treatment of volume shock in mothers;

~~(17)~~ q. Training of hospital staff in discharge planning for identified substance abusing, postpartum women and their infants;

~~(18)~~ r. Written discharge planning for identified substance abusing, postpartum women and their infants. The discharge plans shall include appropriate referral sources available in the community or locality for mother and infants such as:

(~~a~~ 1) Substance abuse treatment services; and

(~~b~~ 2) Comprehensive early intervention services for infants and toddlers with disabilities and their families pursuant to Part H of the Individuals with Disabilities Education Act, 20 USC §1471 et seq.

(3) The discharge planning process shall be coordinated by a health care professional and shall include, to the extent possible:

(a) The father of the infant; and

(b) Any family members who may participate in the follow-up care of the mother or infant.

(c) The discharge plan shall be discussed with the mother and documented in the medical record.

~~b. Policies and procedures for the use of the labor, delivery and recovery rooms/labor, delivery, recovery and postpartum rooms.~~ 2. The obstetric service shall adopt written policies and procedures for the use of the labor, delivery and recovery rooms (LDR)/Labor, delivery, recovery and postpartum rooms (LDRP) that include, but are not limited to the following:

~~(1)~~ a. The philosophy, goals and objectives for the use of the LDR/LDRP rooms;

~~(2)~~ b. Criteria for patient eligibility to use the LDR/LDRP rooms;

~~(3)~~ c. Identification of high-risk conditions which disqualify patients from use of the LDR/LDRP rooms;

~~(4)~~ d. Patient care in LDR/LDRP rooms, including but not limited to, the following;

(~~a~~ 1) Defining vital signs, the intervals at which they shall be taken, and requirements for documentation; and

(~~b~~ 2) Observing, monitoring, and assessing the patient by a registered nurse, certified nurse midwife, or physician;

~~(5)~~ e. The types of analgesia and anesthesia to be used in LDR/LDRP rooms;

~~(6)~~ f. Specifications of conditions of labor or delivery requiring transfer of the patient from LDR/LDRP rooms to the delivery room;

~~(7)~~ g. Specification of conditions requiring the transfer of the mother to the postpartum unit or the newborn to the nursery;

~~(8)~~ h. Criteria for early or routine discharge of the mother and newborn;

~~(9)~~ i. The completion of medical records;

~~(10)~~ j. The presence of family members or chosen companions in the delivery room or operating room in the event that the patient is transferred to the delivery room or operating room;

~~(11)~~ k. The number of visitors allowed in the LDR/LDRP room, and their relationship to the mother;

~~(12)~~ l. Infection control, including, but not limited to, gowning and attire to be worn by persons in the LDR/LDRP room, upon leaving it, and upon returning.

~~5.~~ 12 VAC 5-410-442. Obstetric service design and equipment criteria.

A. In addition to complying with Article 5 of this part, a hospital shall comply with the following requirements of this section for the physical design of obstetric service facilities. Existing hospitals with licensed obstetric and newborn services in operation prior to the effective date of the regulations or revisions thereof, shall comply with all of the regulations of this section with the exception of the minimum dimension and square footage requirements for labor rooms and LDR/LDRP rooms provided for in ~~subdivisions e, f, and i of this subdivision~~ subdivisions B.5, 6 and 9 of this section. Existing hospitals with an obstetric service may not decrease the dimensions of the labor rooms and the LDR/LDRP rooms from what was granted approval at the time the service was licensed.

B. Labor rooms and LDR/LDRP rooms that are renovated or constructed after the effective date of this chapter shall conform with all of the room dimensions specified in this section~~.~~:

~~a~~. 1. The space and arrangement of a hospital building or a section of the hospital designated as the obstetric unit (antepartum and postpartum) shall be designed to assure the separation of obstetric patients from other patients with the exception of clean gynecological patients. Clean gynecological patients shall be defined in approved written hospital policy.

~~b~~ 2. The hospital shall identify specific rooms and beds as obstetric rooms and beds. Adjacent rooms and beds may be used for clean gynecological cases.

~~c~~ 3. Labor, delivery, recovery and labor, delivery, recovery and postpartum rooms

shall be physically separate from emergency and operating rooms.

~~d~~ 4. The obstetric nursing unit shall meet the requirements of 12VAC5-410-750 A of this chapter, except for the following:

~~(1)~~ a. A handwashing lavatory must be provided in each patient room;

~~(2)~~ b. The soiled workroom and janitors' closet in the obstetric nursing unit shall only be shared with the newborn services unit;

~~(3)~~ c. All bathing facilities shall be showers or tub units with showers.

~~e~~ 5. Labor rooms shall be single-bed or two bed rooms with a minimum clear area of 180 square feet for each bed.

~~f~~ 6. In hospitals having only one delivery room, two labor rooms shall be provided. One labor room shall be large enough to function as an emergency delivery room with a minimum of 300 square feet (27.87 sq. m). Each room shall have at least two oxygen and two wall-mount suction outlets. Hospitals must equip a labor room with the same equipment as a delivery room if it is to be used as a delivery room. Each labor room shall contain a handwashing lavatory. Each labor room shall have access to a toilet room. One toilet room may serve two labor rooms. At least one shower shall be provided for labor room patients. A water closet shall be accessible to the shower without patients having to enter a corridor or general area.

~~g~~ 7. The delivery room shall have a minimum clear area of 300 square feet (27.87. sq. m) exclusive of fixed and movable cabinets and shelves. The minimum dimensions shall be 16'0" (4.88 m) in any direction between two walls. Separate resuscitation facilities (electrical outlets, oxygen, suction, and compressed air) shall be provided for newborn infants.

~~h~~ 8. The recovery room shall contain a minimum of two beds, charting facilities located to permit staff to have visual control of all beds, facilities for medicine dispensing, handwashing facilities, a clinical sink with a bedpan flushing device, and storage for supplies and equipment.

~~i~~ 9. Hospitals that include birthing LDR/LDRP rooms in their obstetrical program shall designate room(s) within the labor suite for this purpose. Birthing LDR/LDRP rooms shall be designed to prohibit unrelated traffic through the labor and delivery suite and to be readily accessible to delivery rooms and operating rooms. Birthing LDR/LDRP rooms shall meet the requirements of labor rooms, which may be used as emergency delivery rooms, as specified in 12VAC5-410-830 D of this chapter. The minimum dimensions shall be 16'0" (4.88 m) clear between walls or fixed cabinets or shelving and shall have a clear area of 300 square feet (27.87 sq. m). Each LDR/LDRP room shall have a private water closet, shower, and handwashing lavatory.

~~j~~ 10. When specified in this subsection, service areas shall be located in individual rooms. Alcoves or other open spaces that do not interfere with traffic may be used unless individual rooms are specified. Service areas, except the soiled workroom and the janitors' closet, may be shared within the obstetrical unit. If shared, service areas shall be arranged to avoid direct traffic between the delivery and operating rooms. The following service areas shall be provided:

~~(1)~~ a. A control station that is located to permit visual surveillance of all traffic that enters the labor and delivery suite;

~~(2)~~ b. A supervisor's office or station;

~~(3)~~ c. Sterilizing facilities with high speed autoclaves conveniently located to serve all delivery rooms. If provisions have been made for the replacement of sterile instruments during a delivery, sterilizing facilities will not be required;

~~(4)~~ d. A drug distribution station equipped for storage, preparation, and dispensing of medication;

~~(5)~~ e. At least two scrub stations located near the entrance to each delivery room. Two scrub stations may serve two delivery rooms if the stations are located adjacent to the entrance to each delivery room. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts;

~~(6)~~ f. A soiled workroom for the exclusive use of the labor and delivery room personnel. The workroom shall contain a clinical sink or equivalent flushing type fixture, a work counter, a handwashing lavatory, a waste receptacle and a linen receptacle;

~~(7)~~ g. Fluid waste disposal facilities conveniently located to the delivery rooms. A clinical sink or equivalent equipment in a soiled workroom or soiled holding room may meet this requirement;

~~(8)~~ h. A clean workroom that contains a work counter, handwashing lavatory, and space for clean and sterile supplies;

~~(9)~~ i. Anesthesia storage facilities. Unless official hospital board action, in writing, prohibits use of flammable anesthetics, a separate room shall be provided for storage of flammable gases in accordance with the requirements detailed in NFPA 99 and NFPA 70;

~~(10)~~ j. An anesthesia workroom for cleaning, testing, and storing anesthesia equipment. The workroom shall contain a work counter and sink;

~~(11)~~ k. A space for reserve storage of nitrous oxide and oxygen cylinders;

~~(12)~~ l. ~~Equipment storage~~ Storage rooms for equipment and supplies used in the labor and delivery suite;

~~(13)~~ m. Staff's clothing change areas~~. Clothing change areas shall be provided~~ for personnel working within the labor and delivery suite. The areas shall contain lockers, showers, toilets, handwashing lavatories, and space for donning scrub suits and boots;

~~(14)~~ n. Lounge and toilet facilities for obstetrical staff~~. A nurses' toilet room~~ shall be provided near the labor rooms and recovery room(s);

~~(15)~~ o. A janitors' closet~~. A closet~~ containing a floor receptor or service sink and storage for housekeeping supplies and equipment ~~shall be provided for the labor and delivery suite to~~ . The closet may be shared only with the newborn services unit;

~~(16)~~ p. A stretcher storage area~~. This area shall be~~ that is out of direct line of traffic.

~~6.~~ C. Equipment requirements shall include~~.~~:

~~a~~ 1. Delivery rooms, LDR/LDRP rooms, and nurseries shall be equipped to provide emergency resuscitation for mothers and infants.

~~b~~ 2. Equipment and supplies shall be assigned for exclusive use in the obstetric and newborn units.

~~c~~ 3. The same equipment and supplies required for the labor room and delivery room shall be available for use in the LDR/LDRP rooms during periods of labor, delivery, and recovery.

~~d~~ 4. Sterilizing equipment shall be available in the obstetric unit or in a central sterilizing department. Flash sterilizing equipment or sterile supplies and instruments shall be provided in the obstetric unit.

~~e~~ 5. Daily monitoring is required of the stock of necessary equipment in the labor, delivery, and recovery rooms (LDR) and labor, delivery, recovery and postpartum (LDRP) rooms and nursery.

~~f~~ 6. The hospital shall provide the following equipment in the labor, delivery and recovery rooms and, except where noted, in the LDR/LDRP rooms:

~~(1)~~ a. Labor rooms.

(~~a~~ 1) A labor or birthing bed with adjustable side rails

(~~b~~ 2) Adjustable lighting adequate for the examination of patients

(~~c~~ 3) An emergency signal and intercommunication system

(~~d~~ 4) A sphygmomanometer, stethoscope and fetoscope or doppler

(~~e~~ 5) Fetal monitoring equipment with internal and external attachments

(~~f~~ 6) Mechanical infusion equipment

(~~g~~ 7) Wall-mounted oxygen and suction outlets

(~~h~~ 8) Storage equipment

(~~i~~ 9) Sterile equipment for emergency delivery to include at least one clamp and suction bulb.

(~~j~~ 10) Neonatal resuscitation cart.

~~(2) (b)~~ b. Delivery rooms.

(~~a~~ 1) A delivery room table that allows variation in positions for delivery. This equipment is not required for the LDR/LDRP rooms

(~~b~~ 2) Adequate lighting for vaginal deliveries or cesarean deliveries

(~~c~~ 3) Sterile instruments, equipment, and supplies to include sterile uterine packs for vaginal deliveries or cesarean deliveries, episiotomies or laceration repairs, postpartum sterilizations and cesarean hysterectomies

(~~d~~ 4) Continuous in-wall oxygen source and suction outlets for both mother and infant

(~~e~~ 5) Equipment for inhalation and regional anesthesia. This equipment is not required for LDR/LDRP rooms

(~~f~~ 6) A heated, temperature-controlled infant examination and resuscitation unit

(~~g~~ 7) An emergency call system

(~~h~~ 8) Plastic pharyngeal airways ~~(adult and newborn size)~~ , adult and newborn sizes

(~~i~~ 9) Laryngoscope and endotracheal tubes ~~(adult and newborn size)~~ , adult and newborn sizes

(~~j~~ 10) A self-inflating bag with manometer and adult and newborn masks that can deliver 100% oxygen

(~~k~~ 11) Separate cardiopulmonary crash carts for mothers and infants

(~~l~~ 12) Sphygmomanometer

(~~m~~ 13) Cardiac monitor. This equipment is not required for the LDR/LDRP rooms

(~~n~~ 14) Gavage tubes

(~~o~~ 15) Umbilical vessel catheterization trays. This equipment is not required for LDR/LDRP rooms

(~~p~~ 16) Equipment that provides a source of continuous suction for aspiration of the pharynx and stomach

(~~q~~ 17) Stethoscope

(~~r~~ 18) Fetoscope

(~~s~~ 19) Intravenous solutions and equipment

(~~t~~ 20) Wall clock with a second hand

(~~u~~ 21) Heated bassinets equipped with oxygen and transport incubator

(~~v~~ 22) Neonatal resuscitation cart

~~(3)~~ c. Recovery rooms~~.~~ shall include:

(~~a~~ 1) Beds with side rails

(~~b~~ 2) Adequate lighting

(~~c~~ 3) Bedside stands, overbed tables, or fixed shelving

(~~d~~ 4) An emergency call signal

(~~e~~ 5) Equipment necessary for a complete physical examination

(~~f~~ 6) Accessible oxygen and suction equipment

~~D.~~ 12 VAC 5-410-443. Newborn service requirements; designation of newborn service levels, service levels ~~are as follows:~~ .

~~1. Designation of newborn service levels.~~

~~a~~ A . If a hospital intends to provide newborn services, it shall make application to the department requesting approval for a level of newborn service as specified in ~~subdivision 2 of this~~ subsection B. Application shall be made at least 60 days prior to the desired date of approval. Approval is required to be renewed annually. Newborn service level approval shall be based upon the hospital's certification and the department's verification that the hospital meets the requirements of this ~~chapter~~ section for the level requested.

~~b~~ 1. No approval for a general level newborn service designation will be granted without a Certificate of Public Need (COPN) or without documentation by the applicant that it provided general level newborn services prior to July 1, 1992, or that the provision of general level newborn services was found to be exempt from Certificate of Public Need review pursuant to §32.1-102.11 of the Code of Virginia.

~~c~~ 2. No approval for a newborn service level designation higher than general level will be granted without a Certificate of Public Need or without documentation by the applicant that it provided a newborn service level higher than general level prior to July 1, 1992, or that the

provision of a newborn service level higher than general level was found to be exempt from Certificate of Public Need review pursuant to §32.1-102.11 of the Code of Virginia.

~~2. Service levels.~~

~~a.~~ B. A hospital's newborn service shall be designated as a general level, intermediate level, specialty level, or subspecialty level newborn service. The newborn service levels are designated as follows:

~~(1)~~ 1. A general level newborn service shall provide care to newborns of low risk as specified within the service's medical protocol. A general level newborn nursery shall have the capability to care for newborns who weigh at least 2000 grams at birth or who have completed 34 weeks gestation. Risk assessment shall be provided to identify all high-risk neonates and ensure appropriate consultation. A general level newborn nursery shall have the equipment and staff capabilities to immediately stabilize a sick newborn prior to transporting the newborn to an appropriate higher level nursery. The equipment and staff to receive convalescing neonates from higher level nurseries shall also be provided.

~~(2)~~ 2. An intermediate level newborn service shall provide care as specified within the service's medical protocol to moderately ill neonates or stable-growing low birthweight neonates who require only a weight increase to be ready for discharge. In addition to the capabilities required of the general level newborn nursery, the intermediate level nursery shall have the equipment and staff capabilities to provide controlled temperature environments for each neonate, the insertion and maintenance of umbilical arterial lines, hood oxygen to 40%, continuous monitoring of blood oxygen, and assisted ventilation of a neonate in preparation for transport utilizing a mechanical ventilator or an ambu bag.

~~(3)~~ 3. A specialty level newborn service shall provide intensive care to high-risk neonates with neonatal illnesses as specified in the service's medical protocol. In addition to the capabilities required of the lower level nurseries, the specialty level nursery shall have the equipment and staff capabilities to provide the following: maintenance of central arterial umbilical catheters or peripheral arterial lines with constant pressure monitoring, insertion and maintenance of chest tubes for drainage, administration of total parenteral nutrition (TPN), the maintenance of pressor medications, the administration of surfactant and respiratory support to include the maintenance of hood oxygen, continuous positive airway pressure (CPAP), and neonatal mechanical ventilation beyond the immediate stabilization period.

~~(4)~~ 4. A subspecialty level newborn service shall provide intensive care for high-risk, critically ill neonates with complex neonatal illnesses. The subspecialty level newborn service shall provide, in-house, a full range of pediatric medical and surgical subspecialists to care for critically ill neonates. The pediatric subspecialists required as members of the hospital's staff are those subspecialists required of a Subspecialty Perinatal Center as referenced within the 1993 edition of Toward Improving the Outcome of Pregnancy, March of Dimes Birth Defects Foundation, Appendix 6, Pages 114 and 115. Rarely, the availability of highly technical expertise and specialized physicians at another subspecialty center will indicate consultation and possibly transfer. The subspecialty level nursery shall have the capability to care for neonates born in its facility as well as those referred from lower level nurseries. The subspecialty level nursery shall have all of the technical capabilities required of the lower level nurseries as well as

the equipment and staff capabilities to maintain a neonate on prostaglandin E1 (PgE1) and the ability to perform echocardiography evaluations.

~~b~~ C. The hospital shall establish a written medical protocol, approved by the governing body, that specifies all neonatal conditions routinely managed by the newborn service as well as protocols for those medical conditions which require consultation and may necessitate transfer to a higher level of newborn service.

~~c~~ D. Physician consultation shall occur between physicians at the birth hospital and at the referral hospital to which the newborn may be referred.

~~d~~ E. The physician at the birth hospital shall document in the newborn's medical record any physician's consultation and any agreement to manage the newborn at the birth hospital or to stabilize and then transfer the newborn according to the hospital's collaboration agreement. In the event of disagreement, the attending physician at the birth hospital shall be responsible for the management and care of the newborn and shall document the consultation and results of consultation in the newborn's medical record.

~~3.~~ 12 VAC 5-410-444. ~~Medical~~ Newborn service medical direction; physician consultation and coverage; nursing direction, nurse staffing and coverage; policies and procedures.

~~a~~ A. The governing body shall appoint a physician as medical director of the organized newborn service who meets the qualifications specified in the medical staff bylaws. In addition, the medical director must meet the qualifications specified ~~in this chapter~~ for the medical direction of the highest level of newborn service provided by the hospital~~.~~ :

~~b~~ 1. If a hospital offers only general level newborn services, the medical director shall be a physician qualified to provide normal newborn care, including the ability to immediately resuscitate and stabilize a sick newborn for transfer to a higher level of service.

~~c~~ 2. If a hospital offers intermediate level newborn services, the medical director shall be a board-certified or board-eligible pediatrician with training and experience in the care of preterm neonates, including stabilization and ventilation management.

~~d~~ 3. If a hospital offers specialty level newborn services, the medical director shall be a board-certified or board-eligible neonatologist.

~~e~~ 4. If a hospital offers subspecialty level newborn services, the medical director shall be a board-certified or board-eligible neonatologist.

~~f~~ B. The duties and responsibilities of the medical directors of all levels of newborn service shall include, but not be limited to the:

~~(1)~~ 1. General supervision of the quality of care provided patients admitted

to the service;

~~(2)~~ 2. Establishment of criteria for admission to the service;

~~(3)~~ 3. Adherence of the service to standards of professional practices, policies and procedures, the medical protocol, and the hospital's collaboration agreements adopted by the medical staff and governing body applicable to the service;

~~(4)~~ 4. Development of recommendations to the medical staff on standards of professional practice and staff privileges applicable to the service;

~~(5)~~ 5. Identification of clinical conditions and medical and surgical procedures that require physician consultation;

~~(6)~~ 6. Conducting conferences, at least quarterly, to review routine and emergency surgical procedures, complications and infant and maternal mortality and morbidity. Infant mortality and morbidity shall be discussed with the obstetric service staff;

~~(7)~~ 7. Active participation in the service's quality assurance program.

~~4. Physician consultation and coverage.~~

~~a~~ C. The hospital shall provide the following physician consultation and coverage in the general level newborn nursery service and all higher level nursery services unless unique requirements are specifically imposed ~~within this chapter~~ for the higher level nursery services:

~~(1)~~ D. A physician with pediatric privileges capable of arriving on-site within 30 minutes of notification shall be on the 24-hour on-call duty roster;

~~(2)~~ E. A physician or nurse skilled in neonatal cardiopulmonary resuscitation (CPR) shall be available in the hospital at all times.

~~(3)~~ F. A current roster of physicians, with a delineation of their newborn, pediatric, medical and surgical privileges shall be posted at each nurses' station in the newborn service unit.

~~(4)~~ G. A copy of the 24-hour on-call duty schedule, including a list of on-call consulting physicians, shall be posted at each nurses' station in the newborn service unit.

~~(5)~~ H. If the medical director is not a board-certified or board-eligible pediatrician, the hospital shall have a written agreement with one or more board-certified or board-eligible pediatricians to be available to provide consultation on a 24-hour basis. Consultation may be by telephone.

~~(6)~~ I. If a hospital does not have a neonatologist on staff ~~who is~~ available on a 24-hour basis, it shall have a written agreement with another hospital to provide consultation, at least by telephone, on a 24-hour basis, by a board-certified or board-eligible neonatologist. The consultant shall be available to advise on the development of a protocol for the care and transport of sick newborns.

~~b~~ J. The physician consultation and coverage for the intermediate level newborn nursery service shall be the same as the general level newborn service with the following ~~exception~~ exceptions:

~~(1)~~ 1. ~~Subdivision 4 a (1) of this subsection~~ Subsection C.1 shall not apply.

~~(2)~~ 2. Physician coverage shall be provided on a 24-hour on-call basis by a board-certified or board-eligible pediatrician or pediatricians capable of arriving on-site within 30 minutes of notification.

~~c~~ K. The physician consultation and coverage for the specialty level and the subspecialty level newborn services shall be the same as for the lower level newborn services with the following exceptions:

~~(1)~~ 1. ~~Subdivision 4 a (1) of this subsection~~ Subsection C.1 shall not apply.
~~(2)~~ 2. In-house physician consultation and coverage shall be provided 24 hours a day by:
~~(i)~~ a. a board-certified or board-eligible neonatologist; ~~or~~
~~(ii)~~ b. a board-certified or board-eligible pediatrician; ~~or~~
~~(iii)~~ c. a second year or higher level pediatric resident; or
~~(iv)~~ d. a neonatal nurse practitioner.
~~(3)~~ 3. Whenever in-house coverage is provided as stated in ~~clause ii, iii, or iv of subdivision (2)~~ subdivision 2. b, c, or d ~~above~~, a board-certified or board-eligible neonatologist shall be on-call and available to be on-site within 20 minutes of request.

~~3. Nursing direction, staff and coverage.~~

~~a~~ L. The nursing direction, staff and coverage required for the general level newborn service shall be as follows:

~~(1)~~ 1. The neonatal nursing program shall be under the direction of a registered nurse.
~~(2)~~ 2. The nursing director's responsibilities shall include, but not be limited to:
~~(a)~~ a. Directing neonatal nursing services;
~~(b)~~ b. Guiding the development and implementation of neonatal nursing policies and procedures;
~~(c)~~ c. Collaborating with the medical staff; and
~~(d)~~ d. Consulting with referral hospitals with which a hospital has transfer agreements applicable to the service or services.
~~(3)~~ 3. Each occupied unit of the newborn service shall be under the direct supervision of a registered nurse 24 hours a day. The registered nurse shall have documented competence in neonatal nursing appropriate to the level of service provided.
~~(4)~~ 4. If a general level newborn nursery is organized as a separate nursing unit, staffing shall be based on a formula of a minimum of one nursing personnel to every eight newborns. Staffing shall include at least one registered nurse for the unit for each duty shift to provide direct supervision for nursing care.
~~(5)~~ 5. If the postpartum and general level newborn units are organized as combined rooming-in or modified rooming-in units, staffing shall be based on a formula of one nursing personnel for every four mother-baby units. The rooming-in units shall always be staffed with no less than two nursing personnel assigned to each shift. One of the two nursing personnel shall be a registered nurse to provide direct supervision of nursing care.

~~(6)~~ 6. When infants are present in the nursery, at least one nursing personnel trained in the care of newborn infants, with duties restricted to the care of the infants, shall be assigned to the nursery at all times. This nursing personnel is in addition to the registered nurse who is required to provide supervision.

~~(7)~~ 7. To ensure adequate nursing staff for the nursery for normal newborns, duty schedules shall be developed and actual shift staffing shall occur according to the following minimum nurse to patient ratios:

~~(a)~~ a. 1:4 Recently born infants and those needing close observation

~~(b)~~ b. 1:8 Newborns needing only routine care

~~(c)~~ c. 1:4 Mother-newborn routine care

~~(8)~~ 8. Student nurses, licensed practical nurses and nursing aides who assist in the nursing care of newborn infants shall be under the direct supervision of a registered nurse.

~~(9)~~ 9. At least one nurse on each shift who is skilled in neonatal cardiopulmonary resuscitation must be immediately available to the nursery.

~~(10)~~ 10. All nursing personnel assigned to the newborn service shall have orientation to the nursery ~~which includes~~ , including orientation to patient care appropriate for the service level provided.

~~b.~~ M. The nursing direction, staff and coverage required of the intermediate level newborn service shall be the same as required of the general level newborn service with the following exceptions:

~~(1)~~ 1. To ensure adequate nursing staff for the nursery, duty schedules shall be developed and actual shift staffing shall occur according to a ratio of at least one nurse to four neonates.

~~(2)~~ 2. All registered nurses assigned to the newborn service shall be trained in neonatal cardiopulmonary resuscitation (CPR).

~~c~~ N. The nursing direction, staff and coverage for the specialty level newborn service shall be the same as the lower level newborn service levels with the following exceptions:

~~(1)~~ 1. The newborn nursery service shall have a nurse manager. The nurse manager shall be a registered nurse with advanced training and experience in the nursing management of high-risk neonates and their families. The responsibilities of the nurse manager shall include, but not be limited to:

~~(a)~~ a. Daily management of the nursery;

~~(b)~~ b. Supervision and evaluation of nursing personnel assigned to the nursery;

~~(c)~~ c. Assuring nursing coverage 24 hours a day; and

~~(d)~~ d. Implementing nursing policies and procedures at the service level.

~~(2)~~ 2. All registered nurses shall have advanced training and experience in the management of neonatal patients, including specialized care technology and ventilator care for neonates. Only registered nurses with this advanced training and experience shall be assigned to care for neonates on ventilators.

~~(3)~~ 3. To ensure adequate nursing staff for the nursery, duty schedules shall be developed and actual shift staffing shall occur according to a ratio of at least one nurse to three patients for neonates requiring specialty level care. For those neonates who have been assessed as no longer

needing specialty level care, nurse to patient ratios shall be according to the neonate's appropriate level of service.

~~d~~ O. The nursing direction, staff and coverage for the subspecialty level newborn service shall be the same as all lower levels of newborn services with the following exceptions:

~~(1)~~ 1. A neonatal clinical nurse specialist shall be assigned to the nursery, duties and responsibilities shall include staff consultation, collaboration, and teaching.

~~(2)~~ 2. All registered nurses shall have advanced training and experience, beyond what is required of nurses in the lower level nurseries, in the management of high-risk neonates, including the care of unstable neonates with multisystem problems.

~~(3)~~ 3. To ensure adequate nursing staff for the nursery, duty schedules shall be developed and actual shift staffing shall occur according to the following minimum nurse to patient ratios for neonates requiring subspecialty level care:

~~(a)~~ a. 1:2 Neonates requiring subspecialty level care; and

~~(b)~~ b. 1:1 Neonates requiring multisystem support.

For those neonates who have been assessed as no longer needing subspecialty level care, nurse to patient ratios shall be according to the neonate's appropriate level of service.

~~(4)~~ 4. All nursing patient care shall be provided by registered nurses assigned to the subspecialty level nursery.

~~6. Policies and procedures.~~

~~a~~ P. The governing body shall adopt written policies and procedures approved by the medical and nursing staff of the service, for the medical care of newborns

~~b~~ Q. The policies and procedures for the general level nursery and all higher levels of newborn services shall include, but not be limited to:

~~(1)~~ 1. Medical criteria for the identification of high-risk neonatal patients.

~~(2)~~ 2. Protocols for the management of all neonatal medical conditions that are routinely managed by the service as well as protocols for the stabilization and transfer of neonates that require a higher level of newborn service. These protocols shall be maintained in the nursery in addition to the telephone numbers of each nursery and the names of each referral newborn service medical director.

~~(3)~~ 3. ~~Hospital written~~ Written collaboration agreements with ~~other~~ hospitals ~~that provide~~ with higher levels of newborn services ~~not available in the referring hospital~~. A hospital may enter into more than one collaboration agreement. The collaboration agreements shall specifically identify those medical conditions ~~which~~ that require consultation and may necessitate a neonatal transfer as well as the interim treatment required prior to transfer. Nothing in the regulation shall require a birth hospital to enter into a collaboration agreement with a referral hospital that disagrees with the medical, consultation and transfer protocols adopted by

the birth hospital. All neonatal transfers shall conform with Section 1867 of the Social Security Act, its amendments in force to date and implementing regulations. At the time of any transfer, the medical treatment at the referral hospital shall outweigh the risks to the neonate from ~~effecting~~ affecting the transfer. The collaboration agreements shall include, but not be limited to:

~~(a)~~ a. Criteria for neonatal transfer to the referral nursery;

~~(b)~~ b. Procedures for neonatal transport;

~~(c)~~ c. Back transfer criteria which provides for the return of the neonate to the referring hospital when medically appropriate;

~~(d)~~ d. Annual review by both parties of all cases of neonatal transfer;

~~(e)~~ e. Annual review by both parties of the collaboration agreements; and

~~(f)~~ f. Annual evaluation by both parties of the collaboration agreement and modification of the agreement, as necessary, as indicated by the evaluation results.

~~(4)~~ 4. Establishment and maintenance of an ongoing, documented quality assurance program by the service ~~which~~ that utilizes a multidisciplinary team of health practitioners and administrators for review and is integrated with the hospital's overall quality assurance program.

~~(a)~~ a. The quality assurance program shall include:

~~(i)~~ (1) Problem identification;

~~(ii)~~ (2) Action plans;

~~(iii)~~ (3) Evaluation; and

~~(iv)~~ (4) Follow-up.

~~(b)~~ b. The quality assurance program shall include an annual review of the following:

~~(i)~~ (1) Neonatal transfer cases;

~~(ii)~~ (2) Management of in-house neonatal cases; and

~~(iii)~~ (3) Staff in-house inservice programs.

~~(c)~~ c. Outcome statistics, including morbidity, mortality, and the appropriateness of neonatal transfers, shall be compiled in a standardized manner and reviewed quarterly by a multidisciplinary committee.

~~(5)~~ 5. Immediate resuscitation and stabilization of the sick neonate in accordance with current cardiopulmonary resuscitation (CPR) standards of the American Heart Association and the American Academy of Pediatrics.

~~(6)~~ 6. Care of newborns after delivery to include the following:

~~(a)~~ a. Care of eyes, skin and umbilical cord and the provision of a single parenteral dose of Vitamin K-1, water soluble, as a prophylaxis against hemorrhagic disorder;

~~(b)~~ b. Maintenance of the newborn's airway, respiration, and body temperature; and

~~(c)~~ c. Assessment of the newborn and recording of the one-minute and five-minute Apgar scores.

~~(7)~~ 7. Performance of prophylaxis against ophthalmia neonatorum by the administration of a 1.0% solution of silver nitrate aqueous solution, erythromycin, or tetracycline ointment or solution. This process is to be performed within one hour of delivery with documentation entered in the newborn's medical record. The process may be performed in the nursery.

~~(8)~~ 8. Clamping or tying of the umbilical cord and, when indicated, collecting a sample of cord blood.

~~(9)~~ 9. Performance of Rh type and Coombs' test for every newborn born to a Rh negative mother and performing major blood grouping and Coombs' tests when indicated for every newborn born to an O blood group mother or a mother with a family history of blood incompatibility. If such qualitative tests are performed, the results shall be documented in the newborn's medical record.

~~(10)~~ 10. Identification and treatment of hyperbilirubinemia and hypoglycemia.

~~(11)~~ 11. Identification of each newborn, prior to leaving the delivery room, with two identification bands fastened on the newborn and one identification band fastened on the mother. The newborn's medical record shall accompany the infant from the delivery room.

~~(12)~~ 12. Newborn transport, within the hospital, of all newborns ~~who~~ that are either premature or compromised by using a heated bassinet equipped with oxygen, a transport incubator or other similar equipment.

~~(13)~~ 13. Registered nurse or physician assessment of a newborn within one hour after delivery and documentation of the assessment in the newborn's medical record. Assessment in the delivery area is permitted if the hospital permits a newborn and its mother to remain together during the immediate post-delivery period.

~~(14)~~ 14. Delineation of how infants are to be monitored during stays with their mothers and under what circumstances infants must be taken to the nursery immediately after delivery and not allowed to remain with their mothers.

~~(15)~~ 15. Physician examination of the newborn consistent with guidelines of the American Academy of Pediatrics. A high-risk newborn shall be examined upon admission to the nursery.

~~(16)~~ 16. Ensuring that every bassinet and incubator in the nursery bears the identification of the newborn's last name, sex, date and time of birth, the mother's last name, and the attending physician's name.

~~(17)~~ 17. The management of mothers who utilize breast milk with their newborns. Breast milk shall be collected in ~~sterile~~ aseptic containers, dated, stored under refrigeration and consumed or disposed of within ~~24~~ 48 hours of collection if the breast milk has not been frozen. This policy pertains to breast milk collected while in the hospital or at home for hospital use.

~~(18)~~ 18. Preparation and use of formula including, but not limited to:

~~(a)~~ a. The distribution of feeding units immediately after assembly;

~~(b)~~ b. The use of prepared formula only within the time period designated on the package; and

~~(c)~~ c. The use of presterilized formula only, except in the case of facility-defined emergencies.

~~(19)~~ 19. Screening newborns for risk factors associated with hearing impairment as required in §§32.1-64.1 and 32.1-64.2 of the Code of Virginia and in accordance with the regulations of the Board of Health governing the Virginia Hearing Impairment Identification and Monitoring System (12VAC5-80-10 et seq.).

~~(20)~~ 20. Screening and treatment of genetic, metabolic, and other diseases identifiable in the newborn period as specified in §32.1-65 of the Code of Virginia and in accordance with the Regulations Governing the Newborn Screening and Treatment Program (12VAC5-70-10 et seq.).

~~(21)~~ 21. Reporting to the Department of Health all required reportable congenital defects.

~~(22)~~ 22. Visitor contact with the newborn, including newborns delivered by cesarean section, and premature, sick, congenitally malformed, and dying newborns.

~~(23)~~ 23. Completion of birth certificates.

~~(24)~~ 24. Discharge planning appropriate for the needs of the patient for at-risk infants. The Virginia High Priority Infant Tracking Program Enrollment Form should be used as part of the discharge planning.

~~c~~ R. The additional policies and procedures required for the intermediate level newborn service shall include, but not limited to:

~~(1)~~ 1. Insertion and maintenance of peripheral intravenous lines and use of pediatric infusion pumps that are accurate to plus or minus one milliliter an hour;

~~(2)~~ 2. Insertion and maintenance of umbilical arterial lines and the use of pediatric infusion pumps accurate to plus or minus one milliliter an hour;

~~(3)~~ 3. Use of heated, humidified, and blended supplemental oxygen by hood with a recording of oxygen levels every hour using a calibrated constant oxygen analyzer. The policy shall address consultation with a higher level nursery identified in the collaboration agreement when oxygen levels exceed 40% and remain at 40% or greater for a period of four hours or more;

~~(4)~~ 4. Administration of nasogastric or orogastric feedings;

~~(5)~~ 5. Use of saturation monitor (pulse oximeter or equivalent) for any newborn requiring supplemental oxygen;

~~(6)~~ 6. Use of assisted ventilation in preparation for transport;

~~(7)~~ 7. Initiation of PgE1 prior to transport; and

~~(8)~~ 8. Administration of blood components and a policy for provision of partial and total exchange transfusions.

~~D~~ S. The additional policies and procedures required for the specialty level newborn service shall include, but not be limited to:

~~(1)~~ 1. Provision of ongoing assisted ventilation;

~~(2)~~ 2. Administration of surfactant;

~~(3)~~ 3. Preparation and administration of total parenteral nutrition (TPN);

~~(4)~~ 4. Initiation and maintenance of pressor medications;

~~(5)~~ 5. Provision for developmental follow up;

~~(6)~~ 6. Insertion and maintenance of central umbilical arterial catheters or peripheral arterial lines with constant pressure monitoring;

~~(7)~~ 7. Placement of chest tubes with water seal on an emergency basis;

~~(8)~~ 8. Use of heated, humidified, and blended supplemental oxygen by hood with a recording of oxygen levels every hour using a calibrated constant oxygen analyzer;

~~(9)~~ 9. Administration and maintenance of CPAP including the requirement for in-house physician coverage;

~~(10)~~ 10. Daily availability of appropriate drug peak and trough assays on one milliliter or less of blood;

~~(11)~~ 11.Cardioversion capability specific for newborns; and

~~(12)~~ 12. Provision for ophthalmology consult and requirements regarding the examination of high-risk newborns.

~~e~~ T. The additional policies and procedures required for the subspecialty level newborn service shall include, but not be limited to:

~~(1)~~ 1. Provision for returning patients to the operating room within 30 minutes, if indicated;

~~(2)~~ 2. Provision for echocardiography evaluation;

~~(3)~~ 3. Provision for patient treatment on an extracorporeal membrane oxygenator (ECMO) or a written collaboration agreement with a hospital with this capability;

~~(4)~~ 4. Provision for maintenance of central venous pressure monitoring; and

~~(5)~~ 5. Provision for the maintenance of neonates on prostaglandin E1 (PgE1).

~~7.~~ 12 VAC 5-410-445. Newborn service design and equipment criteria.

A. In addition to complying with 12VAC5-410-430 and 12VAC5-410-790, a hospital shall comply with the following physical design criteria for its newborn services:

~~a~~ 1. The general level nursery design criteria ~~required for the general level nursery~~ are:

~~(1)~~ a. The newborn nursery shall be located adjacent to the obstetric nursing unit. The nursery must have adequate lighting and ventilation and be equipped to prevent direct drafts on infants. The temperature and humidity in the nursery shall be maintained at a level best suited for the protection of newborns as determined by the medical and nursing staff of the newborn service and as recommended by the American Academy of Pediatrics (AAP) and American College of Obstetricians and Gynecologists (ACOG) in the most current edition of Guidelines for Perinatal Care.

~~(2)~~ b. The nursery shall be designed to preclude unrelated traffic. Connecting nurseries shall have the capability to close the doors for infection control purposes.

~~(3)~~ c. Each nursery shall contain the following:

(~~a~~ 1) One handwashing lavatory for every eight bassinets. Lavatories shall be equipped with wrist, knee or foot controls, soap dispenser and paper towel dispenser;

(~~b~~ 2) A nurses' emergency calling system that meets the requirements of 12VAC5-410-1130 D of this chapter; and

(~~c~~ 3) Glazed observation windows to permit infants to be viewed from public areas, from workrooms, and between adjacent nurseries.

~~(4)~~ d. There shall be a minimum of 24 square feet of floor area for each bassinet, exclusive of nonpatient areas, and a minimum of three feet (91 cm) between bassinets in the newborn nursery.

~~(5)~~ e. Each nursery shall contain no more than 16 infant stations in open bassinets, self-contained incubators, open radiant heat infant care systems, or combination thereof. When a rooming-in program is used, the total number of bassinets provided in the general level nursery may be appropriately reduced but the nursery may not be omitted. A hospital designed for 16 infant stations or less shall provide two rooms with eight infant stations so that a room is available to permit cohorting in the case of infection.

~~(6)~~ f. A special care area for infants requiring close observation or stabilization, such as those with low birth weight, is required in hospitals having 25 or more postpartum beds that do not have higher level nurseries. The minimum floor area for each infant station shall be 40 square feet (3.72 sq. m).

~~(7)~~ g. Each nursery shall be served by a connecting workroom. The workroom shall contain gowning facilities at the entrance for staff and personnel, work space with counter, refrigerator, storage space and handwashing lavatory which meets the requirements of 12VAC5-410-1090. One workroom may serve more than one nursery.

~~(8)~~ h. The examination and treatment room shall contain a work counter, storage, handwashing lavatory and charting facilities. This may be part of the workroom.

~~(9)~~ i. A closet for the use of the housekeeping staff in maintaining the nurseries shall be provided. It shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies.

~~(10)~~ j. Lighting and wall finishes shall be sufficient to permit easy detection of jaundice and cyanosis. Shadow-free illumination with at least 100 foot candle intensity at the infant's level using fluorescent lamps with proper diffusers to prevent glare is required.

~~(11)~~ k. All incubators and electrical appliances used in nurseries shall be free from electrical hazards and approved by Underwriters Laboratories.

~~(12)~~ l. One grounded duplex electrical outlet shall be provided for every bassinet.

~~(13)~~ m. Task illumination and selected electrical outlets shall be on the hospital's emergency electrical system. In new construction, one outlet for each bassinet shall be on the hospital's emergency electrical system. Emergency electrical outlets shall be clearly marked. Outlets shall be checked at least monthly for safety and grounding.

~~(14)~~ n. An incubator shall be available and maintained for every 10, or fraction thereof, bassinets.

~~(15)~~ o. Bassinets shall be equipped to allow for medical examinations of newborn infants and for storing necessary supplies and equipment. Bassinets shall be provided in a number to exceed obstetric beds by 25% at the minimum, to accommodate multiple births, extended stays, and fluctuating patient loads. Bassinets are to be separated by a minimum of three feet measuring from the edge of one bassinet to the edge of the adjacent bassinet.

~~(16)~~ p. The hospital shall provide isolation facilities ~~which~~ that follow universal precautions in accordance with its approved policies and procedures and the most recent editions of the Guidelines for Perinatal Care (AAP/ACOG) and the Control of Communicable Diseases in Man (American Public Health Association).

~~b~~ 2. The intermediate level nursery design criteria ~~required for the intermediate level nursery~~ are:

~~(1)~~ a. There shall be efficient and controlled access to the nursery from the labor and delivery area, the emergency room or other referral entry areas. The nursery shall be designed to preclude unrelated traffic.

~~(2)~~ b. Lighting and wall finishes shall be sufficient to permit easy detection of jaundice and cyanosis. Shadow-free illumination with at least 100 foot candle intensity at the infant's level using fluorescent lamps with proper diffusers to prevent glare is required. The level of general lighting shall be adjustable to simulate day-night patterns and to satisfy diagnostic and procedural requirements.

~~(3)~~ c. The temperature, humidity, and ventilation in the nursery shall be maintained at levels best suited for the protection of newborns as determined by the medical and nursing staff of the newborn service and as recommended by the American Academy of Pediatrics (AAP) and American College of Obstetricians and Gynecologists (ACOG) in the most current edition of Guidelines for Perinatal Care. The nursery must be equipped to prevent direct drafts on neonates.

~~(4)~~ d. Each nursery shall contain the following:

~~(a)~~ (1) One handwashing lavatory for at least every four patient stations. Lavatories shall be equipped with wrist, knee or foot controls, soap dispenser and paper towel dispenser; and

~~(b)~~ (2) A nurses' emergency calling system that meets the requirements of 12VAC5-410-1130.

~~(5)~~ e. Each nursery shall be served by a connecting workroom. The workroom shall contain gowning facilities at the entrance for staff and personnel, work space with counter, refrigerator, storage space and handwashing lavatory which meets the requirements of 12VAC5-410-1090 B of this chapter. One workroom may serve more than one nursery.

~~(6)~~ f. A closet for the use of the housekeeping staff in maintaining the nursery shall be provided. It shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies.

~~(7)~~ g. All incubators and electrical appliances used in nurseries shall be free from electrical hazards and approved by Underwriters Laboratories.

~~(8)~~ h. Outlets shall be checked at least monthly for safety and grounding.

~~(9)~~ i. The hospital shall provide isolation facilities ~~which~~ that follow universal precautions in accordance with its approved policies and procedures and the most recent editions of the Guidelines for Perinatal Care (AAP/ACOG) and the Control of Communicable Diseases in Man (American Public Health Association). Connecting nurseries shall have the capability to close the doors for infection control purposes.

~~(10)~~ j. All electrical outlets shall be connected to both regular and auxiliary power.

~~(11)~~ k. An additional outlet wired to accommodate a portable x-ray machine shall be available in each nursery.

~~(12)~~ l. The minimum floor area for each infant station in a nursery constructed or renovated after August 10, 1995, shall be 50 square feet (4.66 sq m) with a minimum of four feet between infant stations and aisles at least five feet wide.

~~(13)~~ m. At least eight electrical outlets, two oxygen outlets, two compressed air outlets and two suction outlets shall be provided for each infant station.

~~c~~ 3. The specialty level and subspecialty level nurseries design criteria ~~required for both specialty level and subspecialty level nurseries~~ are:

~~(1)~~ a. The requirement of ~~12VAC5-410-440 D 7 b (1-11)~~ 12 VAC 5-410-445.A.2.a through k shall apply;

~~(2)~~ b. Nurseries constructed or renovated after August 10, 1995, shall have a minimum floor area for each infant station of 80 square feet with at least six feet between incubators or overhead warmers, and aisles at least eight feet wide.

~~(3)~~ c. Each infant station shall have a least 12 electrical outlets, two oxygen outlets, two compressed air outlets and two suction outlets.

~~8. Equipment requirements.~~

~~a~~ B. The hospital shall provide the following equipment in the general level nursery and all higher level nurseries, unless additional equipment requirements are imposed for the higher level nurseries:

~~(1)~~ 1. Resuscitation equipment as specified for the delivery room in ~~this chapter~~ subsection 12 VAC 5-410-442.C.6.b shall be available in the nursery at all times;

~~(2)~~ 2. Equipment for the delivery of 100% oxygen concentration, properly heated, blended, and humidified, with the ability to measure oxygen delivery in fractional inspired concentration (FI02). The oxygen analyzer shall be calibrated every eight hours and serviced according to the manufacturer's recommendations by a member of the hospital's respiratory therapy department or other responsible personnel trained to perform the task;

~~(3)~~ 3. Saturation monitor (pulse oximeter or equivalent);

~~(4)~~ 4. Equipment for monitoring blood glucose;

~~(5)~~ 5. Infant scales;

~~(6)~~ 6. Intravenous therapy equipment;

~~(7)~~ 7. Equipment and supplies for the insertion of umbilical arterial and venous catheters;

~~(8)~~ 8. Open bassinets, self-contained incubators, open radiant heat infant care system or any combination thereof appropriate to the service level;

~~(9)~~ 9. Equipment for stabilization of a sick infant prior to transfer that includes a radiant heat source capable of maintaining an infant's body temperature at 99°F;

~~(10)~~ 10. Equipment for insertion of a thoracotomy tube; and

~~(11)~~ 11. Equipment for proper administration and maintenance of phototherapy.

~~b~~ C. The additional equipment required for the intermediate level newborn service and for any higher service level is:

~~(1)~~ 1. Pediatric infusion pumps accurate to plus or minus 1 milliliter (ml) per hour;

~~(2)~~ 2. On-site supply of PgE1;

~~(3)~~ 3. Equipment for 24-hour cardiorespiratory monitoring for neonatal use available for every incubator or radiant warmer;

~~(4)~~ 4. Saturation monitor (pulse oximeter or equivalent) available for every infant given supplemental oxygen;

~~(5)~~ 5. Portable x-ray machine; and

~~(6)~~ 6. If a mechanical ventilator is selected to provide assisted ventilation prior to transport, it shall be approved for the use of neonates.

~~c~~ D. The additional equipment required for the specialty level newborn service and a higher newborn service is as follows:

~~(1)~~ 1. Equipment for 24-hour cardiorespiratory monitoring with central blood pressure capability for each neonate with an arterial line;

~~(2)~~ 2. Equipment necessary for ongoing assisted ventilation approved for neonatal use with on-line capabilities for monitoring airway pressure and ventilation performance;

~~(3)~~ 3. Equipment and supplies necessary for insertion and maintenance of chest tube for drainage;

~~(4)~~ 4. On-site supply of surfactant;

~~(5)~~ 5. Computed axial tomography equipment (CAT) or magnetic resonance imaging equipment (MRI);

~~(6)~~ 6. Equipment necessary for initiation and maintenance of continuous positive airway pressure (CPAP) with ability to constantly measure delineated pressures and including alarm for abnormal pressure (i.e., vent with PAP mode); and

~~(7)~~ 7. Cardioversion unit with appropriate neonatal paddles and ability to deliver appropriate small watt discharges.

~~d~~ E. The hospital shall document that it has the appropriate equipment necessary for any of the neonatal surgical and special procedures it provides that are specified in its medical protocol and that are required for the specialty level newborn service.

~~e~~ F. The additional equipment requirements for the subspecialty level newborn service are:

~~(1)~~ 1. Equipment for emergency gastrointestinal, genitourinary, central nervous system, and sonographic studies available 24 hours a day;

~~(2)~~ 2. Pediatric cardiac catheterization equipment;

~~(3)~~ 3. Portable echocardiography equipment; and

~~(4)~~ 4. Computed axial tomography equipment (CAT) and magnetic resonance imaging equipment (MRI).

~~f~~ G. The hospital shall document that it has the appropriate equipment necessary for any of the neonatal surgical and special procedures it provides that are specified in the medical protocol and are required for the subspecialty level newborn service.

~~9~~ 12 VAC 5-410-446. ~~Support~~ Newborn support services and other resources.

~~a.~~ A. The support services and other resources required for the general level newborn service and all higher levels of newborn services shall be as follows:

~~(1)~~ 1. Clinical laboratory services and blood bank services available in the hospital on a 24-hour basis. Laboratory and blood bank personnel available on-site or on-call on a 24-hour basis;

~~(2)~~ 2. Group O Rh negative blood available from the blood bank at all times and the blood bank's ability to provide correctly matched blood within 45 minutes of request;

~~(3)~~ 3. Hospital laboratory and blood bank personnel capability to perform the following tests with less than 1.0 ml of blood within one hour or less of request if specified: (i) blood group and Rh type determination/cross-matching, (ii) arterial blood gases within 20 minutes, (iii) blood glucose within 20 minutes, (iv) complete blood count, (v) total protein and albumin, (vi) total and direct bilirubin, (vii) direct Coombs' test, (viii) electrolytes, (ix) blood urea nitrogen, (x) clotting profile (may require more than one ml of blood); and

~~(4)~~ 4. Portable radiological services for basic radiologic studies in the nursery available on-call, within 30 minutes of request, on a 24-hour basis.

~~b~~ B. The additional support services and resources required of the intermediate level newborn service shall be as follows:

~~(1)~~ 1. A respiratory therapist in-house 24 hours a day. The therapist shall have orientation to the neonatal nursery ~~which includes~~ , including orientation to the appropriate level of care. The therapist shall have documented competence in neonatal respiratory care;

~~(2)~~ 2. A radiology technician in-house 24 hours a day;

~~(3)~~ 3. An ultrasound technician available on-call 24 hours a day;

~~(4)~~ 4. A laboratory technician in-house 24 hours a day;

~~(5)~~ 5. A blood bank technician available on call within 30 minutes of request;

~~(6)~~ 6. A licensed physical therapist or certified occupational therapist available for consultation;

~~(7)~~ 7. A registered dietitian with documented competence in neonatal nutrition available for consultation;

~~(8)~~ 8. A biomedical technician, available to the nursery, responsible for the maintenance and safe functioning of specialized medical equipment;

~~(9)~~ 9. Microvolume assays for xanthines and aminoglycosides available within 12 hours of request;

~~(10)~~ 10. Blood gases to be performed on 0.25 ml or less heparinized blood within 20 minutes of request;

~~(11)~~ 11. Blood components available within two hours of request; and

~~(12)~~ 12. Portable chest x-ray within 20 minutes of request.

~~c~~ C. The specialty level support services and resources ~~that are~~ required in addition to the requirements for the lower level nurseries are as follows:

~~(1)~~ 1. A blood bank technician in-house 24 hours a day;
~~(2)~~ 2. A pharmacist with documented competence in neonatal pharmacology on staff;
~~(3)~~ 3. A licensed physical therapist or certified occupational therapist with documented competence in neonatal care;
~~(4)~~ 4. A medical social worker as a participating member of the service;
~~(5)~~ 5. An ultrasound technician on-call 24 hours a day; and
~~(6)~~ 6. A registered dietitian with documented competence in neonatal nutrition as a participating member of the service.

~~d~~ D. The subspecialty level support services and resources that are required in addition to the requirements of the lower level nurseries are as follows:
~~(1)~~ 1. A radiologist with documented competence in the interpretation of pediatric and neonatal films readily available for providing pediatric and neonatal x-ray procedures and ultrasound interpretation;
~~(2)~~ 2. A developmental pediatrician on staff;
~~(3)~~ 3. A cardiothoracic surgeon with documented competence in pediatric surgical procedures on staff and on-call 24 hours a day;
~~(4)~~ 4. A pediatric surgeon on staff and on-call 24 hours a day;
~~(5)~~ 5. An anesthesiologist with documented competence in neonatal anesthesiology on-call 24 hours a day;
~~(6)~~ 6. The following pediatric subspecialists on staff available to be on-site within 30 minutes of request 24 hours a day:
~~(a)~~ a. Cardiology
~~(b)~~ b. Endocrinology
~~(c)~~ c. Gastroenterology
~~(d)~~ d. Genetics
~~(e)~~ e. Hematology
~~(f)~~ f. Immunology
~~(g)~~ g. Infectious diseases
~~(h)~~ h. Metabolism
~~(i)~~ i. Nephrology
~~(j)~~ j. Neurology
~~(k)~~ k. Nutrition
~~(l)~~ l. Pharmacology
~~(m)~~ m. Pulmonology
~~(7)~~ 7. The following pediatric surgical subspecialists on staff available to be on-site within 30 minutes of request 24 hours a day:
~~(a)~~ a. Neurosurgeon
~~(b)~~ b. Ophthalmologist
~~(c)~~ c. Orthopedic surgeon

~~(d)~~ d. Otolaryngologic surgeon

~~(e)~~ e. Urologic surgeon

~~(8)~~ 8. An echocardiography technician on staff;

~~(9)~~ 9. An American College of Medical Genetics certified or eligible genetics counselor on staff;

~~(10)~~ 10. In-house 24-hour capability for microchemistries;

~~(11)~~ 11. Hospital resources to provide for the medical follow up of discharged, high-risk neonates that incorporate a parent education program that includes, but is not limited to, the following:

~~(a)~~ a. Pediatric cardiopulmonary resuscitation training;

~~(b)~~ b. Home cardiopulmonary monitoring;

~~(c)~~ c. Home oxygen monitoring; and

~~(d)~~ d. Lactation instruction;

~~(12)~~ 12. Hospital resources to provide comprehensive, neonatal continuing education to health professionals external to the hospital;

~~(13)~~ 13. A referral network for cardiovascular surgical consultation; and

~~(14)~~ 14. The operation of a neonatal transport system on a 24-hour basis. Transports shall be initiated within 30 minutes of request. The neonatal transport system shall operate in accordance with the most current editions of the Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients published by the American Academy of Pediatrics and the Neonatal Transport Standards and Guidelines published by the National Association of Neonatal Nurses.

~~E.~~ 12 VAC 5-410-447. Combined obstetric and clean gynecological service; infection control.

A. A hospital may combine obstetric and clean gynecological services. The hospital shall define clean gynecological cases in written hospital policy. A combined obstetric and clean gynecologic service shall be organized under written policies and procedures. The policies and procedures shall be approved by the medical and nursing staff of these services and adopted by the governing body and shall include, but not limited to the following requirements:

1. Cesarean section and ~~obstetrically-related~~ obstetrically related surgery, other than vaginal delivery, shall be carried out in designated operating or delivery rooms. Vaginal deliveries may be performed in designated delivery or operating rooms that are used solely for obstetric or clean gynecologic procedures.

2. Clean gynecological cases may be admitted to the postpartum nursing unit of the obstetric service according to procedures determined by the obstetrics and gynecologic staff and the hospital's infection control committee.

3. Only members of the medical staff with approved privileges shall admit and care for patients in the combined service area. These admissions shall be subject to the medical staff bylaws.

4. Hospitals with a combined service shall limit admission to the service to those patients allowed by policies adopted by the obstetric and gynecological medical staff and the hospital's infection control committee.

5. Unoccupied beds shall be reserved daily in a combined service ready for use by obstetric patients.

6. Patients admitted to the combined service may be taken to radiology or other hospital departments for diagnostic procedures, before or after surgery, if it is not evident that these procedures may be hazardous to the patients or to other patients on the combined service.

7. Patients may receive postpartum or immediate postoperative care in the general recovery room prior to being returned to the combined service area if the following conditions prevail:

a. The recovery room or intensive care unit is a separate unit adjacent to or part of the general surgical operating suite or delivery suite;

b. The recovery room is under the direct supervision of the chairman of the anesthesiology department of the hospital.

c. In separate obstetric recovery rooms, supervision shall be provided by the obstetrician in charge or by physicians approved by the medical staff of the combined service.

8. Nursing care of all patients shall be supervised by a registered nurse.

9. Nursing care of both obstetrical and gynecological patients may be given by the same nursing personnel.

10. Visitor regulations applicable to visitors of obstetric patients shall also apply to visitors of other patients admitted to the combined service.

~~F~~ B. In addition to the infection control requirements specified in 12VAC5-410-490 of this chapter, the hospital's infection control committee, in cooperation with the obstetric and newborn medical and nursing staff, shall establish written policies and procedures for infection control within the obstetric and newborn services. The policies and procedures shall be adopted by the governing body and shall include, but not be limited to, the following:

1. The establishment of criteria for determining infection-related maternal and newborn morbidity;

2. Written criteria for the isolation or segregation of mothers and newborns, in accordance with Guidelines for Perinatal Care (American Academy of Pediatrics/American College of Obstetricians and Gynecologists) and Control of Communicable Diseases in Man (American Public Health Association) to include at least the following categories:

a. Birth prior to admission to the facility;

b. Birth within the facility but prior to admission to the labor and delivery area;

c. Readmission to the service after transfer or discharge;

d. Presence of infection;

e. Elevated temperature; and

f. Presence of rash, diarrhea, or discharging skin lesions;

3. Written policies and procedures for the isolation of patients in accordance with Guidelines for Perinatal Care (AAP/ACOG) and Control of Communicable Diseases in Man (American Public Health Association) including, but not limited to, the following:

a. Ensuring that a physician orders and documents in the patient's medical record the placement of a mother or newborn in isolation;

b. Ensuring that at least one labor room is available for use by a patient requiring isolation;

c. Provisions for the isolation of a mother and newborn together (rooming-in) or separately; and

d. Policies and procedures for assigning nursing personnel to care for patients in isolation;

4. Control of traffic, including personnel and visitors. Policies and procedures shall be established in the event that personnel from other services must work in the obstetric and newborn services or personnel from the obstetric and newborn services must work on other services. Appropriate clothing changes and handwashing shall be required of any individual prior to assuming temporary assignments or substitution from any other area or service in the hospital.

5. Determination of the health status of personnel, and control of personnel with symptoms of communicable infectious disease;

6. Review of cleaning procedures, agents, and schedules in use in the obstetric and newborn services. Incubators or bassinets shall be cleaned with detergent and disinfectant registered by the U.S. Environmental Protection Agency each time a newborn occupying it is discharged or at least every seven days;

7. Techniques of patient care, including handwashing and the use of protective clothing such as gowns, masks, and gloves;

8. Infection control in the nursery, including~~,~~ but not limited to~~, the following~~:

a. Closing of the nursery immediately in the event of an epidemic, as determined by the infection control director in consultation with the medical director and the Department of Health;

b. Assigning a newborn to a clean incubator or bassinet at least every seven days;

c. Using an impervious cover that completely covers the surface of the scale pan if newborns are weighed on a common scale, and changing the cover after each newborn is weighed;

d. Gowning in isolation cases;

e. Requiring ~~that~~ nursery personnel to wear clean scrub attire in the nursery when they are handling infants. Appropriate cover garments shall be worn over scrub attire when personnel are holding infants. Personnel shall wash their hands after contact with each patient and upon entering or leaving the nursery.