

**CHAPTER 139. NEONATAL SERVICES**

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**Authority**

The provisions of this Chapter 139 amended under section 803(2) of the Health Care Facilities Act (35 P. S. § 448.803(2)), unless otherwise noted.

**Source**

The provisions of this Chapter 139 amended June 5, 1998, effective June 6, 1998, 28 Pa.B. 2643, unless otherwise noted. Immediately preceding text appears at serial pages (240280) to (240289).

**GENERAL PROVISIONS****§ 139.1. Principle.**

When a hospital provides neonatal services, they shall be provided in a manner that meets the medical needs of the neonates.

**§ 139.2. Scope.**

This chapter applies to hospitals which provide obstetrical or neonatal infant care, or both. The Department recognizes the following levels of neonatal care:

- (1) Level I: (Normal Neonatal).
- (2) Level II: (Neonatal Intermediate/Intensive Care).
- (3) Level III: (Neonatal Intensive Care).

**§ 139.2a. Definitions.**

The following words and terms, when used in this chapter have the following meaning, unless the context clearly indicates otherwise:

*Board certified*—A physician licensed to practice medicine in this Commonwealth who has successfully passed an examination and has maintained certification in the relevant medical specialty area or subspecialty area, or both, recognized by one of the following groups:

- (i) The American Board of Medical Specialties.
- (ii) The American Osteopathic Association.
- (iii) The foreign equivalent of either group listed in subparagraph (i) or (ii).

*Guidelines*—The term refers to the current *Guidelines for Perinatal Care* issued by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists.

*NICU—Neonatal intensive care unit*—The term refers to a unit which is specifically equipped and staffed for the care and treatment of high-risk infants and those infants otherwise in need of intensive care.

*Neonate*—Patients treated in neonatal care units. The term is synonymous with baby or infant.

*Preboard certification status*—A physician licensed to practice medicine in this Commonwealth who has completed the requirements necessary to take a certification examination offered by a medical specialty board recognized by the American Board of Medical Specialties, the American Osteopathic Association, or the foreign equivalent of either group, and who has been eligible to take the examination for no longer than 3 years.

**§ 139.3. Director.**

(a) A member of the medical staff shall be appointed director of neonatal services. The director shall be certified by the American Board of Pediatrics or an equivalent board.

(b) An interim director may be appointed during the period of time between the departure of the prior director and the selection of a new director. The interim director shall be a physician who is able to demonstrate qualifications acceptable to the medical staff of the hospital and to the Department. The hospital shall apply to the Department for an exception under the procedures in §§ 51.31—51.34 (relating to exceptions). If the exception is granted, the Department will specify the maximum period of time for which the interim director shall be appointed.

**§ 139.4. Nursing services; other health care personnel.**

(a) Neonatal nursing services shall be provided in accordance with Chapter 109 (relating to nursing services) and this section.

(b) A registered professional nurse, especially trained and experienced in the care of normal and high-risk infants, shall be responsible for the neonatal care unit at all times when the unit is occupied. No neonate may be left unattended.

(c) Licensed nursing personnel shall be assigned to duties consistent with their legal scope of practice. Unlicensed assistive personnel shall be assigned duties consistent with standardized training and competency evaluation.

(d) Staffing shall be adequate to meet nursing care goals, standards of nursing practice and nursing care needs of patients. The appropriate number of staff necessary to accomplish these goals, standards and needs shall be established in the written policies of the neonatal service and shall be consistent with the Guidelines.

(e) In addition to the requirements for the nursing staff in subsections (a)—(d), there shall be service goals and objectives, standards of patient care, procedure manuals and written job descriptions for each level of other health care personnel which includes the following:

(1) A means for assessing the needs of patients and determining adequate staffing to meet those needs.

(2) Staffing patterns that are adequate to meet patient care goals, standards of practice and needs of patients.

(3) An adequate number of licensed and unlicensed health care personnel to assure that staffing levels meet the total needs of patients.

(4) Health care personnel in neonatal services shall be assigned to duties consistent with their training, experience and scope of practice when applicable.

**FACILITIES****§ 139.11. Facilities and equipment.**

The maternity and neonatal services shall be separate and apart from other hospital services and especially from potential sources of infection. Access to each neonatal care unit shall be controlled to insure security and safety of all infants.

**Authority**

The provisions of this § 139.11 issued under section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)); and section 803 of the Health Care Facilities Act (35 P. S. § 448.803).

**Source**

The provisions of this § 139.11 amended through December 3, 1982, effective December 4, 1982, 12 Pa.B. 4129. Immediately preceding text appears at serial page (52874).

**§ 139.12. Neonatal care units.**

(a) Hospitals with maternity services shall provide neonatal care units with areas for neonate recovery, observation and isolation and provisions or arrangements for the care of high-risk infants in a neonatal intensive care unit either at the facility of birth or at a transfer site. Space allocation and total number of bassinets shall be consistent with the Guidelines.

(b) There should be an isolation area for the reception and care of infants exposed to potential sources of infection and infants suspected of or having a communicable disease. Infants may be housed and nursed in the isolation area pending diagnosis, disposition or completion of treatment. This isolation area should be served by nursing personnel and shall meet the standards established in the Guidelines for this type of care.

(c) A neonatal intensive care unit is one which is specifically equipped and staffed for the care and treatment of high-risk infants and those otherwise in need of intensive care. The neonatal intensive care unit shall meet the standards established in the Guidelines for this type of care. If such a service is not provided at the facility of birth, arrangements shall be made with an existing neonatal intensive care unit in the area of appropriate referral. The judgment of the attending physician and the policies of the hospital's neonatal services department shall determine the need for consultation with and referral to the hospital with an existing neonatal intensive care unit. The term "high risk infant" means any infant who, on the basis of socioeconomic, genetic or patho-physiologic history prior to delivery or on the basis of findings in the neonate period, manifests or is likely to manifest persistent and significant signs of distress. This may include:

- (1) An infant with a birth weight below 2,000 grams or of less than 34 weeks gestation and any other low birth weight or premature infant who shows any abnormal signs.

(2) An infant showing persistent and significant signs of illness. This includes those with respiratory distress, congenital anomalies, tumors, jaundice, seizures, infections, metabolic distress or other conditions which pose an immediate threat to neonatal survival.

(3) An infant with serious feeding difficulties, excessive lethargy or instability of body temperature.

(4) An infant whose mother is drug addicted or habituated, diabetic, toxic, isoimmunized, or having any other illness or condition which may affect the fetus.

(5) An infant requiring major surgical procedures.

#### Authority

The provisions of this § 139.12 issued under 67 Pa.C.S. §§ 6101—6104; and Reorganization Plan No. 2 of 1973 (71 P. S. § 755-2).

#### Source

The provisions of this § 139.12 amended September 19, 1980, effective September 20, 1980, 10 Pa.B. 3761. Immediately preceding text appears at serial page (37905).

### § 139.13. Equipment and supplies.

(a) Required equipment and supplies shall be in accordance with this section, the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the American Institute of Architects and with written policies of the neonatal service which shall be consistent with the Guidelines.

(b) An individual bassinet and equipment for the exclusive use of the infant to whom it is assigned shall be provided for each infant. All necessary supplies shall be stored in covered containers to permit individualized infant care and minimize risk of infection.

(c) Each neonatal care unit shall have its own sink with hot and cold running water equipped with foot, knee or elbow control so that hand contact with the sink is avoided. A sufficient supply of an antiseptic cleansing agent and disposable towels shall be readily available. Where paper towels are used, a dispenser shall be provided.

(d) Neonatal intensive care units shall be equipped with all equipment and supplies required for other neonatal care units.

### § 139.14. Oxygen control.

Oxygen shall be administered only with proper apparatus for its safe administration and control of concentration. Concentration of oxygen should not exceed a safe level commensurate with current concepts of oxygen therapy as recommended by the Guidelines.

**§ 139.15. Temperature control.**

A stable year-round temperature and humidity shall be maintained in all neonatal care units in accordance with written neonatal service policies consistent with the Guidelines.

**§ 139.16. Housekeeping and maintenance.**

The neonatal care unit shall be maintained in a clean and sanitary manner at all times. An environmental services room shall be provided for the exclusive use of the neonatal unit and shall be directly accessible from the unit.

**§ 139.17. Neonatal intensive care units (Levels II and III).**

In addition to the general requirements for the equipment of neonatal care units, the following provisions shall be required for all new construction, renovation or expansion of neonatal intensive care units and shall be available to all present neonatal intensive care units:

- (1) The construction and arrangement of the neonatal intensive care unit shall permit personnel to observe the infants and have immediate access to them. Total neonatal care unit space, exclusive of anteroom, shall provide adequate floor space consistent with the Guidelines.
- (2) Each infant requiring heat or air control, or both, shall have a separate incubator or other warming device and an individual environment with individualized heat, oxygen, suction and air turnover controls, as appropriate. Any infant whose condition permits may be placed in a bassinet.
- (3) At least one oxygen outlet shall be provided for each patient station. Suction apparatus shall be easily available for each infant. A source of medically pure compressed air shall be available.
- (4) A double-grounded electrical outlet shall be provided for each incubator or radiant warmer. Sufficient extra outlets should be provided for other electronic patient care equipment. Some electrical outlets in the unit shall be on the emergency electrical circuit of the hospital and shall be so marked.
- (5) Resuscitation equipment shall be available within the neonatal intensive care unit. An effective method for preventing heat loss by the infant shall be available while the infant is undergoing any treatment.
- (6) Air within neonatal intensive care units may not be recirculated and shall be frequently turned over each hour.

**POLICIES****§ 139.21. Policies and procedures.**

The director of neonatal services shall be responsible for developing written policies and procedures for the provision of medical services within the neonatal

care unit which shall be available to the medical and nursing staff. The policies and procedures shall be reviewed by the director once a year and revised as necessary, and dated to indicate the time of last review. They shall provide specifications to conform to §§ 139.22—139.29.

**§ 139.22. Physicians' services.**

(a) There shall be a physician available at all times. This physician shall be either certified by the American Board of Pediatrics or an equivalent board, have attained preboard certification status, or have successfully completed an approved residency in pediatrics.

(b) All infants shall have a complete physical examination at or near the time of delivery consistent with the recommendations contained in the Guidelines and the results of the examinations shall be recorded in the infant's medical record.

(c) An infant who displays abnormal signs and symptoms at any time shall be examined by a physician as soon as possible.

(d) Every infant shall be examined by the attending physician or his authorized delegate within 1 day prior to discharge, and the findings recorded shall be in the infant's medical record.

(e) There shall be a method for the proper identification of each infant and mother or other responsible person at the time of discharge from the hospital. Infants discharged or transferred to another neonatal care unit or hospital shall be carefully identified.

**Cross References**

This section cited in 28 Pa. Code § 139.21 (relating to policies and procedures).

**§ 139.23. Delivery suite services.**

(a) Delivery suite facilities shall include a neonatal recovery area specifically equipped for evaluation and treatment of the infant immediately after birth. An area of the delivery room set aside for infant care is acceptable.

(b) The director of obstetrics and the director of neonatal services shall formulate policies and procedures for delivery room care of infants. These policies and procedures shall be written and shall include provisions for:

(1) Notification of the physician in charge of the infant and the nurse responsible for the provision of nursing services in the neonatal care unit when the delivery of a potentially high-risk infant is expected.

(2) Continuity of care for all infants and especially for high-risk infants to be initiated in the delivery area, with constant observation of neonates for distress.

(3) The umbilical cord to be clamped or tied in accordance with standard medical practice.

(4) The collection of sample of cord blood and performance of laboratory studies for blood type, Rh and Coombs Test on every infant born to an Rh negative mother or having a family history of blood incompatibility.

(5) Infant identification, by an accepted duplicate system, for both mother and infant to be carried out in the delivery room and checked by the nurse or physician and, if possible, by the mother.

(6) Prophylaxis with medication under § 27.98 (relating to prophylactic treatment of neonates), to be carried out as soon as the condition of the infant permits.

(7) Every neonate to be examined at the time of delivery and the following noted on his medical record:

- (i) Condition at birth including Apgar score or its equivalent.
- (ii) Time of sustained respirations.
- (iii) Physical abnormalities or pathological states.
- (iv) Evidence of distress.

(8) A carefully planned procedure to be instituted for the transportation of infants to the neonatal care unit from the delivery room to insure maximum protection of the infant. Transfer of distressed infants to the unit shall be done in a manner that minimizes heat loss and to insure adequate oxygenation.

(9) The record of the infant to accompany the infant from the place of delivery to the neonatal care unit and be immediately available to unit personnel. This record shall include information concerning prenatal history, course of labor, delivery, drug administration to mother and infant, Apgar score, relevant conditions of the mother, procedures performed on the infant in the delivery room, complications of any type, and other facts and observations.

#### **Authority**

The provisions of this § 139.23 issued under section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)); section 16 of the Disease Prevention and Control Law of 1955 (35 P. S. § 521.16); and section 803 of the Health Care Facilities Act (35 P. S. § 448.803).

#### **Source**

The provisions of this § 139.23 amended May 4, 1984, effective May 5, 1984, 14 Pa.B. 1553. Immediately preceding text appears at serial pages (37907) to (37909).

#### **Cross References**

This section cited in 28 Pa. Code § 139.21 (relating to policies and procedures).

### **§ 139.24. Neonatal intensive care units (Levels II and III).**

(a) In hospitals with neonatal intensive care units, the director of the neonatal services shall develop written policies and procedures regarding admission of infants to neonatal intensive care units.

(b) Policies for neonatal intensive care units shall include:



(1) Requirements, in accordance with the Guidelines, for staffing of neonatal intensive care units. In addition, these units shall be staffed on every shift by at least one registered professional nurse who has special training, experience and interest in infants requiring special care and who is assigned no other responsibilities.

(2) A requirement that a pediatrician designated by the director of the neonatal services shall be on call 24 hours a day.

(3) A provision that private physicians or specialists may care for their patients in neonatal intensive care units. However, the final authority for policy in neonatal intensive care units shall reside with the director of neonatal services.

(4) A requirement that ancillary personnel employed to meet the needs of infants shall have appropriate, specified skills and training.

(5) Provisions for physicians, nurses and social service staff to assist parents of special care infants to become acquainted with their infant and any problems during the infant's hospitalization.

(6) A definite written policy, developed by the director of neonatal services, which provides for the unique problems involved in the total care of infants in neonatal intensive care units to be met, by making arrangements with the hospital nursing and social service departments and community health and social agencies, and by specifying what provisions will be made for continuing care, follow-up and home assistance.

#### Cross References

This section cited in 28 Pa. Code § 139.21 (relating to policies and procedures).

### § 139.25. Control of infection.

(a) The director of neonatal services through the hospital's infection control program shall establish procedures for the control of infection, governing matters such as appropriate attire, isolation and cleaning of equipment in the neonatal care unit. Infection control procedures for neonatal services may be included among the responsibilities of the committee established under other licensure regulations. These procedures shall be written, reviewed at least annually and dated to indicate the date of last review.

(b) Infection control procedures shall do the following:

(1) Prohibit common or group carriers from transporting infants to their mothers.

(2) Require and specify procedures for scrupulous hand cleansing by all neonatal care unit personnel and visitors before and after each infant contact.

(c) The infection control standards shall be consistent with the current Guidelines.

**Cross References**

This section cited in 28 Pa. Code § 139.21 (relating to policies and procedures).

**§ 139.26. Care given by parents.**

(a) The obstetrical and neonatal care departments of any hospital which provides rooming-in services shall have written policies governing the services. These procedures shall be designed to prevent cross contamination.

(b) When rooming in is provided, it shall be under professional nurse supervision.

(c) "Rooming-in services," as used in this section, shall include any of a variety of arrangements which allows the mother and her infant to be cared for together in a setting that gives the mother access to her infant during all or a substantial part of the day and which allows the father to have extensive contact with the mother and the infant during their hospital stay.

(d) Whether or not a hospital provides rooming-in services, it shall provide new parents with orientation, instructions, and demonstration in neonatal care and hygiene.

**Cross References**

This section cited in 28 Pa. Code § 139.21 (relating to policies and procedures).

**§ 139.27. Laboratory services and radiological services.**

(a) Laboratory services shall be available on a 24-hour-a-day, 7-day-a-week basis for, at a minimum, hemoglobin; hematocrit; Coombs test; blood type; Rh type; urinalysis; bacteriologic cultures; spinal fluid analysis; and microchemical determinations for bilirubin, blood glucose, sodium, potassium, chloride and total protein.

(b) Radiological equipment and services shall be available on a 24-hour-a-day, seven-day-a-week basis.

(c) Each hospital with a neonatal service shall provide immediately available blood transfusion services.

(d) A hospital in which a neonatal intensive care unit is located shall have a licensed blood bank, available or on call to the unit on a 24-hour-a-day, 7-day-a-week basis.

**Cross References**

This section cited in 28 Pa. Code § 139.21 (relating to policies and procedures).

**§ 139.28. Patient medical records.**

Patient medical records shall be maintained in accordance with Chapter 115 (relating to medical records services). The following information shall also be

included in the neonatal record if the entire maternal records are not maintained as the neonatal records in § 115.23(b) (relating to preservation of medical records):

- (1) Obstetrical history of mother's previous pregnancies.
- (2) Description of complications of pregnancy or delivery.
- (3) List of complicating maternal disease.
- (4) Drugs taken by the mother during pregnancy, labor and delivery.
- (5) Duration of ruptured membranes.
- (6) Maternal antenatal blood serology, rubella titer, blood typing, Rh factors, and, when indicated, a Coombs test for maternal antibodies.
- (7) Complete description of progress of labor including reasons for induction and operative procedures, if any, signed by the attending physician or an authorized delegate.
- (8) Anesthesia, analgesia and medications given to mother and infant.
- (9) Condition of infant at birth, including the 1-and 5-minute Apgar Score or its equivalent, resuscitation, time of sustained respirations, details of physical abnormalities, pathological states observed and treatments given before transfer to the neonatal care unit.
- (10) Abnormalities of the placenta and cord vessels.
- (11) Date and hour of birth, birth weight and length, and period of gestation.
- (12) A written verification of eye prophylaxis.
- (13) Report of initial physical examination, including abnormalities, signed by the attending physician or an authorized delegate.
- (14) Discharge physical examination, including head circumference and body length, unless previously done; recommendations; and signature of attending physician or a delegate.
- (15) A listing of all diagnoses since birth, including discharge diagnosis.
- (16) Specific follow-up plans for care of infant.

#### Authority

The provisions of this § 139.28 issued under section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)); and section 803 of the Health Care Facilities Act (35 P. S. § 448.803).

#### Source

The provisions of this § 139.28 amended through December 3, 1982, effective December 4, 1982, 12 Pa.B. 4129. Immediately preceding text appears at serial page (37911).

#### Cross References

This section cited in 28 Pa. Code § 139.21 (relating to policies and procedures).

### § 139.29. Infant nursing records.

Upon admission to a neonatal care unit, nurses shall initiate and maintain records on all infants as to weight, type and volume of feedings; time of first voiding; time of passage of first stool; number, color and consistency of stools;

and temperature. If abnormalities are suspected or recognized, nurses shall also make notations on respiratory rate, dyspnea, color, cyanosis, jaundice, pallor, lethargy, twitching, motor activity, skin and buttocks, vomiting, condition of the eyes and umbilical cord, and other relevant factors as indicated and warranted by the condition of the infant. Treatments, medication and special procedures ordered by a physician should also be recorded with time, date and the name and title of the individual who administers them.

**Cross References**

This section cited in 28 Pa. Code § 139.21 (relating to policies and procedures).

**NUTRITIONAL SERVICES**

**§ 139.31. Policies and procedures.**

Written policies and procedures for infant feeding shall be established and shall be available to the medical and nursing staffs.

**§ 139.32. Commercial formula.**

Precautions shall be taken to prevent the contamination and expiration of commercial formulas.

**§ 139.33. Formula preparation.**

(a) A registered professional nurse or dietitian shall be in charge of formula preparation.

(b) Formula shall be individually bottled and sterilized by pressure method 230|DF. for 25 minutes, with the following exceptions:

(1) If hermetically sealed commercial formula products are used and the hospital's method of dispensing the formula has been approved by the Department.

(2) Special mixtures which cannot be subjected to terminal heating shall be prepared by aseptic technique.

(c) Each formula bottle shall be labeled with the identity of its contents.

(d) Bacteriologic examinations of the equipment used, and analysis of techniques shall be done at least once each month. Plate counts on random sample of 24-hour milk mixtures shall not exceed 25 organisms per milliliter. Results of the bacteriologic tests shall be recorded and maintained on file.

**§ 139.34. Breastfeeding.**

Management of breastfeeding mothers and infants shall be consistent with the Guidelines.

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