

**Subpart E. BIRTH CENTERS**

<b>Chap.</b>		<b>Sec.</b>
<b>501.</b>	<b>BIRTH CENTERS .....</b>	<b>501.1</b>

**Authority**

The provisions of this Subpart E issued under section 2102(a) and (g) of The Administrative Code of 1929 (71 P. S. § 532 (a) and (g)); and the Health Care Facilities Act (35 P. S. §§ 448.801—448.820), specifically §§ 448.801a and 448.803, unless otherwise noted.

**Source**

The provisions of this Subpart E adopted April 26, 1985, effective June 26, 1985, 15 Pa.B. 1530, unless otherwise noted.

**CHAPTER 501. BIRTH CENTERS**

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**GENERAL PROVISIONS**

**§ 501.1. Legal base.**

(a) This subpart is promulgated by the Department under the powers granted and the duties mandated by Chapter 8 of the Health Care Facilities Act (35 P. S. §§ 448.801a—448.820), and by section 2102(a) and (g) of The Administrative Code of 1929 (71 P. S. § 532(a) and (g)).

(b) The Department has the power and its duty is to promulgate, after consultation with the Health Care Policy Board, the rules and regulations necessary to carry out Chapter 8 of the Health Care Facilities Act and to assure that the act is enforced.

(c) The purpose of this chapter is to protect and promote the public health and welfare through the establishment and enforcement of regulations setting minimum standards in the construction, maintenance, and operation of health care facilities. The standards are intended by the Department to assure safe, adequate, and efficient facilities and services, and to promote the health, safety, and adequate care of the patients or residents of the facilities. It is also the purpose of this chapter to assure quality health care through appropriate and nonduplicative review and inspection, with regard to the protection of the health and rights of privacy of patients and without unreasonably interfering with the operation of the health care facility.

#### **§ 501.2. Affected health care facilities.**

(a) This subpart shall apply to birth centers, profit or nonprofit, operated within this Commonwealth.

(b) Existing facilities or sections of facilities, which were being used as birth centers prior to June 26, 1985, shall be required to meet the same standards as facilities or sections constructed, converted or remodeled after June 26, 1985, unless an exception is granted by the Department under § 501.6 (relating to exceptions).

#### **§ 501.3. Reports/contact person.**

(a) The facility shall report regularly to the Department, on forms issued by the Department, statistical information that the Department may request and shall comply with the requirements for recordkeeping in § 28.41 (relating to record-keeping requirements).

(b) Data that could lead to the disclosure of the identity of individuals involved will be considered confidential and may not be released without prior authorization of the legal parent, guardian or newborn infant upon obtaining the age of 18.

(c) Questions concerning reports required should be addressed to Director, Division of Primary Care and Home Health Services, Department of Health, Post Office Box 90, Harrisburg, Pennsylvania 17108.

#### **Authority**

The provisions of this § 501.3 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

**Source**

The provisions of this § 501.3 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial page (245707).

**§ 501.4. Regulations.**

(a) A current copy of this subpart shall be maintained at the facility at all times.

(b) Facilities licensed under this subpart shall comply with environmental, health, sanitation and professional licensure standards which are required by Federal, State and local authorities. This shall include, but not be limited to, standards promulgated by the State Boards of Medicine, Nursing and Pharmacy (49 Pa. Code Chapters 16—18, 21 and 27), and the Department of Environmental Resources (25 Pa. Code Chapters 221—235 (relating to radiological health)). Facilities shall also comply with Chapter 1 (relating to administration of vital records), Chapter 5 (relating to clinical laboratories) and Chapter 27 (relating to communicable and noncommunicable diseases).

(c) If there is a difference in applicable State or local statutes, the standards established under State statute shall apply for the purposes of compliance with this subpart.

**§ 501.5. Inspections.**

All areas of the facility shall be subject to inspection, at reasonable times, by authorized representatives of the Department. Inspections may be scheduled in advance or be unannounced.

**§ 501.6. Exceptions.**

(a) The Department may, within its discretion and for good reason, grant an exception to the standards when the policy objective of those standards is met in existing facilities. The request for an exception shall be made in writing by the facility.

(b) Exceptions will be granted to the standards for physical plant and environment only if the facility is unable to comply because of structural features, which preclude modification, and if the rights, privacy, health and safety of the patients are not jeopardized.

**Cross References**

This section cited in 28 Pa. Code § 501.2 (relating to affected health care facilities); and 28 Pa. Code § 501.81 (relating to safety from fire).

**§ 501.7. Definitions.**

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

*Basement*—A story or floor level below the main or street floor. Where due to grade differences, there are two levels each qualifying as a street floor, a basement is a floor level below the lower of the two street floors. Basements may not be counted in determining the height of a building in stories.

*Bathing facility*—A bathtub or shower, or both.

*Birth center*—A facility not part of a hospital which provides maternity care to childbearing families not requiring hospitalization. A birth center provides a home-like atmosphere for maternity care, including prenatal labor delivery and postpartum care related to medically uncomplicated pregnancies.

*Birth room*—A room designed, equipped, and arranged to provide for the care of a woman and newborn, and which includes accommodations for support persons during the process of vaginal childbirth, including the three stages of labor and recovery of a woman and newborn.



*Department*—The Department of Health of the Commonwealth.

*Grade*—The average elevation of the ground, paved or unpaved, adjoining a building or structure, at the center of each exterior wall.

*Hazardous area*—Areas of structures, buildings or parts thereof, used for purposes that involve highly combustible, highly flammable, or explosive products or materials which are likely to burn with extreme rapidity, or which may produce poisonous fumes or gases, including highly toxic, or noxious alkalies, acids, or other liquids or chemicals, which involve flame, fume, explosive, poisonous, or irritant hazards; also uses that cause division of material into fine particles or dust subject to explosion or spontaneous combustion, and uses that constitute a high hazard because of the form, character, or volume of the material used.

*Licensed practical nurse*—A practical nurse who holds a current and valid license to practice in this Commonwealth, under the Practical Nurse Law (63 P. S. §§ 651—667).

*Low risk individual*—A woman experiencing normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal, uncomplicated, birth as defined by reasonably and currently accepted criteria of maternal and fetal health.

*Midwife*—A certified midwife holding a valid and current license to practice midwifery in this Commonwealth, under the act of April 4, 1929 (P. L. 160, No. 155) (63 P. S. §§ 171—176).

*Minor alterations*—Structural or functional changes which do not affect the use of a room or an area.

*New construction*—Construction started after June 26, 1985, for use as a birth center, including:

- (i) New buildings.
- (ii) Additions to existing buildings.
- (iii) Alterations, other than minor alterations.

*Owner*—The individual, partnership, association, or corporation which is authorized to operate a facility for licensure by the Department.

*Physician*—A Doctor of Medicine or a Doctor of Osteopathy, who holds a current and valid license to practice in this Commonwealth.

*Registered nurse*—A nurse licensed to practice in this Commonwealth under The Professional Nursing Law (63 P. S. §§ 211—225).

*Support person*—The individual selected or chosen by a patient to provide emotional support and to assist her during the process of labor and childbirth.

**OWNERSHIP****§ 501.11. General.**

(a) The owner of a birth center may be an individual, partnership, association, corporation, or a combination thereof. The following applies to facilities according to the mode of ownership:

(1) *Individual ownership.* A complete list of names and addresses of the persons in charge shall be submitted with the application. When death occurs to a person who was a sole owner of the facility, the executor or administrator of the estate may apply for, and the Department may, after review, grant a license for the facility.

(2) *Partnerships.* A complete list of names and addresses of the persons in charge and all partners responsible for the management of the facility shall be submitted with the application. When a license is issued to a partnership and one or more of the partners dies, the executor or administrator of the deceased's estate, together with the surviving partner, if any, may apply for a license. After review, the Department may grant the license.

(3) *Association or corporation.* A complete list of names and addresses of the officers, directors, principal stockholders, either beneficial or of record, of the corporate owner and of the parent corporation, if applicable, and of the persons in charge who are responsible for the management of the facility, shall be submitted with the application.

(b) The Department shall be notified, in writing, within 30 days whenever a change in the partners, officers, directors, principal stockholders, or persons in charge of a facility owned by a partnership or corporation has taken place.

(c) The facility shall identify each person who has a direct or indirect ownership interest of 5.0% or more in the birth center.

(d) The Department shall be notified, in writing, at least 90 days before change in ownership or the form of ownership or name of the facility takes place. The license is transferrable upon approval by the Department.

(e) A physically noncontiguous branch of the birth center shall meet all requirements for licensure and shall be independently licensed.

**Cross References**

This section cited in 28 Pa. Code § 501.32 (relating to governing body).

**§ 501.12. Profit or nonprofit status.**

A facility may be operated as a profit-making enterprise or on a nonprofit basis.



**LICENSURE****§ 501.21. Licensure process.**

(a) An application for license to operate a birth center shall be made under section 807 of the Health Care Facilities Act (35 P. S. § 448.807).

(b) The application form for a license to operate a birth center shall be obtained from the Department of Health, Division of Primary Care and Home Health Services, P.O. Box 90, Harrisburg, Pennsylvania 17108.

(c) Application or renewal forms shall be accompanied by a fee of \$50.

**§ 501.22. Issuance of license.**

(a) The Department will grant a regular license to operate a birth center after a survey conducted by the Department indicates that the applicant is in substantial compliance with this subpart. The survey shall include an onsite inspection and a review of written approvals by regulatory agencies responsible for building, electric, fire, and environmental safety. New construction, alterations, or renovations that provide space for patient services or rooms shall not be used or occupied until authorization for the occupancy has been received by the birth center from the Department.

(b) A regular license issued by the Department shall expire 1 year from the date of issue. A regular license is issued when, in the judgment of the Department, there is substantial compliance with all applicable regulations.

(c) A provisional license is issued when there are multiple minor deficiencies or a serious specific deficiency, which indicates that the facility is not in compliance with applicable statutes, ordinances, or rules, and the Department finds all of the following:

(1) The applicant is taking appropriate steps to correct the deficiencies in accordance with a timetable submitted by the applicant and agreed upon by the Department.

(2) There is no pattern of deficiencies over a period of 2 or more years.

(3) There is no danger to the health or safety of the patients of the facility or newborn infants.

(d) The Department may issue a provisional license for a specific period of not more than 6 months. A provisional license may be renewed no more than three times.

(e) The current license shall be posted in a conspicuous place in the birth center.

**§ 501.23. Responsibility of facility owners.**

(a) The owner shall be responsible for meeting the minimum standards for the operation of a birth center, as set forth by the Department, and by other State and local agencies responsible for the health, welfare, and safety of the patients therein.

(b) When services for the administration or management of the facility are purchased, the owner shall be responsible for insuring compliance with this title, as well as those of other appropriate agencies.

(c) The owner, or person in charge, shall immediately report, by telephone to the Department and by a written follow-up report as soon as possible, any catastrophic incident, such as fire or flood, or any incident which may cause interruption or cessation of the delivery of services, or another interruption of services which would affect the health and safety of either the patient or newborn infant.

### § 501.24. Restrictions on a license.

The Department may refuse to renew a license, or may suspend, revoke, or limit a license of a birth center or may suspend admissions for any of the following reasons:

- (1) A serious violation of this subpart, or of the Health Care Facilities Act (35 P. S. §§ 448.101—448.904), or of other statutes, which seriously threatens the health, safety, and welfare of patients.
- (2) Failure of an owner to submit a reasonable timetable for correction of deficiencies.
- (3) The existence of a cyclical pattern of deficiencies that extends over a period of 2 or more years.
- (4) Failure, by the holder of a provisional license, to correct deficiencies in accordance with a timetable submitted by the applicant and agreed upon by the Department.
- (5) Fraud or deceit in obtaining, or attempting to obtain, a license.
- (6) Lending, borrowing, or using the license of another, or in knowingly aiding or abetting the improper granting of a license.
- (7) Incompetence, negligence, or misconduct in operating the birth center or in providing services to individuals.
- (8) Mistreating or abusing individuals cared for by the birth center.

## ORGANIZATION

### § 501.31. General.

(a) The birth center shall develop a written table of organization, which shall be available at the birth center at all times.

(b) The table of organization shall identify a governing body, which has full authority and responsibility for the operation of the birth center.

### § 501.32. Governing body.

The governing body shall be responsible for all of the following:

- (1) Developing, adopting and enforcing rules and regulations relative to:

- (i) The assurance of a safe and professionally acceptable level of comprehensive care at the birth center.
  - (ii) Protection of personal and property rights of the patient, newborn infant, and support persons.
  - (iii) The general operation of the birth center.
- (2) Providing ownership information as stated in § 501.11 (relating to general).
- (3) Appointing a full time person in charge, who has authority and responsibility for the operation of the birth center at all times. Qualifications, authority, responsibilities, and duties of the person in charge shall be defined in a written statement adopted by the governing body.
- (4) Adopting effective policies and bylaws governing operation of the facility in accordance with legal requirements. The policies and bylaws shall be in writing, dated and available for public review. These shall include, but not be limited to, policies and procedures which assure that there shall be:
- (i) Obstetric, pediatric, and midwifery services available on a 24-hour basis, 7 days a week, and shall include obstetric and pediatric consultative services, transportation in case of emergency, and provision for referral to outside resources.
  - (ii) Written birth center policies developed by the Physician Director of Medical Affairs and Director of Midwifery Services readily available to all staff. All staff members shall be oriented to existing policies and procedures. There shall be prompt notification to all staff of changes in policy or procedures.

## MANAGEMENT

### § 501.41. Personnel policies.

- (a) Personnel policies shall be reviewed, revised, and approved by the governing body periodically, but no less often than once every 2 years.
- (b) An individual personnel record shall be maintained for each person employed by the birth center which shall include, but not be limited to, the following:
  - (1) A current job description for each person, which is reviewed and revised as needed.
  - (2) Evidence of a pre-employment examination, which shall include the results of a rubella antibody titer, a tuberculin skin test, and, if indicated, a chest x-ray.
  - (3) Evidence of the education, training, and experience of the individual, in addition to a copy of the current appropriate license or certification credentials, or both.
  - (4) Records which reflect the orientation, in-service, and out-service educational program of the birth center.

- (c) Personnel policies shall be written and available to staff members.
- (d) New employes shall be oriented to their specific job description, facility personnel policies, philosophy, and emergency procedures during the first week of employment.
- (e) Staffing schedules, time-worked schedules, on-call, and payroll records shall be retained and available in the facility at all times. All records must be maintained for 1 year.

**§ 501.42. Use of outside resources.**

If the facility does not employ a qualified professional for a specific service to be provided by the birth center, the governing body shall make arrangements and approve each written policy and procedure for services provided by the use of outside resources.

**§ 501.43. Agreements.**

The governing body, through the person in charge of the birth center, shall assume full responsibility for the initiation and maintenance of current contracts or agreements.

**Cross References**

This section cited in 28 Pa. Code § 501.75 (relating to laboratory services).

**§ 501.44. Transfer agreement with physicians.**

- (a) The birth center shall have a written transfer agreement with physicians who have admitting privileges to a hospital obstetric/newborn service for the mother and infant when complications or emergencies arise.
- (b) The terms of the transfer agreement shall include, but not be limited to, the following:
  - (1) That the medical necessity for transfer is based upon criteria developed by Director of Midwifery Services and Physician Director of Medical Affairs. The criteria shall be reviewed, revised, and approved annually by the governing body.
  - (2) In the case of a newborn infant transfer, that a transfer incubator must be available.
  - (3) That a complete health record, relating to the mother or newborn infant, shall be provided at the time of the transfer to the support person, or authorized individual, for hospital use.

**§ 501.45. Emergency transportation agreement.**

- (a) The birth center shall have a written agreement for emergency transportation of the mother or newborn infant which includes, but is not limited to, the following:

- (1) That the transportation service shall provide the birth center information relative to the service's emergency medical service certification status.
- (2) The types of services that are to be provided.
- (b) The birth center shall insure that an alternative service, in the area, with equivalent services, is available in the event that the primary transportation service is unable to accept a call.

**§ 501.46. Patient's rights.**

- (a) The birth center shall have written policies and procedures to assure the individual mother the right to dignity, privacy, and safety and shall include, but not be limited to, the items listed in subsection (b). The policies and procedures shall be developed by the Physician Director of Medical Affairs and Director of Midwifery Services and approved by the governing body. The policies shall be reviewed, revised, and approved annually by the governing body.
- (b) It is the right of every mother, or support person, to expect and receive:
  - (1) Good quality care and high professional standards that are continually maintained and reviewed.
  - (2) Answers to questions, regarding services and treatment, and the names and functions of the staff person providing services.
  - (3) Confidentiality, anonymity, and privacy.
  - (4) Respectful and dignified treatment at all times.
  - (5) Information regarding cost and counseling on the availability of known financial resources to the service being rendered.
  - (6) Disclosure and discussion of the nature, purposes, expected effects, and results of the medical treatment under consideration, prior to signing an informed consent.
  - (7) Control over the release of her health record information. Except in an emergency, a written release, signed by the mother, shall be required, prior to the release of health record information, except as otherwise provided by law or third party contractual arrangements.
  - (8) Availability of, or actual contact with, a physician, midwife, or registered nurse on a 24 hour per day, 7 day per week basis, as established by the written policies of the birth center.
  - (9) The right to refuse treatment, at any time, after treatment has begun.
  - (10) Full information on the medical consequences of refusal of treatment.
  - (11) A copy of the center's rules that apply to conduct as a mother, spouse, and support person.
  - (12) A written set of the rights guaranteed by this subpart and by the birth center.
  - (13) Treatment without discrimination based upon race, color, religion, sex, sexual preference, national origin, or source of payment.
  - (14) The right to review, or obtain, a copy of the mother's medical records.
  - (15) The right to expect emergency procedures to be implemented without unnecessary delay.

(16) Full information of the mother's and newborn infant's continuing health care requirements, following discharge and the means for meeting them.

**§ 501.47. Patient education.**

The birth center shall have a written plan for patient education, which is consistent with current professional standards.

**§ 501.48. Birth center policies and procedures.**

(a) The birth center policies and procedures shall include but not be limited to the following:

(1) A philosophy of care for the birth center.

(2) Standards, policies and procedures for providing safe and appropriate plans of care to meet the needs of each mother, her family, and her newborn infant. These shall be in keeping with current professional standards for uncomplicated pregnancy, intrapartum care, postpartum care, and newborn care and shall include the following:

(i) Written criteria for the admission of only uncomplicated pregnancies into the birth center system of care.

(ii) Written screening, protocol, and health records which identify high risk and potentially high risk individuals, which shall exclude them from birth center care.

(iii) Written protocols for referral of high risk pregnant women and newborns to appropriate providers of obstetrical and newborn care.

(iv) Program to prevent isoimmunization of Rh-negative mothers and neonatal disease due to Rh incompatibilities.

(b) Policies and procedures shall be consistent with the current professional standards of the American College of Nurse Midwives, the American College of Obstetricians and Gynecologists, and the American Academy of Pediatrics, and shall be approved by the Director of Midwifery Services and the Physician Director of Medical Affairs. A support person for each mother shall be required.

**§ 501.49. Newborn infant care policies and procedures.**

The newborn infant care policies, protocols and procedures shall include the following:

(1) Resuscitation equipment for newborn infant care management of short-term assisted ventilation shall include bag and mask or bag and endotracheal tube, with oxygen supply available.

(2) Medication approved by the Department in § 27.98 (relating to prophylactic treatment of newborns), shall be instilled in the eyes of the newborn infant according to statute. If the parent or guardian of the newborn child objects on the ground that the prophylactic treatment conflicts with the parent's religious beliefs or practices, prophylactic treatment will be withheld, and an entry in the child's record indicating the reason for withholding treatment shall be made and signed by the Physician Director of Medical Affairs and the parent or guardian of the newborn infant.

(3) Before discharge from the center, the newborn infant shall be examined by a midwife or a physician, and the results shall be entered in the health record. An infant with identified abnormalities shall be referred for appropriate follow-up, in accordance with the birth center policies.

(4) The birth center shall explain to the mother the purpose and nature of the screening tests for diseases of the newborn, required by Chapter 28 (relating to screening and follow-up for diseases of the newborn), give her an informational pamphlet provided by the Department, inform her of her right to refuse the tests because of religious beliefs or practices, and see that the recorded written objection is entered into the medical record of the newborn child and signed by the parent or guardian, if screening is refused.

(5) The birth center shall comply with the requirements for specimen collection, testing and follow-up in §§ 28.21—21.28 (relating to specimen collection and followup).

(6) Policies and other criteria, which govern discharge of newborn infants, shall be in accordance with birth center policies.

(7) The birth center shall communicate with the pediatric care provider and transfer birth and newborn records to the pediatric care provider.

(8) The birth center shall provide a list of available counselors and counseling services, compiled under 23 Pa.C.S. § 2505 (relating to counseling), to mothers who are known to be considering relinquishing or termination of parental rights under 23 Pa.C.S. §§ 2101—2909 (relating to the Adoption Act).

#### Authority

The provisions of this § 501.49 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

#### Source

The provisions of this § 501.49 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial pages (245716) to (245717).

## HEALTH RECORDS

### § 501.61. General.

(a) The birth center, in establishing its policy and procedures for a system of health record keeping, shall take into consideration professional standards and practices appropriate to primary care of the patient and newborn infant as established by the American College of Obstetricians and Gynecologists, 600 Maryland Avenue, SW, Suite 300 East, Washington, DC 20024; American College of Nurse-Midwives, 1522 K Street, N.W., Suite 1120, Washington, DC 20005; American Academy of Pediatrics, P.O. Box 1034, 1801 Hinman Avenue, Evanston, Illinois 60204; and other professional standards and practices approved by the Department. The policy and procedures shall be approved by the governing

body, at the recommendation of the Physician Director of Medical Affairs, and by the Director of Midwifery Services.

(b) An individual shall be designated who shall have the responsibility for maintaining health record files and developing statistical reports.

**§ 501.62. Health record transfer, retention and confidentiality.**

(a) In the event a referral or transfer to another level of care provider is needed during pregnancy, delivery or post-delivery period, the patient's record, or a complete copy of the record, shall accompany the mother or newborn infant at the time of transfer.

(b) The birth center shall comply with the act of April 29, 1925 (P. L. 358, No. 209) (35 P. S. §§ 351 and 352), regarding footprinting and infant identification.

(c) Health records shall be retained by the birth center for the mother and newborn infant, as recommended by the Department for outpatient facilities, as follows:

(1) The mother's entire record shall be retained for 7 years after discharge and date of last entry.

(2) The newborn infant's entire record shall be retained for 7 years after the child reaches 18 years of age.

(3) Health records shall be stored to provide protection from loss, damage, or unauthorized access.

(4) A written authorization for release of health record information, outside the birth center, shall be signed by the mother, prior to the release of health record information.

(5) In the event of a request for newborn infant health record information, authorization shall be signed by the legal parent or guardian except that, if the newborn infant has reached 18 years of age, or is otherwise legally emancipated, the written authorization shall be granted by the person.

(d) In the case of newborn adoptions, medical history information shall be delivered by the attending physician, or other designated person, to the intermediary, who shall deliver the information to the adopting parents or their physician. In cases where there is no intermediary, medical history information shall be delivered directly to the adopting parents or their physician.

(e) In cases of newborn adoption, medical history information shall be edited before a copy is transferred so as to remove contents which would identify the adoptee's natural family.

**§ 501.63. Birth certificate.**

A certificate of birth shall be filed for each birth, within 10 days of the birth, with the local registrar of vital statistics, in the district where the birth occurs, under Chapter 1 (relating to administration of vital records).



**OPERATIONS****§ 501.71. Midwifery services.**

Midwifery services provided at the birth center shall be in compliance with applicable Federal, State and local statutes, and shall include, but not be limited to, the following:

- (1) Midwifery services shall be under the supervision of the Director of Midwifery Services.
- (2) Each midwife shall be licensed to practice midwifery in this Commonwealth. The license shall be current and displayed in the birth center.
- (3) Midwifery services at the birth center shall be provided within the scope of written medical and midwifery protocols, approved by the Director of Midwifery Services and the Physician Director of Medical Affairs. These shall be reviewed, revised, signed and dated by both, on an annual basis.
- (4) Policies, procedures and service delivery protocols, shall be developed to assure comprehensive quality care for the patient and newborn infant.
- (5) Inservice training for professional staff shall be provided on a regular basis. The training shall include the areas of medication, patient education, as well as normal patterns and complications of pregnancy.
- (6) Adequate health supervision of mother and newborn at the time of referral or discharge from the birth center services shall be provided.
- (7) A certified midwife or physician shall be physically present, at all times, when a mother is laboring in the birth center.

**Cross References**

This section cited in 28 Pa. Code § 501.74 (relating to pharmaceutical services).

**§ 501.72. Birth center services.**

- (a) There shall be a Physician Director of Medical Affairs who is a licensed physician.
- (b) A Physician Director of Medical Affairs, who is not certified as an obstetrician or pediatrician, shall have developed consultant services in these specialties for the birth center by contractual arrangement.
- (c) The Physician Director of Medical Affairs shall insure that the following services are provided:
  - (1) Immediate availability of physician services through direct communication, by radio, telephone or telecommunications.
  - (2) An agreement with a Board certified obstetrician and Board certified pediatrician, including arrangements for hospital admission of mother and newborn infant, in order to ensure effective care in life threatening situations.

(3) Review, by the Physician Director of Medical Affairs and Director of Midwifery Services on a semiannual basis, of records of mothers and newborn infants discharged or transferred from the birth center during that 6 month period.

**§ 501.73. Nursing services.**

(a) Nursing services at the birth center shall be under the supervision of the Director of Midwifery Services.

(b) Nursing staff shall be provided with orientation and in-service training on a regular basis by the Physician Director of Medical Affairs and Director of Midwifery Services. Opportunities for out-service training shall be offered to licensed and professional staff members.

**§ 501.74. Pharmaceutical services.**

(a) There shall be a listing of all drugs and biologicals, including intravenous solutions, which are to be retained for emergency use in the birth center, which is consistent with the midwifery and medical protocols as required in § 501.71(3) (relating to midwifery services). The listing shall be developed and approved by the Physician Director of Medical Affairs. The listing shall include the identity of birth center staff who are authorized to administer the drugs, biologicals, or intravenous solutions. The purchase and use of drugs shall be done under the direction of the Physician Director of Medical Affairs or supervising physician.

(b) If a drug, biological, or intravenous solution is obtained on an emergency basis, it shall only be done upon an order, written or oral, by a physician, and it must be noted in the current list.

(c) Drugs and biologicals must be secured in an appropriate cabinet, or when refrigeration is necessary, must be stored in a separate refrigerator located in a controlled area for staff use only or in a locked stationary container, if stored in a refrigerator to which the public has access.

**§ 501.75. Laboratory services.**

(a) The birth center shall provide laboratory services directly or by arrangement with a licensed provider.

(b) If the service is provided directly, the facility must be licensed and approved by the Department to perform the necessary tests under the Clinical Laboratory Act (35 P.S. §§ 2151—2165) and Chapter 5 (relating to clinical laboratories).

(c) If the service is provided by arrangement, the written agreement shall meet the requirements of § 501.43 (relating to agreements) and shall be available for review.

(d) If services are provided by arrangement with, or referral to, an outside provider of services, the original copy of the signed and dated report shall become a part of the mother's permanent record.

(e) Tests completed at the birth center shall be entered, dated, and signed in the mother's record by the individual who performed the test. Abnormal test findings shall be promptly referred to the consulting physician.

### ENVIRONMENTAL SERVICES

#### § 501.81. Safety from fire.

(a) Birth centers are classified as C-1 modified occupancy and must comply with the following:

(1) Buildings of one story in height may be constructed of fire resistive, noncombustible, ordinary, or wood frame construction as defined in National Fire Prevention Association, 1961 Edition, *Standard Types of Building Construction*.

(2) Buildings of two stories or more in height shall be constructed of fire resistive or noncombustible construction as defined in National Fire Prevention Association, 1961 Edition, *Standard Types of Building Construction*.

(3) Means of egress requirements shall comply with the following:

(i) Each floor or fire section of the building shall have at least two means of egress, remotely located from each other.

(A) At least one means of egress shall be a stairway directly to grade, door directly to grade, horizontal exit, or ramp directly to grade.

(B) The other means of egress shall be a fire escape or outside stair if two means of egress are not provided in accordance with clause (A).

(ii) Width of stairways, fire escapes, and ramps.

(A) Stairs shall have a minimum width of 30 inches. Winders in stairs are not acceptable.

(B) Fire escapes shall have a minimum width of 24 inches. Fire escapes shall be constructed of steel.

(C) Ramps shall have a minimum width of 30 inches. Slope of ramps shall not exceed 2 inches in 12 inches.

(D) Handrails shall be provided. Handrails may protrude into the stairs, but not more than 3 inches on either side.

(iii) Travel distance.

(A) The travel distance between a room door, required as exit access, and an exit may not exceed 100 feet.

(B) The travel distance between a point in a room and an exit may not exceed 150 feet.

(iv) Illumination of means of egress.

(A) Each facility shall provide illumination of the means of egress.

(B) The floors of the means of egress shall be illuminated at all points, including angles and intersections of corridors and passageways, stairways, landings of stairs, and exit doors to values of not less than one footcandle measured at the floor.

- (4) Interior finish on walls, floors, and ceilings throughout shall be Class C, 200 flame spread rating or less.
  - (5) Operable residential type smoke detectors shall be installed in all rooms, corridors, and means of egress. The number of detectors shall be determined by the manufacturer's specifications on coverage.
  - (6) Occupancy shall comply with the following:
    - (i) Birthing rooms shall be limited to the lowest level with direct grade access, unless an exception is granted by the Department under § 501.6 (relating to exceptions). Basement occupancy by patients shall be prohibited.
    - (ii) Examination rooms are permitted above the first floor.
  - (7) Rooms or spaces, including repair shops, used for storage of combustible supplies and equipment in quantities deemed hazardous by the Department shall comply with the following:
    - (i) One-hour separation from all adjacent areas.
    - (ii) Automatic sprinkler system water source, which can be from the domestic water system. Installation and maintenance shall comply with National Fire Prevention Association 13 and 13A.
  - (8) All types of occupancies, which are not classified as C-1 modified, shall be separated by a 2-hour fire wall from the birth center.
  - (9) Fire extinguishers shall comply with the following:
    - (i) Portable fire extinguishers shall be provided. At least two extinguishers shall be provided per floor with a travel distance of 50 feet maximum to each extinguisher.
    - (ii) Fire extinguishers shall be the ABC type.
    - (iii) Maintenance shall be yearly.
- (b) Prior to construction, birth centers shall submit plans for review by the Department, using the procedures set forth in 34 Pa. Code § 49.3 (relating to submission of plans). A certificate of occupancy will be issued, in accordance with those procedures, when it is determined by the Department that the birth center is in compliance with subsection (a).
- (c) All necessary accommodations shall be made to meet the needs of persons with semi-ambulatory disabilities, sight and hearing disabilities, and disabilities in coordination, and to meet the requirements of 45 CFR § 84.23 (relating to new construction), concerning design, construction, and alteration of facilities. Conformity with the *American National Standards Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped*, published by the American National Standards Institute, Inc. (ANSI A117.1 1961 (R 1971), constitutes compliance with this subsection.

**§ 501.82. Physical environment.**

- (a) At a minimum, each birth room shall have a toilet and sink with hot and cold running water in the room or convenient access to it. The bathroom shall not

be shared by more than two patients, support persons, and family. Toilet facilities for staff members shall be separate from birth room toilet facilities.

(b) If a kitchen is available for birth room occupants and their family members or support persons, the kitchen shall be maintained in a safe and sanitary manner and should contain a refrigerator, sink, stove, and oven.

(c) The birth center shall adequately meet the comfort and privacy needs of the laboring woman and her family or support persons through the provision of:

- (1) Comfortable chairs for laboring.
- (2) An interview room with facilities for assured privacy.
- (3) Consultation and examining rooms to meet the needs of the patient, consultant, and family.

**§ 501.83. Infection control.**

The birth center shall develop infection control policies and procedures to minimize and control possibilities of infection, which shall include, but not be limited to, the following:

- (1) Handwashing techniques for adequate protection of the mother or newborn infant from infection and other contamination.
- (2) Contagious disease control measures for staff personnel, carrier or suspected carrier, spouse, or support persons.
- (3) Sterilization methods and procedures.
- (4) Infection control measures, including birth room cleaning policies and birth room waste disposal policies and procedures.

**§ 501.84. Disposal of placenta.**

Pathological and bacteriological waste, surgical and obstetrical wastes, contaminated wastes, and similar materials shall be incinerated on the premises or disposed of by a method approved by the Department of Environmental Resources and in compliance with local regulations.

**§ 501.85. Water supply.**

If the water supply is from an individual well source, a water sample testing report shall be obtained annually from a testing laboratory, and a report of the findings shall be made available to the Department.

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(245724) No. 285 Aug. 98

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