**Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

**Subtitle 05 FREESTANDING AMBULATORY CARE FACILITIES**

**Chapter 02 Freestanding Birthing Centers**

**Authority: Health-General Article, §19-3B-01 et seq., Annotated Code of Maryland**

*10.05.02.01*

**.01 Definitions.**

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Board" means the Board of Nursing.

(2) "Certified nurse midwife" means a registered nurse who is certified:

(a) By the American College of Nurse Midwives Certification Council; and

(b) To practice nurse midwifery in this State by the Board.

(3) Freestanding Birthing Center.

(a) "Freestanding birthing center" means a facility that provides nurse midwife services through individuals licensed to practice under Health Occupations Article, Title 8, Subtitle 6, Annotated Code of Maryland.

(b) "Freestanding birthing center" does not include:

(i) Birthing services that are licensed or accredited as a unit of a hospital; or

(ii) The private residence of the patient.

(4) "Midwifery" means the antepartum, intrapartum, and postpartum management and care of women and their newborns.

(5) "Newborn" means an infant in the first 48 hours of life.

(6) Normal Maternity.

(a) "Normal maternity" means a low risk, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal, uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health.

(b) "Normal maternity" does not include the use of drugs for induction or augmentation of labor, general and regional anesthesia, vacuum extractors, forceps, recorded electronic fetal monitors, ultrasound imaging, cesarean section, or surgical procedures other than episiotomy or perineal repair.

(7) "Nurse midwife services" means those services permitted to be provided by individuals licensed to practice nurse midwifery under Health Occupations Article, Title 8, Subtitle 6, Annotated Code of Maryland.

*10.05.02.02*

**.02 License Requirements.**

A freestanding birthing center shall only provide normal maternity care and shall meet all general licensing requirements for a facility as provided in COMAR 10.05.01 and all requirements of this chapter.

*10.05.02.03*

**.03 Licensing Procedure.**

A freestanding birthing center shall submit a nonrefundable fee of $300 with an application for initial licensure or $300 with an application for license renewal.

*10.05.02.04*

**.04 Surveys.**

A. A licensee operating a freestanding birthing center shall undergo a routine annual survey.

B. A licensee shall allow an on-site survey by the Department at any time during the center’s normal hours of operation to evaluate the center’s compliance with the applicable requirements and standards of this chapter.

C. Center employees shall make data and records accessible within a reasonable time during the on-site survey.

*10.05.02.05*

**.05 Personnel.**

A. Administrator. The licensee shall appoint an administrator of the freestanding birthing center who is responsible for the:

(1) Daily administration of the center; and

(2) Training and supervision of all nonprofessional staff, unlicensed staff, and volunteers.

B. Director of Midwifery Services. The administrator shall appoint a certified nurse midwife as director of midwifery services who is responsible for the employment, training, and supervision of the licensed professional staff.

C. A physician shall be on call and available to provide medical assistance to the freestanding birthing center whenever the center is treating a patient.

D. Medical Director. The medical director shall:

(1) Be a physician with:

(a) Board certification in a specialty that provides services for pregnant and postpartum patients, or

(b) Appropriate experience in the care of pregnant and postpartum patients;

(2) Have staff privileges at a hospital licensed by this State; and

(3) Be responsible for advising and consulting with the center staff on all matters related to medical management of pregnancy, birth, postpartum, newborn, and gynecologic health care.

E. Two licensed staff individuals, one of whom shall be a certified nurse midwife, shall attend each birth. They shall be currently certified in:

(1) Adult CPR equivalent to the American Heart Association Class C basic life support; and

(2) Neonatal CPR equivalent to that of the American Academy of Pediatrics and the American Heart Association.

*10.05.02.06*

**.06 Protocols.**

A. The medical director and director of nurse midwifery shall develop protocols for the management of routine and emergency care of the patient and her fetus or newborn during pregnancy, birth, and postpartum through discharge, whether through completion of the pregnancy or referral or transfer to other levels of care. The protocol shall include procedures for the transfer of patients or newborns for appropriate hospital obstetric and newborn care.

B. The administrator shall:

(1) Ensure that all protocols are fully implemented;

(2) Periodically review the protocols and revise them when necessary; and

(3) Make the protocols available to staff for reference on site at all times.

*10.05.02.07*

**.07 Referral System.**

A freestanding birthing center shall have a system for consultation with and referral to a physician who is Board-certified in a specialty that provides services for pregnant and postpartum patients, or a physician who has appropriate experience in the care of pregnant and postpartum patients.

*10.05.02.08*

**.08 Quality Assurance Program.**

A. A freestanding birthing center shall develop and implement a quality assurance program.

B. A freestanding birthing center shall collect the following evaluative data in addition to that required in COMAR 10.05.01.08:

(1) Number of births;

(2) Intrapartum transfer rates and indications for transfer; and

(3) Postpartum maternal and neonatal hospital admissions.

*10.05.02.09*

**.09 Physical Plant.**

A. Bedrooms. A freestanding birthing center shall:

(1) Locate bedrooms so as to provide unimpeded, rapid access to an exit of the building where emergency transportation vehicles may be accommodated;

(2) Have bedrooms that can accommodate:

(a) A double bed or a bed large enough to safely accommodate patient and baby,

(b) Birth attendants and support persons,

(c) Space for supplies, equipment, and family belongings, and

(d) Access to a sink with hot and cold running water equipped with elbow-wrist controls such as are common in home kitchens.

B. Toilet Facilities. A freestanding birthing center shall make available separate fixed toilet facilities to the laboring patient and separate toilet facilities for family and staff use.

C. Bath Facilities. A freestanding birthing center shall make bath and shower facilities available to the laboring patient and have separate washing facilities available for staff and family.

D. Storage, Utility, and Laundry Facilities. A freestanding birthing center shall have facilities that are designed and equipped for washing, sterilizing, storing, and handling equipment, linens, and medical supplies in a manner which ensures separation of clean linen, and sterile supplies and equipment from those that are soiled or contaminated.

E. Heating and Ventilation. A freestanding birthing center shall have a safe and adequate source of heat and ventilation capable of maintaining temperature in the birthing unit between 75°F and 85°F.

F. Lighting and Power. A freestanding birthing center shall have adequate lighting in the birthing rooms.

*10.05.02.10*

**.10 Fire Safety and Emergency Preparedness.**

A. Fire Safety Protection.

(1) Smoke Alarms. A freestanding birthing center shall place smoke alarms on each floor and at points as recommended by the State Fire Marshal or local fire authority. A freestanding birthing center shall have alarms that are audible throughout the center.

(2) Fire Extinguishers. A freestanding birthing center shall provide at least one approved fire extinguisher on each floor, including below ground level.

(3) Lighting and Power. A freestanding birthing center shall ensure that:

(a) Exits are illuminated during time of occupancy; and

(b) Emergency lighting is located to provide illumination in event of a power failure.

B. Evacuation.

(1) A freestanding birthing center shall make written copies of its fire evacuation plan available to all personnel and instruct all personnel in the implementation of the evacuation plan.

(2) A freestanding birthing center shall keep all personnel informed of their responsibilities under the plan and conduct supervised evacuation drills at regular intervals.

C. Transfer of Patients.

(1) A freestanding birthing center shall have emergency transportation available at all times, as demonstrated by:

(a) A written agreement with an ambulance service;

(b) Evidence that the center has confirmed that municipal ambulance services are available; or

(c) When located on the grounds of an acute care hospital, a written protocol which describes emergency transportation by means other than ambulance.

(2) A freestanding birthing center shall have a procedure for emergency communication with the ambulance service, or other emergency transportation mechanisms.

*10.05.02.11*

**.11 Equipment.**

A. Equipment and furnishings shall be constructed of materials that are easily cleaned and maintained and shall include, at a minimum:

(1) A heat source for infant examination or resuscitation;

(2) A transfer incubator or isolette or demonstrated capability of ready access to a transfer incubator;

(3) A sterilizer or demonstration of sterilizing capability;

(4) Blood pressure equipment, thermometers, and fetoscope or doptone;

(5) Intravenous equipment;

(6) Oxygen equipment for patient and newborn that is stored in accordance with Standards for Health Care Facilities, NFPA 99, which is incorporated by reference as part of COMAR 29.06.01.06B(2); and

(7) Instruments for delivery, episiotomy, and repair.

B. Laundry.

(1) A freestanding birthing center shall provide for the sanitary handling of soiled linens in accordance with 29 CFR §1910.1030, which is incorporated by reference.

(2) A freestanding birthing center may have on-site laundry facilities or use a laundry service that is experienced in handling linens for health care facilities.

(3) When a freestanding birthing center uses on-site laundry facilities, the center shall disinfect soiled linens by using one of the following methods:

(a) Hot water at 160°F; or

(b) A low-temperature wash formula which specifies time, temperature, concentration, and pH control in conjunction with chlorine bleach as recommended by the detergent manufacturer for use in a health care setting.

(4) A freestanding birthing center shall maintain an adequate linen supply.

*10.05.02.12*

**.12 Health Record.**

A. In addition to meeting the requirements of this regulation, a freestanding birthing center shall comply with the requirements of COMAR 10.05.01.09.

B. The health record of each patient shall contain documentation of all services provided while the patient and her fetus or newborn are under the care of the freestanding birthing center, including reports by outside providers who have examined or treated the patient at the request of the center.

C. A freestanding birthing center shall:

(1) Send a copy of the health record with the patient or newborn, or both, on referral to another health care provider or on transfer to a hospital; and

(2) Maintain birth and death certificates on file, as required by Health-General Article, Title 4, Subtitle 2, Annotated Code of Maryland.