

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 142.000: OPERATION AND MAINTENANCE OF BIRTH CENTERS

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142.001: Purpose

105 CMR 142.000 sets forth standards for the maintenance and operation of birth centers.

142.002: Authority

105 CMR 142.000 is adopted under the authority of M.G.L. c. 111, §§ 3 and 51 through 56.

142.003: Citation

105 CMR 142.000 shall be known and may be cited as 105 CMR 142.000 *Operation and Maintenance of Birth Centers*.

142.004: Scope

105 CMR 142.000 applies to every birth center subject to licensing either as a clinic as defined in M.G.L. c. 111, § 52 or as a facility operating under a hospital license pursuant to M.G.L. c. 111, § 51.

142.100: Definitions

A Birth Center is a home-like facility where low risks births are planned to occur following normal, uncomplicated pregnancy. A birth center has sufficient space to accommodate participating family members and support people of the women's choice. A Birth Center provides professional midwifery practice to childbearing women during pregnancy, birth, and puerperium and to the infant during the immediate newborn period by nurse-midwives or by an obstetrician or family practitioner with obstetrical privileges in a nearby hospital licensed in Massachusetts or operated by the Commonwealth. A Birth Center has specified access to acute care obstetric and newborn services.

Clinic means any entity, however organized, whether conducted for profit or not for profit, which is advertised, announced, established, or maintained for the purpose of providing ambulatory medical, surgical, dental, physical rehabilitation or mental health. In addition, Clinic shall

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include any entity, however organized, whether conducted for profit or not for profit, which is advertised, announced, established, or maintained under a name which includes the word Clinic, "dispensary", or "institute", and which suggests that ambulatory medical, surgical, dental, physical rehabilitation or mental health are rendered therein. With respect to any entity which is not advertised, announced, established, or maintained under one of the names in the preceding sentence, Clinic shall not include a medical office building, or one or more practitioners engaged in a solo or group practice, whether conducted for profit or not for profit, and however organized, so long as such practice is wholly owned and controlled by one or more of the practitioners so

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associated, or, in the case of a not for profit organization, its only members are one or more of the practitioners so associated or a clinic established solely to provide service to employees or students of such corporation or institution. No matter how the clinic is named, Clinic shall not include a clinic conducted by a hospital licensed under M.G.L. c. 111, § 51 or by the federal government, the commonwealth, or a local health department.

Commissioner means the Commissioner of the Department of Public Health or her or his designee.

Controlled Substance means a drug, substance, or immediate precursor in any schedule or class referred to in the Controlled Substances Act M.G.L. c. 94C.

Critical Congenital Heart Disease means a group of defects that cause severe and life-threatening symptoms and require intervention within the first days or first year of life.

Department means the Massachusetts Department of Public Health.

Free-standing Birth Center means a birth center which is not maintained and operated by a hospital. For purposes of licensure, a free-standing birth center is a clinic.

Hospital means any institution, however named, whether conducted for charity or for profit, which is advertised, announced, established or maintained for the purpose of caring for persons admitted thereto for diagnosis, medical, surgical or restorative treatment which is rendered within said institution.

Hospital-affiliated Birth Center means a birth center which is maintained and operated by a hospital. The birth center must be nearby but not be physically attached in any manner, including connection by corridors, to any other hospital services including the obstetrics service. A birth center is not a birth room or birthing suite or other short stay in-patient service.

Hospital Birth Room, also known as a birthing suite, means a room in or immediately adjacent to the labor and delivery room suite of a hospital where a low risk, normal, full term woman is allowed to labor and deliver her infant, and recover after delivery with her infant.

Licensed Nurse means an individual registered as a nurse under M.G.L. c. 112, § 74 or licensed as a practical nurse under M.G.L. c. 112, § 74A.

Nearby means within ten minutes normal driving time of a hospital, or otherwise reasonably accessible to a hospital as determined by the Department.

Nurse-midwife means an individual licensed by the Board of Registration in Nursing under M.G.L. c. 112, § 74 and authorized to practice as a nurse-midwife pursuant to 244 CMR 4.00: *Advanced Practice Registered Nursing*.

Physician means an individual registered by the Board of Registration in Medicine under M.G.L. c. 112, § 2 as a qualified physician.

Professional Midwifery Practice means the independent management of care of essentially normal newborns and low risk women, antepartally, intrapartally, and postpartally occurring

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within a health care system which provides for medical consultation, collaborative management, or referral and is in accord with the *Functions, Standards, and Qualifications for Nurse-Midwifery Practice* as defined by the American College of Nurse-midwives. The nurse-midwife, or physician provides care for the low risk mother during pregnancy and stays with her during labor from the time of admission to the birth center through the immediate post-partum period providing continuous physical and emotional support, evaluating progress,

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and assisting the woman in labor and delivery. Care includes evaluation and provision of immediate care to the normal newborn. The qualified midwife or physician provides assistance to the mother in caring for herself and her infant; in adjusting to the home situation and the new child; and in providing family planning. The nurse midwife or physician teaches, interprets and provides support as an integral part of his or her service.

142.200: Waiver of Requirements Imposed on Birth Centers

(A) The Commissioner or his or her designee may waive the applicability to a particular free-standing birth center of one or more of the requirements imposed on free-standing birth centers by 105 CMR 142.000 if upon inspection of the birth center the Department finds that:

- (1) compliance would cause undue hardship to the birth center;
- (2) the birth center is in substantial compliance with the spirit of the requirement; and
- (3) the birth center's non-compliance does not jeopardize the health or safety of its clients and does not limit the birth center's capacity to give adequate care.

(B) Waiver provisions set forth in 105 CMR 130.050: *Waiver of Requirements Imposed on Hospitals* are applicable to hospital-affiliated birth centers.

(C) If a birth center is located in a geographically isolated area as defined by the Department, the Department may waive the distance requirement set forth in 105 CMR 142.150 provided that the birth center demonstrates that the nurse-midwives are trained to perform neonatal resuscitation.

142.301: Licensing of Free-standing Birth Centers

Free-standing birth centers are required to obtain clinic licensure pursuant to M.G.L. c. 111, §§ 51 through 56 and to comply with the licensure and administrative requirements set forth in 105 CMR 140.000: *Subpart A* (105 CMR 140.100 through 140.199).

142.302: Licensing of Hospital-affiliated Birth Centers

Hospital-affiliated birth centers are required to operate under a hospital license issued pursuant to M.G.L. c. 111, §§ 51 through 56 and to comply with the requirements of 105 CMR 130.000: *Hospital Licensure* with the exception of those standards governing obstetric and newborn services (105 CMR 130.600 through 130.699).

142.303: Newborn Screening

(A) Notwithstanding the provisions of 105 CMR 142.302, free-standing and hospital-affiliated birth centers are subject to the regulations regarding the provision of newborn infant hearing screening as described in the hospital licensure regulations at 105 CMR 130.629: *Universal Newborn Hearing Screening Programs*. Notwithstanding the requirements of those sections, if a birth center does not have the equipment or ability to conduct such a screening, the newborn infant shall be referred prior to discharge from the birth center to a hospital or birth center approved by the Department for such screening.

- (1) Prior to discharge, a birth center that is not able to conduct a hearing screening shall make an appointment for a screening for each newborn infant at a Department approved screening site.
- (2) Prior to discharge, written information shall be provided in the language understood by

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the parent or guardian to the parent or guardian about the importance of the screening, coverage of the costs of the screening by third party payers, the time of any screening appointment scheduled, and the location and phone number of the hearing screening site.

(3) The birth center shall within two weeks of the birth of a child perform a follow-up call to the parent or guardian of the newborn infant to verify the infant has received the hearing screening. Records shall be kept to document the conversation about the performance of the screening. As part of the annual report submitted to the Department pursuant to 105 CMR 130.629(C)(3)(k), the birth center shall submit information regarding the follow-up for hearing screening of newborn infants.

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(4) The birth center shall submit a screening protocol for those portions of 105 CMR 130.629: *Universal Newborn Hearing Screening Programs* designated by the Department in the Universal Newborn Hearing Screening Guidelines.

(B) Each birth center shall adopt protocols for screening newborns for critical congenital heart disease with pulse oximetry or another test approved by the Department in accordance with Department guidelines. Such protocols shall provide that the screening shall not be performed if the parent or guardian of the newborn infant objects to the screening based upon the sincerely held religious beliefs of the parent or guardian.

142.400: Compliance with Public Safety Standards

Prior to original licensure and licensure renewal each freestanding birth center shall submit a certificate of inspection issued by the head of the local fire department certifying compliance with local ordinances and a certificate of inspection issued by the Department of Public Safety or local body with jurisdiction over the premises.

142.405: Space, Equipment and Supplies

Each birth center shall provide adequate space, and provide equipment and supplies appropriate and sufficient to render birth center services.

142.410: Hallways and Doors

Hallways and doors providing ingress and egress to the birth center and rooms in which births take place shall be of adequate width and conformation to accommodate movement of a standard ambulance stretcher or cot.

142.415: Climate Control

Each birth center must provide and maintain a safe and adequate source of heat and air conditioning for stable climate control.

142.420: Lighting

There shall be adequate lights in each examination and treatment area and in rooms in which births take place.

142.425: Rooms in Which Births Take Place

(A) Rooms in which births take place shall be located on a grade level to provide unimpeded, rapid access to an exit of the building where emergency transportation vehicles may be accommodated. Such rooms may be located on a level above or below a grade level provided that such levels have access to a grade level via an elevator of adequate size to accommodate a standard ambulance stretcher or cot.

(B) Each room in which births take place shall be spacious enough to accommodate family belongings and the following equipment and supplies:

- (1) A double bed or a bed large enough to safely accommodate mother and baby;
- (2) Chairs;

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- (3) Bedside/procedure tables;
- (4) A bassinet.

(C) Each room in which births take place shall have access to a sink with hot and cold running water with elbow-wrist controls.

142.430: Toilet and Bath Facilities

Each birth center shall make toilet and bath or shower facilities available to the laboring mother. A separate toilet facility must be available for family and staff use.

142.435: Family Room

Each birth center must have a family room which includes a play area for children and a living room setting of tables, chairs and sofa that may be converted into a bed for use by family members.

142.440: Kitchen or Kitchenette

Each birth center must have a kitchen which includes refrigerator, stove, sink, cupboard, and counter space for the convenience of families.

142.445: Maintenance of Furnishings and Equipment

Birth center furnishings and equipment shall be kept clean and in good repair.

142.450: Reception and Office Areas

Each birth center shall provide adequate space and equipment for reception and waiting areas, for administrative and staff offices and for storage of client records.

142.455: Examination and Treatment Areas

Exam rooms and treatment areas shall include an examination table, handwashing facilities and shall ensure privacy and confidentiality.

142.460: Support Areas

Support service areas such as a library, and area for minor laboratory tests, must be clearly identified.

142.470: Storage, Utility Areas and Waste Disposal

(A) Each birth center must have adequate utility and storage equipment for washing, sterilizing, storing and other handling of equipment, linens, and medical supplies.

(B) Clean linen and sterile supplies and equipment must be segregated from soiled and/or contaminated linen, equipment and supplies.

(C) Waste products and materials shall be disposed of in a safe and appropriate manner. Tissue shall be disposed of in a manner approved by the Department.

(D) Each birth center must be either equipped to launder linens and other washable goods properly on site at the center, on site at the parent hospital or provide for satisfactory arrangements with a commercial laundry. Water temperature for laundering shall be at least 160°F.

142.475: Equipment and Supplies for Infants

Each birth center must have a standard neonatal warming device and a transfer incubator which conforms with the standards of Underwriter's Laboratories, Inc.

142.480: Diagnostic Equipment

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(A) Each birth center shall maintain a microscope for routine office examination of vaginal smears.

(B) A sufficient number of sphygmomanometers and auscultation equipment shall be available.

142.485: Emergency Equipment and Supplies

(A) Each birth center shall have available emergency equipment, medication and supplies as outlined in the birth center's policies and procedures and as approved by the Director of Medical Affairs.

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(B) Equipment and supplies for administration of intravenous fluids, and full adult and infant resuscitation as required by procedures outlined in the birth center's protocols, shall be maintained.

(C) Each birth center shall have a limited supply of oxygen including portable oxygen available for emergency use. Oxygen shall be properly stored.

(D) Each birth center shall have portable suction available for both the mother and the infant.

(E) Each birth center shall have a source of emergency lighting.

142.490: Smoke Alarms

Smoke alarms shall be placed on every floor.

142.495: Evacuation Plan and Drills

Written copies of a plan for evacuation in event of fire shall be available to all personnel. All personnel shall be instructed and kept informed of their responsibilities under the plan and supervised drills shall be conducted at regular intervals.

142.500: Birth Center Governing Body

(A) Each free-standing birth center, whether organized as proprietary or not for profit health services, under sole ownership, partnership or corporate group, shall identify a governing body with full authority and responsibility for overall policy and fiscal management of the facility and the services.

(B) The governing body of a free-standing birth center shall develop and maintain a written organizational plan.

(C) The governing body of the parent hospital of a hospital-affiliated birth center assumes full authority and responsibility for the overall policy, fiscal management and services provided by the birth center.

(D) The governing body is responsible for the appointment of the clinical birth center staff and the delineation of all clinical privileges.

142.501: Director of the Birth Center

(A) Each free-standing birth center shall have a director who shall be responsible to the governing body for the operation and maintenance of the center.

(B) The director of a free-standing birth center must be a certified nurse-midwife, or an obstetrician or family practitioner with obstetrical privileges in a nearby hospital licensed in Massachusetts or operated by the Commonwealth.

(C) Each hospital-affiliated birth center shall have a director who shall be administratively responsible to the administrator of the hospital for the operation and maintenance of the birth center.

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(D) The director of a hospital-affiliated birth center must be a certified nurse-midwife, or an obstetrician or family practitioner with obstetrical privileges in the parent hospital. If the parent hospital does not provide obstetrics and newborn services, the Director must meet the requirements set forth in 105 CMR 142.501(B).

142.502: Director of Medical Affairs

(A) Each free-standing birth center shall designate a Director of Medical Affairs who shall be a board certified or board eligible obstetrician/gynecologist with full obstetrical privileges at a nearby hospital.

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(B) Each hospital operating a hospital-affiliated birth center shall appoint a Director of Medical Affairs for the birth center who shall be a board certified or board eligible obstetrician/gynecologist with full obstetrical privileges at the parent hospital.

If the parent hospital does not provide obstetrics and newborn services, the Director of Medical Affairs must meet the requirements set forth in 105 CMR 142.502(A).

(C) The Director of Medical Affairs shall be responsible for advising and consulting with the primary care staff of the birth center on all matters related to medical management of pregnancy, birth, post-partum, newborn and gynecologic health care including policies, procedures and protocols for midwifery management of care.

(D) The Director of Medical Affairs shall develop policies and procedures governing administration of controlled substances by nurse midwives under standing orders. These policies and procedures are subject to approval by the Commissioner.

142.503: Administrative Records

(A) Each birth center shall maintain current, complete, and accurate administrative records in a safe location. The birth center shall make all administrative records available promptly to any agent of the Department seeking to determine compliance with 105 CMR 142.000.

(B) Administrative records in a free-standing birth center shall include:

- (1) Updated articles of organization and by-laws or partnership agreement, as appropriate. The documents shall specify the organizational structure of the governing body and the method of selection of members.
- (2) Updated lists of the names, addresses, and professions of the members; and of the names and addresses of directors and officers.
- (3) Minutes of meetings of the governing body and of the members.
- (4) An organizational chart for the entire organization.
- (5) Personnel records for each employee, including any license or registration number; documentation of any specialty certificate, education and job experience.

(C) Each birth center shall develop written policies governing:

- (1) Selection of personnel and the qualifications for each position. A job description for each position must be included in the administrative records.
- (2) Client admission criteria including specific information by which a woman's risk status will be established. This policy shall also be available for public inspection.
- (3) The provision of emergency care and the retention of emergency equipment, medication and supplies appropriate to its client population. This policy shall be reviewed at least annually.
- (4) Off-hour coverage. This policy shall also be posted conspicuously in the birth center.
- (5) Consultation and referral for obstetric and pediatric care.
- (6) Informed consent.
- (7) Specific client transfer criteria.
- (8) Infection control including procedures and guidelines.
- (9) Adult and neonatal intubation and resuscitation.
- (10) Standards for medication procurement, storage and administration.

142.504: Client Records

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(A) Each birth center shall keep in one centralized location records indicating all the services rendered to birth center clients.

(B) Client records in hospital-affiliated birth centers shall be part of the hospital's record system and shall be maintained in conformance with hospital birth center record standards established in written policies and procedures.

(C) Each client shall have a single integrated record. Each entry into each client record shall be dated and signed by the staff member making the entry, indicating name and title. Each page of each client's record shall have two unique forms of identification. The record with respect to each client shall be accurate and complete and include the following:

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- (1) Client's name, date of birth, home address and telephone number, and spouse or other person to contact in an emergency.
 - (2) Date of each client visit with birth center staff, at the birth center or elsewhere.
 - (3) Obstetrical and medical history.
 - (4) Diagnostic observations, evaluations, and therapeutic plans.
 - (5) Orders for any medication, test, or treatment.
 - (6) Records of any administration of medications, treatment, or therapy.
 - (7) Laboratory, radiology, and other diagnostic reports.
 - (8) Progress notes.
 - (9) Reports of any consultations, special examinations, or procedures.
 - (10) Referrals to other agencies.
 - (11) Discharge summary where appropriate.
- (D) Each birth center shall record the following information with respect to each newborn:
- (1) The condition of the infant at birth to include Apgar Score (or its equivalent) at one minute and five minutes, time of sustained respiration, details of physical abnormalities and pathological states.
 - (2) Date and hour of birth, birth weight and period of gestation.
 - (3) Number of cord vessels and any abnormalities of the placenta.
 - (4) Verification of eye prophylaxis.
 - (5) Metabolic screening.
 - (6) Treatments, medications and special procedures.
 - (7) Condition at discharge or transfer.
- (E) Each birth center shall keep each client's record for 20 years after its final treatment of that client.
- (F) Each birth center shall maintain client records under lock or code and use them in a manner to protect the confidentiality of the information contained therein. Printed copies of electronically stored records shall be disposed of in a manner which assures the confidentiality of client information.
- (G) Each birth center shall make all client records available promptly to any authorized agent of the Department.

142.505: Off-hour Coverage

Each birth center shall make arrangements for the provision of services 24 hours a day. These requirements can be met through on call coverage by a certified nurse-midwife or physician on the staff of the birth center during the hours when it is not open. These arrangements shall be reflected in a written policy that is made available to all the birth center's clients.

142.506: System for Referral

- (A) The free-standing birth center shall have a written agreement with a board-certified or eligible obstetrician/gynecologist, and a pediatrician or neonatologist for the provision of 24 hour consultation, referral and transfer to appropriate hospital facilities for obstetric/newborn care.
- (B) Each hospital-affiliated birth center shall develop written agreements or policies for the

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provision of 24 hour consultation with a board-certified or eligible obstetrician/gynecologist and a pediatrician or neonatologist with clinical privileges at the parent hospital. If the parent hospital does not provide obstetrics and newborn services, the birth center must meet the requirements set forth in 105 CMR 142.506(A).

142.507: Emergency Transfer Agreements

(A) Each birth center shall have a written agreement with a nearby or the parent hospital providing obstetrical and newborn services for the transfer of their clients for emergency treatment beyond that provided by the birth center.

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(B) Each birth center shall have a written agreement with a board certified or eligible obstetrician with full obstetrical privileges at a nearby or the parent hospital, and a written agreement with a board certified or eligible pediatrician with full pediatric privileges at a nearby or the parent hospital for the care and transfer of clients for emergency treatment beyond that provided by the birth center.

142.508: Transfer of a Client or Newborn

(A) Each birth center shall develop written procedures for the prompt and safe transfer of the obstetrical client and of the newborn for emergency treatment beyond that provided in the birth center.

(B) Whenever a birth center refers a client to the parent facility or to another facility, agency or health care provider, it shall send a copy of relevant portions of the birth center's records on the client to such facility, agency, or provider.

(C) A birth attendant as described in 105 CMR 142.510(A) shall accompany the client and newborn upon transfer to the parent or nearby hospital.

142.509: Evaluation of Quality

(A) Each birth center shall have an on-going program for the review and evaluation of the quality and appropriateness of services provided by the birth center.

(B) Each birth center shall document all such reviews conducted and their findings and shall make such documentation available to the Department upon request.

142.510: Birth Attendants

A certified nurse-midwife, or an obstetrician or family practitioner with obstetrical privileges in the parent or nearby hospital shall attend each woman in labor from the time of admission; during labor; during the birth; and through the immediate postpartum period. Such attendance may be delegated only to another certified nurse midwife or physician.

142.515: Birth Assistant

(A) A second staff person shall also be present at each birth. The second staff person must be either a nurse-midwife, or a licensed nurse.

(B) Licensed nurses must have labor and delivery experience within one year of employment in a licensed obstetrical service which includes training in:

- (1) full adult and infant resuscitation;
- (2) assessing the phases and stages of labor;
- (3) psychology and physiology of labor and delivery; and
- (4) equipment and supplies used for labor and delivery.

142.520: Other Staff Requirements

(A) There shall be sufficient professional staff to provide services for safe operation and maintenance of the birth center.

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- (B) Qualified professional staff shall be on duty at all times when clients are present.
- (C) Professional staff shall be responsible for training and supervision of all non-professional staff, unlicensed staff and volunteers.
- (D) All staff must have an pre-employment physical exam including tuberculin testing.
- (E) Prior to employment by the birth center each individual shall demonstrate evidence of immunization to rubella or shall receive a rubella vaccination prior to employment.

142.600: Selection of Clients

- (A) Standards governing medical risk factors which exclude women from care at the birth center are established separately as Department guidelines.
- (B) The Director of Medical Affairs shall develop and review annually a list of medical and social risk factors for the birth center in consultation with the birth center's primary care staff which:
 - (1) includes but is not limited to the risk factors set forth in the Department guidelines; and
 - (2) is approved by the Commissioner.

142.610: Orientation

Each birth center shall provide an orientation program for clients and childbearing families. Such program shall include:

- (A) the philosophy and goals of the birth center;
- (B) the services that are available in the center and the services to which clients will have access by referral, consultation or contract including but not limited to education, nutrition counselling, and family guidance;
- (C) all charges for care; and
- (D) a tour of the facility.

142.620: Program of Care

The birth center shall provide a program of care to include at least the following:

- (A) a personal and family history;
- (B) a physical examination and appropriate laboratory tests;
- (C) continuous assessment of risk to mother and baby;
- (D) a program of prenatal care that shall include components of self-help, self-care, and fetal assessment;
- (E) a program of prenatal education that shall include the importance of nutrition, preparation for birth and breast feeding, and information on adverse effects of smoking, alcohol and other drugs;
- (F) intrapartum and postpartum services that foster parental control and responsibility for the birth experience and infant parental bonding;
- (G) labor support for the woman and her family;
- (H) professional attendance at the birth;
- (I) immediate postpartum care and newborn assessment;

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- (J) required eye prophylaxis;
- (K) postpartum laboratory examination and program for prevention of Rh immunization;
- (L) newborn metabolic screening and other such tests as may be required;
- (M) a plan for follow-up;

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- (N) a postpartum examination and family planning; and
- (O) a plan for well woman routine gynecologic health care.

142.630: Other Services

- (A) The birth center shall have access to diagnostic services including clinical laboratory, sonography, radiology, electronic monitoring.
- (B) All services used by the birth center shall meet applicable standards of the Department.
- (C) Other services not provided by the birth center shall be made available to clients through referral as needed.

142.640: Surgical Procedures

- (A) Surgical procedures shall be limited to those normally accomplished during uncomplicated childbirth, such as episiotomy and repair.
- (B) Surgical procedures such as forceps delivery, tubal ligation, abortion, or Cesarean section shall not be performed in birth centers.

142.650: Use of Medications

- (A) Controlled substances may be administered by a nurse-midwife only in a medical emergency and only in accordance with client specific standing orders written by a physician.
- (B) Local anesthesia for the infiltration of the perineum for episiotomy repair may be administered in accordance with client specific standing orders written by the physician.
- (C) The following practices are prohibited:
 - (1) use of any analgesics subject to regulation under M.G.L. c. 94C for pain control during labor;
 - (2) inhibition, stimulation or augmentation of the first or second stage of labor with controlled substances;
 - (3) use of general or regional anesthesia except as permitted in 105 CMR 142.650(B);
 - (4) maintenance of controlled substances or provision of controlled substances for self-administration outside of the birth center.
- (D) Prescriptions shall be issued for all controlled substances required by clients outside of the birth center.

142.660: Discharge Follow-up

- (A) Mothers and infants shall be discharged or transferred within 24 hours after birth.
- (B) There shall be 24 hour telephone service to a professional birth attendant.
- (C) Maternal and newborn examinations shall be performed by the birth center professional staff, or a physician or certified nurse-midwife of the family's choice within 72 hours of birth.

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Such examinations shall include required laboratory tests for health screening.

(D) A plan for pediatric care, contraception services and assessment of breast feeding and mother-infant bonding shall be developed for each mother and infant after birth.

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142.670: Reporting Requirements

(A) Birth centers shall report all births to Registrars and City Clerks within ten days of the event and forward the confidential section of the birth record to the Department.

(B) Birth centers shall report any child with low birth weight, congenital abnormalities, and other high risk infants as defined by the Department.

142.700: Definition: "Clinical Laboratory Services"

Biological, serological, chemical, immunohematological, cytological, pathological, or other examinations of materials derived from a human body shall be described in 105 CMR 142.700 through 142.730 as "clinical laboratory services".

142.710: Approval of In-house Clinical Laboratory Services

In-house clinical laboratory services offered by a birth center are subject to clinical laboratory approval as set forth in 105 CMR 180.000: *Operation, Approval and Licensing of Clinical Laboratories*.

142.720: Contracting for Outside Clinical Laboratory Services

A birth center may enter into a written contract for the provision of all or part of its clinical laboratory services with a laboratory independent of the birth center which is licensed, approved or certified by the appropriate federal or state agencies. The birth center must have detailed written statements of policy on procedures for the collection, transport, and handling of specimens referred to such an outside laboratory, which are available for review by the Commissioner.

142.730: Affidavits Concerning Clinical Laboratory Services

Each birth center shall submit an annual affidavit to the Commissioner specifying the nature of all its testing services, the individuals performing the tests, the individuals responsible for the accuracy of the tests, the methods of testing employed, the quality control practice employed and any other information required by the Department.

REGULATORY AUTHORITY

105 CMR 142.000: M.G.L. c. 111, §§ 3 and 51 through 56.

NON-TEXT PAGE