

State of Connecticut
Regulation of
Department of Public Health
Concerning
Birth Centers

Section 1. The Regulations of Connecticut State Agencies are amended by adding sections 19a-566-1 to 19a-566-19, inclusive, as follows:

Sec. 19a-566-1. Definitions

- (1) “Accredited” means accredited by the Commission for the Accreditation of Birth Centers or CABC;
- (2) “Advance practice registered nurse” or APRN means an advanced practice registered nurse licensed pursuant to Chapter 378 of the Connecticut General Statutes;
- (3) “Adverse event” has the same meaning as Section 19a-127n of the Connecticut General Statutes;
- (4) “Birth center” has the same meaning as Section 19a-490(v) of the Connecticut General Statutes;
- (5) “Birth center services” has the same meaning as Section 19a-566(a) of the Connecticut General Statutes;
- (6) “Certification in cardiopulmonary resuscitation” or “CPR” means training and certification in CPR by the American Heart Association, the American Red Cross, the American Safety and Health Institute or an organization using guidelines for cardiopulmonary resuscitation and emergency cardiovascular care published by the American Heart Association and the International Liaison Committee on Resuscitation;
- (7) “Centers for Disease Control and Prevention” or “CDC” means the Centers for Disease Control and Prevention of the United States Department of Health and Human Services;
- (8) “CLIA” means the regulations adopted pursuant to the Clinical Laboratory Improvement Amendments of 1988, set forth in 42 CFR 493 as amended from time to time;
- (9) “Clinical staff” means both licensed maternity care providers and professional staff as defined in this section;
- (10) “Commission for the Accreditation of Birth Centers” or “CABC” means the Commission for the Accreditation of Birth Centers, the national accreditation organization for birth centers;
- (11) “Commissioner” means the Commissioner of the Department of Public Health or the commissioner’s designee;
- (12) “Compounding” has the same meaning as Section 20-571(6) of the Connecticut General Statutes;
- (13) “Department” means the Connecticut Department of Public Health;
- (14) “Disaster planning” means planning for evacuation and facility emergencies;
- (15) “Discharge” means the patient and newborn are clinically stable and meet the discharge criteria set forth by the licensee in accord with Section 19a-566-8 of the Regulations of Connecticut State Agencies, in order to safely leave the birth center for home;
- (16) “Doula” has the same meaning as Section 20-86aa of the Connecticut General Statutes;

- (17) “Emergency medical services” or “EMS” means emergency medical services certified or licensed pursuant to Chapter 368d of the Connecticut General Statutes;
- (18) “Emergency planning” means planning for maternal and newborn medical emergencies;
- (19) “Facility Guidelines Institute” or “FGI” means the Facility Guidelines Institute which issues the FGI Guidelines for Design and Construction of health environments;
- (20) “Governing authority” means the entity established by the licensee with legal authority and responsibility for the overall management and operation of the birth center;
- (21) “Health Insurance Portability and Accountability Act of 1996” or “HIPAA” means the federal privacy and security rules under 45 CFR 160 and 45 CFR 164;
- (22) “Intrapartum” means pertaining to the period of labor and birth;
- (23) “Lactation consultant” means a health care professional who specializes in breastfeeding;
- (24) “Licensed maternity care provider” means a health care provider licensed in the State of Connecticut whose professional scope of practice includes preconception, prenatal, intrapartum and postpartum care and early care of the newborn, and whose scope of practice allows the provider to be the primary attendant during the perinatal period;
- (25) “Licensee” means a birth center licensed pursuant to the Regulations of Connecticut State Agencies;
- (26) “Low-risk pregnancy” has the same meaning as Section 19-490(v) of the Connecticut General Statutes;
- (27) “Manufacturer” has the same meaning as Section 21a-70(a) of the Connecticut General Statutes;
- (28) “Midwife” means a licensed nurse-midwife licensed pursuant to Chapter 377 of the Connecticut General Statutes;
- (29) “Newborn” means a newborn infant up to twenty-eight days of life;
- (30) “Patient capacity” means the maximum number of licensed beds for laboring or birthing patients that may safely be occupied at the birth center at any given time;
- (31) “Pharmacy” has the same meaning as Section 20-571 of the Connecticut General Statutes;
- (32) “Physician” means a physician licensed pursuant to Chapter 370 of the Connecticut General Statutes;
- (33) “Professional staff” means personnel qualified through their professional scope, and certified or licensed in the state of Connecticut as applicable, to provide services at birth centers other than licensed maternity care providers as defined in this section;
- (34) “Sentinel event” means an unexpected occurrence at a birth center involving death or serious harm to a patient, or risk of death or serious harm to a patient;
- (35) “Transfer” means transfer to a hospital for care that exceeds the scope of services provided at the birth center;
- (36) “Uncomplicated delivery” means childbirth where no medical, obstetric, fetal, or neonatal condition precludes an anticipated labor, birth and postpartum at a birth center as defined in this section and within the criteria for eligibility for birth center services; and
- (37) “Wholesaler” has the same meaning as Section 21a-70(a) of the Connecticut General Statutes.

Sec. 19a-566-2. Applicability

- (a) On or after January 1, 2024, the Commissioner of Public Health shall not grant or renew a maternity hospital license granted pursuant to Section 19a-505 of the Connecticut General

Statutes. Upon such date no person, entity, firm, partnership, corporation, limited liability company or association shall establish, conduct, operate or maintain a birth center, as defined in Section 19a-490(v) of the General Statutes, in this State without obtaining a license pursuant to the provisions in these regulations.

- (b) A maternity or labor and delivery facility, including such service titled a birth center, that is a hospital facility, or attached to or located in a hospital licensed under Chapter 368v of the Connecticut General Statutes, shall operate under the hospital license.

Sec. 19a-566-3. Licensure Procedures

- (a) Any person, entity, firm, partnership, corporation, limited liability company or association proposing to establish, conduct, operate or maintain a birth center shall apply for a license pursuant to Section 19a-566 of the Connecticut General Statutes and the provisions set forth herein. A license issued under this section is non-delegable and non-transferable.
- (b) Application for initial or renewal license.
 - (1) Application for initial or renewal licensure shall be made by the applicant in a form and manner prescribed by the department. No birth center services shall be conducted until the applicant has been notified in writing by the department that the license is issued and in effect. No birth center services shall be conducted upon the expiration of licensure or if the license has been suspended, denied, or revoked.
 - (2) Application for the grant of initial licensure or licensure renewal shall include, but not be limited to, the following:
 - (A) Name and address of the facility;
 - (B) Statement of ownership and operation including any beneficial ownership, and including the name and address of the licensee, name and address of the legal operating entity, or both, as applicable;
 - (C) Name, address and qualifications of the birth center clinical director and the birth center administrative director;
 - (D) Roster and resumes of clinical staff;
 - (E) Certificates of professional and medical liability insurance;
 - (F) Certificates of general liability insurance;
 - (G) Certificates of worker's compensation insurance;
 - (H) A list of proposed services;
 - (I) Policies and procedures required for the operation of a birth center pursuant to the Regulations of Connecticut State Agencies;
 - (J) Documentation of current accreditation or accreditation in progress by the Commission for the Accreditation of Birth Centers;
 - (K) All information required pursuant to Section 19a-566(c)(1) of the Connecticut General Statutes;
 - (L) Local Fire Marshal's license or certificate;
 - (M) Documentation of zoning approval as applicable;
 - (N) The licensing fee provided in section 19a-491(c) of the Connecticut General Statutes;

- (O) A statement of patient capacity; and
 - (P) Such additional information as the department may require.
- (3) Accreditation.
 - (A) Each birth center shall have submitted a complete application for accreditation by the Commission for the Accreditation of Birth Centers (CABC) before applying for a license.
 - (B) As part of the application review, the commissioner shall review the information submitted by the birth center for accreditation from the CABC. The commissioner may deny the application based upon the commissioner's disapproval of any such information. Such review shall include, but not be limited to, the following information:
 - (i) The birth center's plan, pursuant to section 19a-566-8 of the Regulations of Connecticut State Agencies, for ongoing risk assessment and adherence to patient eligibility criteria during the provision of birth center services to a patient during the delivery of birth center services to a patient; and
 - (ii) Policies and procedures, pursuant to section 19a-566-11 of the Regulations of Connecticut State Agencies, for the prenatal, intrapartum or postpartum transfer of a patient in the event that such patient no longer meets such patient eligibility criteria.
- (c) Inspection. Upon determination that the initial application materials are complete, the department shall notify the applicant of inspection of the birth center.
- (d) Issuance and renewal of license.
 - (1) The commissioner may issue a license or renewal of license to operate a birth center if the commissioner determines following inspection that the facility complies with the statutes and regulations pertaining to its licensure.
 - (2) An initial birth center license shall be for a period of one year. In accordance with Section 19a-566(b) of the Connecticut General Statutes, as amended by Public Act 24-68, the commissioner may, at the commissioner's discretion, renew once for a period of not more than one year while a birth center is completing accreditation. Absent such action by the commissioner the birth center shall be accredited on or before the renewal of its license and shall maintain such accreditation.
 - (3) If a birth center is denied accreditation prior to the renewal of its initial license or loses its accreditation after renewal of its license, the birth center shall immediately notify the commissioner and cease providing birth center services to patients until authorized by the commissioner to reinstate such services.
 - (4) The commissioner shall issue a license to the birth center in the name of the licensee appearing on the application.
 - (5) A licensee operating more than one birth center shall require a separate license for each facility.
 - (6) The licensee shall post the license in a conspicuous location at the birth center.
 - (7) After the conclusion of the initial licensure period, a birth center license shall be renewable biennially in accordance with Section 19a-566(b) of the Connecticut General Statutes.

- (8) Each license shall specify the following:
 - (A) The patient capacity;
 - (B) The names of the birth center clinical director and the birth center administrative director; and
 - (C) Any waivers of the Regulations of Connecticut State Agencies that have been granted to the birth center.
- (e) Denial, suspension or revocation of licensure.
 - (1) The commissioner may, in the commissioner's discretion, deny an initial or renewal application for licensure for any of the following reasons:
 - (A) The application for initial or renewal license is incomplete. Any incomplete application which has remained inactive for one year will be destroyed in accordance with the agency's record retention schedule. Application fees are not refundable. To reactivate the application process, a new application and fee will be required;
 - (B) Failure of the birth center to secure and maintain accreditation by the CABC as required pursuant to subsection (d) of this section;
 - (C) The submission of any false or misleading statements to the department in order to obtain an initial or renewal of a birth center's license; or
 - (D) A determination by the department that the birth center does not meet the requirements for licensure set forth in the applicable statutes and regulations.
 - (2) A license issued pursuant to this section may be revoked or suspended in accordance with Chapter 54 of the Connecticut General Statutes, or subject to any other disciplinary action pursuant to Section 19a-494 of the Connecticut General Statutes for the following reasons:
 - (A) The licensee has failed to comply with applicable federal, state and local laws and regulations;
 - (B) The licensee is denied accreditation prior to the renewal of its license; or
 - (C) Failure of a licensee to comply with Section (d)(3) shall be grounds for summary suspension of the birth center's license.
- (f) Change in director or facilities. Any entity licensed pursuant to this section proposing to enact changes in director, or proposing an expansion or alteration of its facility shall comply with the requirements of Section 19a-491(f) of the Connecticut General Statutes.
- (g) Waiver.
 - (1) The commissioner may waive provisions of this section as provided in Section 19a-495 of the Connecticut General Statutes if the commissioner determines that such waiver would not endanger the health, safety, or welfare of any patient. The commissioner may not waive statutory requirements reflected in the Regulations of the Connecticut State Agencies. The commissioner may impose conditions upon granting the waiver that assure the health, safety, and welfare of patients, and may revoke the waiver upon a finding that the health, safety, or welfare of any patient has been jeopardized.
 - (2) The licensee requesting a waiver shall do so in a form and manner prescribed by the commissioner. Such request shall include:
 - (A) The specific regulations for which the waiver is requested;

- (B) Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the birth center upon enforcement of the regulations;
 - (C) The specific relief requested;
 - (D) Any documentation that supports the request for waiver; and
 - (E) Alternative policies and procedures proposed.
- (3) In consideration of any request for waiver, the commissioner may consider:
 - (A) The impact of a waiver on services provided; and
 - (B) Alternative policies or procedures proposed by the birth center.
- (4) The department reserves the right to request additional information before processing the request for waiver.
- (h) Change of ownership. Any change of ownership of a birth center licensed pursuant to this section shall accord with the requirements of Section 19a-493(c) of the Connecticut General Statutes.
- (i) Closure. In the event of closure of a birth center licensed pursuant to this section, the licensee shall ensure a plan for the continuity of care for all patients is developed and implemented. The licensee shall notify the department and provide a copy of said plan to the department not less than thirty days prior to the planned closure and shall remit the birth center license immediately upon closure.

Sec. 19a-566-4. Organization and Administration

- (a) Each birth center shall have an organized governing authority or equivalent legal entity responsible for, but not limited to, the following:
 - (1) The adoption and regular review of bylaws for the governing authority;
 - (2) A mission statement for the birth center;
 - (3) Appointment of birth center clinical director and birth center administrative director;
 - (4) Overall administration of the birth center;
 - (5) Fiscal management and oversight;
 - (6) Annual review;
 - (7) Quality assurance and performance improvement;
 - (8) Mechanisms in accordance with the requirements of section 19a-566-9 and 19a-566-10 of the Regulations of Connecticut State Agencies for the collaboration, referral, and transfer of patients from the birth center to other providers;
 - (9) Development, approval, implementation and review of all required policies and procedures;
 - (10) Delegation of authority to the birth center clinical and administrative directors as applicable;
 - (11) Physical plant and equipment;
 - (12) Duly qualified professional staff and supporting staff; and
 - (13) Approval of the birth center as an educational program site for clinical experience, as applicable.
- (b) The licensee shall be responsible for compliance with all federal and state laws and regulations.

- (c) Both the governing authority and the birth center staff shall include midwives to ensure the midwifery model of care is delivered. The governing authority shall ensure a mechanism is in place for both staff and patients to provide input to the birth center clinical director and birth center administrative director.
- (d) All birth center policies and procedures shall be available to the governing authority, to the birth center director or directors, to birth center staff, and to current and prospective patients and their families on request.

Sec. 19a-566-5. Liability and malpractice insurance

- (a) The licensee shall maintain general liability insurance for the facility and for providers, and shall provide certificates documenting such insurance to the department upon request.
- (b) The licensee shall maintain the following professional medical liability insurance and provide certificates documenting such insurance upon request:
 - (1) Proof of medical malpractice coverage for any employed or contracted licensed clinical provider in accord with minimums determined by the provider's statutory requirements pursuant to the Connecticut General Statutes, or for employed or contracted midwives coverage of not less than one million dollars;
 - (2) Proof of medical malpractice coverage in accord with the requirements of Chapter 370 of the Connecticut General Statutes for any collaborative physician who provides care at the birth center;
 - (3) Proof of medical malpractice coverage for the birth center as a facility, including coverage for any unlicensed personnel and any students participating in an educational program located at the birth center by agreement as specified in section 19a-566-6 of the Regulations of Connecticut State Agencies.
- (c) The amount of insurance which the licensee shall maintain for the facility as insurance or indemnity against claims for injury or death for professional malpractice shall be not less than one million dollars for one person, per occurrence, with an aggregate of not less than three million dollars.
- (d) Any patient or potential patient of the birth center has the right to review all insurance certificates and be informed of the insurance status of all providers.

Sec. 19a-566-6. Personnel

- (a) The licensee shall be responsible for ensuring an adequate number of suitably qualified personnel is available to ensure the health and safety of patients and families, and to successfully provide all services offered.
- (b) The licensee shall maintain the following for all classifications of personnel:
 - (1) Job description including required qualifications, responsibilities, and a description of the supervision of the role;
 - (2) Hiring processes and procedures for both direct employees and contracted professionals;

- (3) Evidence of current and unrestricted professional licensure in the state of Connecticut, as applicable;
 - (4) Evidence of credentials including hospital privileges and professional certifications, if any; and
 - (5) Proof of medical malpractice coverage as required in Section 19a-566-5 of the Regulations of Connecticut State Agencies.
- (c) The licensee shall provide orientation to all personnel. Such orientation shall include training in all birth center policies and procedures, including but not limited to emergency planning and transfer.
- (d) The licensee shall provide in-service training for all staff that shall include training on implicit bias and cultural competency.
- (e) All birth center staff shall have documented and current training in both adult cardiopulmonary resuscitation and neonatal resuscitation. At each birth, at least two staff members shall be onsite who are trained and certified in adult cardiopulmonary resuscitation and neonatal resuscitation.
- (f) Staffing levels. The birth center shall ensure adequate clinical and support staffing levels to meet the demands of routine services, to provide coverage during periods of high demand or emergency, and to ensure the safety and quality of the model of care as follows:
 - (1) There shall be at least two clinical staff members attending each birth; at least one of which shall be a licensed maternity provider;
 - (2) The birth center shall develop and implement policies and procedures to ensure the continuity of care when more than one patient needs care such that there is at least one more clinical staff member on site than number of patients in labor at all times;
 - (3) The birth center shall develop and implement policies and procedures to ensure coverage in the event of staff absence or illness; and
 - (4) If any clinical staff members also attend births in other settings such as homes or hospitals, the birth center shall develop and implement policies and procedures to ensure adequate staffing of births at the birth center when births are occurring in more than one location simultaneously.
- (g) Qualifications and responsibilities of birth center clinical director.
 - (1) The clinical director shall be either a midwife or an obstetrician-gynecologist licensed in the state of Connecticut;
 - (2) The clinical director shall have documented clinical experience with the management and direction of maternity care services;
 - (3) The clinical director shall be responsible for developing, implementing, and ensuring adherence to best practices and evidence-based standards of care for all patients and families, and shall be responsible for implementing and overseeing policies and procedures pertaining to clinical care;
 - (4) The clinical director shall be the designated liaison with the governing authority regarding clinical management of the birth center;
 - (5) The clinical director shall be responsible for compliance with all applicable state, federal and local laws and regulations;
 - (6) The clinical director shall be responsible for identifying a designee who is a licensed maternity care provider to assume the same responsibilities as the clinical director when the clinical director is temporarily not available; and

- (7) The clinical director shall be responsible for the hiring and management of all clinical staff, including planning for continuity of care for each patient individually and for the management of more than one patient simultaneously.
- (h) Qualifications and responsibilities of birth center administrative director.
 - (1) The administrative director shall have a minimum of one year of experience in healthcare administration and management;
 - (2) The administrative director shall be responsible for the daily operation and administrative management of the birth center. Responsibilities may include but not be limited to the administrative management of hiring and staffing needs; maintaining collaborative and referral agreements with outside providers and facilities; billing; maintaining personnel records and medical records; coordinating emergency planning; overseeing maintenance schedules for facilities, supplies and equipment; and maintaining staffing schedules; and
 - (3) The administrative director shall be responsible for implementing and overseeing all operational policies and procedures at the birth center.
- (i) Qualifications and responsibilities of clinical and professional staff.
 - (1) Midwifery staff shall have current certification and licensure in accord with Chapter 377 of the Connecticut General Statutes;
 - (2) Clinical staff shall maintain a mechanism to ensure immediate telephone contact with an obstetrician-gynecologist and a pediatrician, either on a collaborative basis or as part of the clinical staff of the birth center twenty-four hours a day, seven days a week;
 - (3) Clinical staff may include professional staff licensed or certified pursuant to the Connecticut General Statutes whose professional scope of practice includes those services offered at a birth center licensed in accord with the Regulations of Connecticut State Agencies. All clinical staff shall provide services in accordance with all legal requirements including their statutory scope of practice;
 - (4) Clinical staff shall have demonstrated experience, training and skills to support physiologic birth and breastfeeding to maintain a family-centered model of care without separation of the parent-infant dyad; and
 - (5) Licensed maternity care providers shall be the primary attendants during birth. Such providers shall have primary responsibility for the following components of care provided at the birth center:
 - (A) Initial patient evaluation including initial risk assessment to determine eligibility for birth center services;
 - (B) Care and triage upon admission for delivery;
 - (C) Care of patient and newborn during delivery;
 - (D) Care and assessment of patient and newborn after delivery;
 - (E) Remaining on-site at all times during the intrapartum period; and
 - (F) Remaining on-site after birth until both patient and newborn are clinically stable and approved for discharge in accord with birth center policies and procedures.
 - (6) Any doula on staff at the birth center shall be a certified doula in accord with Chapter 377a of the Connecticut General Statutes, or shall maintain equivalent qualifications

to the requirements set forth pursuant to Chapter 377a of the Connecticut General Statutes.

- (j) Qualifications and responsibilities of support staff.
 - (1) Nonprofessional, unlicensed support staff shall demonstrate the knowledge, training and experience to perform the responsibilities of their position at the birth center as determined by the applicable hiring staff.
- (k) Continuing education and training.
 - (1) Documentation of all initial and annual training, staff orientation, and continuing education shall be maintained and available for department review on request.
 - (2) The birth center shall ensure annual training to meet OSHA regulations and any other applicable infection control guidelines. OSHA training shall be completed in accordance with staff responsibilities for administrative staff, support staff, and clinical staff.
 - (3) All staff shall receive HIPAA training upon hire, and the birth center shall maintain documented annual review of HIPAA training.
 - (4) All clinical staff shall maintain continuing education and training in accord with the requirements of their licensure and to maintain best evidence-informed practice within their professional scope.
- (l) Students. A birth center may engage with educational programs with an accreditation recognized by the state of Connecticut to provide clinical learning experiences for students preparing for a healthcare occupation permitted to provide services at a birth center as set forth in the Regulations of Connecticut State Agencies, as follows:
 - (1) A signed written agreement with the educational program or institution for each student for student education or field experience shall be approved by the birth center's governing authority following review of the educational programs' objectives; and
 - (2) All clinical notes taken by students shall be co-signed by the birth center clinical staff member responsible for the patient.
- (m) Personnel records. The licensee shall maintain personnel records as follows:
 - (1) Records shall be maintained for all staff including those contracted and directly employed by the birth center and including students placed at the birth center;
 - (2) Records shall undergo regular review coordinated by the administrative director and clinical director, as applicable, to ensure files are complete and up to date;
 - (3) Documentation of both external continuing education and in-service education completed by each staff member;
 - (4) Documentation of adult cardiopulmonary and neonatal resuscitation training and current certification completed and maintained by personnel;
 - (5) Records shall include applicable insurance certificates;
 - (6) Records of staff health information shall be maintained in accordance with applicable state and federal privacy laws;
 - (7) Annual performance evaluations shall be conducted and entered into each personnel file;
 - (8) Documentation that each staff person is fully trained in birth center policies and procedures;

- (9) Documentation of initial and annual HIPAA training for all staff;
- (10) Evidence of current licensure as applicable; and
- (11) Maintenance of records shall be assigned to a dedicated staff person.

Sec. 19a-566-7. Services, limitations, and eligibility for birth center care

- (a) A birth center shall not provide services exceeding the scope of services set forth in Section 19a-566(a) of the Connecticut General Statutes under the terms of the birth center license. A birth center may seek dual licensure as an outpatient clinic in accord with section 19a-493d of the Connecticut General Statutes in order to offer services exceeding the scope of services set forth in Section 19a-566(a) of the Connecticut General Statutes.
- (b) Each birth center shall develop and implement policies and procedures for an orientation to educate patients and potential patients regarding the model of care and range of services offered. Such orientation shall include informing patients of which services are offered on-site at the birth center, and which may be offered by referral, consultation or collaboration with other providers or entities.
- (c) Birth center services shall include availability of licensed maternity providers on the birth center clinical staff for consultation twenty-four hours a day seven days a week for all patients either in person or through telephone or telehealth consultation.
- (d) Eligibility for services. Each birth center shall develop and implement policies and procedures for eligibility for admission to, and continuing participation in, the birth center's model of care and available services. In accord with Section 19a-490(v) of the Connecticut General Statutes, birth centers may serve only patients with low-risk pregnancies. If a birth center elects to include the trial of labor after cesarean or medication dependent gestational diabetes within the policies and procedures for eligibility for admission, criteria shall accord with best practices and the licensed maternity provider's clinical judgment. Such criteria shall include but need not be limited to the following:
 - (1) Trial of labor after cesarean, which shall include, but not be limited to:
 - (A) No more than one prior cesarean birth;
 - (B) A documented low transverse incision;
 - (C) Ultrasound confirmation of placental location; and
 - (D) Patient otherwise remains consistent with all risk criteria for admission to the birth center.
 - (2) Medication dependent gestational diabetes, which shall include, but not be limited to:
 - (A) No evidence of diabetes prior to pregnancy;
 - (B) Consultation with obstetrician or maternal-fetal medicine specialist with a documented plan of care for glucose monitoring, fetal surveillance, and the timing of delivery; and
 - (C) Review of weekly glucose monitoring throughout pregnancy.
- (e) Ongoing risk assessment. Each birth center shall establish policies and procedures for conducting ongoing risk assessment throughout the course of providing services to each patient. Risk assessment shall be determined by evaluation and examination conducted by a

licensed health care provider acting within the scope of such's provider's practice in accord with Section 19a-490(v). Such assessment shall include:

- (1) Identifying each risk criterion that would permanently or temporarily disqualify a patient from receiving services at the birth center in accord with national accreditation standards, including, but not limited to, the following:
 - (A) Labor and delivery at a gestational age prior to thirty six weeks or later than forty two weeks;
 - (B) Multiple pregnancy;
 - (C) Known breech or non-vertex presentation at time of admission for labor and delivery;
 - (D) Hypertensive disorders;
 - (E) Gestational diabetes that does not comport with the birth center's eligibility policies and procedures if so established according to subsection (d) of this section; and
 - (F) Trial of labor after cesarean that does not comport with the birth center's eligibility policies and procedures if so established according to subsection (d) of this section.
 - (2) Identifying criteria for transferring prenatal, intrapartum, postpartum, and neonatal care to alternative providers in both emergency and non-emergency circumstances in accord with Section 19a-566-10 of the Regulations of Connecticut State Agency.
- (f) Intrapartum care. Each birth center shall offer comprehensive intrapartum care in accordance with accreditation standards and evidence-based practices for midwifery care. A licensed maternity care provider shall be present and available to the patient at all times during labor and delivery and until both patient and newborn are determined to be medically stable. The birth center shall establish policies and procedures including, but not limited to, the following:
- (1) Pre-term labor;
 - (2) Cervical sweeps;
 - (3) Artificial rupture of membranes;
 - (4) Use of non-pharmacological methods to induce or augment labor; and
 - (5) The promotion of physiologic birth including, but not limited to, the following:
 - (A) Accommodation of support persons of the patient's choice throughout labor and delivery and the postpartum stay, including accommodation of such persons' participation as determined by the patient;
 - (B) Supportive care during labor;
 - (C) Freedom of movement;
 - (D) Maintaining a low-stress environment;
 - (E) Permitted pain relief strategies; and
 - (F) Regular assessment of patient and fetus at determined intervals.
- (g) Postpartum care. The birth center shall develop and implement policies and procedures including, but not limited to, the following components of postpartum care:
- (1) Criteria for determining that both patient and newborn are medically stable immediately postpartum;

- (2) Maternal postpartum assessment to include the monitoring of vital signs while ensuring bonding and skin-to-skin contact whenever doing so is safe for both patient and newborn;
 - (3) A postpartum care plan to include home care instructions and a plan for follow-up care and evaluation for each patient. The postpartum care plan shall include but not be limited to the following care:
 - (A) Breastfeeding and infant feeding support and referral;
 - (B) Postpartum mental health screenings; and
 - (C) Family planning services or referral as required.
- (h) Newborn care. The birth center shall develop and implement policies and procedures including, but not limited to, the following components of postnatal newborn care:
 - (1) Newborn assessment to include the monitoring of vital signs while ensuring bonding and skin-to-skin contact whenever doing so is safe for both patient and newborn;
 - (2) Evidence-based policies for identification, assessment and treatment of neonatal hypoglycemia;
 - (3) Required newborn screening in accordance with Sections 19a-55 and 19a-59 of the Connecticut General Statutes and regulations promulgated under such authority, or a waiver indicating objection to newborn screening signed by the parents and submitted to the department on forms issued by the department pursuant to section 19a-55-3 of the Regulations of Connecticut State Agencies;
 - (4) Evidence-based information for parents regarding required newborn screening and procedures in accordance with Section 19a-55 of the Connecticut General Statutes;
 - (5) Support and education on feeding methods;
 - (6) Referral for ongoing pediatric care;
 - (7) A postnatal care plan to include home care instructions, and a plan for follow up care and evaluation for each newborn.
- (i) Limitations.
 - (1) Anesthesia. The birth center shall not offer general, subdural, or epidural anesthesia. Pain relief may be offered within the scope of practice of a midwife. Local anesthesia for episiotomy or repair may be performed.
 - (2) Surgical procedures. The use of vacuum extraction or vaginal forceps is prohibited. No operative obstetrics or delivery by cesarean section shall be performed. Only those surgical interventions normally performed during an uncomplicated delivery may be performed, including episiotomy and repair. Any such interventions shall be performed only within the scope of the provider's professional license.
 - (3) Pharmacological agents to induce or augment labor. Labor shall not be induced, stimulated, or augmented with pharmacological agents acting directly on the uterus during the first or second stages of labor or before labor. Pharmacological agents may be used in accord with best practices appropriate to the birth center setting for cervical ripening.
 - (4) Electronic fetal monitoring. No continuous electronic fetal monitoring shall be performed. Intermittent fetal monitoring may be performed in accord with professional standards of care.

- (j) Water immersion during labor and delivery. If a birth center offers water immersion during labor, delivery, or both, the birth center shall establish policies and procedures including:
 - (1) Maternal and fetal eligibility and contraindications for water immersion;
 - (2) Water temperature guidelines, measurement and documentation;
 - (3) Monitoring maternal temperature during immersion;
 - (4) Infection control prior to and during water immersion;
 - (5) Water safety precautions in accord with evidence;
 - (6) Fetal monitoring in accord with professional standards of care;
 - (7) Emergency procedures; and
 - (8) Training in the use of and access to adequate protective attire for all staff who attend labor or delivery in water.

Sec. 19a-566-8. Discharge

- (a) Birth center services encompass on-site postpartum care for persons with low-risk pregnancy and delivery and healthy newborns for a period of typically less than twenty-four hours.
- (b) The licensee shall develop and implement discharge criteria. No patient or newborn shall be discharged from the facility unless both patient and newborn are clinically stable in accord with such discharge criteria.
- (c) No discharge shall be permitted less than four hours after delivery.
- (d) Prior to discharge, the provider shall provide newborn screening in accord with the requirements of Sections 19a-55 and 19a-59 of the Connecticut General Statutes and regulations promulgated thereunder.
- (e) Discharge shall include an individual plan for postpartum and postnatal follow-up care, in accord with the birth center's policies and procedures for postpartum and postnatal care as established according to Section 19a-566-7 of the Regulations of Connecticut State Agencies. Maternal and newborn follow-up care shall be documented.

Sec.19a-566-9. Referral and collaboration

- (a) The birth center shall establish and maintain written plans for collaboration, consultation, or referral as appropriate with other healthcare providers, individuals, agencies, or organizations for services not provided on-site by the birth center staff within the terms of the birth center license. Such written plans shall be established and maintained for such services including but not limited to the following:
 - (1) Outside laboratory services;
 - (2) Outside ultrasound services;
 - (3) Lactation support services;
 - (4) Childbirth education services;
 - (5) Doula services;
 - (6) Obstetric and gynecologic consultation and referral;
 - (7) Pediatric consultation and referral;

- (8) Psychiatric consultation and referral; and
- (9) Referral to other specialists and support services as required.
- (b) The birth center shall develop and implement policies and procedures for the collaboration and inclusion of doulas and other support persons during the provision of birth center services. Such policies and procedures shall accommodate the participation of support persons of the patient's choice for any services received at the birth center.
- (c) The birth center shall develop and implement policies and procedures regarding the identification of maternal mental health needs. Such policies and procedures shall include referrals to support services including, but not limited to, counseling services.

Sec. 19a-566-10. Transfers and emergency planning

- (a) Transfers. The birth center shall establish and maintain a written plan to obtain services for patients and newborns with care needs that require transfer to a level of care beyond the scope of the birth center's services. Each hospital licensed pursuant to chapter 368v of the Connecticut General Statutes that maintains an emergency department, other than a children's hospital, is required to work collaboratively with the licensee to coordinate care for the patient in the event of transfer to a hospital pursuant to Section 19a-566(d) of the Connecticut General Statutes. Each children's hospital that maintains an emergency department is required to work collaboratively with the licensee to coordinate care of neonatal patients in the event of transfer to a children's hospital pursuant to Section 19a-566(d) of the Connecticut General Statutes.
 - (1) Each birth center shall develop and implement policies and procedures for transfer of care in both emergent and non-emergent cases and for each of the prenatal, intrapartum and postpartum periods. Transfer policies and procedures shall include transfer of care that may be required for either the patient, the newborn, or both, when the patient fails to meet the patient eligibility criteria. Transfer policies and procedures shall be aligned with the ongoing risk assessment required under Section 19a-566-7 of the Regulations of Connecticut State Agencies.
 - (2) No birth center shall fail to refer or transfer a patient or newborn in need of care beyond the scope of the services provided at the birth center, according to the risk criteria established by the birth center under Section 19a-566-7 of the Regulations of Connecticut State Agencies and according to national accreditation standards.
 - (3) Transfer policies and procedures shall include a prearranged plan for access to acute care services whereby the birth center shall notify the receiving provider or hospital of the transfer in advance. Such notification shall include the reason for transfer, relevant clinical history, planned mode of transport, and expected time of arrival. Notification shall occur by both verbal report, and transfer of records from the birth center. Verbal reports made during transfer shall be documented and shall include the time, the information communicated, and the name of the receiving provider or hospital, or both.
- (b) Emergency planning. The licensee shall develop and implement an emergency plan which shall include engaging in routine and periodic emergency drills. Drills shall include but not be limited to the following:
 - (1) Be conducted at least quarterly;
 - (2) Include both maternal and newborn medical emergencies;

- (3) Be documented; and
 - (4) Each staff person shall attend at least three of the four quarterly drills conducted each year.
- (c) Disaster planning. Each birth center shall develop and implement policies and procedures regarding disaster planning which shall include, but not be limited to, the following:
 - (1) Planning for fires, severe weather and other threats to patient and staff safety;
 - (2) Staff training in necessary disaster response;
 - (3) Transfer of patients in event of disaster;
 - (4) Complete evacuation protocols;
 - (5) Disaster response shall be included in the emergency drills required under this section; and
 - (6) Staff attendance in disaster planning, training, and drills shall be recorded.

Sec. 19a-566-11. Laboratory Services

- (a) The birth center shall provide routine point-of-care testing for patients and newborns in accord with evidence-based best practices.
- (b) The birth center shall develop and implement quality control for all testing procedures in accord with applicable federal and state law, and with best practices.
- (c) If the birth center offers on-site provider-performed microscopy procedures for diagnostic purposes, the licensee shall comply with all CLIA requirements and obtain the necessary certificate or certificate of waiver for any microscopy performed.
- (d) If the birth center submits samples to or refers patients to a contracted laboratory located in the state of Connecticut, such laboratory shall require a clinical laboratory license pursuant to section 19a-565(b) of the Connecticut General Statutes.

Sec. 19a-566-12. Pharmaceutical Services

- (a) The birth center shall develop and implement policies and procedures governing pharmaceutical services in accordance with all applicable federal and state laws and regulations.
- (b) The birth center shall develop and implement policies and procedures governing the receipt, use, storage and destruction of patients' own medications.
- (c) The birth center shall maintain the minimum medications required by national accreditation standards in a safe and readily accessible manner, and in accord with security and traceability requirements for any controlled substances.
- (d) The birth center shall ensure that all drugs and medications, including controlled substances, are possessed, dispensed, prescribed and administered by a licensed provider in accordance with their respective scope of practice, and in accordance with all applicable federal and state laws and

regulations. Dispensing of drugs on-site shall accord with Section 20-14e of the Connecticut General Statutes.

- (e) Medications possessed, distributed, or administered at a birth center shall be procured by contract with a wholesaler, manufacturer or pharmacy licensed under Section 21a-70 of the Connecticut General Statutes. No compounding of pharmaceuticals shall occur on-site at such birth center. Preparation of pharmaceuticals per manufacturer's instructions is permitted.
- (f) All drugs, medications, and biologicals shall be handled, stored and disposed of in a safe manner and in accordance with all applicable federal and state laws and regulations and the manufacturer's instructions.
- (g) Upon discharge of patients according to Section 19a-566-8 of the Regulations of Connecticut State Agencies, and upon transfer of patients according to Section 19a-566-10 of the Regulations of Connecticut State Agencies, the patient's medical record shall include complete records of all medications, including complete records of any drug dispensed in accord with Section 20-14e of the Connecticut General Statutes.

Sec. 19a-566-13. Dietary Services

- (a) The birth center shall have the capacity to provide patients and families with appropriate nourishment and light snacks.
- (b) The birth center shall permit onsite preparation, storage, heating and serving of food to birthing patients and families whether provided by families or by the birth center. The birth center shall maintain the following minimum kitchen facilities and equipment:
 - (1) A refrigerator able to maintain a temperature of forty-one degrees or lower;
 - (2) A microwave;
 - (3) A sink;
 - (4) Dishes and flatware; and
 - (5) Counterspace.
- (c) If food service is provided by contract between the birth center and a food service provider or other food establishment, the following shall apply:
 - (1) Such food service provider or food establishment shall comply with the Model Food Code pursuant to Section 19a-36h to 19a-36m, inclusive, of the Connecticut General Statutes and regulations authorized thereunder, and shall comply with any applicable local requirements;
 - (2) Sufficient staff shall be available to meet the dietary needs of patients; and
 - (3) Food offered shall be nutritionally balanced and shall meet the preferences and needs of patients.
- (d) Food storage shall be separate from medication storage.

Sec. 19a-566-14. Medical Records

- (a) The birth center shall maintain a clinical record for each patient and newborn served. Copies of each patient's record shall be readily accessible to the patient and health care team in accord with

applicable state and federal law and shall be maintained in a secure system for storage and retrieval that complies with state and federal requirements for privacy and security.

- (b) Clinical records shall include documentation of all informed consent processes required in the course of the patient's care including, but not limited to, informed consent regarding the birth center's scope of services, transfer policies, prenatal and newborn screening, and payment plans. Informed consent documentation shall reflect decision-making processes documenting an explanation of options, the provider's recommended option, the patient's option, the provider's evaluation of the patient's option, signed informed refusal as applicable, and possible consequences of refusal as appropriate.
- (c) Each patient's and newborn's clinical record shall meet the requirements of Section 19a-14-40 and 19a-14-41 of the Regulations of Connecticut State Agencies, and shall accord with the standards required for accreditation and evidence-based clinical standards at each stage of care.
- (d) The birth center shall utilize a transport record documenting all information required in the event of transfer in both emergent and non-emergent cases, and shall develop and implement a mechanism for providing the complete health record of patient, newborn, or both upon transfer or referral to other levels of care.
- (e) The birth center shall comply with the filing requirements for birth certificates set forth in Section 7-48 of the Connecticut General Statutes and Section 19a-41-1 et seq of the Regulations of Connecticut State Agencies. Each clinical record shall include the information required pursuant to these sections.
- (f) The birth center shall comply with the requirements of Sections 7-51, 7-52, 7-60, and 7-61, inclusive, of the Connecticut General Statutes regarding the filing of death certificates and fetal death certificates. Each clinical record shall include the information required to meet the requirements of these sections.

Sec. 19a-566-15. Facilities

- (a) Each birth center shall follow the 2022 FGI Chapter 2.4 or the most current edition of FGI guidelines for health care facilities as adopted by the department. Each birth center shall comply with local, state and federal codes, regulations and ordinances for construction, fire prevention, public safety and access, as applicable to birth centers.
- (b) Any birth center that is planning a project for construction or building operation shall comport with Section 19a-491(f) of the Connecticut General Statutes.
- (c) Facilities and furnishings shall be kept clean and in good repair.
- (d) Facilities shall be designed and constructed to ensure a home-like environment that provides privacy for families, and facilitates emergency exit of patients and newborns in the event of emergency. Facilities shall include, but are not limited to, the following:
 - (1) An accessible entrance and exit, a waiting area, and at least one bathroom accessible to the waiting area that is suitable for those requiring accommodations for mobility;
 - (2) A permanent or mobile ramp to allow wheelchair access into and out of the birth center;
 - (3) Adequate provision of heat, ventilation, lighting and emergency lighting, waste disposal, and water supply;

- (4) Administrative space to ensure confidentiality of records, including but not limited to:
 - (A) Secure medical records storage;
 - (B) Separate utility and work spaces so designated for the purposes of infection control;
 - (C) Medical supplies storage; and
 - (D) Separate staff areas.
- (5) Adequate bathing and toilet facilities for families, laboring patients, and staff, with separate bathroom facilities for staff separate from patients who are in labor or postpartum;
- (6) The birth center shall provide birth rooms in accord with the following requirements:
 - (A) Each birth room shall have no more than one labor and delivery bed;
 - (B) Each birth room shall provide adequate space for access to perform routine and emergency care for patient and newborn, and shall provide adequate privacy for laboring and postpartum patients, newborns, labor support persons, families, and visitors;
 - (C) Each birth room shall provide safe and adequate accommodation for support persons of the patient's choice throughout the patient's stay at the birth center;
 - (D) Each birth room shall include direct access to a private bathroom and include toilet, handwash station and shower or tub;
 - (E) Each birth room shall have an outside window; and
 - (F) Each birth room shall have a minimum clear floor area of one hundred and twenty square feet, and no wall shall be less than ten feet in dimension.
- (7) Adequate handwashing facilities for families and personnel, including provision for children to reach sinks safely for handwashing;
- (8) Adequate trash storage and removal in compliance with federal and state regulations;
- (9) Adequate waste handling and removal systems for biomedical waste to ensure compliance with local, state and federal regulations including compliance with bloodborne pathogen standards and separate storage of contaminated items and biohazardous waste from medications and food;
- (10) Adequate laundry facilities or systems which shall include, but not be limited to, the following:
 - (A) Adequate provision of hygienically cleaned linens, towels, bedding, mattress covers for each family;
 - (B) Placing laundry contaminated with bodily fluids in securely fastened bags or receptacles to move to laundry area or dispatch to laundry service;
 - (C) Laundry storage in an area inaccessible to families;
 - (D) Onsite laundry or laundry service to ensure hygienically clean processes in accord with CDC standards for health care facilities; and
 - (E) Replacement of any wet or damaged mattresses, or damaged mattress covers.
- (11) Adequate parking. Parking shall include one space for each birth room plus one space for each employee on shift; and
- (12) An environmental services space for housekeeping supplies and equipment.
- (e) Facilities shall permit adequate access for emergency medical service personnel, including but not limited to the following:

- (1) Doors shall be thirty two inches or greater in width to allow for access to stretchers, wheelchairs, and other emergency equipment;
 - (2) Birthing rooms shall be located to allow unimpeded access to emergency transportation and equipment;
 - (3) No barriers shall block access to patients or newborns; and
 - (4) Emergency medical service personnel shall have ability to move patients safely if not ambulatory, including where the birth center has stairs at or in the facility.
- (f) Electrical requirements. The birth center shall be equipped with an emergency power source, which shall be adequate to maintain the operation of light for egress, fire detection equipment, and alarms.
- (g) The facility shall eliminate hazards to patients and visitors. In areas accessible to children, elimination of hazards shall include, but not be limited, uncovered electrical outlets.
- (h) Biohazardous waste. The birth center shall develop and implement policies and procedures for the sanitary disposal of biohazardous waste including blood, bodily fluids, placentas and sharps. The birth center shall maintain facilities that segregate biohazardous waste from other waste.

Sec. 19a-566-16. Equipment and supplies

- (a) Equipment shall be adequate and in good working order at all times as considered necessary for the proper performance of services offered. Equipment shall be:
 - (1) Checked, maintained and repaired;
 - (2) Qualified for its intended use according to the manufacturer's written instructions; and
 - (3) Monitored for compliance with requirements according to a documented maintenance schedule.
- (b) Each birth center licensed pursuant to this section shall maintain emergency equipment and medications as follows:
 - (1) An emergency cart or tray to provide emergency lifesaving procedures for both adults and newborns including but not limited to an automated external defibrillator;
 - (2) Oxygen and positive pressure masks;
 - (3) Newborn suction equipment;
 - (4) Newborn warming equipment;
 - (5) Medication identified and approved for emergency use by the clinical director; and
 - (6) Any other equipment identified and approved for emergency use by the clinical director and required for compliance with national accreditation standards.
- (c) Birthing tubs. If a birth center offers water immersion during labor, delivery, or both, the birth center shall establish policies and procedures to ensure tub cleaning and maintenance according to generally accepted national standards and the manufacturer's written instructions. The birth tub shall not have jets, and the water shall be completely replaced at regular intervals in accord with best practices.

Sec. 19a-566-17. Quality assurance, data collection and reporting requirements

- (a) The birth center shall develop and implement a quality assurance program with written policies and procedures including, but not limited to, the following:
 - (1) A mechanism for review of all policies and procedures to evaluate the quality of care offered in the full scope of the birth center's services, and to assess the appropriateness and efficacy of the established risk criteria for admission;
 - (2) Inclusion of all staff, not just clinical staff, in quality review and improvement efforts;
 - (3) Regular review of patient feedback;
 - (4) Maintenance and assessment of data regarding outcomes in accord with accreditation standards;
 - (5) Structured case review of all adverse events at least annually;
 - (6) Structured case review of all transfers at least annually in both emergent and non-emergent cases for both maternal and newborn care needs as set forth in Section 19a-566-17(c) of the Regulations of Connecticut State Agencies;
 - (7) Structured case review of all cases to ensure ongoing evaluation of compliance with established risk criteria; and
 - (8) A regular schedule of data review by the birth center's directors and the governing authority.
- (b) Case review. The birth center shall maintain complete, documented review of all adverse events, transfers, and sentinel events, which shall include root cause analysis. Reviews shall include collaborative review with any collaborating or referral providers as appropriate. The birth center shall develop and implement policies and procedures for collecting data, analyzing, and responding to sentinel events as required per accreditation standards.
- (c) Transfer review. All transfers of care from a birth center shall be documented. The birth center shall maintain records of all transfers, whether emergent or non-emergent, for seven years, and shall provide transfer review reports to the department upon request. Such transfer review reports shall include the following:
 - (1) Signature of the clinical director;
 - (2) Documentation of the reason for transfer including data on any recurrent causes of transfer; and
 - (3) Transfer reviews including analysis and plans to address any identified issues with compliance, policies and procedures, or risk assessment.
- (d) Adverse events. A birth center licensed pursuant to this section shall report adverse events in accordance with Section 19a-127n of the Connecticut General Statutes.
 - (1) The following adverse events shall be reported to the department:
 - (A) Any event listed on the National Quality Forum List of Serious Reportable Events;
 - (B) Each incidence of an emergent transfer of patient, newborn, or both;
 - (C) Maternal hemorrhagic shock or transfusion;
 - (D) Fetal or newborn death including a stillbirth;
 - (E) Traumatic physical or neurological birth injuries;
 - (F) Equipment malfunction or error resulting in death or serious injury of a patient;

- (G) Abuse or assault of a patient or staff member at the birth center facility; and
 - (H) Fires, disasters, or other emergency situations impacting the provision of birth center services.
- (2) All such adverse events listed in 19a-566-17(d)(1) of the Regulations of Connecticut State Agencies shall be reported by the birth center on forms prescribed by the commissioner as follows:
 - (A) An adverse event deemed emergent shall be reported immediately by telephone and confirmed by written or electronic report within twenty-four hours of occurrence;
 - (B) An adverse event not deemed emergent shall be reported by written or electronic report within seven days of occurrence;
 - (C) All adverse event reports shall contain the following information as requested on forms prescribed by the commissioner:
 - (i) Demographic data for the birth center;
 - (ii) Birth center information including birth center name and address, reporter's name, contact person's name and contact information;
 - (iii) Patient information;
 - (iv) Description of event and outcome;
 - (v) Documentation of notifications provided to patient and to any other entity listed in the adverse event reporting form, and
 - (vi) An immediate plan of action, which shall include the immediate care provided to the patient or patients and the immediate actions taken by the licensee to reduce the risk of a similar event occurring again.
 - (D) All adverse events reports shall be followed by a corrective action plan submitted to the department not later than thirty days after the occurrence of the adverse event. Such corrective action plan shall comply with the requirements of Section 19a-127n-2(f) of the Regulations of Connecticut State Agencies.
- (e) Data collection. All data collected in accord with this section shall be available to the department on request. Review of data shall be undertaken at regular intervals by the birth center's directors and governing authority. The birth center shall develop and implement a mechanism for up-to-date collection and analysis of data including, but not limited to:
 - (1) Case reviews in accord with policies and procedures developed pursuant to section 19a-566-17(b) of the Regulations of Connecticut State Agencies;
 - (2) Transfer data including calculated transfer rates by reason for transfer;
 - (3) Data on utilization of birth center services; and
 - (4) Patient feedback to assess patient satisfaction.

Sec. 19a-566-18. Infection control

- (a) Infection control. The birth center shall develop and implement policies and procedures to ensure adequate and standardized infection control measures in accord with CDC standards and

applicable federal and state laws and regulations. Infection control policies and procedures shall include but not be limited to the following:

- (1) Infection surveillance;
 - (2) Training of birth center staff at specified intervals to maintain knowledge and skills required for successful infection control policies and procedures;
 - (3) Documentation and reporting of infection data;
 - (4) Terminal cleaning of all facilities and equipment used after each family's discharge from the birth center;
 - (5) Food preparation facilities and equipment shall be kept separate from medications, laboratory, or utility areas;
 - (6) All contaminated equipment and supplies shall be physically separated from clean or sterilized equipment and supplies;
 - (7) Sterilization. The birth center shall provide or contract for sterilization services for reusable supplies and instruments. Such services shall include, but are not limited to, the following:
 - (A) Maintaining a log of sterilizer use;
 - (B) Regular cleaning of the sterilizing equipment;
 - (C) Staff training on the use of the sterilizing equipment; and
 - (D) Ensuring successful functioning of the sterilizing equipment at every use.
- (b) The birth center may develop and implement policies and procedures for issuing the placenta to the patient upon discharge in accord with section 19a-490v of the Connecticut General Statutes. If the birth center policies and procedures on the removal of placenta allow for storage of the placenta on site until the patient is discharged, the birth center shall maintain adequate separate refrigeration space for such storage.

Sec. 19a-566-19. Patients' rights

- (a) Each birth center shall develop and implement a written bill of patient rights. All patients and prospective patients of a birth center shall be informed of their rights. Patient rights shall be posted in the birth center and made available in writing to each patient prior to engaging to provide birth center services:
- (b) Patient rights shall include, but not be limited to, the rights to:
 - (1) Respectful and dignified treatment;
 - (2) Confidentiality in accord with federal and state laws and regulations;
 - (3) Information regarding the benefits, risks, limitations, and eligibility to receive care and deliver at a birth center;
 - (4) Information sufficient to participate in decision-making regarding their care;
 - (5) Information regarding the plans for transfer and emergency care for patients and newborns;
 - (6) Information regarding the birth center's health outcomes for maternal and infant care;
 - (7) Information regarding the licensure, privileges, and qualifications of all clinical staff and collaborating providers and facilities;

- (8) Information regarding the liability and malpractice insurance status of clinical staff;
- (9) Freedom from mistreatment, discrimination and abuse;
- (10) Information regarding grievance procedures against the birth center or a provider offering care at the birth center, including both internal procedures and procedures for a filing a complaint with the department;
- (11) Access to an on-call licensed maternity care provider on the birth center's clinical staff twenty-four hours a day and seven days a week; and
- (12) Receipt of a written statement of fees for all charges made by the birth center.

Sec. 2. Section 19-13-D14 of the Regulations of Connecticut State Agencies is repealed.

Statutory Authority

The statutory authority for the proposed regulations adding sections 19a-566-1 to 19a-566-19, inclusive, to the Regulations of Connecticut State Agencies, is Section 19a-566(c) of the Connecticut General Statutes.

Statement of Purpose

The purpose of the proposed regulations is to provide licensure procedures and standards of operations for birth centers, as defined in Section 19a-490 of the Connecticut General Statutes, to offer an out-of-hospital setting for the midwifery model of care for labor and delivery. The proposed regulations fulfill Section 19a-566 of the Connecticut General Statutes to set forth birth center requirements regarding accreditation, administration, liability coverage, the scope of services for patients and newborns, and personnel. The proposed regulations set forth standards for eligibility for birth center services, discharge criteria, and procedures for referral and collaboration with outside providers, and procedures for transfer of care when patient needs exceed the scope of services available at a birth center. Final proposed sections govern records, facilities, amenities, ancillary services including pharmaceutical and laboratory services, quality assurance, data collection and reporting, and patient rights.