

Birth Center Licensing Rule

1. Authority

This rule is adopted pursuant to 18 V.S.A. § 2359.

2. Purpose

This rule sets forth the standards that apply to the licensing of Birth Centers in Vermont as defined in 18 V.S.A. Chapter 53.

3. Definitions

3.1. “Birth center” means a facility the primary purposes of which are to provide midwifery care, low-risk deliveries, and newborn care immediately after delivery, for a stay of generally less than 24 hours. The term does not include:

3.1.1. A facility that is a hospital, is part of a hospital, or is owned by a hospital, although a birth center may be located on the grounds of a hospital;

3.1.2. A facility that is an ambulatory surgical center; or

3.1.3. The residence of the individual giving birth.

3.2. “Certified nurse midwife” means an advanced practice registered nurse licensed in accordance with 26 V.S.A. chapter 28, subchapter 2 who has specialized training in childbirth, newborn care, and reproductive health care services.

3.3. “Corrective action plan” means a plan that a licensee is required to submit to address any identified deficiency to bring the birth center into compliance with these rules and applicable law.

3.4. “Deficiency” means a policy, procedure, practice, or any other action by a birth center that results in the birth center not being in compliance with this rule or applicable laws.

3.5. “Department” means the Department of Health.

3.6. “Licensed maternity care provider” means a licensed provider whose professional scope of practice, as established under Vermont law, includes preconception, prenatal, labor, birth, and postpartum care and early care of a newborn and who may be the primary attendant during the perinatal period.

- 3.7. “Licensed midwife” means a professional licensed in accordance with 26 V.S.A. chapter 85.
- 3.8. “Licensed provider” means an individual licensed or certified in Vermont to provide specific health care-related services within a scope of practice defined by licensing statutes and rules, and may include advanced practice registered nurses, including certified nurse midwives; licensed midwives; physician assistants; naturopathic physicians with a childbirth endorsement in accordance with 26 V.S.A. §§ 4122(b) and 4125(b); and physicians.
- 3.9. “Patient complaint” means any expression of dissatisfaction related to the care and treatment provided by a Birth Center, from a patient or the patient’s representative.
- 3.10. “Risk factors” or “risk criteria” means factors present in the patient’s medical, social or obstetrical history, or developing during pregnancy, labor and birth, postpartum or in the neonate, that may increase the risk of complications or adverse outcomes and preclude out-of-hospital birth or continuing care in the birth center.

4. Incorporation by Reference

- 4.1. This rule incorporates by reference American Association of Birth Centers (AABC) Standards for Birth Centers as published on October 17, 2017, including any further revisions or amendments thereof, only to the extent that the provisions therein are not inconsistent with this rule.
- 4.2. This rule incorporates by reference Commission for the Accreditation of Birth Centers (CABC) Indicators for Compliance with Standards for Birth Centers Reference Edition 2.3, including any further revisions or amendments thereof, only to the extent that the provisions therein are not inconsistent with this rule.

5. Birth Center Licensing

5.1. General Provisions

- 5.1.1. No person shall establish, maintain, or operate a birth center in Vermont without first obtaining a license from the Department for the birth center.
- 5.1.2. No person shall represent itself as a “birth center” or use the term “birth center” in its title or in its advertising, publications, or other form of communication unless the

person has been licensed as a birth center in accordance with 18 V.S.A. Chapter 53 and this rule.

5.1.3. Every Vermont birth center license shall expire one year from the date of issuance of each year unless otherwise revoked.

5.2. License Application and Initial Inspection

5.2.1. An application for a birth center license or license renewal must be submitted using forms provided by the Department.

5.2.2. The application must contain all information required by the Department and be accompanied by a license fee in the amount required by 18 V.S.A. § 2353.

5.2.3. Applications for an initial license shall include:

5.2.3.1. Identifying information and facility location.

5.2.3.2. Proof of registration with the Vermont Secretary of State.

5.2.3.3. A chart or description of the birth center's ownership or organizational hierarchy, including the names of the owners.

5.2.3.4. All materials submitted by the birth center to the CABC as part of the accreditation process, including the accreditation application and self-evaluation report.

5.2.3.5. Documentation of a completed application for accreditation with the CABC.

5.2.3.6. A written plan for access to and use of emergency medical transport services that includes evidence of work to develop a collaborative relationship through meetings and drills. The written plan shall be shared with the emergency medical transport services.

5.2.3.7. A written plan for consultation with physicians and other health care providers, and for emergency transfer of an infant or a patient to an appropriate health care facility that includes a health care facility with 24/7 obstetric services and includes evidence of work to develop a collaborative relationship

through meetings and drills. The written plan shall be shared with the health care facilities.

5.2.3.8. The procedures and policies required under Section 6.2.2 - 6.2.9.

5.2.3.9. Any other information as required by the Department.

5.2.4. Upon receipt of a complete application for a license and the licensing fee, the Department or its designee will schedule an inspection of the applicant's buildings, grounds and records.

5.2.5. If the birth center is determined to be substantially in compliance with the standards in these Rules and applicable statutes, the Department may issue a license.

5.3. Inspections and Corrective Actions

5.3.1. The Department or its designee may conduct inspections of licensed birth centers, including routine inspections and inspections in response to complaints or grievances, as necessary.

5.3.2. A birth center, its building and grounds, and its records are subject to inspection by the Department or its designee at all times.

5.3.3. If the Department or its designee finds a birth center is out of compliance with any requirement in these rules or applicable statutes, the Department or its designee shall notify the birth center of the deficiency.

5.3.4. When notified of a deficiency, a birth center shall, within 30 days, or such shorter period as may be specified in the notice for good cause, develop and submit a corrective action plan for addressing any identified deficiencies and for achieving compliance with this rule and applicable statutes.

5.3.5. A corrective action plan shall identify the root cause of the deficiencies, outline procedures for correcting the deficiencies, and establish procedures for monitoring to ensure quality improvement and future compliance.

5.3.6. The Department shall determine whether a corrective action plan submitted pursuant to Section 5.3.4 of this rule is sufficient to effectively address each

identified deficiency and bring the birth center into compliance with the requirements of this rule and applicable statutes.

5.3.7. Within thirty (30) days after receipt of a corrective action plan, the Department shall notify the birth center whether the Department

5.3.7.1. Accepts the proposed corrective action plan; or

5.3.7.2. Requests a revision to the corrective action plan, specifying the reason for the request.

5.3.8. A birth center required to submit a revised corrective action plan shall develop and submit the revision within thirty (30) days during which time the Department or its designee shall make available a representative to review with the birth center any proposed revisions.

5.3.9. Notwithstanding the issuance of a corrective action plan, the Department may exercise any and all powers granted to it under Vermont law, including the authority to condition, suspend, deny, or revoke a birth center's license.

5.3.10. Deficiencies and violations of this rule and of corrective action plans shall be posted on the Department's website.

5.4. License Renewal

5.4.1. Licenses are valid for one year from the date of issuance. A license becomes inactive if not renewed by midnight on the date of expiration.

5.4.2. Renewal applications must be submitted using forms provided by the Department on or before the deadline set by the Department.

5.4.3. Renewal forms must contain all information required by the Department and be accompanied by a license renewal fee in the amount required by 18 V.S.A. 2353.

5.4.4. A birth center shall be accredited by the CABC to be eligible to renew a license.

5.4.5. Upon receipt of a complete application for a license renewal and the licensing fee, the Department or its designee may, at the Department's discretion, schedule an

inspection of the applicant's buildings, grounds and records to determine compliance with Section 6 of this rule.

5.5. Change of Ownership

- 5.5.1. Licenses are not transferable or assignable, and are only applicable to the premises and persons named in the application.
- 5.5.2. A licensed birth center changing ownership, closing or eliminating or significantly reducing services shall provide at least 90 days' advance notice to the Department and to its patients.
- 5.5.3. New owners shall apply to the Department for a new license as required in Section 5.2. New owners shall not operate a birthing center until they obtain a license from the Department.

5.6. License Posting

- 5.6.1. The birth center license must be posted in a conspicuous place on the licensed facility's premises.

5.7. License Denial, Suspension, Revocation

- 5.7.1. The Department may condition, deny, suspend, or revoke a birth center license if it finds that there has been a substantial failure to comply with the requirements established in this rule or applicable statutes.
 - 5.7.1.1. If the Department finds that public health, safety, or welfare imperatively requires emergency action, and incorporates a finding to that effect in its notice, summary suspension of a birth center's license may be ordered pending proceedings for conditioning, denying, suspending, or revoking a birth center's license.
 - 5.7.1.2. A hearing on an order of summary suspension proceedings shall be instituted and held in compliance with Section 5.7.3 within five (5) business days of the initial summary suspension and an order shall be issued within two (2) business days of the conclusion of the hearing.
- 5.7.2. When the Department or its designee finds that a birth center has substantially failed to comply with the requirements established in this rule or applicable statutes,

the Department shall serve a written notice to the birth center by registered mail or by personal service. The notice shall set forth the reasons for the proposed action, and shall set a date not less than 60 days from the date of the mailing or service on which the applicant or licensee shall be given opportunity for a hearing.

5.7.3. The hearing shall be before the Commissioner or designee.

5.7.3.1. At a hearing, a birth center shall have the opportunity to respond to the Department's findings and reasons included in the notice sent pursuant to Rule 5.7.2 and to present evidence and argument regarding the same.

5.7.3.2. The Department shall have an opportunity to present evidence and argument to support its findings and reasons included in the notice sent pursuant to Rule 5.7.2 and to respond to a birth center's response made in accordance with Rule 5.7.3.1.

5.7.4. After the hearing, or upon default of the applicant or licensee, the Commissioner shall file its findings of fact and conclusions of law and send a copy of the findings and decision by registered mail or serve the copy personally upon the applicant or licensee.

5.7.5. Any applicant or licensee aggrieved by the decision of the Commissioner after a hearing may appeal the decision in accordance with 18 V.S.A. § 128.

6. Standards for Birth Center Licensure

6.1. Accreditation

6.1.1. To obtain an initial license in Vermont, each birth center shall have submitted a complete application for CABC accreditation before applying for a license.

6.1.2. To renew and retain licensure, each birth center shall have current accreditation from the CABC.

6.1.3. If the birth center loses its accreditation or has its accreditation restricted, the birth center must immediately notify the Department and its patients.

6.1.4. Upon request, the birth center shall provide the Department or designee with any material submitted by the birth center to the CABC and from the CABC to the birth

center as part of the accreditation process, including the accreditation application, self-evaluation report, accreditation decision letter from the CABC, any progress reports or interim status reports submitted by the birth center to the CABC, and any reports from the CABC following a site visit.

6.1.5. Notwithstanding the CABC's determination that a birth center is in substantial compliance with all CABC indicators, the Department or its designee may:

6.1.5.1. Inspect, independently review, or investigate a birth center at any time to determine whether a birth center is in compliance with these rules and applicable statutes; and

6.1.5.2. Require a corrective action plan in accordance with these Rules; and

6.1.5.3. Condition, suspend, deny or revoke a birth center's license if the Department finds the birth center is not in substantial compliance with these rules and applicable statutes.

6.2. Standards: To be licensed and retain licensure in Vermont, each birth center must meet and demonstrate substantial compliance with all of the following requirements.

6.2.1. **Standards and Indicators:** A birth center shall demonstrate and remain in compliance with AABC's Standards for Birth Centers and the CABC's Indicators for Compliance with Standards for Birth Centers, including all critical and required indicators of compliance.

6.2.2. **Accreditation:** A birth center shall remain accredited after initial accreditation. Loss or restriction of accreditation may result in a corrective action plan in accordance with Section 5.3 or suspension, conditioning, denial, or revocation of a license.

6.2.3. **Scope of Services:** A birth center shall perform a limited scope of services as follows:

6.2.3.1. A birth center shall provide only prenatal care, low-risk deliveries, newborn care, and postpartum care.

6.2.3.2. The use of general or regional anesthesia, including epidurals, is prohibited.

- 6.2.3.3. Local anesthesia, systemic analgesia, nitrous oxide, and other forms of pain relief may be administered at the birth center if it is performed within the provider's scope of practice, and as determined by the birth center's policies and procedures.
- 6.2.3.4. Labor shall not be induced, stimulated, or augmented with pharmacologic agents during the first or second stages of labor or before labor.
- 6.2.3.5. Surgical services must be limited to those normally performed during an uncomplicated birth, including repairing tears or performing and repairing episiotomies as necessary per scope of practice. No operative obstetrics or cesarean sections shall be performed.
- 6.2.3.6. The use of vacuum extractors, vaginal forceps, or continuous electronic fetal monitoring is prohibited.
- 6.2.3.7. Nothing in this rule shall be construed to expand or limit the scope of the services that a licensed midwife, certified nurse midwife, or other provider may offer at a birth center or perform in a space that is shared with or adjacent to a birth center.
- 6.2.3.8. All licensed providers must provide health care-related services only within their scope of practice and in compliance with the relevant licensing statutes and rules.
- 6.2.3.9. A birth center may serve as a location for additional services offered in shared or adjacent spaces, including outpatient gynecologic care, primary care, and education and support services, provided that any licensed provider providing services in those spaces shall only provide those services that are within the licensed provider's authorized scope of practice.
- 6.2.3.9.1. Services offered and performed by the birth center are subject to these rules and statutes governing birth centers, regardless of whether the services are provided in a shared or adjacent space.
- 6.2.3.10. Licensed providers may prescribe or administer medications only as allowed by their respective authorized scope of practice.

6.2.4. **Risk Factors, Risk Criteria:** A birth center shall not provide services to patients who have risk factors or risk criteria which, when present, would preclude the patient from being considered a low-risk patient, and make the patient ineligible for a birth center birth. Birth centers shall ensure ongoing risk assessments are conducted.

6.2.4.1. Risk factors or risk criteria that preclude a patient from receiving services at a birth center include, but are not limited to:

- 6.2.4.1.1. More than one cesarean birth;
- 6.2.4.1.2. Classical uterine scar;
- 6.2.4.1.3. BMI greater than defined limits;
- 6.2.4.1.4. Preexisting diabetes;
- 6.2.4.1.5. Medication-dependent gestational diabetes (with exception of metformin);
- 6.2.4.1.6. Chronic hypertension with or without medication;
- 6.2.4.1.7. Known breech or non-vertex presentation at the onset of labor or delivery;
- 6.2.4.1.8. Multiple gestation, including twins;
- 6.2.4.1.9. Gestation less than 36 weeks and 0 days, or greater than 42 weeks and 0 days;
- 6.2.4.1.10. Other risk factors or risk criteria established by the birth center or the Department.

6.2.4.2. A birth center shall ensure the ongoing assessment of patients seeking perinatal care to determine whether the patient continues to not have any risk factors or criteria.

6.2.5. **Staffing:** A birth center must have adequate and competent staffing consistent with the scope of services in order to provide safe maintenance and operation of the birth center.

- 6.2.5.1. The birth center shall develop a staffing pattern consistent with the caseload and size of the birth center.
 - 6.2.5.2. A birth center shall ensure all staff have documentation of the training required to provide the services offered by the birth center and their job duties, including professional licenses and required certifications.
 - 6.2.5.3. All licensed providers on staff shall have certification of current training in neonatal and adult resuscitation.
 - 6.2.5.4. The birth center shall ensure 24-hour staffing coverage by licensed maternity care providers and appropriate support staff.
 - 6.2.5.5. The birth center shall ensure at least one licensed maternity care provider is present at each labor and birth. A second person who is a licensed provider must be immediately available in the building at each labor and birth.
- 6.2.6. **Collaboration, Transfer and Services Policies:** In addition to plans for emergency transport and emergency transfer of clients and newborns, a birth center shall have policies and procedures in place for collaboration with hospitals, agencies, other facilities, and individuals to provide services to patients. These policies and procedures must be provided to the relevant service providers and the Department, along with any agreements with these entities, and must include:
- 6.2.6.1. Obstetric and pediatric consultation, referral, transfer of care;
 - 6.2.6.2. Emergency transfer and transport of a newborn to a newborn nursery or neonatal intensive care nursery;
 - 6.2.6.3. Emergency transfer or transport of a patient to an appropriate hospital when additional care is necessary, including at least one hospital with 24/7 obstetric services;
 - 6.2.6.4. Laboratory and diagnostic services; and
 - 6.2.6.5. Community education and home health services.

6.2.7. **Pharmaceuticals:** A birth center shall comply with State and federal laws regarding obtaining, storing, possessing, prescribing, administering, and dispensing drugs, as that term is defined in 26 V.S.A. § 2022(6).

6.2.7.1. A birth center shall ensure that all drugs, including controlled substances, are possessed, obtained, stored, prescribed, administered, and dispensed by a licensed provider in accordance with their professional scope of practice, and in accordance with all applicable federal and state laws.

6.2.7.2. Drugs shall be handled and stored in a safe and effective manner, as determined by the birth center's policies and procedures, and the drug manufacturer's instructions, and applicable state and federal laws.

6.2.7.3. If controlled substances are kept at the birth center, they shall be stored pursuant to federal and state law.

6.2.8. **Facility, Equipment and Supplies:** A birth center shall ensure that the facility, equipment, and supplies in a birth center are maintained to ensure safety, sanitation, and health of patients and staff. A birth center shall:

6.2.8.1. Comply with applicable federal, state and local codes, regulations and ordinances for construction, fire prevention, public safety and accessibility;

6.2.8.2. Ensure the regular inspection, maintenance and cleaning of facility, equipment and supplies; and

6.2.8.3. Have an adequate amount of supplies for routine and emergency care of patients.

6.2.9. **Record Retention and Confidentiality:** A birth center shall maintain patient records and ensure confidentiality of those records according to applicable law. A birth center shall:

6.2.9.1. Maintain a health record for every patient for the purposes of making decisions about the patient's care and for continuity and evaluation of care, in accordance with professional standards;

6.2.9.2. Document any organized care and services provided to the patient in a way to easily facilitate the accessibility of information;

- 6.2.9.3. Update records accurately, appropriately and in a timely manner;
- 6.2.9.4. Provide a complete record in the event of a transfer of care;
- 6.2.9.5. Retain and disclose records in accordance with federal and state privacy and other applicable laws;
- 6.2.9.6. Ensure records are confidential, and prevented from loss, destruction, unauthorized use or disclosure; and
- 6.2.9.7. Allow patients to access their own records in accordance with state and federal law.

6.2.10. Complaint Process and Tracking: A birth center shall have and comply with processes for filing and receiving complaints, communicating the complaint process to patients, responding to complaints, and tracking complaints, including:

- 6.2.10.1. A process for providing all patients entering care with written information regarding:
 - 6.2.10.1.1. How and where a patient can make a complaint with the birth center and appeal a decision regarding a complaint made by the birth center;
 - 6.2.10.1.2. How the complainant can contact the Department, the Vermont Office of the Healthcare Advocate, the Board of Medical Practice, and the Office of Professional Regulation;
 - 6.2.10.1.3. A time frame for processing and resolving complaints and appeals within the birth center; and
 - 6.2.10.1.4. A description of internal procedures for receiving, processing, responding to and resolving complaints from or filed on behalf of patients.
- 6.2.10.2. Procedures for responding to patient complaints, including a time frame for processing, resolving, and appealing complaints.

6.2.10.3. Procedures for maintaining complaint records.

6.2.10.4. Procedures for tracking complaints and reporting to the Department annually in accordance with Section 6.2.11.

6.2.11. Annual Report of Complaints: A birth center shall report the following to the Department annually:

6.2.11.1.1. The number of patients served during the licensing period;

6.2.11.1.2. The total number of complaints received;

6.2.11.1.3. The total number of complaints in each of the categories the birth center uses to track complaints; and

6.2.11.1.4. A brief narrative report describing examples of actions taken to resolve complaints during the licensing period.

6.2.12. Quality Assurance and Improvement: A birth center shall ensure there is a process in place for evaluating the quality of care provided to patients and the environment in which the services are provided. The process must include:

6.2.12.1. Ongoing monitoring and evaluation of the birth center's program of care;

6.2.12.2. A mechanism to review and respond to patient feedback and complaints;

6.2.12.3. Documentation and review of adverse events;

6.2.12.4. Documentation and review of emergent transfers, including appropriateness and quality of transfer;

6.2.12.5. Regular review of health records for accuracy, completeness, and compliance with applicable state and federal laws;

6.2.12.6. In-service drills with all clinical staff; and

6.2.12.7. Annual reviews of protocols, policies and procedures.

6.2.13. Written Policies, Guidelines and Protocols: A birth center shall have written practice policies, guidelines or protocols on topics in Sections 6.2.3 - 6.2.12, in addition to any required by the CABC Indicators for Compliance with Standards for Birth Centers. The birth center shall continuously comply with these processes and policies and make these available to the Department or its designee for review and inspection.

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