

Summary of Changes to Birthing Center Rules OAR chapter 333, division 077

Administrative Rules are Effective November 3, 2025

The Health Care Regulation and Quality Improvement (HCRQI) Section has permanently amended and renumbered administrative rules for Freestanding Birthing Centers (Birthing Centers).

- **New applicants for licensure:** Any individual or organization applying for a Birthing Center license on or after November 3, 2025, must fully comply with the revised rules.
- **Existing licensees**: Birthing Centers licensed before November 3, 2025, must transition to the revised rules by July 1, 2026.
- During the transition period: Until a licensed Birthing Center achieves full compliance with the revised rules, it must continue to follow the <u>rules that were</u> in effect as of November 2, 2025.

Several new rules have been adopted that address standard operating procedures that apply to all licensed facility types. These rules include:

- The license application process review, approval, denial, expiration, renewal, suspension, or revocation;
- Request for waivers;
- Complaint procedures and investigations;
- In-person licensing surveys;
- · Enforcement actions; and
- Civil penalties.

The following summaries of rules are provided for awareness, based on changes made, and are not a full description of the requirements for each rule. It is each Birthing Center's responsibility to review the entire set of regulations and comply with requirements based on the applicable dates noted above.

OAR 333-077-0070 – Governing Body Responsibility

The responsibilities of the Birthing Center's governing body have been clarified. The governing body must:

- Employ or contract with an administrator or chief executive officer;
- Establish an organizational plan that sets forth policies, procedures, by-laws, and clinical provider responsibilities and accountability;
- Establish scope of services, administrative policies and procedures, responsibilities for the operation of the Birthing Center; and
- Establish qualifications for an administrator.

The governing body must ensure that:

- Client care is under the supervision of a manager who is a licensed direct entry midwife, certified nurse midwife, or a physician, as those terms are defined in rule;
- There are personnel, facilities, equipment, supplies, and other services to meet the needs of clients;
- All clinical providers admitted to practice, effectively review the professional practices of the Birthing Center for purposes of reducing morbidity and mortality and for improving client care; and
- There is a quality improvement program to ensure that performance improvement activities of clinical staff result in continuous improvement of client health outcomes.

OAR 333-077-0080 - Personnel

The Birthing Center must have enough clinical staff on duty and on-call to provide effective client care and other related services.

- One clinical staff person trained in the use of emergency equipment and certified in neonatal resuscitation must be on-duty at all times a client is present.
- One <u>clinical provider</u> must be present at each birth and a second <u>clinical staff</u> person trained in the use of emergency equipment and certified in neonatal resuscitation must be present during each birth.
- Clinical staff must maintain certification in CPR.

OAR 333-077-0090 - Policies and Procedures

Requirements for policies and procedures include, but are not limited to:

- Types of services and procedures that will be provided;
- Staff training requirements;
- Systems for ensuring 24-hour coverage;

- Client care and services activities;
- Admission and discharge criteria;
- Assessment of risk and consultation;
- Infection control requirements;
- Equipment storage, maintenance and sterilization;
- Provision of life saving measures; availability of emergency transportation;
- Newborn screening; and
- Procedures for providing health care interpreter services to clients who prefer to communicate in a language other than English.

OAR 333-077-0100 – Client Services

Clients registering for care shall receive an orientation and written information about services to be provided. Clients must receive a statement of client rights and disclosures. Minimum services that must be provided to a client, including intrapartum and postpartum care are identified.

A client's risk status must be assessed throughout pregnancy, labor, and delivery by the Birthing Center to determine if receiving care from the Birthing Center is appropriate.

The rule makes provisions for the use of telemedicine through synchronous communication.

OAR 333-077-0110 - Admission and Discharge

A Birthing Center shall only admit a client for whom medical history, physical exam, laboratory screening, and risk assessment do not exclude them from receiving care and services. Clients who meet certain risk factor criteria must be referred to an appropriate health care provider or facility. Discharge plans must be developed and communicated to the client and must include provisions for newborn screening follow-up care and whether a follow-up visit is necessary.

OAR 333-077-0120 – Client Transfer

A Birthing Center must have a policy for essential lifesaving measures, stabilization, and immediate transfer of a client or newborn to a hospital for medical care that exceeds the capability of the Birthing Center. This rule specifies minimum requirements for the policy. The rule further acknowledges that imminent fetal delivery may delay or preclude transfer prior to birth.

OAR 333-077-0125 – Risk Status Assessment and Consultation Requirements A clinical provider at the Birthing Center is responsibility for assessing a client's risk status throughout pregnancy to determine whether the client may continue to receive care and services, including delivery, in a Birthing Center.

- New risk factor tables have been adopted. Risk factors identified in the tables
 are not comprehensive and other conditions may arise that may require further
 consultation or transfer to a hospital.
- An in-person risk assessment be completed within the first 21 days after the
 first prenatal care visit, and risk assessments must be updated throughout the
 pregnancy, labor, and delivery. Appropriate referral to a hospital must be
 prompt if the client, fetus, or newborn meet any of the exclusion criteria
 identified in the relevant risk factor table.
- Based on the risk assessment findings and associated risk factor tables, a
 Birthing Center clinical provider may be required to consult with a certified
 nurse midwife, licensed direct entry midwife, physician, physician associate, or
 nurse who has experience handling complications of the risk factor(s) found.
- A client must be present for the consultation, or if the client is unavailable, the client must be notified about any findings and recommendations suggested by the consultant.
- Outcomes of the consultation and decisions made about the plan of care must be implemented and documented.
- A client who must be referred or transferred to higher level of care based on a risk assessment may continue to receive prenatal care at the Birthing Center if certain criteria are met.

OAR 333-077-0130 - Medical Records

Medical records must be maintained for each client and newborn and they must be completely and accurately documented, readily available, and organized for easy retrieval of information. Minimum documentation requirements are specified.

All entries in the client's labor records must be promptly dated and authenticated. If an entry is made 48 hours after care has been provided, the entry must be identified as an addendum or an amended entry and must include the date and time of entry.

The completion of the medical record is the responsibility of the attending clinical provider.

In the even that a client must be transferred, the Birthing Center must ensure that the client's medical history, prenatal flow sheet, diagnostic studies, laboratory findings, and client and newborn care notes accompany the client to the care of another clinician or hospital-based care.

As part of a Birthing Center's quality assessment and performance improvement program, it must measure and evaluate its documentation of care, including timeliness of documentation, and shall implement performance improvement activities based on the evaluation.

OAR 333-077-0140 - Surgical Services

Surgical procedures are limited to those directly related to pregnancy, labor, and delivery care. Only procedures typically performed during uncomplicated childbirth—such as episiotomy and its repair—are permitted and must fall within the provider's clinical scope of practice. Tubal ligations and abortions are strictly prohibited.

OAR 333-077-0145 - Laboratory Services

Laboratory services must be provided or made available using a licensed clinical laboratory that meets the requirements of ORS chapter 438 and OAR chapter 333, division 024.

OAR 333-077-0150 - Pharmacy and Anesthetic Services

Medication must be handled by clinical providers within their licensed scope of practice. The clinical provider is responsible for:

- Administering the correct medication and dosage to clients;
- Ensuring proper labeling in accordance with the standards adopted by the Oregon Board of Pharmacy;
- Determining whether the Birthing Center must register as a Dispensing Practitioner Drug Outlet; and
- Maintaining a compliant system for medication inventory and monitoring.

OAR 333-077-0160 - Dietary Services

The Birthing Center must be able to store, refrigerate and reheat food to meet the needs of its clients.

- Refrigerator use, including temperature control of foods is specified;
- Food brought by a client must be labeled, ready-to-eat, and discarded after service;
- Food prepared after admission must be consumed within 24 hours or discarded after discharge;
- All staff handling food must complete a certified food handler training.
- The Birthing Center may arrange for food service through an external vendor and have delivered.
- Utensils must be provided by the Birthing Center and sanitized in accordance with OAR chapter 333, division 150, chapter 4 (parts 4-5, 4-6, and 4-7) or alternatively, the Birthing Center may provide single-use utensils or provide specific notice to clients regarding sanitation.
- All food service equipment and surfaces must be kept clean and in good repair. Surfaces that come in contact with food must be washed, rinsed, and sanitized after each use in accordance with OAR chapter 333, division 150, chapter 4 (parts 4-5, 4-6, and 4-7).

800 NE Oregon Street, Suite 465, Portland, OR, 97232 Voice: (971) 673-0540 | Fax: (971) 673-0556 | All relay calls accepted http://www.healthoregon.org/hflc | mailbox.hclc@odhsoha.oregon.gov

OAR 333-077-0170 - Newborn Care and Screening

Various newborn screenings and care are required pursuant to other rules adopted by the Oregon Health Authority including administering Vitamin K, metabolic disease screening, newborn hearing screening, evaluation and treatment for gonococcal conjunctivitis, and pulse oximeter screening.

OAR 333-077-0180 – Equipment and Supplies

The Birthing Center must have and must maintain appropriate equipment and other supplies required to provide care for a client and newborn and must be able to provide emergency procedures in a life-threatening event.

- Minimum equipment requirements are specified in the rule.
- Equipment and supplies must be regularly maintained and tested, and there must be enough supplies to meet the needs of clients.
- Appropriate infection control procedures must be implemented.

OAR 333-077-0190 - Infection Control

A Birthing Center must establish and maintain an infection control program that is managed by a qualified individual and overseen by a committee responsible for investigating, controlling, and preventing infections in the Birthing Center.

- Infection control policies must be adopted and reviewed annually, including a plan to assess and screen employees for Tuberculosis.
- The Birthing Center must comply with regulations in regard to control of communicable diseases – OAR chapter 333, divisions 019 and 056.
- The Birthing Center must comply with Oregon Occupational Safety and Health Division regulations relating to bloodborne pathogen standards – OAR 437-002-0360(2).
- Infection control procedures for cleaning, disinfection, and sterilization of client care equipment must comply with the Centers for Disease Control and Prevention, "Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008 – May 2019."

OAR 333-077-0200 – Quality Assessment and Performance Improvement
A Birthing Center must implement a facility-wide quality assessment and
performance improvement program to ensure that services meet quality standards
and to maintain and improve client health and safety and reduce medical errors.

- The Birthing Center must measure, analyze and track quality indicators, adverse client events, infection control and other aspects of performance that includes care and services provided in the Birthing Center.
- Quarterly activities are required and must be documented.

- Facility-wide preventive strategies must be developed and implemented after an analysis of the causes of an adverse event and staff must be trained to ensure familiarity with preventive strategies.
- Priorities for performance improvement activities must be set.

OAR 333-077-0210 – Facility Safety and Emergency Preparedness Client care must be provided in a functional, clean, sanitary, safe, and comfortable setting.

- The building must be kept clean and in good repair and measures must be taken to prevent rodents, flies and other insects.
- Provisions must be made for proper cleaning of linen and other washable goods.
- Provisions must be made for proper disposal of all garbage.
- An emergency preparedness plan mut be developed and maintained. The plan must:
 - Include an assessment of potential hazards;
 - Strategies for addressing issues identified in the assessment;
 - Contact information for local emergency management; and
 - Development and annual review of an emergency preparedness policy.
- Emergency preparedness policy and procedures must be adopted, as well as an orientation and training program.
- Two drills must be conducted every year that document and demonstrate the staff have practiced specific duties and assignments in the emergency preparedness plan.

OAR 333-077-0220

New physical environment requirements have been adopted for new facilities being constructed and when a facility is being altered or renovated.

- A Birthing Center must meet all applicable local, state, or federal building and specialty codes.
- Any subsequent modifications to the facility after initial licensure must comply with relevant rules and regulations in effect at the time of modification.
- The Birthing Center must continue to meet all building standards including structural, mechanical, electrical, plumbing, and fire and life safety codes.
- Minimum requirements that must be met for the building space for security and safety, site and exterior, birthing suites, support areas including support areas for visitors and staff, and materials and finishes are specified.
- A Birthing Center may request a waiver from physical environment standards under certain conditions.