



RULE-MAKING ORDER

PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: July 15, 2025

TIME: 5:09 PM

WSR 25-15-078

Agency: Department of Health

Effective date of rule:

Permanent Rules

- ☒ 31 days after filing.
☐ Other (specify) _____ (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

- ☐ Yes ☒ No If Yes, explain:

Purpose: Chapter 246-329 WAC, Childbirth Centers. The adopted rules revise and update industry language, licensing requirements, and operational standards for birthing centers. The adopted rules amend WAC 246-329-005 through 246-329-990 and establish a new section WAC 246-329-125.

The adopted rules update chapter 246-329 WAC to current industry and department standards to promote safe and quality care for clients receiving labor and delivery services from licensed birthing centers. The adopted rule:

- Has significant restructuring within many of the rule sections in order to clarify clinical staff and birthing center responsibilities.
- Updates requirements and terminology to reflect current industry standards and practices.
- Removes certain requirements that are either no longer relevant, determined to be duplicative, or overly restrictive.
- Adds a range of new and amended requirements that will promote increased safety and quality of care, and improved access to labor and delivery services.

Rule amendments were necessary because:

- The licensing rules had not been updated since 2007 and did not reflect current industry and department standards.
- The existing rules contained certain requirements that were either no longer relevant, determined to be duplicative, or overly restrictive.
- New and amended requirements were needed to promote increased safety and quality of care, and improve access to labor and delivery services.
- To update the definition of "low risk" pregnancy.

Citation of rules affected by this order:

New: WAC 246-329-125

Repealed: None

Amended: WAC 246-329-005, 246-329-010, 246-329-020, 246-329-025, 246-329-030, 246-329-045, 246-329-055, 246-329-065, 246-329-075, 246-329-085, 246-329-095, 246-329-110, 246-329-120, 246-329-130, 246-329-140, 246-329-150, 246-329-160, 246-329-170, 246-329-180, and 246-329-990.

Suspended: None

Statutory authority for adoption: RCW 18.46.060 and 43.70.250

Other authority: None

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 25-09-095 on April 18, 2025 (date).

Describe any changes other than editing from proposed to adopted version: None

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

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**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

The number of sections adopted at the request of a nongovernmental entity:

New	<u>1</u>	Amended	20	Repealed	<u>0</u>
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The number of sections adopted on the agency's own initiative:

New	<u>1</u>	Amended	<u>20</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>1</u>	Amended	<u>20</u>	Repealed	<u>0</u>
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The number of sections adopted using:

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>1</u>	Amended	<u>20</u>	Repealed	<u>0</u>

Date Adopted: July 15, 2025

Name: Kristin Peterson, JD for Dennis E. Worsham

Title: Chief of Policy for Secretary of Health

Signature:



Chapter 246-329 WAC
((CHILDBIRTH)) BIRTHING CENTERS

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-005 Scope and purpose. (1) These rules implement chapter 18.46 RCW which requires the department of health to set minimum health and safety standards for ~~((childbirth))~~ birthing centers.

(2) Applicants and licensees must meet the requirements of this chapter and other applicable state and local laws.

(3) This chapter does not apply to services provided by persons exempt from requirements of chapter 18.46 RCW.

(4) A ~~((childbirth))~~ birthing center may not provide services unless the ~~((childbirth))~~ birthing center is licensed under this chapter.

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-010 Definitions. For purposes of this chapter, the following words and phrases will have the following meanings unless the context clearly indicates otherwise:

(1) "Administration of drugs" means an act in which a single dose of a prescribed drug or biological is given to a ~~((client))~~ patient by an authorized person in accordance with all laws and rules governing these acts. The complete act of administration entails removing an individual dose from a previously dispensed, properly labeled container, including a unit dose container, verifying it with the orders of a practitioner who is legally authorized to prescribe, giving the individual dose to the proper ~~((client))~~ patient and properly recording the time and dose given.

(2) "Applicant" means a person or entity seeking licensure as a ~~((childbirth))~~ birthing center under this chapter.

(3) "Authenticated or authentication" means authorization of ~~((a written))~~ an entry in a record by means of a written or electronic signature which ~~((shall))~~ must include, minimally, first initial, last name, and title or unique identifier verifying accuracy of information.

(4) "Bathing facility" means a bathtub or shower.

(5) "Bathroom" means a room containing a toilet and a handwashing sink. A bathroom must provide privacy by way of walls or other provisions. A bathroom may or may not include a bathtub or shower. A bathroom that exists inside of a birthing room does not need an additional handwashing sink nor additional privacy walls.

(6) "Birthing center" ~~((or "childbirth center"))~~ or "birth center" means any health facility, not part of a hospital or in a hospital, that provides facilities and clinical staff to support a birth service to low-risk maternity clients and their newborns. This chapter does not apply to any hospital approved by the American College of

Surgeons, American Osteopathic Association, or its successor. A birthing center is considered B occupancy according to state adopted building codes.

((+6+)) (7) "Birthing room" means a room designed, equipped, and arranged to provide for the care of a ~~((woman and))~~ patient and their newborn and to accommodate ~~((her))~~ their support ~~((person or persons))~~ people during the process of vaginal childbirth~~((,))~~ (the three stages of labor and recovery of ~~((a woman))~~ both patient and newborn).

((+7+)) (8) "Birth service" means the ~~((prenatal,))~~ intrapartum~~((,))~~ and immediate postpartum care provided for low-risk maternity clients, including newborn care during transition and stabilization.

((+8+)) (9) "Client" means a ~~((woman, fetus, and newborn))~~ pregnant or postpartum patient, receiving care and services provided by a birth center during ~~((pregnancy and childbirth and recovery))~~ labor, birth, and immediate postpartum.

((+9+)) (10) "Clinical staff" means physicians and midwives, including contractors, appointed by the governing body or their representative to practice within the birth center and governed by rules and policies and procedures approved by the governing body.

((+10+)) (11) "Consultation" means the process used by the clinical staff of a ~~((childbirth))~~ birthing center who maintain primary management responsibilities for the ~~((client's))~~ client or newborn's care to seek the opinion of a licensed ~~((physician))~~ health care provider on clinical issues that are ~~((client))~~ patient specific. The ~~((physician))~~ health care provider consulted must be qualified by training and experience in the specific ~~((client))~~ patient need for which consultation is sought. ~~((Consultation, appropriate to client need, must be available during all times birth services are provided in a childbirth center.~~

((+11+)) (12) "Contractor" means an individual who has a written contract with a ~~((birth))~~ birthing center licensee to provide birth services. The written contract must be approved by the governing body or their representative, ~~((including appointment))~~ and must include documentation of specific clinical privileges ~~((by the governing body))~~ granted. Birth services provided by contractors in licensed ~~((birth))~~ birthing centers must meet requirements of this chapter, unless otherwise noted.

((+12+)) (13) "Department" means the Washington state department of health.

((+13+)) (14) "Emergency" means a medical emergency or injury requiring immediate medical or surgical intervention to prevent death or disability.

((+14+)) (15) "Emergency transfer" means the transfer of a ~~((maternal))~~ client ~~((or newborn))~~ in an emergent situation to a facility that can manage obstetrical and neonatal emergencies beyond the scope of community birth, including the ability to perform cesarean delivery.

((+15+)) (16) "Governing body" means the person or persons responsible for establishing and approving the purposes and policies and procedures of the ~~((childbirth))~~ birthing center.

((+16+)) (17) "Hospital" means any institution, place, building, or agency ~~((which provides))~~ providing accommodations, facilities, and services ~~((over a continuous period of twenty-four hours or more, for observation, diagnosis, or care, of two or more individuals not related to the operator or suffering from any other condition which obstetrical, medical, or surgical services would be appropriate for care or diagnosis.~~ "Hospital" as used in this definition includes facili-

ties licensed under chapter 70.41 RCW. "Hospital" as used in this definition does not include:

(a) Hotels, or similar places furnishing only food and lodging, or simply, domiciliary care;

(b) Clinics or physicians' offices where patients are not regularly kept as bed patients for twenty-four hours or more;

(c) Nursing homes, defined and licensed under chapter 18.51 RCW;

(d) Childbirth centers licensed under this chapter and chapter 18.46 RCW;

(e) Psychiatric hospitals, licensed under chapter 71.12 RCW; or

(f) Any other hospital or institution specifically intended for use and the diagnosis and care of those suffering from mental illness, mental retardation, convulsive disorders, or other abnormal mental conditions. Nothing in this definition shall be construed as authorizing the supervision, regulation, or control of the remedial care or treatment of residents or patients in any hospital conducted for those who rely primarily upon treatment by prayer or spiritual means in accordance with creed or tenets of any well-recognized church or religious denomination.

(17) "Lavatory" means a plumbing fixture designed and equipped with a handwash device.

(18) "Low-risk maternal client" means an individual who:

(a) Is at term gestation, in general good health with uncomplicated prenatal course and participating in ongoing prenatal care, and prospects for a normal uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health;

(b) Has no previous major uterine wall surgery, cesarean section, or obstetrical complications likely to recur;

(c) Has no significant signs or symptoms of anemia, active herpes genitalia, placenta praevia, known noncephalic presentation during active labor, pregnancy-induced hypertension, persistent polyhydramnios or persistent oligohydramnios, abruptio placenta, chorioamnionitis, known multiple gestation, intrauterine growth restriction, or substance abuse;

(d) Is in progressive labor; and

(e) Is appropriate for a setting where methods of anesthesia are limited.) as defined in chapter 70.41 RCW.

(18) "Low-risk pregnancy" means a normal, uncomplicated prenatal course as determined by documentation of adequate prenatal care, and anticipation of a normal uncomplicated labor and birth, as defined by reasonable and generally accepted criteria of maternal and fetal health and adopted by the Commission for the Accreditation of Birth Centers (CABC) indicators of compliance with standards for birth centers, reference edition 2.3, effective September 15, 2023.

(19) "Midwife" means a person licensed under chapter 18.79 RCW, or chapter 18.50 RCW, Midwifery.

(20) "Newborn" means a baby delivered by the pregnant client who is admitted to the birth center. Newborns are admitted to the birth center at delivery and receive care by the clinical staff at the birth center until discharge.

(21) "New construction" means any of the following:

(a) New buildings to be used as a birth center;

(b) Addition or additions to an existing building or buildings to be used as a ((childbirth)) birthing center;

(c) Conversion of existing buildings or portions thereof for use as a ((childbirth)) birthing center;

(d) Alterations or modifications other than minor alterations. "Minor alterations" means any structural or physical modification within an existing birth center which does not change the approved use of a room or an area. Minor alterations performed under this definition do not require prior review of the department; however, this does not constitute a release from other applicable requirements;

(e) Changes in the approved use of rooms or areas of the birth center.

~~((+21+))~~ (22) "Patient" means a client or newborn who is admitted to the birth center and under the care of the clinical staff.

(23) "Person" means any individual, firm, partnership, corporation, company, association, or joint stock association, and the legal successor thereof.

~~((+22+))~~ (24) "Personnel" means individuals employed by the birth center, contractors of the birth center, students and volunteers.

~~((+23+))~~ (25) "Physician" means a person licensed under chapter 18.71 RCW, "Physicians," and rules adopted under chapter 246-919 WAC or chapter 18.57 RCW, "Osteopathy—Osteopathic medicine and surgery," and rules adopted under chapter 246-853 WAC.

~~((+24+))~~ (26) "Referral" means the process by which the clinical staff of a ~~((childbirth))~~ birthing center directs the ~~((client))~~ patient to a ~~((physician))~~ health care provider for management of a particular problem or aspect of the ~~((client's))~~ patient's care.

~~((+25+))~~ (27) "Registered nurse" means a person licensed under chapter 18.79 RCW, and rules adopted under chapter 246-840 WAC.

~~((+26+))~~ (28) "Recovery" means that period or duration of time starting at birth and ending with discharge of a client or newborn from the birth center ~~((or the period of time between the birth and the time a client leaves the premises of the birth center.~~

~~(27) "Shall" means compliance is mandatory)).~~

~~((+28+))~~ (29) "Support person" means the individual or individuals selected or chosen by ~~((a maternal))~~ the client to provide emotional support and ~~((to assist her))~~ assistance during the process of labor and childbirth.

~~((+29) "Toilet" means a room containing at least one water closet.))~~

(30) "Transfer of care" means the process by which the clinical staff of a ~~((childbirth))~~ birthing center directs the client or newborn to a physician or other licensed health care provider for complete management of ~~((client's))~~ the client or newborn's care. ~~((Transfer of care to an appropriate obstetrical department, patient care area or hospital, or physician(s) qualified in obstetrics or newborn/pediatric care respectively with admitting privileges to a hospital must be available twenty-four hours per day.))~~

(31) "Volunteer" means an individual who is an unpaid worker in the birth center, other than a support person.

~~((+32) "Water closet" means a plumbing fixture for defecation fitted with a seat and a device for flushing the bowl of the fixture with water.))~~

WAC 246-329-020 Licensure. A person must possess a current birth center license issued by the department before advertising, operating, managing, conducting, opening or maintaining a ~~((childbirth)) birthing~~ center unless exempt under chapter 18.46 RCW. A birth center applicant working towards licensure may begin advertising via website or other means provided that language clearly communicates that the center is not currently licensed.

(1) Application for license. An applicant for initial licensure of a ~~((childbirth)) birthing~~ center must:

(a) Submit a completed application on forms provided by the department;

(b) Submit disclosure statements and criminal history background checks no older than three months preceding the application date for the administrator, owner and director of services in accordance with RCW 43.43.830 through 43.43.845;

(c) Submit the following information:

(i) Name of managing personnel, officers, administrator, director of ~~((clinical)) services ((or supervisor of clinical services))~~, and partners or individuals owning ~~((ten)) 10~~ percent or more of the applicant's voting stock;

(ii) A description of the organizational structure;

(iii) ~~((Name, address, and phone numbers of all office locations that provide services within the state;~~

~~((iv)))~~ A copy of the current business license(s);

(d) Submit evidence of completion of the department's construction review process;

(e) Submit evidence of compliance with local codes and ordinances;

(f) Submit evidence of approval of the state fire marshal as required per RCW 18.46.110;

(g) Submit evidence that a certificate of occupancy by the local building official has been approved and issued;

(h) Submit other information as required by the department;

(i) Submit fees as specified in WAC 246-329-990;

~~(j) ((Furnish to the department full and complete information and promptly report any changes which would affect the current accuracy of this information as to the identity of each officer and director of the corporation, if the birth center is operated by a legally incorporated entity, profit or nonprofit, and of each partner if the birth center is operated through a legal partnership;~~

~~((k)))~~ Develop and approve policies and procedures addressing the content of this chapter; and

~~((l)))~~ (k) Meet the requirements of this chapter as determined by an initial survey conducted by the department.

(2) License renewal.

(a) A license, unless suspended or revoked, ~~((shall)) must~~ be renewed annually.

Applications for renewal must be on forms provided by the department and must be filed with the department not less than ~~((thirty)) 30~~ days prior to expiration and must also include disclosure statements and criminal history background checks no older than three months preceding the renewal date for the administrator, owner, and director of services when these individuals are new to the birth center since ini-

tial licensure or last renewal, in accordance with RCW 43.43.830 through 43.43.845.

(b) The department may inspect and investigate each ~~((child-birth))~~ birthing center every ~~((twenty-four))~~ 24 months or as needed to determine compliance with these rules and chapter 18.46 RCW.

(c) Each license ~~((shall))~~ must be issued only for the premises and persons named. Licenses ~~((shall))~~ must be ~~((transferrable))~~ transferable or assignable only with written approval by the department.

(d) Licenses must be posted in a conspicuous place on the licensed premises.

(3) Change of ownership. At least ~~((thirty))~~ 30 days prior to changing ownership of a ~~((childbirth))~~ birthing center:

(a) The licensee must submit in writing to the department:

(i) The full name, address and phone number of the current and prospective owner;

(ii) The name, address, and phone number of the currently licensed ~~((childbirth))~~ birthing center and the name under which the prospective agency will operate; and

(iii) Date of the proposed change of ownership; ~~((and~~

~~(iv) Any changes in the office location, if relevant;))~~

(b) The prospective new owner must submit:

(i) Information listed in subsection (1)(b) ~~((through))~~ and (c) of this section; and

(ii) The change of ownership fee specified in WAC 246-329-990.

(4) The department may conduct a survey after a change of ownership approval to assess the new ownership's delivery of care to patients. The decision to conduct a survey would be based on department surveys, complaint investigations, and enforcement actions associated with the new owner(s).

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-025 Exemptions, alternative methods, and interpretations. The purpose of this section is to provide birth centers a mechanism to request an interpretation, exemption, or approval to use an alternative method. This chapter is not intended to prevent use of any systems, materials, alternate design, or methods of construction as alternatives to those prescribed by these rules.

(1) A birth center requesting exemption from this chapter must submit a written request to the department asking for an exemption. The request must specify the section or sections, explain the reason for the exemption and, when appropriate, include supporting documentation.

(2) A birth center requesting approval for use of alternative materials, design, and methods must submit a written request to the department asking for approval to use an alternative. The request must explain the reason(s) for the use of an alternative and must be supported by technical documentation.

(3) The department may:

(a) Exempt a birth center from complying with portions of this chapter when:

(i) The exemption is not contrary to the intent of chapter 18.46 RCW and the requirements of these rules.

(ii) After review and consideration, the department determines the exemption will not:

(A) Negate the purpose and intent of these rules;

(B) Place the safety or health of the patients in the birth center in jeopardy;

(C) Lessen any fire and life safety or infection control provision of other codes or regulations; and

(D) Affect any structural integrity of the building;

(b) Approve the use of alternative materials, designs, and methods when:

(i) The birth center complies with subsection (2) of this section; and

(ii) After review and consideration, such alternative:

(A) Meets the intent and purpose of these rules; and

(B) Is at least equivalent to the methods prescribed in these rules.

(4) A birth center requesting an interpretation of rule contained in this chapter must submit a written request to the department. The request must specify the section or sections for which an interpretation is needed and details of the circumstances to which the rule is being applied. The birth center must provide any other information the department deems necessary.

(5) The department will, in response to a written request, send a written interpretation of a rule or regulation within ~~((thirty))~~ 30 calendar days after the department has received complete information relevant to the requested interpretation.

(6) The ~~((department and birth center will))~~ birthing center must keep a copy of each exemption ~~((or))~~, alternative ~~((granted))~~ method, or interpretation issued under this section ~~((on file))~~ and have them available for department surveyors at all times.

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-030 Governance. The purpose of this section is to provide organizational guidance and oversight and to ensure resources and staff to support safe and adequate patient care.

(1) The birth center ~~((shall))~~ must have a governing body.

(2) The governing body ~~((shall))~~ must be responsible for providing personnel, facilities, equipment, supplies, and special services to meet the needs of the ~~((clients))~~ patients.

(3) The governing body ~~((shall))~~ must adopt policies for the care of ~~((clients))~~ patients within or on the premises of the birth center. Policies must be reviewed, at minimum, annually.

(4) The governing body ~~((shall))~~ must appoint an administrator or director responsible for implementing the policies adopted by the governing body.

(5) The governing body ~~((shall))~~ must establish and maintain a current written organizational plan which includes all positions and delineates responsibilities, authority, and relationship of positions within the birth center.

(6) The governing body ~~((shall))~~ must have the authority and responsibility for appointments and reappointments of clinical staff, approval of written contracts and appointment of contractors, approval

of clinical bylaws and to ensure that only members of the clinical staff admit clients to the birth center.

(a) Each birth center (~~((shall have access to physician))~~) must utilize consultation and appropriate clinical services as defined in WAC 246-329-095(2).

(b) Each physician and midwife, including contractors, appointed to the clinical staff (~~((shall))~~) must provide evidence of current licensure in the state of Washington.

(c) Members of the clinical staff (~~((shall))~~) must develop and adopt bylaws, policies, and procedures subject to the approval of the governing body including requirements for clinical staff membership; delineation of clinical privileges and the organization of clinical staff.

(7) The governing body must adopt policies for the delegation of responsibilities to staff including which responsibilities can and cannot be delegated and which staff are and are not appropriate for specific responsibilities.

(8) The governing body (~~((shall))~~) must be responsible for assuring a quality improvement program is implemented according to WAC 246-329-180.

(~~((8))~~) (9) The governing body (~~((shall have responsibility))~~) must be responsible for the legal and financial management of the birth center.

AMENDATORY SECTION (Amending WSR 12-16-057, filed 7/30/12, effective 10/1/12)

WAC 246-329-045 Applicant or licensee rights and responsibilities. This section describes the applicant or licensee's responsibilities in the fulfillment of the requirements of this chapter.

(1) An applicant or licensee must:

(a) Comply with chapter 18.46 RCW and this chapter;

(b) Establish, implement and periodically review all policies and procedures which address the contents of this chapter;

(c) Display the license issued by the department in an area accessible to the public;

(d) Notify the department in writing:

(i) Within (~~((thirty))~~) 30 days of changes of an administrator, owner or the director of (~~((clinical))~~) services;

(ii) Thirty or more days before ceasing operations;

(e) Cooperate with the department during surveys which may include reviewing licensee and client records and conducting client interviews with client consent;

(f) Respond to a statement of deficiencies by submitting to the department:

(i) A written plan of correction, within (~~((ten))~~) 10 working days of receipt. The applicant or licensee must complete all corrections within (~~((sixty))~~) 60 days after the survey exit date, unless otherwise specified by the department; and

(ii) A progress report, when required, describing corrections made and ongoing monitoring actions, within (~~((ninety))~~) 90 days after the survey exit date, unless the department specifies another date.

(2) An applicant or licensee may:

(a) Discuss findings observed during a survey with the surveyor; and

(b) Discuss the statement of deficiencies with the department's manager.

(3)(a) A ~~((childbirth))~~ birthing center must report adverse health events to the department in accordance with chapter 70.56 RCW. ~~((The National Quality Forum identifies and defines twenty-nine serious reportable events (adverse health events) as updated and adopted in 2011.))~~

(b) A ~~((childbirth))~~ birthing center must comply with the reporting requirements under chapter 246-302 WAC. Reporting requirements under chapter 246-302 WAC do not relieve a birth center from complying with other applicable reporting or notification requirements of this chapter or those requirements relating to law enforcement or professional regulatory agencies.

~~((c) Adverse health events are listed in chapter 246-302 WAC.))~~

(4) An applicant or licensee has the right to respond to and contest a statement of charges according to the following provisions:

(a) RCW 43.70.115, department of health authority for license approval, denial, restriction, conditioning, modification, suspension and revocation;

(b) Chapter 34.05 RCW, the Administrative Procedure Act; and

(c) Chapter 246-10 WAC, Adjudicative proceedings.

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-055 Department responsibilities. This section describes the department's responsibilities in the fulfillment of the requirements of this chapter:

(1) The department may, in accordance with chapter 18.46 RCW:

(a) Issue an initial license for ~~((twelve))~~ 12 months following submission of a completed application and appropriate fee, and following a survey that documents the applicant meets all the requirements of this chapter;

(b) Issue a renewal license for the ~~((twelve))~~ 12-month period following submission of a completed application and appropriate fee;

(c) Issue a license for change of ownership to the new ~~((licensee))~~ licensee for the remainder of the current license period following submission of the required information and appropriate fee, under WAC 246-329-990.

(2) The department may:

(a) Conduct surveys and investigations every ~~((twenty-four))~~ 24 months or as needed to determine compliance with chapter 18.46 RCW and this chapter. Surveys and investigations may be announced or unannounced;

(b) Investigate any person suspected of:

(i) Advertising, operating, managing, conducting, opening or maintaining a ~~((childbirth))~~ birthing center without a license unless exempt from licensure under chapter 18.46 RCW; or

(ii) Survey a licensee at anytime if the department has reason to believe the licensee is providing unsafe, insufficient, inadequate or inappropriate care;

(c) Investigate allegations of noncompliance with RCW 43.43.830 through 43.43.845, when necessary, in consultation with law enforcement personnel;

(d) Require licensees to complete additional disclosure statements and background inquiries for an individual associated with the licensee or having direct contact with children under ~~((sixteen))~~ 16 years of age, people with developmental disabilities, or vulnerable adults if the department has reason to believe that offenses specified under RCW 43.43.830 have occurred since completion of the previous disclosure statement and criminal background inquiry; and

(e) Issue a statement of deficiencies following a survey which identifies noncompliance with chapter 18.46 RCW and this chapter.

(3) The department may deny, suspend, or revoke a license if the applicant or licensee fails or refuses to comply with the requirements of chapter 18.46 RCW ~~((and/or))~~ and these rules. The department's notice of denial, suspension, modification, or revocation of a license ~~((shall))~~ must be consistent with RCW 43.70.115. An applicant or license holder has the right to an adjudicative proceeding to contest the decision.

(4) The department may prepare and serve upon the licensee or applicant at the earliest practical time a statement of charges following a survey which identifies noncompliance with chapter 18.46 RCW and this chapter. The statement of charges must include a notice that the licensee or applicant may request a hearing to contest the charges.

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-065 New construction—Major alterations. The purpose of this section is to provide minimum standards for a safe and efficient patient care environment consistent with other rules. The rules are intended to allow flexibility in achieving desired outcomes and enable birth centers to respond to changes in technologies and health care innovations.

(1) When a licensee or applicant is contemplating new construction or major alteration, the licensee or applicant ~~((shall))~~ must:

(a) Under chapters 70.40 RCW and 246-329 WAC, submit an application and construction documents to the department's construction review services program for all new construction and major alterations, as defined in WAC 246-329-010. In addition to the application and construction documents, the construction review services program may require documentation of approval from local zoning commissions, fire departments, and building departments, if applicable;

(b) Respond in writing when the department requests additional or corrected construction documents;

(c) Not begin construction until the construction documents are approved by the local jurisdictions and same local jurisdictions have issued any required permits;

(d) Complete construction consistent with the final "department approved" documents;

(e) Notify the department in writing when construction is completed; and

(f) Submit to the department a copy of the local jurisdictions' certificate of occupancy.

(2) A ~~((childbirth))~~ birthing center applicant or licensee must, through its design, construction and necessary permits demonstrate compliance with the following codes and local jurisdiction standards:

(a) The state building code as adopted by the state building code council.

(b) *Accepted Procedure and Practice in Cross-contamination Control, Pacific Northwest Edition, 9th Edition, American Waterworks Association*; and

(c) If planning on caring for patients with mycobacterium tuberculosis, *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care ((Facilities, 1994)) Settings, 2005. Morbidity and Mortality Weekly Report (MMWR), Volume ((43, October 28, 1994)) 54, December 30, 2005.*

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-075 Criminal history, disclosure, and background inquiries. The purpose of this section is to ensure criminal history background inquiries are conducted for any employee or prospective employee who has or will have unsupervised access to children, vulnerable adults, and individuals with developmental disabilities.

(1) A ~~((childbirth))~~ birthing center applicant or licensee must establish and implement policies and procedures regarding Washington state patrol criminal background inquiries and disclosure statements under RCW 43.43.830 through 43.43.845 for the administrator, owner, director of services and personnel, contractors, volunteers, students, and any other individual associated with the licensee having direct contact with children under ~~((sixteen))~~ 16 years of age, individuals with developmental disabilities, or vulnerable adults.

(2) The department may require licensees to complete additional disclosure statements or background inquiries for a person associated with the licensed facility having direct contact with vulnerable adults if the department has reason to believe that offenses specified under RCW 43.43.830 have occurred since completion of the previous disclosure statement or background inquiry.

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-085 Client bill of rights. The purpose of this section is to ~~((help))~~ improve patient outcomes by ~~((respecting each client and conducting all relationships with clients and the public in an ethical manner))~~ ensuring birthing centers inform clients of specific rights.

The ~~((birth))~~ birthing center at the time of registration, including clients of contractors, must provide each client with ~~((a))~~ an electronic or written bill of rights ~~((, verified by client or representative signature))~~. The bill of rights is part of the informed con-

sent process in WAC 246-329-120(2), affirming each ((individual's)) client's rights to:

~~(1) A listing of the services provided by the birth center ((and a description of other levels of maternal/fetal services available in the community));~~

~~(2) Be informed of the ((policy)) policies and procedures for admission and discharge;~~

~~(3) Be informed of the definition of a low-risk ((maternal client,)) pregnancy and the benefits and risks of out-of-hospital labor and birth ((and complete a written informed consent, prior to the onset of labor that shall include, but not be limited to, evidence of an explanation by personnel of the birth services offered and potential risks and emergency transfer and transport procedures));~~

~~(4) Be informed of ((what constitutes being ineligible for birth center services and the transfer policy and procedures of clients who, during the course of pregnancy or labor or recovery, are determined to be ineligible, including the birth center's plan for provisions of emergency and nonemergency care in the event of complications to mother and newborn)) the eligibility criteria for birth center services;~~

~~(5) Be informed of the policies and procedures for clients who choose hospital transfer during their admission to the birth center;~~

~~(6) Be informed of the policies and procedures for emergency and nonemergency care in the event of complications to client and newborn;~~

~~(7) Be informed that unexpected neonatal emergencies requiring complex resuscitation are rare, but can occur((. Be informed that the birth)), and the birthing center staff ((is)) are prepared to provide initial steps of newborn resuscitation ((upper airway clearance with a bulb or mechanical suction) and provide bag and mask ventilation until emergency medical service providers arrive to provide complete resuscitation procedures if required)) until the newborn has been transported and discharged to another provider for additional medical care;~~

~~((+6)) (8) Participate in decisions relating to the plan for management of care ((and all changes in that plan once established including consultation, referral and transfer to other practitioners or other levels of care)) including informed consent, informed refusal, and reassessment of these plans as conditions change;~~

~~((+7)) (9) Be informed of the ((policy)) policies and procedures for consultation, referral, transfer of care and transport of a ((newborn and maternal)) client or newborn to a hospital ((where appropriate care is available)) when additional care is necessary;~~

~~((+8) Be informed of prenatal screening under chapter 70.54 RCW and chapter 246-680 WAC;~~

~~(9) Be informed of newborn screening requirements under chapter 70.83 RCW and chapter 246-650 WAC, including a provision of a copy of the parent information pamphlet "Newborn Screening Tests and Your Baby" which is available from the department's newborn screening program;~~

~~(10) Be informed that rapid HIV testing is available for all maternal clients without a documented history of HIV testing during prenatal care;~~

~~(11) Be informed of prophylactic treatment of the eyes of the newborn in accordance with WAC 246-100-206 (6) (b);~~

~~(12) Be informed that vitamin K administration for the newborn is available;~~

~~(13) Be informed that newborn hearing screening tests are offered in most hospitals;~~

~~((14) A description))~~ (10) Be informed of the process for submitting and addressing complaints;
~~((15))~~ (11) Submit complaints without retaliation and to have the complaint addressed by the licensee;
~~((16))~~ (12) Be informed of the state complaint hotline number;
~~((17))~~ (13) Be treated with courtesy, dignity, respect, privacy, and freedom from abuse and discrimination;
~~((18) Refuse treatment or services;~~
~~(19))~~ (14) Privacy of personal information and confidentiality of health care records;
~~((20))~~ (15) Be cared for by properly trained personnel, contractors, students and volunteers and be informed of the qualifications of clinical staff, consultants and related services and institutions;
~~((21) Be informed of all diagnostic procedures and reports, recommendations and treatments;~~
~~(22))~~ (16) A fully itemized billing statement upon request, including the date of each service and the charge. Estimated billing statements will be provided within five business days after the request. Finalized billing statements will be provided after third party processing has been completed;
~~((23))~~ (17) Be informed about advanced directives and the ((licensee's)) birth center's scope of responsibility ((to implement them));
~~((24) Be informed of the client's right with regards to participation in research or student education programs;~~
~~(25))~~ (18) Be informed of the liability insurance coverage of practitioners on request; and
~~((26))~~ (19) Be informed ((of child passenger restraint systems to be used when transporting children in motor vehicles, including information describing the risks of death or serious injury associated with the failure to use a child passenger restraint system)) that newborns must be secured in an appropriate motor vehicle restraint system before being discharged from the facility.

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-095 Staffing. The purpose of the staffing section is to ensure the birth center provides competent staff consistent with the scope of services.

(1) The birth center ~~((shall))~~ must have sufficient, qualified personnel and clinical staff to provide the services needed by ~~((clients))~~ patients and for safe maintenance and operation of the birth center.

(2) The birth center ~~((shall have written plans))~~ must develop and implement policies and procedures for consultation, referral, transfer of care, emergency transfer and transport of a newborn to a newborn nursery or neonatal intensive care nursery, and emergency transfer or transport of a ~~((maternal))~~ client to an appropriate obstetrical department, patient care area or hospital ~~((where appropriate care is available))~~ when additional care is necessary.

(3) The birth center ~~((shall))~~ must:

(a) Employ, contract or use appropriately trained personnel and clinical staff; and

(b) ~~((Assure))~~ Ensure clinical staff or personnel have evidence of current training in neonatal and adult resuscitation.

(c) ~~((Assure))~~ Ensure a physician or midwife is present at each birth. A second person who is ~~((an employee, student or member of the clinical staff))~~ a qualified personnel, student, or clinical staff member with evidence of current training in neonatal and adult resuscitation skills ~~((shall))~~ must be immediately available in the birthing center during each birth.

(d) Ensure ~~((twenty-four))~~ 24 hour coverage, including the provision that appropriate, qualified personnel ~~((and/or))~~ or clinical staff ~~((shall))~~ must be present in the birth center at all times when clients are present.

AMENDATORY SECTION (Amending WSR 21-02-002, filed 12/23/20, effective 1/23/21)

WAC 246-329-110 Personnel policy and procedures and records.

The purpose of this section is to ensure the birth center provides direction and standards in the employment, contracting and recording of personnel procedures.

(1) A ~~((childbirth))~~ birthing center applicant or licensee must establish and implement ~~((policy))~~ policies and procedures which include, but are not limited to:

(a) ~~((For those birth centers operated by an employer as defined by RCW 49.60.040(3),))~~ Employment criteria ~~((consistent))~~ regarding discrimination with chapter 49.60 RCW;

(b) Job descriptions for employees, contractor agreements, volunteer responsibility statements and agreements with students commensurate with responsibilities and ~~((consent))~~ consistent with health care professional credentialing and scope of practice as defined in relevant practice acts and associated rules;

(c) Verification of clinical staff credentials;

(d) Verification of appointment letters for privileged staff which delineates clinical privileges;

(e) Orientation to current ~~((agency))~~ birth center policies and procedures and verification of skills or training for all clinical staff;

~~((e))~~ (f) Current neonatal and adult cardiopulmonary resuscitation training consistent with ~~((agency))~~ birth center policies and procedures and community standards for all clinical staff;

~~((f))~~ Infection control practices for clinical staff including communicable disease testing, immunization, vaccination and universal precautions or equivalent method of preventing the transmission of infection according to current local health authorities and shall include the availability of equipment necessary to implement plans of care and infection control policies and procedures;

(i) Birth centers must establish and implement a TB screening program for personnel;

(ii) Birth centers must provide or offer to employees Hepatitis B vaccination according to WAC 296-62-08001; and

~~(iii) Birth centers must assure that all contractors have received or been offered Hepatitis B vaccination according to WAC 296-62-08001;))~~

(g) Performance evaluations of all personnel, including evaluations of contractor and student agreements to be conducted per birth center's policy and procedure; ~~((and))~~

(h) Washington state patrol criminal background inquiries and disclosure statements under RCW 43.43.830 through 43.43.845 for the administrator, owner, director of services and personnel, contractors, volunteers, students, and any other individual associated with the licensee who has direct contact with children under ~~((sixteen))~~ 16 years of age, people with developmental disabilities or vulnerable adults;

(i) Infection control training which includes, but is not limited to, blood borne pathogens and universal precautions; and

(j) Annual emergency clinical skills training.

(2) ~~((Each))~~ The licensee maintain records on all employees, contractors, students, and volunteers ~~((shall have a current record maintained by the birth center which contains, but is not limited to,))~~ to include the following information:

(a) Documentation of the items stated above in subsection (1)(b) through ~~((e), (g), and (h)))~~ (j) of this section((-)); and

(b) Evidence of communicable disease testing as required by local health authorities and per birth center policy and procedures and ~~((shall))~~ must include, at a minimum, documented evidence of tuberculin (TB) screening as required in ~~((WAC 246-329-110(1)(f)))~~ subsection (1)(i) of this section and documented evidence of Hepatitis B vaccination being provided or offered according to ~~((WAC 296-62-08001))~~ chapter 296-823 WAC.

AMENDATORY SECTION (Amending WSR 10-05-033, filed 2/9/10, effective 3/12/10)

WAC 246-329-120 Birth center policies and procedures. The purpose of this section is to ensure the birth center is able to provide safe and appropriate care to the ~~((clients))~~ patients of the birth center.

(1) An applicant or licensee must establish and implement ~~((policy))~~ policies and procedures which include, but are not limited to:

(a) Definition of a low-risk ~~((maternal))~~ client who is eligible for birth services offered by the birth center. An applicant or licensee wanting to use a more recent version of the CABC indicators for compliance for the purpose of defining a low-risk client may submit an alternative method request following the process in WAC 246-329-025.

~~((b) ((Definition of a client who is ineligible for birth services at the birth center.~~

~~((c) Identification and transfer of clients who, during the course of pregnancy, are determined to be ineligible.~~

~~((d))~~ Identification and transfer of clients and newborns who, during the course of labor or recovery, are determined to be ineligible for continued care in the birth center.

~~((e) Written plans for))~~ (c) Consultation, referral and transfer of care for ((maternal)) client and newborn((- Written plans for)), including emergency transfer and transport of a newborn to a newborn nursery or neonatal intensive care nursery, and emergency transfer and

transport of a ~~((maternal))~~ client to an appropriate obstetrical department, patient care area, or hospital ~~((where appropriate care is available))~~ when additional care is necessary.

~~((f))~~ (d) Transfer and discharge of ~~((neonates to minimize risk of newborn abduction))~~ clients and newborns.

~~((g) Protocol for medications and laboratory testing during labor and recovery if the birth center plans to deliver HIV positive clients.~~

~~(h) Rapid HIV testing using the opt out approach for women who have undocumented HIV test results when presenting to the birth center in labor.~~

~~((i))~~ (e) Protocol for ~~((electronic fetal heart monitoring or))~~ intermittent auscultation to monitor fetal status during labor.

~~((j) Protocol for the provision of MMR vaccine to nonimmune postpartum women.~~

~~(k) Protocol for the provision of anti D immune globulin to postpartum women who are unsensitized D-Negative and who deliver a D positive or Du positive infant.~~

~~(2) The applicant or licensee shall assure that transfer of care shall be available twenty-four hours per day to an appropriate obstetrical department, patient care area, or hospital where appropriate care is available.~~

~~(3))~~ (f) Actions to be taken upon death of a patient.

(g) Protocol for use of inhaled nitrous gas as an analgesic. Protocol must include, at minimum, the following:

(i) A process for establishing staff competency in nitrous oxide use prior to client self-administration;

(ii) Nitrous oxide being administered with oxygen by a member of the clinical staff. The maximum concentration of nitrous oxide is limited to 50 percent;

(iii) The client must always self-administer the nitrous oxide (the laboring person holds the mask or mouthpiece without any assistance from staff);

(iv) A clinical staff member is responsible for the counseling and education of the patient on nitrous oxide therapy and the setup and preparation of the nitrous oxide delivery system. These responsibilities cannot be delegated to other birth center personnel;

(v) Birth centers that offer nitrous oxide for labor analgesia must meet the equipment requirements in WAC 246-329-130 (1)(c).

(h) Birth centers that do not offer inhaled nitrous gas are not required to establish the policies, procedures, and protocols in (g) of this subsection.

(2) Clients ~~((shall))~~ must receive and sign written informed consent which ~~((shall))~~ must be obtained prior to ~~((the onset of labor and shall))~~ admission and must include, but is not limited to:

(a) ~~((Evidence of an))~~ Explanation ~~((by personnel))~~ of the birth services offered~~((, limitation of services,))~~ and potential risks;

(b) ~~((Explanation of the definition of low-risk maternal client))~~ Eligibility requirements for the admission to the birth center;

(c) ~~((Explanation of a client who is ineligible for childbirth center services))~~ Client bill of rights according to WAC 246-329-085;

(d) Explanation of ~~((the birth center policies and procedures for consultation, referral,))~~ transfer of care and emergency transfer and transport;

(e) ~~((Explanation of prophylactic treatment of the eyes of the newborn. The prophylactic treatment is administered to the newborn according to WAC 246-100-202 (1)(e);~~

~~(f) Explanation of screening of newborns under chapter 70.83 RCW and chapter 246-650 WAC; and~~

~~(g) Explanation of why rapid HIV testing is available if documentation of an HIV test during prenatal care is not available;~~

~~(h) Explanation of the need for prophylactic administration of RhIG (immune globulin) within seventy-two hours of delivery for an Rh negative mother whose newborn(s) are Rh positive)) Notification and recommendation to acquire peripartum services and whether those services are available at the birth center, including:~~

~~(i) Newborn metabolic and heart disease screening recommendations per chapters 70.83 RCW and 246-650 WAC.~~

~~(ii) Newborn hearing screening.~~

~~(iii) Prophylactic treatment of the eyes of the newborn in accordance with WAC 246-100-202.~~

~~(iv) Vitamin K injection for the newborn.~~

~~(v) Bilirubin screening for the newborn.~~

~~(vi) Medications for GBS prophylaxis.~~

~~(vii) Prophylactic administration of RhIG (immune globulin) within 72 hours of delivery for an Rh negative mother whose newborn(s) are Rh positive.~~

~~(viii) MMR vaccination for nonimmune newly postpartum clients.~~

~~((4)) (3) The birth center ((shall)) must provide or ((assure)) ensure:~~

~~(a) ((Education of clients, family and support persons in child-birth and newborn care.~~

~~(b) Plans for immediate and long-term follow-up of clients after discharge from the birth center.~~

~~(c) Registration of birth and reporting of complications and anomalies, including sentinel birth defect reporting under chapter 70.58 RCW.~~

~~(d) Prophylactic treatment of the eyes of the newborn in accordance with WAC 246-100-206 (5)(b).~~

~~(e) Collection of a newborn screening blood specimen, or signed refusal, and submission to the department's newborn screening program under the requirements of WAC 246-650-020.~~

~~(f) Rapid HIV testing when documentation of an HIV test during prenatal care is not available, unless the client refuses to give consent and the refusal is documented.~~

~~(g) For HIV positive women, the antiretroviral medications during delivery and perform or arrange appropriate lab tests.~~

~~(h) Intrapartum intravenous antibiotics for Group B Strep positive women per the CDC protocol.~~

~~(i) For Hepatitis B positive women, HBIG and Hepatitis B immunization for the newborn.~~

~~(j) Infection control to housekeeping; cleaning, sterilization, sanitization, and storage of supplies and equipment, and health of personnel and clients.~~

~~(k) Actions to take when personnel, volunteers, contractors, or patients or clients exhibit or report symptoms of a communicable disease in an infectious stage in accordance with chapter 246-100 WAC, Communicable and certain other diseases and chapter 246-101 WAC, Notifiable conditions.~~

~~(l) Authorization and administration of medications, legend drugs and devices per appropriate health profession rules.~~

~~(m) Actions to address patient or client communication needs.~~

~~(n)) Reporting of patient/client abuse and neglect according to chapter 74.34 RCW.~~

- ~~((e)) Emergency care of client.~~
- ~~(p) Actions to be taken upon death of a client.~~
- ~~(q))~~ (b) Plans for service delivery when natural or man-made emergencies occur that prevent normal clinical operation.
- ~~((r))~~ (c) Waived laboratory tests, if applicable, including the procurement of a medical test site waiver under chapter 246-338 WAC.
- (d) Privileged clinical staff, employed or contracted, who agree to execute the following responsibilities:
 - (i) Education of clients, family and support persons in child-birth and newborn care.
 - (ii) Plans for immediate and long-term follow-up of clients and newborns after discharge from the birth center.
 - (iii) Registration of birth and reporting of complications and anomalies, including sentinel birth defect reporting under chapter 70.58 RCW.
 - (iv) Prophylactic treatment of the eyes of the newborn in accordance with WAC 246-100-202 (1)(e).
 - (v) Collection of a newborn screening blood specimen, or signed refusal, and submission to the department's newborn screening program under the requirements of WAC 246-650-020.
 - (vi) For HIV positive patients, appropriate testing, treatment, and risk assessment.
 - (vii) Intrapartum intravenous antibiotics for Group B Strep positive clients per the CDC protocol.
 - (viii) For Hepatitis B positive clients, HBIG and Hepatitis B immunization for the newborn.
 - (ix) Authorization and administration of medications, legend drugs and devices per appropriate health profession rules.
 - (x) Actions to address patient communication needs.
 - (xi) Emergency medical care of patient.
 - (xii) Reporting of patient/client abuse and neglect according to chapter 74.34 RCW.
 - (xiii) When a patient is transferred or discharged to another provider or facility, the clinical staff must provide a summary of care to the provider or facility to whom the patient is transferred or discharged.

NEW SECTION

WAC 246-329-125 Infection control. The purpose of this section is to identify and reduce the risk of acquiring and transmitting infections and communicable diseases between patients, staff, medical staff, and visitors.

A birthing center must:

- (1) Develop and implement infection control policies and procedures consistent with the guidelines of the Centers for Disease Control and Prevention (CDC);
- (2) Ensure the infection control policies and procedures address, but are not limited to, the following:
 - (a) Infection control practices for clinical staff including communicable disease testing, immunization, vaccination and universal precautions or equivalent method of preventing the transmission of infection according to current local health authorities and must include

the availability of equipment necessary to implement plans of care and infection control policies and procedures;

(b) Receipt, use, disposal, sterilizing, processing, or reuse of equipment to prevent disease transmission;

(c) Providing and maintaining utility and storage facilities designed and equipped for washing, disinfecting, storing, and other handling of equipment and medical supplies in a manner which ensures segregation of clean and sterile supplies and equipment from those that are soiled and contaminated;

(d) Handwashing;

(e) Ensure all sewage, garbage, refuse, biohazardous waste, human tissue, needles and sharps, and liquid waste are collected and disposed of in a manner to prevent the creation of an unsafe or unsanitary condition;

(f) Tuberculosis screening for new and current employees consistent with the *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Healthcare Facilities*, 2005. *Morbidity Mortality Weekly Report (MMWR)* Volume 54, December 30, 2005;

(g) Documenting the receipt and offer of Hepatitis B vaccination to all employees and contractors according to WAC 296-823-130; and

(h) Actions to take when personnel, volunteers, contractors, or patients exhibit or report symptoms of a communicable disease in an infectious stage in accordance with chapter 246-100 WAC, Communicable and certain other diseases and chapter 246-101 WAC, Notifiable conditions.

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-130 Birth center equipment and supplies. The purpose of this section is to ensure the birth center provides safe and appropriate equipment and supplies necessary ~~((to))~~ for the safe provision of patient care ~~((to the client of the birth center))~~.

(1) The applicant or licensee ~~((shall assure))~~ must ensure the birth center has the adequate, appropriate size and type equipment and supplies maintained for the ~~((maternal))~~ client and the newborn to include:

(a) A bed suitable for labor, birth, and recovery;

(b) ~~((Separate))~~ Oxygen with flow meters and masks or equivalent;

(c) If offering nitrous oxide, the nitrous oxide equipment must include the following:

(i) A demand valve to stop the supply when the patient is not inhaling; and

(ii) A gas waste scavenging systems to prevent secondary exposure to the exhaled/waste nitrous oxide;

(d) Suction equipment for the ~~((maternal client and))~~ newborn to include bulb and delee suction ~~((apparatus, either operated from a wall outlet or portable equipment, and bulb suction as appropriate))~~ devices. These devices must be immediately available in the birth center;

~~((d))~~ (e) Resuscitation equipment to include adult and ~~((neo-nate))~~ neonatal resuscitation bags and term and preterm size face masks ~~((, and neonatal-sized oxygen bags))~~ for assisted ventilation~~((~~

~~Newborn resuscitation equipment shall include method to deliver free flow oxygen));~~

~~((e) Firm))~~ (f) Suitable surfaces ((suitable)) for resuscitation. Suitable surfaces include, but are not limited to, a firm board or floor;

~~((f))~~ (g) Fetal monitoring equipment, minimally to include a fetoscope((,)) or doppler ((or electronic monitor));

~~((g))~~ (h) Equipment for monitoring and maintaining the optimum body temperature of the newborn. A heat source appropriate for use in warming newborns ((shall)) must be available((, and may include an incubator));

~~((h))~~ (i) A time keeping device such as a wall clock, smart phone, or computer;

~~((i))~~ (j) Sterile suturing equipment and supplies;

~~((j))~~ (k) Glucose meter appropriately calibrated to screen glucose level in newborns and associated test supplies;

~~((k))~~ (l) Examination lighting device with a shatterproof bulb or protective shield;

~~((l))~~ (m) Containers for soiled linen and waste materials which ((shall)) must be closed or covered.

(2) A telephone (land-line or cellular) or equivalent communication device must be accessible in the ~~((client care))~~ birthing room area.

(3) ~~((The licensee must clean, sterilize, disinfect and store equipment according to manufacturer guidelines and department requirements, if applicable. Clean and soiled equipment and supplies must be stored in separate areas.~~

~~(4))~~ The applicant or licensee ~~((shall))~~ must provide and maintain infection control equipment and supplies for clinical staff.

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-140 ((Client)) Patient records. The purpose of this section is to ~~((assure))~~ ensure the birthing center obtains, manages, and uses information to improve patient care and outcomes ~~((and the performance of the birth center in patient care))~~.

(1) The ~~((birth center shall))~~ birthing center must have a defined ~~((client))~~ patient record system, policies and procedures which provide for identification, security, confidentiality, control, retrieval, and preservation of ~~((client))~~ patient care data and information.

(2) The ~~((childbirth))~~ birthing center must maintain a health record for each ~~((maternal and newborn))~~ client and newborn in a legally acceptable~~((, integrated and chronological))~~ document ~~((on the licensee's standardized forms))~~ consistent with chapter 70.02 RCW, Medical records—Health care information access and disclosure. Each record must include:

(a) Client's ~~((demographic information and client identification to include at a minimum client's))~~ name, birth date, age, and address;

(b) Client's signed informed consent ~~((for care, service, treatment and receipt of the client bill of rights))~~ according to WAC 246-329-120(2);

(c) Signed and authenticated notes describing the client and newborn's ~~((and maternal))~~ status during ~~((prenatal,))~~ labor, birth, and recovery including, but not limited to:

~~((i))~~ ~~((Documentation that verifies the client's low-risk maternal client status))~~ Risk assessment completed and signed by privileged clinical staff, employed or contracted, before admission ensuring that the client is low-risk. Include the following statement: If the client develops a condition that makes them ineligible for birth center delivery, the privileged clinical staff will not admit the client to the birth center; ~~((and))~~

~~((ii))~~ Labor summary;

~~((iii))~~ Newborn status including Apgar scores ~~((, maternal newborn))~~ and parent-newborn interaction; ~~((and))~~

~~((iv))~~ Physical assessment of ~~((the mother))~~ client and newborn during recovery;

~~((d))~~ ~~((Documentation that a newborn screening specimen was collected (or signed refusal on the back of the specimen form) and submitted to the department's newborn screening program under WAC 246-650-020;~~

~~((e))~~ Documentation and authentication of orders by clinical staff and birth center personnel who administer drugs and treatments or make observations and assessments;

~~((f))~~ (e) Laboratory and diagnostic testing results pertaining to labor and immediate postpartum;

~~((g))~~ (f) Consultation reports pertaining to labor and immediate postpartum;

~~((h))~~ (g) Referral, transfer of care, emergency transfer and transport documentation pertaining to labor and immediate postpartum;

~~((i))~~ (h) Prophylactic treatment of the eyes of the newborn in accordance with WAC ((246-100-206 (6) (b))) 246-100-202 (1) (e);

~~((j))~~ Prenatal screening under chapters 70.54 RCW and 246-680 WAC, including client's refusal;

~~((k))~~ Documentation of refusal of rapid HIV testing if documentation of an HIV test during prenatal care is not available;

~~((l))~~ For HIV positive women, the antiretroviral medications during delivery and recommended lab tests;

~~((m))~~ (i) Intrapartum antibiotics for Group B Strep positive ((women)) clients per the CDC protocol;

~~((n))~~ (j) For Hepatitis B positive ((women)) clients, HBIG and Hepatitis B immunization for newborn;

~~((o))~~ (k) Refusal of any recommended test or treatment;

~~((p))~~ Documentation of birth registration per chapter 70.58 RCW-))

(3) All care and treatment entries into the patient record must be completed in a timely fashion.

(4) Entries in the patient record must be typewritten, written legibly in ink or retrievable by electronic means.

(5) For clients managed by a contractor in a ((birth)) birthing center, the licensee ((shall)) must ensure that each ((client)) patient record of labor, birth, and immediate postpartum is maintained by the birth center and must contain the information as stated in subsection (2) (a) through ((p)) (k) of this section. ((Services provided by the contractor, prior to the client's admission to the birth center, shall be summarized or placed in the record in their entirety.

(4) Entries in the client record shall be typewritten, retrievable by electronic means or written legibly in ink.

(5) Documentation and record keeping shall include:

~~((a)) Completion of a birth certificate and, if applicable, a sentinel birth defect report under chapters 70.58 RCW and 246-491 WAC.~~

~~((b))~~ (6) Documentation of orders for medical treatment ~~((and/or))~~ and medication administered by the provider. Each order ~~((shall))~~ must be specific to the ~~((client))~~ patient and ~~((shall))~~ must be authenticated, at the time the order is received, by an appropriate health care professional authorized to approve the order or medication.

~~((6))~~ (7) The licensee ~~((shall))~~ must:

(a) ~~((Assure client))~~ Ensure patient records are kept confidential;

(b) ~~((Fasten client records together;~~

~~((c))~~ Consider ~~((client))~~ patient records property of the birth center; and

~~((d))~~ (c) Provide a ~~((client))~~ patient access to their ~~((client))~~ patient record under the licensee's policy and procedure and applicable rules.

~~((7))~~ When a client is transferred or discharged to another provider or facility, the birth center must provide a summary of care to the provider or facility to whom the client is transferred or discharged.)

(8) The licensee ~~((shall))~~ must maintain records for:

(a) Adults - Three years following the date of termination of services; and

(b) Minors - Three years after attaining age ~~((eighteen))~~ 18, or five years following discharge, whichever is longer.

(9) The licensee ~~((shall))~~ must:

(a) Store records to prevent loss of information and to maintain the integrity of the record and protect against unauthorized use;

(b) Maintain or release records after a patient's ~~((or client's))~~ death according to chapter 70.02 RCW, Medical records—Health care information access and disclosure; and

(c) After ceasing operation, retain or dispose of records in a confidential manner according to the time frames in this subsection.

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-150 Pharmaceuticals. The purpose of this section is to ~~((assure))~~ ensure that ~~((client))~~ patient pharmaceutical needs are met ~~((in a planned and organized manner.~~

~~((1))~~ The licensee shall maintain written prescriptions or orders signed by a practitioner legally authorized to prescribe for all drugs administered to clients within the birth center.

~~((2))~~ The licensee shall have written policies and procedures addressing the receiving, transcribing, and implementing of orders for administration of drugs.

~~((3))~~ consistent with chapter 246-945 WAC and the following requirements:

(1) The licensee ~~((shall))~~ must establish and implement written policies to address the type ~~((and intended use)), indications, dosage, contraindications, and side effects~~ of any drug ~~((or device))~~ to be used by patients within the facility.

~~((4))~~ (2) The licensee ~~((shall assure))~~ must ensure that only local anesthetics are used. Inhaled nitrous oxide can be used as an analgesic.

~~((5))~~ (3) The licensee ~~((shall))~~ must ensure:

(a) Drugs are only administered by personnel or clinical staff licensed to administer drugs;

(b) Drugs kept anywhere in the center are clearly labeled with drug name, strength, and expiration date;

(c) Expired drugs are removed from the storage units and destroyed properly;

(d) Drugs are stored and secured in specifically designated cabinets, closets, drawers, or storerooms and made accessible only to authorized persons;

~~((e))~~ ~~((Drugs for external use must be stored apart from drugs for internal use;~~

~~((f))~~ Poisonous or caustic medications and materials including housekeeping and personal grooming supplies must show proper warning or poison labels and must be stored safely and separately from other medications and food supplies;

~~((g))~~ (f) Drugs requiring refrigeration must be kept in a separate refrigeration unit according to manufacturer's directions;

~~((h))~~ (g) Schedule II-IV controlled substances are:

(i) Kept in a separate locked storage ~~((unit))~~ container within a lockable room; and

(ii) If heat sensitive, kept in a ~~((locked))~~ refrigeration unit within a lockable room;

~~((i))~~ (iii) Schedule II-IV controlled substances no longer needed by the patient must be disposed of in compliance with chapter ~~((246-865))~~ 246-945 WAC.

~~((6))~~ ~~If emergency drugs and intravenous fluids are maintained in the facility, these are considered an extension of the drug supply owned by the legally authorized prescribing practitioner; these drugs remain the responsibility of the legally authorized prescribing practitioner.))~~ (4) Administration of medications stored at the birth center is the responsibility of the legally authorized practitioner who is administering that medication.

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-160 Birth center—Physical environment. The purpose of this section is to reduce and control environmental hazards and risks, prevent accidents and injuries, and maintain safe conditions and equipment for ~~((clients))~~ patients, visitors, and staff.

(1) The licensee ~~((shall))~~ must provide and maintain a safe and clean environment. The licensee ~~((shall))~~ must maintain the facility consistent with this chapter. Birthing centers built before the adoption of this chapter ~~((shall))~~ must be maintained to the standards that were in place at the time the ~~((facility))~~ center was originally licensed. If the licensee modifies or alters the facility, the altered areas must meet and be maintained consistent with this chapter and in accordance with the approved plans.

(2) The licensee ~~((shall))~~ must provide at least one birthing room ~~((that is))~~. Birthing rooms must have a minimum of ~~((three hundred square feet and has a minimum dimension of fifteen))~~ 156 square feet, with each dimension having a minimum of 11 feet. The room ~~((shall))~~ must be adequate and appropriate to provide for the equipment, staff, supplies, and emergency procedures required for the physical and emotional care of ~~((a maternal))~~ the client, ~~((her support person or persons, and the))~~ newborn, and their support people during ~~((birth, labor, and the recovery))~~ labor, birth, and the immediate postpartum period.

~~((a))~~ Additional birthing rooms shall have a gross floor space of one hundred fifty-six square feet or fourteen and one-half square meters and a minimum room dimension of eleven feet.

~~((b))~~ (3) The licensee ~~((shall))~~ must locate birthing rooms to provide unimpeded, rapid access to an exit of the building which will accommodate emergency transportation vehicles.

~~((3))~~ (4) The licensee ~~((shall))~~ must provide at least five square feet of fixed or portable work surface areas for use in the birthing room or rooms.

~~((4))~~ (5) The licensee ~~((shall))~~ must provide and maintain ~~((toilet))~~ bathrooms, handwashing sinks, and bathing facilities.

(a) ~~((Toilet and lavatory shall))~~ Bathrooms and handwashing sinks must be located in the vicinity of the birthing room or rooms.

(b) At least one bathroom must be accessible in accordance with the state adopted building code.

(c) A bathing facility must be available for ~~((client))~~ patient use.

~~((e))~~ (d) The licensee ~~((shall))~~ must keep clean and in good repair all floor surfaces, wall surfaces, ~~((water closets, lavatories))~~ bathrooms, handwashing sinks, tubs, and showers.

~~((5))~~ (6) The licensee ~~((shall))~~ must provide a space suitable for ~~((hanging full length garments and secure))~~ storage of ~~((clients'))~~ client and support person's personal belongings ~~((and valuables))~~.

~~((6))~~ (7) The licensee ~~((shall))~~ must provide visual privacy for each ~~((maternal))~~ client and ~~((her))~~ their support person or persons.

~~((7))~~ (8) The licensee ~~((shall assure))~~ must ensure hallways and doors providing access and entry into the birth center and birthing room or rooms are adequate width and conformation to accommodate maneuvering of ambulance stretchers and wheelchairs.

~~((8))~~ (9) Water supply. The licensee ~~((shall assure))~~ must ensure an adequate supply of hot and cold running water under pressure consistent with chapter 246-290 WAC, regarding public water supplies. The licensee ~~((shall))~~ must provide and maintain equipment required to deliver hot water at point of use as follows: ~~((a))~~ 120°F or less for handwash sinks and bathing fixtures;

~~((b)) 160°F or more for laundry washers;~~

~~((c)) 120°F or more for laundry washers using chemical sanitation;~~

~~((d)) 120°F or more for mechanical dishwashers using chemical sanitation;~~

~~((e)) 140°F or more for mechanical dishwashers using high temperature sanitation; and~~

~~((f)) 180°F or more for sanitation cycle in high temperature mechanical dishwashers.~~

~~((9))~~ (10) The licensee ~~((shall))~~ must provide heating and ventilation that:

(a) Provides a safe and adequate source of heat capable of maintaining a room temperature of at least 72°F.

(b) Provides ventilation sufficient to remove odors, excessive heat, and condensation.

~~((10))~~ (11) The licensee ~~((shall))~~ must provide and maintain lighting and power and ~~((shall))~~ must provide and maintain:

(a) Emergency lighting throughout the center, which can include plug-in battery pathway lighting;

(b) General lighting ~~((and))~~ throughout the center;

~~((c) Adequate examination lighting devices with shatterproof bulbs or protective shields, in the birthing room;~~

~~((e) Tamperproof))~~ (d) Tamper resistant electrical receptacles in birthing rooms, toilets, bathing facilities and family rooms and waiting areas; and

~~((d))~~ (e) Ground fault circuit interrupter (GFCI) receptacle when located within five feet of water source and above counters that contain sinks.

~~((11))~~ (12) The licensee ~~((shall assure))~~ must ensure linen and laundry service~~((, and shall))~~ that provides:

(a) Soiled linen/laundry storage and sorting areas physically separated from clean linen storage and handling areas, kitchen and eating facilities or ensure that any work or function performed in or around a combined linen/laundry area is performed without significant risk of contamination to storing or handling clean linen/laundry;

(b) Laundry services ~~((and shall))~~ must include a commercial laundry service or the following equipment:

(i) Washing machine(s) ~~((providing hot water at a temperature of 160°F or 120°F for laundry washers using))~~ must have a designated sanitation cycle or laundry protocols must include chemical sanitation (e.g., bleach);

~~((ii) ((Floor drains as required for equipment;~~

~~iii))~~ Dryer(s);

~~((iv))~~ (iii) Dryer exhaust to the exterior; and

~~((v))~~ (iv) A ~~((handwash))~~ handwashing sink for hand sanitation and a utility sink for heavily soiled linens/laundry or a two-compartment sink.

~~((12))~~ (13) The licensee ~~((shall))~~ must provide utility, house-keeping, garbage, and waste services ~~((and:~~

~~(a) Provide and maintain utility and storage facilities designed and equipped for washing, disinfecting, storing, and other handling of equipment and medical supplies in a manner which ensures physical segregation of clean and sterile supplies and equipment from those that are soiled and/or contaminated; and~~

~~(b) Assure all sewage, garbage, refuse, biomedical waste, human tissue, needles and sharps and liquid waste are collected and disposed of in a manner to prevent the creation of an unsafe or unsanitary condition).~~

~~((13))~~ (14) Medical gases. If ~~((oxygen is))~~ medical gases are stored or used on the premises, the licensee ~~((shall, in addition to meeting other))~~ must meet all codes and regulations:

(a) ~~((Assure))~~ Ensure electrical equipment used in oxygen-enriched environments is designed for use with oxygen and is labeled for use with oxygen; and

(b) Post "no smoking" signs or open flames where ~~((oxygen is))~~ medical gases are being administered.

~~((14))~~ (15) Food storage ~~((and/or))~~ and preparation. The licensee ~~((shall))~~ must not provide food preparation and service except

when the birth center policy allows the preparation or storage of personal food brought in by the client or families of clients for consumption by that family. In this case, the licensee (~~shall~~) must provide an electric or gas refrigerator capable of maintaining a temperature of 45°F or lower and if furnishing reusable utensils and dishes for client use, provide dishwashing facilities (~~assuring hot water at a temperature of not less than 140°F or 120°F or more for mechanical dishwashers using chemical sanitation~~) with a sanitation cycle or cleaning protocols must use chemical sanitation (e.g. bleach).

~~((15) The applicant may, as an alternate method for the design of new construction, use the 2006 edition of the Guidelines for Design and Construction of Health Care Facilities for the physical environment standards))~~ (16) An applicant or licensee wanting to use an alternative method for the design of new construction including, but not limited to, the Guidelines for Design and Construction of Health Care Facilities, may submit a request following the process in WAC 246-329-025.

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-170 Emergency preparedness. The purpose of this section is to establish and implement a disaster plan designed to meet both internal and external disasters.

Each applicant or licensee (~~shall~~) must:

(1) Develop and implement written policies and procedures governing emergency preparedness and fire protection;

(2) Develop an acceptable written plan, periodically rehearsed with personnel, contractors, and volunteers, to be followed in the event of an internal or external emergency, and for the care of casualties of the patient and family, personnel, contractors and volunteers arising from such emergencies; and

(3) Develop a fire protection plan to include:

(a) Instruction for all personnel, contractors or volunteers in use of alarms, firefighting equipment, methods of fire containment, evacuation routes and procedures for calling the fire department and the assignment of specific tasks to all personnel, contractors and volunteers in response to an alarm; and

(b) Semiannual evacuation and fire drills for each shift of personnel.

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-180 Quality improvement. The purpose of this section is to ensure that performance improvement activities of clinical staff result in continuous improvement of client health outcomes.

Each (~~childbirth~~) birthing center licensee must maintain a quality improvement program to (~~assure~~) ensure the quality of care and services provided that includes, at a minimum:

(1) A complaint process that includes a procedure for the receipt, investigation, and disposition of complaints regarding services;

(2) A method to identify, monitor and evaluate:

(a) Services; and

(b) Referral, transfer, consultation, and transport experience and plans; and

(c) Complications of (~~(pregnancy,)~~) labor and immediate postpartum; and

(d) Other aspects of services which affect quality care.

(3) A method to identify, evaluate, monitor and correct problems identified by clients, families, clinical staff, volunteers, students or consultants.

(4) A method to identify, evaluate, monitor and correct problems associated with events reported to the department in WAC 246-329-045

(3) (a) (~~((through (1) and (4) (a)))~~) and (b) as required by chapter 70.56 RCW.

(5) A method to monitor, evaluate and modify as needed corrective actions taken.

(6) A system to assess client satisfaction.

AMENDATORY SECTION (Amending WSR 08-12-036, filed 5/30/08, effective 7/1/08)

WAC 246-329-990 Fees. The purpose of the fees section is to describe the fees associated with licensing, renewal and other charges assessed by the department.

(1) (~~((Childbirth))~~) Birthing centers licensed under chapter 18.46 RCW (~~((shall))~~) must submit an annual fee of (~~((seven hundred thirteen dollars and zero cents))~~) \$713 to the department unless a center is a charitable, nonprofit, or government-operated institution under RCW 18.46.030.

(2) A change of ownership fee of (~~((one hundred seventy-eight dollars))~~) \$178. A new license will be issued and valid for the remainder of the current license period.

(3) The department may charge and collect from a licensee a fee of (~~((eight hundred ninety-two dollars))~~) \$892 for:

(a) (~~((A second on-site visit resulting from failure of the licensee to adequately respond to a statement of deficiencies;~~

~~(b) A complete on-site survey resulting from a substantiated complaint; or~~

~~(c) A follow-up compliance survey.))~~ An on-site follow-up compliance survey deemed necessary in order to complete the standard survey process;

(b) An on-site compliance survey deemed necessary due to failure of the licensee to adequately respond to a statement of deficiencies; or

(c) An on-site compliance survey deemed necessary due to a substantiated complaint investigation.

(4) A licensee (~~((shall))~~) must submit an additional late fee in the amount of (~~((twenty-nine dollars))~~) \$29 per day, not to exceed (~~((five hundred ninety-five dollars))~~) \$595, from the renewal date (which is (~~((thirty))~~) 30 days before the current license expiration date) until the date of mailing the fee, as evidenced by the postmark.

(5) Refunds. The department (~~shall~~) must refund fees paid by the applicant for initial licensure as follows:

(a) If an application has been received but no on-site survey or technical assistance has been performed by the department, two-thirds of the fees paid, less a (~~fifty-dollar~~) \$50 processing fee; or

(b) If an application has been received and an on-site survey or technical assistance has been performed by the department, one-third of the fees paid, less a (~~fifty-dollar~~) \$50 processing fee.

(c) The department may not refund applicant fees if:

(i) The department has performed more than one on-site visit for any purpose;

(ii) One year has elapsed since an initial licensure application is received by the department, but no license is issued because applicant failed to complete requirements for licensure; or

(iii) The amount to be refunded as calculated by (a) or (b) of this subsection is (~~ten-dollars~~) \$10 or less.