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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED
12/24/2024 2:55 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Freestanding Birthing Center Licensure Requirements

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 02/03/2025 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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800 NE Oregon St. Suite 465
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Filed By:
Public Health Division
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 01/17/2025
TIME: 1:00 PM
OFFICER: Staff

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 971-277-2343
CONFERENCE ID: 527407684
SPECIAL INSTRUCTIONS:
This hearing is being held remotely via Microsoft Teams. To provide oral (spoken) testimony during this hearing, please contact publichealth.rules@odhsoha.oregon.gov to register and receive the link for the Microsoft Teams video conference via calendar appointment, or you may access the hearing using the meeting URL above. Alternatively, you may dial 971- 277-2343, Phone Conference ID 527 407 684# for audio (listen) only.

This hearing will close no later than 2:15PM but may close as early as 1:30PM if everyone who signs up to provide testimony has been heard from.

Accessibility Statement: For individuals with disabilities or individuals who speak a language other than English, OHA can provide free help. Some examples are: sign language and spoken language interpreters, real-time captioning, braille, large print, audio, and written materials in other languages. If you need help with these services, please contact the Public Health Division at 971-673-1222, 711 TTY or publichealth.rules@odhsoha.oregon.gov at least 48 hours before the meeting. All relay calls are accepted. To best ensure our ability to provide a modification please contact us if you are considering attending the meeting and require a modification. The earlier you make a request the more likely we can meet the need.

NEED FOR THE RULE(S)

The Oregon Health Authority (OHA), Public Health Division, Health Care Regulation and Quality Improvement (HCRQI) program is proposing to permanently adopt administrative rules in chapter 333, division 077 and repeal administrative rules, and amend and renumber administrative rules in chapter 333, division 076 relating to the licensing requirements for freestanding birthing centers.

In accordance with ORS chapter 441, the OHA is responsible to ensure a safe and healthy environment is provided by over 800 health-related facilities and agencies. The OHA is required to license and conduct on-site inspections of these facilities which include freestanding birthing centers.

The freestanding birthing center rules were last revised in 2006 and the rules currently fall in between rules adopted for ambulatory surgery centers and extended stay centers. To clearly differentiate the licensing requirements for freestanding birthing centers, the OHA is renumbering the rules and assigning these facilities their own division number. The OHA is amending the rules to add and amend definitions; update licensing processes to align language with other licensed health care facilities and for better clarity including clarifying the review and approval process for a license application; identifying governing body responsibilities and personnel requirements; allowing waivers; clarifying the complaint, investigation, survey, and enforcement processes; and updating policies and procedures. New emergency preparedness requirements have been added based on consideration of new federal regulations for other health care facility types. Construction standards for these facilities have also been revised. The OHA is also identifying requirements for admission, discharge, client care and client services. Additionally, risk factor tables are being amended and consultation requirements added based on separate, although similar, standards adopted by the OHA, Health Licensing Office (Board of Direct Entry Midwifery) as well as the Health Evidence Review Commission. Non-substantive edits are also being made to ensure consistent terminology throughout HCRQI rules and policies, makes general updates consistent with OHA practices, updates statutory and rule references, corrects formatting and punctuation, and makes changes to improve the accuracy, structure and clarity of the rules.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

- ORS chapter 433 (https://www.oregonlegislature.gov/bills_laws/ors/ors433.html)
- ORS chapter 441 (https://www.oregonlegislature.gov/bills_laws/ors/ors441.html)
- ORS chapter 442 (https://www.oregonlegislature.gov/bills_laws/ors/ors442.html)
- ORS chapter 678 (https://www.oregonlegislature.gov/bills_laws/ors/ors678.html)
- ORS chapter 684 (https://www.oregonlegislature.gov/bills_laws/ors/ors684.html)
- ORS chapter 685 (https://www.oregonlegislature.gov/bills_laws/ors/ors685.html)
- ORS chapter 687 (https://www.oregonlegislature.gov/bills_laws/ors/ors687.html)
- OAR chapter 332, division 25
(https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1213)
- OAR chapter 333, division 20
(https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1235)
- OAR chapter 333, division 21
(https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1236)
- OAR chapter 333, division 24
(https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1239)
- OAR chapter 811, division 15 (https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=260078)
- OAR chapter 850, division 35
(https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3916)
- OAR chapter 851, division 55

(https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=5986)

- Federal Register, Vol. 81, No. 180, Department of Health and Human Services, Centers for Medicare and Medicaid Services, 42 CFR Parts 403, 416, 418, et al. – Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers; Final Rule (https://www.govinfo.gov/content/pkg/FR-2016-09-16/pdf/2016-21404.pdf)
- Health Evidence Review Commission (HERC), Coverage Guidance: Planned Out-of-Hospital Birth, Approved 08/13/2020 (https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/CG-OOHB-2020-Final.pdf)
- Health Evidence Review Commission (HERC), Coverage Guidance: Planned Out-of-Hospital Birth, Approved 11/12/2015 (available upon request, please contact Mellony Bernal by electronic mail at mellony.c.bernal@oha.oregon.gov)
- 2017, American Association of Birth Centers, Standards for Birth Centers (https://www.birthcenters.org/page/Standards)
- 2018, Commission for the Accreditation of Birth Centers, Indicators of Compliance with Standards for Birth Centers, Reference Edition v. 2.1, v. 2.2 and v. 2.3 (https://www.birthcenteraccreditation.org/go/get-cabc-indicators/)
- Centers for Disease Control and Prevention, 2008, Guidelines for Disinfection and Sterilization in Healthcare Facilities, Update: May 2019 (https://www.cdc.gov/infectioncontrol/guidelines/disinfection/)
- 2018, Facility Guidelines Institute, Guidelines for the Construction of Outpatient Facilities (available for review at the agency – please contact Mellony Bernal by electronic mail at mellony.c.bernal@oha.oregon.gov)
- 2022, Oregon Structural Specialty Code: (https://codes.iccsafe.org/content/ORSSC2022P2)
- 2009 and 2017, International Code Council (ICC), American National Standards Institute (ANSI) A117.1 (https://codes.iccsafe.org/content/icca117-12017P4) and (https://codes.iccsafe.org/content/icca117-12009)

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The Strong Start Initiative(1) , a collaboration between the Centers for Medicare and Medicaid Services (CMS) the Health Resour Administration (HRSA), and the Administration on Children and Families (ACF), was a four-year initiative from 2013 to 2017 to "t enhanced prenatal care interventions for women enrolled in Medicaid or the Children's Health Insurance Program who were at ri birth. The goal of the initiative was to determine if these approaches to care could reduce the rate of preterm births, improve the pregnant women and newborns, and decrease the anticipated total cost of medical care during pregnancy, delivery and over the f children born to mothers in Medicaid or CHIP." Findings from this initiative as stated in the Strong Start for Mothers and Newbor Project Synthesis(2) , include:

- Participant focus groups gave voice to the experiences of pregnant and postpartum women, who overwhelmingly said that the time, support, and education Strong Start provided. Most women with prior pregnancies said they were more satisfied with their experiences under Strong Start than they had with typical maternity care in the past.
- Patient risk profiles and rates of preterm birth varied considerably across the three Strong Start models, with women served b experiencing the lowest risk levels. Birth Center participants had dramatically lower rates of preterm birth (4.5 percent) than wor Group Prenatal Care (12 percent) or Maternity Care Homes (12.9 percent). Similarly, rates of low birthweight among Birth Cente much lower (3.6 percent) than for Group Prenatal Care and Maternity Care Home participants (10 percent and 10.5 percent, resp Cesarean section (C-section) deliveries for Strong Start participants were, by far, lowest for women in Birth Centers (13 percent). approximately 30 percent of Group Prenatal Care and Maternity Care Home participants had C-sections.

Based on data received from the Center for Health Statistics, in 2023:

- Persons giving birth in a freestanding birthing center were 73.6% White, 0.8% Black, 0.8% American Indian/Alaska Native, 1.1 other/unknown, 5.9% multiple, and 10.3% Hispanic.
- 45.1% of hospital births were Medicaid/OHP/CAWEM clients compared to 29.3% in freestanding birthing centers.

The proposed administrative rules would allow a freestanding birthing center to continue to provide prenatal care for birthing pe risk factor(s) that would otherwise require a birth to occur in a hospital-based care setting. Pregnant persons from marginalized c

factors would potentially benefit from access to additional prenatal care support. Additionally, based on community feedback and current rules will remain in effect allowing a freestanding birthing center to offer a vaginal birth after cesarean (VBAC) if certain s met. Similarly, these individuals from marginalized communities would have continued access to VBAC in this setting. Risk factors that require a freestanding birthing center to consult with a perinatal provider that are not required under current rule. The purpo is to help inform the health and safety of a client to give birth in a freestanding birthing center versus transferring to a hospital-ba Consultation based on risk factors is not required under existing rules, however, the OHA notes that existing regulations for licen Midwives already require consultation for certain conditions or risk factors. There are no similar requirements for Naturopathic P Chiropractic Physicians that this office is aware of.

According to the Oregon Health Authority, Maternal and Child Health program, and information reviewed by the Oregon Matern Morbidity Review Committee (MMMRC)(3), over the past 10 years, the number of Oregon maternal deaths per year has ranged f However, the current method of case finding may undercount actual deaths by as much as one-third. It is also important to note t who dies, there are approximately 50 who suffer severe maternal morbidity--very severe complications of pregnancy, labor, and c close to death. Oregon's maternal death rate, measured as the number of maternal deaths per 100,000 live births, varies from yea overall small number of deaths but is typically at or below that of the U.S. overall.

The following information was pulled from the January 2023, Oregon Maternal Mortality and Morbidity Review Committee (MM Report(4):

- As of January 2023, 37 deaths occurred between 2018-2020 of persons who died during, and the year following, pregnancy.
- 46% of these cases were determined to be pregnancy-related.
- 53% were considered by the MMMRC to be preventable.
- Nearly half of underlying causes of death were due to mental health issues or substance use disorders.
- The mean age at time of death was 31 years.
- 18% self-reported as Asian; 6% self-reported as Hispanic; and 6% self-reported as American Indian/Alaska Native.

The following recommendations were made by the MMMRC:

- Ensure culturally specific coordination of care and support before, during, and after pregnancy.
- Expand utilization of doulas in health care systems.
- Ensure pregnant and postpartum people with mental health conditions obtain the services they need to manage their conditio
- Ensure pregnant and postpartum people with histories of substance use disorders obtain the services they need to manager th

Current rules do not require that birthing persons experiencing a behavioral health condition must be transferred to hospital-bas under the proposed rules, a freestanding birthing center would be required to consult with a perinatal care provider. The addition will benefit pregnant persons from marginalized communities by ensuring the connection of physical, mental and social well-being

Under the current rule, birthing persons with "current substance abuse which has the potential to adversely affect labor and/or th to be transferred to hospital-based care. This condition will continue to require hospital-based care under the proposed rules whi the Rule Advisory Committee (RAC).

In terms of the types of providers that can attend births, the proposed administrative rules do not restrict provider types who can than what is already allowed under Oregon law. Birthing centers are primarily operated by licensed direct entry midwives, naturo certified nurse midwives. The proposed rules added chiropractic physicians who also have a certification for natural childbirth un practice. The OHA recognizes that there is a critical need for more culturally diverse providers who can attend births and support boards in their aim to increase culturally diverse provider options. According to data obtained from the health licensing regulator

- 447 active licensed nurse midwives
- 102 active licensed direct entry midwives

- 34 active licensed naturopathic physicians with a natural birth certification
- 1 active licensed chiropractic physician with certification of special competency in natural childbirth

- The 2023 Oregon Health Care Workforce Needs Assessment(5) is a biennial Health Care Workforce Needs Assessment that ir
to ensure culturally and linguistically responsive care for all. One of the key findings is that Oregon must improve the diversity of
order to achieve the strategic goal of eliminating health inequities. This report recommends reducing barriers to entry and advanc
color in the workforce and increase investments in training, recruiting, and retaining health care workers. It further concludes tha
expand, and diversify Oregon's health care workforce so that it can deliver culturally responsive, effective health care services to
need increased compensation to attract new individuals and increase retention; 2) Many professions with unclear career pathway
paths for increasing skills, pay, and impact; and 3) All professions need more support around resiliency and well-being."

- Per Table 4.5 in the 2023 Oregon Health Care Workforce Needs Assessment, compared to the population in Oregon:
Nurse practitioners: 1.3% identify as American Indian/Alaska Native; 4.7% identify as Asian; 2.2% identify as Black/African Ameri
Latino; 0.3% identify as Native Hawaiian or Pacific Islander; 0.7% identify as other; and 85.6% identify as white.
Naturopathic physicians: 2.9% identify as American Indian/Alaska Native; 6.3% identify as Asian; 0.9% identify as Black/African A
as Latino/a/x; 0.8% identify as Native Hawaiian or Pacific Islander; 0.8% identify as other; and 83.8% identify as white.
Chiropractic physicians: 2.1% identify as American Indian/Alaska Native; 7.2% identify as Asian; 0.5% identify as Black/African Ar
as Latino/a/x; 0.6% identify as Native Hawaiian or Pacific Islander; 0.8% identify as other; and 85.7% identify as white.
Per data obtained from the Board of Direct Entry Midwifery of the 102 active licensed direct entry midwives only 8 identified as a
unassigned and 47 identified as white.

- Per Table 4.6 in the 2023, Oregon Health Care Workforce Needs Assessment, "Spanish is the most common language spoken c
among licensed providers (about 10%). The next most common languages spoken are Chinese (including Mandarin and Cantonese
French, and Russian. Less than 1% of the licensed health care providers are native speakers or have advanced proficiency in each
Thus, many patients who speak a language other than English need the assistance of a Health Care Interpreter. ORS 413.559 and
thereunder require that health care providers, including health care facilities defined under ORS 442.015, must work with a healt
the health care interpreter registry for persons who prefer to communicate in a language other than English. The proposed rules r
requirement.

(1) Centers for Medicare and Medicaid Services, Strong Start for Mothers and Newborns Initiative: Enhanced Prenatal Care Mod
https://www.cms.gov/priorities/innovation/innovation-models/strong-start-strategy-2
(2) Urban Institute, Strong Start for Mothers and Newborns Evaluation: Year 5 Project Synthesis, Volume 1: Cross-Cutting Fining
https://downloads.cms.gov/files/cmmi/strongstart-prenatal-finalevalrpt-v1.pdf
(3) Oregon Health Authority, Healthy People and Families, Maternal and Children Health, Maternal Mortality and Morbidity Revi
webpage: https://www.oregon.gov/oha/ph/healthypeoplefamilies/datareports/pages/maternal-mortality-morbidity-review-com
(4) Oregon Health Authority, Oregon Maternal Mortality and Morbidity Review Committee Biennial Report, January 2023:
https://www.oregon.gov/oha/PH/HEALTHYPEOPLEFAMILIES/DATAREPORTS/MCHTITLEV/Documents/January2023Biennie

(5) Oregon State University, College of Public Health and Human Sciences, Oregon's Health Care Workforce Needs Assessment
Prepared for the Oregon Health Authority, Oregon Health Policy Board

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FISCAL AND ECONOMIC IMPACT:

The OHA is responsible for licensing and conducting on-site inspections and investigations of freestanding birthing centers. There are currently 13 licensed freestanding birthing centers.

According to data obtained from Oregon Center for Health Statistics in 2023 there were a total of 632 births which occurred in freestanding birthing centers. Attendants of those births consisted of:

- 56% attended by certified nurse midwives.
- 37% attended by licensed direct entry midwives.
- 7% attended by naturopathic physicians.

Based on the amendments and adoption of proposed rules, the OHA has identified the following possible fiscal impacts for a freestanding birthing center:

• A birthing center must report organizational changes within 30 days. Previously there was no time requirement for reports. Timely reporting will result in additional monitoring and tracking.

• A birthing center must timely renew its license. The OHA will not renew a license if application for renewal is received no less than 30 days prior to expiration. A birthing center that does not timely renew will be required to file for initial licensure and comply with all of the rules including a licensing survey. This would mean a birthing center could not offer services until a new license which may result in a loss of funds.

• If voluntarily closing, a birthing center will be required to notify the public 30 days in advance including updating webpages, posting information on social media (if used by the birthing center), and issue a press release. The tasks associated with notification will require staff time and resources.

• Governing body responsibilities that must be identified in writing including:

o Client care and services of the birthing center must be under the supervision of a manager who is a licensed direct entry midwife, certified nurse midwife, or physician (as defined in rule).

o Adoption and implementation of a quality improvement program to ensure that performance improvement activities of clinical staff result in continuous improvement of client health outcomes. While it is common for licensed facilities to have quality improvement programs, the requirement was not in previous rules. This will result in additional staff time and includes documentation requirements.

• Additional policies and procedures must be adopted, maintained and reviewed annually. This will require staff time. New policies and procedures include:

o Assurance that all personnel are certified in basic life support (BLS) for healthcare providers. Current rules only require CPR certification The cost of BLS training is approximately $100 per person. The OHA does not collect data on the number of personnel in each licensed freestanding birthing center so it is unable to determine the estimated total average cost for each birthing center.

o Job descriptions for each position and annual performance evaluations.

o Threats against clients or newborns.

o Visitor conduct and control.

o Client grievance procedures.

o Storage and maintenance of equipment.

o Financial interest notification.

o Health care interpreter services.

• Additional requirements for client services that may result in additional costs include:

o Required client orientation and disclosures.

o Consultation with perinatal provider for specified risk factors.

o Risk assessment within 21 days of first prenatal care visit.

o Allows telemedicine, however, requires certain number of in-person assessments.

o Specifies newborn follow-up visits at two weeks and between 6-8 weeks.

• Additional documentation requirements for the identification, dispensing, storage and security of medications.

• Changes to dietary services allows a birthing center to make arrangements with external vendors to prepare or deliver food which based on feedback from the RAC is current practice. Specifies requirements in terms of food storage

for clients. Specifies that only single service utensils can be used. The costs of a box of 400 pack plastic cutlery is approximately $25. Refrigerator used for food storage may not be used to store infectious material such as a placenta. This may require an additional refrigerator. The average price of a smart refrigerator is between $2,500 to $5,000. There are budget friendly refrigerators that can be obtained for approximately $1,000.

• Proposed rules specify minimum equipment necessary. One item that is required which may result in additional costs to a birthing center is oxygen with flow meter and positive pressure mask. The estimated cost is approximately $100.

• Physical environment rules were drafted taking into consideration current Commission on Accreditation of Birthing Centers requirements as many licensed birthing centers pursue accreditation. Although many proposed rules imply they are a new requirement when comparing to existing rules, many of the new requirements actually clarify or put on notice items that are already required in state adopted building codes, state adopted fire codes and cross-referenced standards, state and federally adopted accessibility codes, or other Oregon administrative rules that already exist. It is worth noting that lack of compliance with some newly listed items would result in possible complaint investigation or survey citation, no matter the rules adopted and this includes: client and newborn safety (prevent falls, prevent abductions or elopements if the baby is not deemed acceptable to leave yet, maintain safe temperatures, preclude access to hazardous materials and toxic chemicals), client dignity (do not allow the public to freely walk into any birthing room), infection prevention (where handwashing stations are needed, securing infectious waste from incidental contact, sterilizing tools and equipment for reuse, sanitizing soiled linens, prevent cross-contamination of clean versus soiled), and HIPAA (protect the client's private health information). Excluding the above list of existing requirements by other authorities having jurisdiction or items already subject to survey citation, the following fiscal impacts are anticipated for freestanding birthing centers seeking initial licensure and for currently licensed freestanding birthing centers seeking to remodel meeting a threshold:

o All electrical outlets accessible to the public must be tamper-resistant. An internet search with a commonly available building supply retailer in Oregon suggests the cost delta will be $2.65 each for standard compared to $3.31 each for tamper resistant feature.

o Extension cords are not allowed for tripping prevention plus fire prevention and will instead require additional hardwired electrical receptacles adequate in quantity to serve all powered equipment. It is unknown how many existing birthing centers may not be in compliance with this rule. Actual costs will vary based on existing conditions of a structure versus new construction.

o Provide adequate site and parking light. It is unknown how many existing birthing centers may not be in compliance with this rule. Cost vary depending on site features available. Birthing centers are not required to have parking lots.

o Entrances must be clearly marked with signage, but are not required to be powered or illuminated. As such, for birthing centers that do not already have signage, this one-time cost should be minimal.

o A birthing center must provide access to a telephone. Since most clients and their caregivers will likely have access to a phone, as well as staff on-site, the costs are expected to be minimal. A charger for cell phones should be kept on-site.

o Kitchens or kitchenettes must include a hand-washing station, means to keep food cold, and means to heat food. See previous comment regarding approximate costs for refrigerators.

o Toilet rooms must not open to rooms where food is being prepared, and may require thoughtful space planning layout.

o Requiring birthing rooms to be a minimum size may require additional space.

o Newborn care area under direct visual observation of client may require thoughtful space planning layout.

o Requiring 10 square feet of storage for every birthing room, may require additional space.

o Adding a children's play area to the waiting room, may require additional space.

o Providing staff work area, may require additional space.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the

expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) There is no anticipated cost of compliance to state agencies or impact on units of local government. The OHA currently conducts the survey and licensing requirements for freestanding birthing centers. It is possible that clients of freestanding birthing centers may see an increase in cost if licensed freestanding birthing centers choose to pass down any costs associated with increased licensing standards.

(2)(a) There are currently 13 licensed freestanding birthing centers that are considered a small business that will be subject to these new and amended rules.

(b) Based on changes to the required policies and procedures and other documentation requirements, there will be an increase in projected reporting, record keeping and other administrative activities as identified under the fiscal impact statement above.

(c) The OHA anticipates that freestanding birthing centers are already in compliance with a majority of the proposed equipment and supply standards. There is an anticipated increase in administrative costs based on revised requirements for the governing body and new and amended policies and procedures.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

There were five licensed birthing centers that participated on the Rulemaking Advisory Committee all of which are considered small businesses. Additionally, a representative from the Oregon Association of Birth Centers participated and described themself as representing all Oregon licensed freestanding birthing centers.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

333-076-0490, 333-076-0560, 333-076-0570, 333-076-0590, 333-076-0650, 333-077-0000, 333-077-0010, 333-077-0015, 333-077-0020, 333-077-0025, 333-077-0030, 333-077-0035, 333-077-0040, 333-077-0045, 333-077-0050, 333-077-0055, 333-077-0060, 333-077-0065, 333-077-0070, 333-077-0080, 333-077-0090, 333-077-0100, 333-077-0110, 333-077-0120, 333-077-0125, 333-077-0130, 333-077-0140, 333-077-0145, 333-077-0150, 333-077-0160, 333-077-0170, 333-077-0180, 333-077-0190, 333-077-0200, 333-077-0210, 333-077-0220, 333-077-0230, 333-077-0240, 333-077-0250, 333-077-0260

REPEAL: 333-076-0490

RULE SUMMARY: Repeal OAR 333-076-0490

Text from this rule is duplicative. All health care facilities proposing to make certain alterations or additions to existing facilities or to construct new facilities are required to comply with OAR chapter 333, division 675.

CHANGES TO RULE:

~~333-076-0490~~
~~Birthing Centers: Submission of Plans~~
~~(1) Any party proposing to make certain alterations or additions to an existing health care facility or to construct new facilities must, before commencing such alteration, addition or new construction, submit plans and specifications to the Division for preliminary inspection and approval of recommendations with respect to compliance with Division rules. Submissions shall be in accord with, OAR 333-675-0000. Plans should also be submitted to the local building division having authority for review and approval in accordance with state building~~

~~codes.¶~~
~~(2) Centers must keep the Division informed of any changes in ownership, organizational structure, procedures performed and privileges permitted and any information requested on the application form, in writing within 30 days of the change. Failure to notify the Division may result in revocation of license.~~
~~Statutory/Other Authority: ORS 441.060, 442.015~~
~~Statutes/Other Implemented: ORS 441.060, 442.015~~

REPEAL: 333-076-0560

RULE SUMMARY: Repeal OAR 333-076-0560

The rule text is outdated and refers generally to classifications of all health care facilities. Rule text under section (1) was moved to OAR 333-077-0025.

CHANGES TO RULE:

~~333-076-0560~~
~~Birthing Centers: Classification~~
~~(1) Health care facilities licensed by the Division may neither assume a descriptive title or be held out under any descriptive title other than the classification title established by the Division and under which the facility is licensed.¶~~
~~(2) No change in the licensed classification of any health care facility, as set out in this rule, may be allowed by the Division unless such facility files a new application, accompanied by the required license fee, with the Division. If the Division finds that the applicant and facility comply with Health Care Facility laws and the regulations of the Division relating to the new classification for which application for licensure is made, the Division may issue a license for such classification.~~
~~Statutory/Other Authority: ORS 441.025, 442.015~~
~~Statutes/Other Implemented: ORS 441.025, 442.015~~

REPEAL: 333-076-0570

RULE SUMMARY: Repeal OAR 333-076-0570

Rule text has been amended and added to OAR 333-077-0040.

CHANGES TO RULE:

~~333-076-0570~~
~~Birthing Centers: Hearings~~
~~Upon written notification by the Division of revocation, suspension or denial to issue or renew a license; a written request by the Center for a hearing in accordance with ORS 183.310 to 183.500 may be granted by the Division.~~
~~Statutory/Other Authority: ORS 441.037, 442.015~~
~~Statutes/Other Implemented: ORS 441.037, 442.015~~

REPEAL: 333-076-0590

RULE SUMMARY: Repeal OAR 333-076-0590

Rule text is no longer necessary. Previous standards that were adopted in rule have been removed.

CHANGES TO RULE:

~~333-076-0590~~
~~Birthing Centers: Adoption by Reference~~
~~All rules, standards and publications referred to in this division are made a part thereof. Copies are available for inspection at the Division during office hours. Where publications are in conflict with the rules, the rules govern.~~
~~Statutory/Other Authority: ORS 441.025, 442.015~~
~~Statutes/Other Implemented: ORS 441.086, 442.015~~

REPEAL: 333-076-0650

RULE SUMMARY: Repeal OAR 333-076-0650

Rule text has been amended and added to OAR 333-077-0150

CHANGES TO RULE:

~~333-076-0650~~
~~Birthing Centers: Service Restrictions~~
~~(1) Procedures permitted, including surgical procedures, must be limited to those directly pertaining to pregnancy, labor and delivery care of women experiencing low risk pregnancy. Procedures performed will be consistent with the individual practitioner's licensure and/or scope of practice. Tubal ligation and abortion must not be performed. Table I outlines absolute risk factors that, if present on admission to the birthing center for labor and delivery, would prohibit admission to the birthing center. Table II outlines absolute risk factors that, if they develop during labor and delivery, require transfer of the client to a higher level of care. Table III outlines absolute risk factors that, if they develop during the postpartum period in the mother or infant, would require transfer to a higher level of care. [Tables not included. See ED. NOTE.]¶~~
~~(2) General, spinal, caudal, and/or epidural anesthesia must not be administered in the Center.¶~~
~~(3) Labor shall not be induced, stimulated, or augmented with chemical agents during the first or second stages of labor.¶~~
~~(4) Chemical agents may be administered within the individual practitioner's scope of practice to inhibit labor, as a temporary measure, until referral/transfer of the client is complete.¶~~
~~[ED. NOTE: Tables referenced are available from the agency.]~~
~~Statutory/Other Authority: ORS 441.025, 442.015~~
~~Statutes/Other Implemented: ORS 441.025, 442.015~~

ADOPT: 333-077-0000

RULE SUMMARY: Adopt OAR 333-077-0000

Clarifies that the purpose of the birthing center rules is to establish licensing standards for birthing centers to ensure the health and safety of persons who receive services.

CHANGES TO RULE:

333-077-0000
Applicability
The purpose of OAR chapter 333, division 77 is to establish standards for the licensure of freestanding birthing centers to ensure the health and safety of individuals who receive services from these centers.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.015 - 441.098, ORS 441.990, ORS 441.991, ORS 442.015

AMEND: 333-077-0010

RULE SUMMARY: Amend OAR 333-077-0010 (Renumbered from 333-076-0450)

Several new definitions have been added and definitions for terms that are not used in rule text were removed. Definition for free standing birthing center was modified for clarity.

CHANGES TO RULE:

333-077-0010
~~Birthing Centers:~~ Definitions ¶

(1) "~~Free Standing Birth Center" ("Birthing Center" or "Center") means any health care facility (HCF),~~Authentication" means verification that an entry in the client medical record is genuine.¶
(2) "Authority" means the Oregon Health Authority.¶
(3) "Birthing center licensing laws" means ORS 441.015 through 441.990, as applicable, and rules adopted thereunder.¶
(4) "Certified nurse midwife" means a registered nurse licensed under ORS chapter 678 as a nurse practitioner specializing in nurse midwifery.¶
(5) "Client" means the person seeking services at the birthing center. ¶
(6) "Client audit" means review of the medical record or client observation including the care provided to a client from admission to discharge. ¶
(7) "Clinical provider" means any individual among clinical staff who is ultimately responsible for the clinical care of a client.¶
(8) "Clinical staff" means any individual among all staff who perform tasks or have responsibilities in clinical care.¶
(9) "Discharge" means, following admission:¶
(a) The release of a client or newborn, who was a client of a birthing center, to home;¶
(b) The transfer of a client or newborn to hospital-based care; or ¶
(c) A client or newborn who has died. ¶
(10) "Financial interest" means a five percent or greater direct or indirect ownership interest. ¶
(11) "Free standing birthing center" ("birthing center") means a facility licensed for the primary purpose of performing low risk deliveries that is not a hospital, or ~~in~~located inside a hospital, and where births are planned to occur away from the ~~mother~~client's usual residence following normal, uncomplicated pregnancy.¶
(12) "~~Division" means the Oregon Health Authority, Public Health Division.¶~~
~~(3) "Low Risk Pregnancy" means a normal, uncomplicated prenatal course as de~~Governmental unit" has the same meaning given that term in ORS 442.015.¶
(13) "Health care facility" has the same meaning given that term in ORS 442.015.¶
(14) "Hospital" has the meaning given that term in ORS 442.015. ¶
(15) "Indirect ownership interest" means any ownership interest in an entity that has an ownership interest in the disclosing entity. The term in~~ed 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.¶~~
~~(4) "Absolute risk factors" are those condition~~cludes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.¶
(16) "Licensed direct entry midwife" means an individual licensed under ORS 687.405 to 687.495.¶
(17) "Person" has the meaning given that term in ORS 442.015. ¶
(18) "Physician" means: ¶
(a) An individual licensed as a doctor of medicine or osteopathy under ORS chapter 677; ¶
(b) An individual licensed as a naturopathic physician under ORS chapter 685, and who has obtained a certificate of special competency in natural childbirth in accordance with OAR chapter 850, division 35; or¶
(c) An individual licensed as a chiropractic physician as that~~, if present, prohibit care in a~~ term is defined in ORS 684.010, and who has obtained a certificate of special competency in natural childbirth in~~g center.¶~~
~~(5) "Patient audit" means review of the clinical record and/or physical inspection of a client.¶~~
~~(6) "Reasonable and generally accepted criteria" means criteria or standards of care adopted by professional groups for maternal, fetal and neonatal health care, and g~~ accordance with OAR chapter 811, division 15. ¶
(19) "Plan of correction" means a document executed by a birthing center in response to a statement of deficiencies issued by the Authority that describes with specificity how and when deficiencies of birthing center licensing laws shall be corrected.¶
(20) "Statement of deficiencies" means a document issued by the Authority that describes a birthing center's deficiencies in complying with birthing center licensing laws. ¶

(21) "Survey" means an inspection of a birthing centerally accepted and followed by the care providers to whom they apply, and accepted by the Division as reasonable to determine the extent to which a birthing center is in compliance with birthing center licensing laws.¶
(22) "These rules" means OAR 333-077-0000 through OAR 333-077-0260.
Statutory/Other Authority: ORS 441.025, 442.015
Statutes/Other Implemented: ORS 442.015, ORS 441.015 - 441.0986

AMEND: 333-077-0015

RULE SUMMARY: Amend OAR 333-077-0015 (Renumbered from 333-076-0470)
Steps to apply for a new license or renew an existing license have been modified to align with other licensed facility processes. Applicants must complete a form required by the Oregon Health Authority (Authority) and pay the license fee established under ORS 441.020. The rule clarifies that an applicant seeking to construct a new birthing center or renovate an existing birthing center must provide evidence of plans review approval. It requires notifying the Authority of any changes to ownership and operational structure within 30 days of change. Failure of a birthing center to report changes may result in penalties.

CHANGES TO RULE:

333-077-0015
Birthing Centers: LicensingLicense Application and Fees ¶

(1) Application for a person applying for a new or renewal license to operate a Bbirthing Ccenter must be in writingsubmit an application on a form providescribed by the Division, including demographic, ownership and administrative information. The form must specify such information required by the Division.¶
(2) No health care facility licensed pursuant to the provisions of ORS Chapter 441, may in any manner or by any means assert, represent, offer, provide or imply that such facility is or may render care or services other than that which is permitted by or that is within the scope ofOregon Health Authority (Authority) and pay the applicable, non-refundable fee specified in ORS 441.020.¶
(2) If an applicant is proposing to construct a new birthing center or proposing to make certain alterations or additions to an existing birthing center, the license issued to such facility by the Division nor may any service be offered or provided that is not authorized within the scope of the license issued to such facility or licensed practitioner providing services in the facility.¶
(3) The Bapplicant shall also submit evidence of plans review approval as required by OAR chapter 333, division 675. ¶
(3) A birthing Ccenter license must be conspicuously posted in the area where clients are admitted.¶
(4) A license that has been suspended or revoked may be reissued aftemust inform the Authority in writing of any changes in ownership, organizational structure, or othe Division determines that compliance with Health Carer information required on the application form, within 30 days of the change. Facility laws has been achieved satisfactorilyure to notify the Authority may result in sanctions as described in OAR 333-077-0040.
Statutory/Other Authority: ORS 441.015, 442.0125
Statutes/Other Implemented: 442ORS 441.020, ORS 441.0125, ORS 441.01560

ADOPT: 333-077-0020

RULE SUMMARY: Adopt OAR 333-077-0020

Specifies the application review process by the Oregon Health Authority (Authority) which includes conducting an in-person survey and consultation with the Oregon State Fire Marshal. The Authority will verify compliance with administrative rules and related statutes and consider factors to ensure the health and safety of individuals to be cared for and the ability of the operator to safely operate the facility.

CHANGES TO RULE:

333-077-0020
Application Review
(1) In reviewing an application for a new birthing center, the Oregon Health Authority (Authority) shall: ¶
(a) Verify compliance with the applicable sections of ORS chapters 441, 442, these rules and OAR chapter 333, division 675; ¶
(b) Conduct an in-person licensing survey in accordance with OAR 333-077-0060; and¶
(c) Consult with the State Fire Marshal, deputy or approved authority to ensure the applicant has not received a certificate of non-compliance pursuant to ORS 479.215. ¶
(2) In determining whether to license a birthing center, the Authority may not consider whether the birthing center is or shall be a governmental, charitable or other nonprofit institution or whether it is or shall be an institution for profit.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025, ORS 441.022

ADOPT: 333-077-0025

RULE SUMMARY: Adopt OAR 333-077-0025

Identifies Oregon Health Authority notification requirements when a license is approved and limits on the licensee including the license is non-transferrable and must be clearly posted. It specifies that a licensee may not hold themselves out as anything other than a birthing center and services provided must be within the scope of the license.

CHANGES TO RULE:

333-077-0025
Approval of License Application
(1) The Oregon Health Authority (Authority) shall notify an applicant in writing if a license application is approved and shall include the license with the notification.¶
(2) A license shall be issued only for the premises and persons or governmental units named in the application and is not transferable or assignable. ¶
(3) The license shall be conspicuously posted in an area where clients are admitted. ¶
(4) A birthing center licensed pursuant to the provisions of ORS chapter 441 and these rules shall not, in any manner or by any means:¶
(a) Assume a descriptive title or be held out under any descriptive title other than the classification title established by the Authority and under which the facility is licensed; ¶
(b) Assert, represent, offer, provide or imply that such person or birthing center is or may render care or services other than that which is permitted by or which is within the scope of the license issued to the birthing center by the Authority; or¶
(c) Offer or provide any service which is not authorized within the scope of the license issued to the birthing center.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025, ORS 441.015, ORS 441.022

AMEND: 333-077-0030

RULE SUMMARY: Amend OAR 333-077-0030 (Renumbered from 333-076-0530)
Identifies that if the Oregon Health Authority intends to deny a license application it will comply with the Administrative Procedures Act under ORS chapter 183.

CHANGES TO RULE:

333-077-0030
~~Birthing Centers: Denial or Revocation of a License~~Denial of a License Application ¶

~~(1) A license for any Birthing Center may be denied, suspended or revoked by the Division when the Division finds that there has been a substantial failure to comply with the provisions of Health Care Facility licensing law.¶~~
~~(2) A person or persons in charge of a Birthing Center must not permit, aid or abet any illegal act affecting the welfare of the license.¶~~
~~(3) A license will be denied, suspended or revoked in any case where the State Fire Marshal certifies that there was failure to comply with all applicable laws, lawful ordinances and rules relating to safety from fire.¶~~
~~(4) A license may be suspended or revoked for failure to comply with a Division order arising from a Center's substantial lack of compliance with the rules or statutes~~If the Oregon Health Authority intends to deny a license application, it shall issue a Notice of Intent to Deny in accordance with ORS 183.411 through ORS 183.470.
Statutory/Other Authority: ORS 441.0~~30, 442.01~~25
Statutes/Other Implemented: ORS 44~~2~~1.0~~1~~25, ORS 441.030

AMEND: 333-077-0035

RULE SUMMARY: Amend OAR 333-077-0035 (Renumbered from 333-076-0510)
Specifies that a license expires every year on December 31 and an application to renew a license must be received by the Oregon Health Authority at least 30 days prior to expiration. A birthing center that fails to timely renew must seek a new license and comply with all of the rules in effect. Services cannot be provided until a new license is issued.

CHANGES TO RULE:

333-077-0035
Birthing Centers: Expiration and Renewal of License ¶

(1) Each license to operate a Bbirthing Ccenter wishall expire on December 31 of each calendar year following the date of issue, and if a renewal is desired, the licensee must make application at least.¶
(2) A birthing center shall submit a completed application for renewal on a form prescribed by the Oregon Health Authority (Authority), accompanied by the required fee, to the Authority not less than 30 days prior to the license expiration date upon a form prescribed by the Division as described in.¶
(3) The Authority may issue a renewal license contingent upon evidence of the birthing center's compliance with birthing center licensing laws. ¶
(4) A birthing center that fails to timely renew in accordance with section (2) of this rule is no longer eligible for license renewal.¶
(5) The birthing center that fails to timely renew:¶
(a) Must submit an initial application in accordance with OAR 333-0767-0470015 to seek re-licensure. ¶
(b) May not provide services until a new license has been issued.¶
(c) Must comply with all rules in effect at the time that the application seeking re-licensure is submitted.
Statutory/Other Authority: ORS 441.025, 442.015
Statutes/Other Implemented: 442.015ORS 441.025, ORS 183.430, ORS 441.0250

ADOPT: 333-077-0040

RULE SUMMARY: Adopt OAR 333-077-0040

Specifies that the Oregon Health Authority may deny, suspend or revoke a birthing center license or may impose a civil penalty for failure to comply with licensing laws.

CHANGES TO RULE:

333-077-0040
Denial, Suspension, or Revocation of License
(1) The Oregon Health Authority (Authority) may impose a civil penalty or deny, suspend or revoke a birthing center's license for failure to comply with birthing center licensing laws. ¶
(2) If the Authority intends to impose a civil penalty or deny, suspend or revoke a birthing center's license, it shall do so in accordance with ORS 183.411 through 183.470.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025, ORS 441.030

AMEND: 333-077-0045

RULE SUMMARY: Amend OAR 333-077-0045 (Renumbered from 333-076-0550)
Identifies steps that a birthing center must take if it voluntarily closes including steps to notify persons about the closure and how persons can access their medical records. The rule requires a birthing center to take certain actions prior to closing.

CHANGES TO RULE:

333-077-0045
~~Birthing Centers: Ret~~Return of License and Closur~~n~~e of ~~Facility License~~Birthing Center ¶

~~Each~~(1) If a birthing center's license is suspended or revoked, or if a birthing center decides to permanently close, the license certificate in the licensee's possession ~~must~~shall be returned to the ~~Division immediately on the suspension or revocation of the license, failure to renew the license by December 31, or if operation is discontinued by the voluntary action of~~Oregon Health Authority (Authority) immediately.¶
(2) If a birthing center voluntarily closes, at least 30 days prior to closure, it shall notify the public by:¶
(a) Issuing a press release to multiple media outlets;¶
(b) Updating the birthing center website; and ¶
(c) Posting information through social media, such as Facebook, Instagram, and X (formerly known as Twitter), if such applications are used by the birthing center. ¶
(d) Information posted on the website, through social media, and released to media outlets shall include information about how a client or a client's legal representative may obtain their medical records.¶
(3) A birthing center that decides to voluntarily permanently close shall notify the Authority at least 14 calendar days prior to the closure and submit plans for the orderly transfer of the clients and the storage and disposal of medical records. Medical records not claimed must be retained for the time period specified under OAR 333-077-0130, and then may be destroyed. ¶
(4) The Authority may deny a birthing center the ability to surrender their license~~e~~ in lieu of an investigation or to avoid an administrative action.
Statutory/Other Authority: ORS 441.0~~86, 442.01~~25
Statutes/Other Implemented:~~ 442.015,~~ ORS 441.0~~86~~25

ADOPT: 333-077-0050

RULE SUMMARY: Adopt OAR 333-077-0050

Allows a birthing center to request a waiver from specific requirements and the Oregon Health Authority (Authority) may consider and approve such requests. It further identifies information that must be submitted to the Authority for consideration. In an emergency, the Authority may waive a rule that a birthing center is unable to meet for reasons beyond their control.

CHANGES TO RULE:

333-077-0050
Waivers
(1) While all birthing centers are required to maintain continuous compliance with the Oregon Health Authority's (Authority's) rules, these requirements do not prohibit the use of alternative concepts, methods, procedures, techniques, equipment, facilities, personnel qualifications or the conduct of pilot projects or research. A request for a waiver from a rule must: ¶
(a) Be submitted to the Authority in writing; ¶
(b) Identify the specific rule for which a waiver is requested; ¶
(c) Identify the special circumstances relied upon to justify the waiver; ¶
(d) Explain why the birthing center is unable to be in compliance, what alternatives were considered if any, and why alternatives (including compliance) were not selected; ¶
(e) Demonstrate that the proposed waiver is desirable to maintain or improve the health and safety of the clients, to meet the individual and aggregate needs of clients, and shall not jeopardize client health and safety; and ¶
(f) Include the proposed duration of the waiver. ¶
(2) Upon finding that the birthing center has satisfied the conditions of this rule, the Authority may grant a waiver. ¶
(3) A birthing center may not implement a waiver until it has received written approval from the Authority. ¶
(4) During an emergency, the Authority may waive a rule that a birthing center is unable to meet for reasons beyond the birthing's center control. If the Authority waives a rule under this section, it shall issue an order, in writing, specifying which rules are waived, which birthing centers are subject to the order, and how long the order shall remain in effect.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

AMEND: 333-077-0055

RULE SUMMARY: Amend OAR 333-077-0055 (Renumbered from 333-076-0610)
Specifies processes and procedures relating to complaints. It clarifies that the identity of a person making a complaint is confidential. A birthing center is required to post information about where someone may file a complaint. The rule further identifies reporting requirements if a provider has knowledge of inappropriate care or violation of birthing center laws.

CHANGES TO RULE:

333-077-0055
~~Birthing Centers: Division Procedure~~Complaints ¶

~~Inspections and investigations:¶~~
~~(1) Complaints:¶~~
(~~a~~1) Any person may make a complaint ~~to the Division regarding violation of health care facility laws or regulations. A complaint investigation will be carried out as soon as practicable and may include but not be limited to, as applicable to facts alleged:~~verbally or in writing to the Oregon Health Authority (Authority) regarding an allegation against a birthing center of a violation of birthing center licensing laws or regulations. ¶
(~~A~~2) ~~Interviews of the complainant, client(s), witnesses, and Center management and staff;¶~~
~~(B) Observations of the client(s), staff performance, client environment and physical environment; and¶~~
~~(C) Review of documents and records~~The identity of a person making a complaint and any personally identifiable information, as that is defined in ORS 432.005, is confidential and not subject to disclosure under ORS 192.311 to 192.478.¶
(~~b~~3) ~~Copies of all complaint~~An investigations will be ~~available from the Division provided that the identity~~carried out as soon as practicable after receipt of a~~ny~~ complain~~ant and any client referred to in an investigation will not be disclosed without legal authorization.¶~~
~~(2) Inspections:¶~~
~~(a) The Division may, in addition to any inspections conducted pursuant to complaint investigations, conduct at least one general inspection of each Center to determine compliance with Health Care Facility laws during each calendar year and at such other times as the Division deems necessary;¶~~
~~(b) Inspections may inclu~~t in accordance with OAR 333-077-0060.¶
(4) A birthing center shall post a complaint notice in the birthing center that is clearly visible to the public and includes the Authority's complaint reporting phone number, electronic mail address and website address. ¶
(5) An employee or contract provider with knowledge of inappropriate care or any violation of birthing center licensing laws shall use the reporting procedures established by the birthing center before notifying the Authority or other state agency of the inappropriate care or violation, unless the employee or contract provider b~~ut not be limited to those procedures stated in sub~~elieves a patient's health or safety is in immediate jeopardy or files a complaint in accordance with section (1)~~(a)~~ of this rule~~;~~.¶
(~~c~~6) ~~The inspection may include a client audit;¶~~
~~(d) When documents and records are requested under sections (1) or (2) of this rule, the Center must make the requested materials available to the investigator for review and copying~~If the complaint involves an allegation of criminal conduct or an allegation that is within the jurisdiction of another local, state, or federal agency, the Authority will refer the matter to that agency.
Statutory/Other Authority: ORS 441.025~~, 442.015~~
Statutes/Other Implemented: ORS 44~~2~~1.0~~1~~25, ORS 441.0~~86~~44

ADOPT: 333-077-0060

RULE SUMMARY: Adopt OAR 333-077-0060

Specifies that the Oregon Health Authority (Authority) shall investigate a complaint as soon as practicable after receiving the complaint and a birthing center must give Authority staff access to the birthing center to investigate. It specifies that an investigation includes at least interviews with the complainant, client, client family members, staff, and others; on-site observations of clients, staff and the physical environment; and review of documents and records. The rule further clarifies that information obtained during an investigation is confidential.

CHANGES TO RULE:

333-077-0060
Investigations
(1) As soon as practicable after receiving a complaint, taking into consideration the nature of the complaint, Oregon Health Authority (Authority) staff will begin an investigation.¶
(2) A birthing center shall permit Authority staff access to the birthing center during an investigation and make all requested documents and records available to Authority staff for review and copying.¶
(3) An investigation may include but is not limited to:¶
(a) Interviews of the complainant, clients of the birthing center, client family members or legal representatives, witnesses, birthing center management and staff;¶
(b) On-site observations of clients, staff performance and the physical environment of the birthing center; and¶
(c) Review of documents and records.¶
(4) Following the investigation, Authority staff may conduct an exit conference and prepare and provide the birthing center administrator or the administrator's designee written notice of the findings in accordance with OAR 333-077-0065.¶
(5) Information obtained by the Authority during an investigation of a complaint or reported violation under this section is confidential and not subject to public disclosure under ORS 192.410 to 192.505. Upon the conclusion of the investigation, the Authority may publicly release a report of its findings but may not include information in the report that could be used to identify the complainant or any client at the birthing center. The Authority may use any information obtained during an investigation in an administrative or judicial proceeding concerning the licensing of a birthing center, and may report information obtained during an investigation to a health professional regulatory board as defined in ORS 676.160 as that information pertains to a licensee of the board.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025, ORS 441.044

ADOPT: 333-077-0065

RULE SUMMARY: Adopt OAR 333-077-0065

Specifies that in addition to a complaint investigation, the Oregon Health Authority (Authority) will conduct an in-person licensing survey at least once every three years. The birthing center shall give Authority staff access to the birthing center. Specifies that the survey may include interviews of clients, client family members, staff, and others; on-site observations of clients, staff performance and the physical environment; review of documents and records; and client audits. Following a survey, Authority staff may conduct an exit conference and share initial results.

CHANGES TO RULE:

333-077-0065
Surveys
(1) The Oregon Health Authority (Authority) shall, in addition to any investigations conducted under OAR 333-077-0060, conduct at least one in-person licensing survey of each birthing center every three years to determine compliance with birthing center licensing laws and at such other times as the Authority deems necessary. ¶
(2) A birthing center shall permit Authority staff access to the birthing center during a survey. ¶
(3) A survey may include but is not limited to: ¶
(a) Interviews of clients, client family members or legal representatives, birthing center management and staff; ¶
(b) On-site observations of clients, staff performance, and the physical environment of the birthing center; ¶
(c) Review of documents and records; and ¶
(d) Client audits. ¶
(4) A birthing center shall make all requested documents and records available to the surveyor for review and copying. ¶
(5) Following a survey, Authority staff may conduct an exit conference with the birthing center administrator or the administrator's designee. If an exit conference is conducted, Authority staff shall: ¶
(a) Inform the birthing center representative of the preliminary findings of the inspection; and ¶
(b) Give the birthing center representative a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings.¶
(6) Following the survey, Authority staff shall prepare and provide the birthing center administrator or the administrator's designee specific and timely written notice of the findings. ¶
(7) If the findings result in a referral to another regulatory agency, Authority staff shall submit the applicable information to that referral agency for its review and determination of appropriate action. ¶
(8) If no deficiencies are found during a survey, the Authority shall issue written findings to the birthing center administrator indicating that fact. ¶
(9) If deficiencies are found, the Authority shall take informal or formal enforcement action in accordance with OAR 333-077-0240 or 333-077-0250.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025, ORS 441.060

AMEND: 333-077-0070

RULE SUMMARY: Amend OAR 333-077-0070 (Renumbered from 333-076-0630)
Clarifies the responsibilities of the birthing center's governing body. It requires the governing body to employ or contract with an administrator or chief executive officer; establish an organizational plan that identifies policies and procedures; establish scope of services, responsibilities for operation, client care and services, admitting privileges, adoption of quality improvement program, and review of the professional practices of the birthing center to reduce morbidity and mortality.

CHANGES TO RULE:

333-077-0070
Birthing Centers: AdministrationGoverning Body Responsibility ¶

(1) Each Cbirthing center must have a governing body or person clearly identified as being legally responsible for setting of policies and procedures, and assuring that they are implemented.the control and operation of the birthing center, the selection of the clinical staff, and the quality of care and services provided in the birthing center.¶
(2) The governing body shall employ or contract with an administrator or chief executive officer who is responsible for the administrative operation of the birthing center and who ensures compliance with all policies and procedures, birthing center licensing laws and these rules. ¶
(3) The governing body shall establish in writing: ¶
(a) A formal organizational plan that clearly sets forth policies, procedures and by-laws, and the responsibilities, accountability, and relationships of clinical providers, clinical staff and other personnel including volunteers;¶
(b) The scope of services provided by the birthing center;¶
(c) Administrative policies and procedures including but not limited to the policies and procedures specified in OAR 333-077-0090;¶
(d) Responsibilities for the operation of the birthing center; ¶
(e) Qualifications for an administrator or chief executive officer;¶
(f) That client care and services of the birthing center is under the supervision of a manager who is a licensed direct entry midwife, certified nurse midwife, or physician. ¶
(g) That all clinical staff for whom state licenses are required are currently licensed, certified or registered;¶
(h) That all clinical providers admitted to practice in the facility are granted privileges consistent with their individual training, experience, and other qualifications;¶
(i) Criteria and procedures for granting, restricting, and terminating privileges of all clinical providers, and that such procedures are reviewed on a regular basis;¶
(j) The provision of sufficient personnel, facilities, equipment, supplies and other services to meet the needs of clients; and¶
(k) Adoption and implementation of a quality improvement program in accordance with OAR 333-077-0200 to ensure that performance improvement activities of clinical staff result in continuous improvement of client health outcomes.¶
(4) The governing body shall ensure that all clinical providers admitted to practice in the birthing center shall effectively review the professional practices of the birthing center for purposes of reducing morbidity and mortality and for improving client care
Statutory/Other Authority: ORS 441.025, 442.015
Statutes/Other Implemented: ORS 4421.0125, ORS 441.08655

ADOPT: 333-077-0080

RULE SUMMARY: Adopt OAR 333-077-0080

Specifies that a birthing center must maintain minimum number of clinical staff to provide effective services and to ensure no client in active labor is left unattended. It further specifies minimum training requirements for clinical staff. Staff are required to have a position description, annual performance evaluation, and continuing education. The rule requires the birthing center to maintain personnel records and necessary documentation. A birthing center must comply with rules relating to restricting the work of employees with certain diseases.

CHANGES TO RULE:

333-077-0080
Personnel
(1) A birthing center shall, at a minimum:¶
(a) Maintain a sufficient number of clinical staff on duty and on call to provide effective client care and all other related services, and to ensure that no client in active labor shall be left unattended;¶
(b) Have one clinical staff person trained in the use of emergency equipment and certified in neonatal resuscitation endorsed by the American Academy of Pediatrics, on duty at all times a client is present;¶
(c) Have one clinical provider present at each birth;¶
(d) Have a second clinical staff person trained in the use of emergency equipment and certified in neonatal resuscitation endorsed by the American Academy of Pediatrics present during each birth;¶
(e) Maintain for all clinical staff providing direct client care a completion document that certifies that the clinical staff person holds a current American Heart Association, Basic Life Support (BLS) Provider or equivalent cardiopulmonary resuscitation (CPR) course that includes a practical skills evaluation; ¶
(f) Have a job description for each position that delineates the qualifications, duties, authority and responsibilities essential in each position;¶
(g) Conduct an annual work performance evaluation for each employee; and¶
(h) Create an annual continuing education plan for its employees. ¶
(2) A birthing center shall maintain personnel records on all employees, contractors, and volunteers working at the facility that include documentation of required licensure, certification(s), qualifications, health screenings, training and development, and annual performance evaluations. ¶
(3) A birthing center shall restrict the work of employees, contractors and volunteers with restrictable diseases in accordance with OAR chapter 333, division 19.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

AMEND: 333-077-0090

RULE SUMMARY: Amend OAR 333-077-0090 (Renumbered from 333-076-0670)

Requirements for policies and procedures that a birthing center must have were amended and include 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; visitor conduct and control; client grievance procedures; assessment of risk and consultation; medical record content; infection control requirements; equipment storage, maintenance and sterilization; provision of life saving measures; availability of emergency transportation; orientation and education of clients and families; performance of laboratory services; procurement, storage and administration of drugs; collection of blood for newborn screening; performance of pulse oximetry screening; systems to ensure filing of appropriate vital records; procedures for notifying clients of any financial interest; and procedures for providing health care interpreter services to clients who prefer to communicate in a language other than English.

CHANGES TO RULE:

333-077-0090
~~Birthing Centers:~~ Policies and Procedures ¶

~~Each Center must have a detailed Policies and Procedures Manual in easily accessible form, that has been approved by the governing body or person. In order to be approved by the Division for licensing purposes, these policies and procedures must meet North American Registry of Midwives (NARM) standards. All the above noted policies must be made available to representatives of the Division on request, and subject to their approval. Failure of approval will be adequate reason for the finding of deficienci~~(1) A birthing center shall develop and implement written policies and procedures that include, but are not limited to, the following:¶
(a) Types of services and procedures that m~~ust~~ay be ~~corrected for continuation of licensure. The policies must be implemented as applicable, and there must be documented evidence of implementation of the above noted policies. The policies and procedures that will be developed as applicable and implemented include:¶~~
~~(1) A detailed organizational chart that shows the governing body or person, and clearly delineates lines of authority, responsibility and accountability for each position included in the organization, including volunteers.~~performed in the birthing center;¶
(b) Training requirements for clinical providers, clinical staff and other personnel that include, but are not limited to: ¶
(~~2~~A) ~~Staffing - The governing body or person must ensure, through the policies and procedures, that there are adequate numbers of qualified and, where required, licensed or registered personnel on duty and immediately available to provide services intended for mothers and families, and to provide for safe maintenance of the Center.¶~~
~~(3) Detail of procedures to be permitted, and by whom, and method of determining the qualifications and privileges of all personnel. Staff will be required to provide documented evidence of such qualifications. Such evidence must be maintained by the Center.¶~~
~~(4) System for ensuring 24-hour coverage of the Center, including constant attendance by qualified attendants while a client is in the Center.~~Infection control measures; and¶
(B) Emergency procedures, including but not limited to: ¶
(i) Procedures for fire and other disasters; ¶
(ii) Procedures in life threatening situations including but not limited to cardiopulmonary resuscitation and other life saving techniques; and ¶
(iii) Threats against clients or newborns. ¶
(~~5~~c) System for ~~training and for continuing education for all personnel according to their assigned duties and evaluation of skills consistent with the individual practitioners' scopes of practice. All personnel providing direct client care must be trained in cardiopulmonary resuscitation (CPR) and there must be a record of current CPR certification. In addition there must be present at each birth one practitioner trained in c~~ensuring 24-hour coverage of the birthing center, consistent with the requirements in OAR 333-077-0080;¶
(d) Client care and services activities;¶
(e) Admission and discharge ~~and resuscitation of the newborn.~~criteria;¶
(~~6~~f) ~~System delineating how and when the Center will seek consultation with clinical specialists in obstetrics and pediatrics in order to ensure that all services, policies, and procedures meet North American Registry of Midwives (NARM) standards.¶~~
~~(7) Protocol for referral or transfer to appropriate health care facilities all clients whose risk status exceeds that~~

for "low risk pregnancy."¶
(8) Procedures by which risk status will be assessed during the antepartal, intrapartal, and post partum period, and the identification of medical and social factors which exclude women, fetuses and newborns from the low-risk group; and for the annual review of these methods. Documentation of such assessments must be maintained in cliVisitor conduct and control;¶
(g) Client grievance procedures;¶
(h) Assessment of risk status and consultation requirements in accordance with OAR 333-077-0125;¶
(i) Content and form of medical records and release of medical information consistent with the requirements in OAR 333-077-0130;¶
(j) Infection control requirement's clinical records. Only those clients for whom prenatal and intrapartum history, physical examination, and laboratory screening procedures have demonstrated a low risk pregnancy and labor will be accepted into the Center for childbirth.¶
(9) System by which the Center will ensure the presence and continuing maintenance, as recommended by the manufacturer(s), of equipment needed to provide low risk maternity care, and to initiate emergency procedures in life-threatening events to the mother or baby.¶
(10) Plan and protocols for ensuring that emergency situations in either the mother or newborn are recognized in a timely fashion, and care is provided withinin accordance with OAR 333-077-0190;¶
(k) Equipment storage, maintenance and sterilization in accordance with OAR 333-077-0180;¶
(l) Provision of life saving measures within the clinical provider's scope of practice and arrangements for transfer to hospital-based care for the climits of the practitioner's scope of practice.¶
(11) System delineating how emergency transportation will be promptly availableent or newborn;¶
(m) Prompt availability of emergency transportation for transport of the mother and/client or newborn to a health care facilityhospital-based care with the capacity for emergency care of womenpersons, in all the stages of labor, and newborns. The written policy must include a listing of situations for the mother and/or newborn that would have the potential to necessitate emergency transfer. The policy must also include the requirement that a transfer plemergency care of newborns;¶
(n) Orientation and education of clients and for each patient be developed.¶
(12) Systemamily members for ensuring the orientation and education of women and families registering for care at the Center so that they will be informed as to the benefits and risks of the services available to them at the Center and the qualifications and licensure status of practitioners at the Center. They must be fully informed of the risk criteria as defined in OAR 333-076-0650 and provide written consent. The client, as a part of the informed consent, must also agree in advance to transfer to another clinicianlegal representatives registering for care including the services available, required disclosures, client rights, and exclusion, transfer, and consultation requirements; ¶
(o) Performance orf appropriate health care facility, should the need occur due to the development of unexpected risk factors after admission to the Center. The client must be informed of the benefits and risks of such a transfer.¶
(13) System for the sterilization of equipment and supplies, unless only pre-packaged and pre-sterilized items are used.¶
(14) System to ensure the performance of appropriate laboratory studies and to ensure thatlaboratory services including tests required pursuant to ORS 433.017 and the rules adopted the results are available in a timely mannunder.;¶
(15) System for thep) Procurement, storage and administration of drugs. All medications must be prescribed and/or administered within the individual practitioner's licensure and/or scope of practice.¶
(16) System to ensure the t, including:¶
(A) Timely administration of Rh immune globulin to the motherclient, where applicable.¶
(17) System to ensure the timely appropriate; and¶
(B) Timely administration of Vitamin K to thea newborn, according to rules of the Division.¶
(a) The purpose of ORS 433.303 to 433.314 is to protect newborn infants against hemorrhagic disease of the newborn.¶
(b) The Vitamin K forms suitable for use are forms of Vitamin K1 (Phytonadione), available in injectable or oral forms: as Mephyton for oral use, or as aquamephyton or konakion for injectable use. The Vitamin K dose is to be administered within the first 24 hours of delivery. Menadione (Vitamin K3) is not recommended for prophylaxis and treatment of hemorrhagic disease of the newborn.¶
(c) The dose of any of the Vitamin K1 forms to be administered is one dose of 0.5 to 1.0 mg., if given by injection, or one dose of 1.0 to 2.0 mg. if given orally.¶
(d) A parent may, after being provided a full and clear explanation,nd prevention of ophthalmia neonatorum in a newborn in accordance with OAR 333-077-0170. If Vitamin K or gonococcal ophthalmia neonatorum prophylaxis cannot be administered by the clinical provider decline to permit the administration of Vitamin K based on

~~religious tenets and practices. In this event, the parent must sign a form acknowledging his/her understanding of the reason for administration of Vitamin K and possible adverse consequences in the presence of a person who witnessed the instruction of the parent, and who must also sign the form. The form must become a part of the clinical record of the newborn infant.¶~~
~~(18) System to ensure the timely and appropriate~~vering the newborn, methods must be described to ensure that these services are arranged by referral;¶
(q) Appropriate and timely collection of blood from ~~the~~a newborn for testing by the Oregon State Public Health Laboratory~~, Newborn Screening Program, for the M~~ for metabolic ~~D~~diseases ~~listed in 333-024-0210.¶~~
~~(19) System to ensure that pulse oximetry screening is performed on every newborn infant delivered at the Birthing Center before the infant is discharged in conformance with the following requirements:¶~~
~~(a) The~~in accordance with OAR 333-077-0170;¶
(r) Performance of pulse oximetry screening ~~must be performed using evidence-based guidelines such as those recommended by Strategies for Implementing Screening for Critical Congenital Heart Disease, AR Kemper et al., Pediatrics 2011;128(5): e1259-1267.¶~~
~~(b) The Birthing Center must have policies and procedures based on the guidelines required by subsection (a) of this section for:¶~~
~~(A) Determining what is considered a positive screening result; and¶~~
~~(B) Determining what follow-up services, treatment or referrals must be provided if a newborn infant has a positive screening result.~~on every newborn in accordance with OAR 333-077-0170;¶
(~~c~~s) ~~A Federal Drug Administration (FDA) approved motion tolerant pulse oximeter must be used.¶~~
~~(d) The pulse oximetry screening must be performed no sooner than 24 hours after birth or as close to discharge of the newborn infant as possible.¶~~
~~(e) Before performing pulse oximetry screening on newborn infants, individuals must have received training on how to correctly operate the pulse oximeter and the policies and procedures associated with the screening. The Birthing Center must document this training.¶~~
~~(f) If a newborn infant is admitted to a hospital as the result of a transfer from the Birthing Center before a pulse oximetry screening is performed, the hospital from which the newborn infant is discharged to home is responsible for performing the screening.~~Systems to ensure that appropriate vital records are filed according to ORS 432.088;¶
(~~g~~t) ~~The Birthing Center must provide the following notifications and document them in the newborn infant's medical record:¶~~
~~(A) Prior to the pulse oximetry screening, notify a parent or legal representative of the newborn about the reasons for the screening and the risks and consequences of not screening.¶~~
~~(B) Following the pulse oximetry screening, notify the health care provider responsible for the newborn infant and the infa~~Procedures for notifying client~~'~~s ~~primary care provider of the results of the screening.¶~~
~~(C) Following the pulse oximetry screening and prior to discharge, notify a parent or legal representative of the newborn infant of the screening result, an explanation of its meaning and, if it is a positive screening result, provide information about the importance of timely diagnosis and intervention.¶~~
~~(h) A parent or legal representative of a newborn infant may decline pulse oximetry screening and, if screening is declined, the Birthing Center must document the declination in the newborn infant's medical record.¶~~
~~(i) Following the pulse oximetry screening, the Birthing Center, in accordance with the applicable standard of care, must provide any appropriate follow-up services or treatment for the newborn infant if necessary or provide a referral to a parent or legal representative of the newborn for follow-up services or treatment if necessary.¶~~
~~(j) The Birthing Center must document in the newborn infant's medical record that the screening was performed, the screening result, the names of the health care providers who were notified of the screening result, and any follow-up services or treatment or referral for services or treatment.¶~~
~~(k) No newborn infant may be refused screening because of the inability of a~~orally and in writing of any financial interest as required by ORS 441.098; and¶
(u) Procedures for providing health care interpreter services to clients who pare~~nt or legal representative to pay for the screening.¶~~
~~(20) Protocol delineating the steps to ensure the prompt and safe evacuation of the Center in the event of emergency situations, such as fire. The Center must ensure the evaluation of staff in managing such situations by periodic drills for fire, and/or other emergencies. Such drills must be documented.¶~~
~~(21) System of infection control to address the prevention and early recognition of the possibility of infection, and timely and acceptable methods of control. This includes written documentation of the problem, and measures taken for control, and must at least meet the requirements of the rules of the Division. Documentation must also include methods for the control and prevention of cross-infection between clients and services in accordance with 2003 Center for Disease Control and Prevention "Guidelines for Environmental Infection Control in Health-Care Facilities."¶~~

(22) System to be used for the prevention of Ophthalmia Neonatorum in the newborn OAR 333-019-0036fer to communicate in a language other than English in accordance with ORS 413.559 and OAR 950-050-0160.¶
(2). Prophylaxis for Gonococcal Ophthalmia Neonatorum:¶
(a) The practitioner attending the birth of an infant must, after evaluating the infant as being at risk and within two hours of delivery, instill appropriate prophylactic antibiotic ointment from single patient use applicators into each eye of the newborn infant;¶
(b) Parent(s) refusing to allow prophylaxis for their infant(s) must be informed, by tholicies and procedures shall be evaluated annually and be attmending Health Care Provider, of the risks attendant to such action and must sign a witnessed affidavit to testify that they have been so informed and nonetheless refuse to allow prophylaxis.¶
(c) If Vitamin K and/or Gonococcal Ophthalmia Neonatorum Prophylaxis cannot be administered by the individual delivering the newborn, methods must be described to ensure that these services are arranged by referral.¶
(23) System to ensure that appropriate vital records are filed according to the rules of the Division.¶
(24) System for a semi-annual clinical record audit to evaluate the care process and outcomeed or rewritten as needed. Documentation of the annual evaluation is required.
Statutory/Other Authority: ORS 441.025, 442.015
Statutes/Other Implemented: ORS 4421.0125, ORS 441.02533.017

ADOPT: 333-077-0100

RULE SUMMARY: Adopt OAR 333-077-0100

Specifies that 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 and specifies the information that must be disclosed. The rule further identifies the minimum services that must be provided, which includes intrapartum and postpartum care, and allows a birthing center to provide prenatal care. A birthing center must assess the client's risk status throughout pregnancy, labor and delivery to determine if receiving care at the birthing center is appropriate. The rule allows the birthing center to consult with perinatal care or other specialty care providers. The rule makes provisions for the use of telemedicine through synchronous communication.

CHANGES TO RULE:

333-077-0100
Client Care Services
(1) Clients registering for care at a birthing center shall receive an orientation and written information regarding the services provided at the birthing center including a statement of client rights in accordance with section (3) of this rule.¶
(2) Each client shall sign, and receive a copy of, a client disclosure form which includes, but is not limited to, the following information:¶
(a) Services provided to the client and newborn;¶
(b) Risks, benefits, and eligibility requirements;¶
(c) Responsibilities of the client and family members or legal representatives;¶
(d) Fees for services including financial arrangements;¶
(e) Malpractice coverage or professional liability coverage; ¶
(f) Risk assessment, consultation, and transfer requirements;¶
(g) Emergency care and transport plan in the event of complications to the client or newborn; and¶
(h) Identity and qualifications of clinical staff.¶
(3) The statement of client rights shall include, but is not limited to, the following:¶
(a) Clients shall be treated with courtesy, dignity, respect, privacy, and freedom from abuse;¶
(b) Clients shall be offered services without discrimination as to race, ethnicity, color, religion, gender identification, sexual orientation, national origin, or source of payment;¶
(c) Privacy of personal information and confidentiality of health care records;¶
(d) Clients shall be informed of all laboratory and diagnostic tests, reports, recommendations, and treatments in a timely fashion; ¶
(e) Participation in a plan of care and any changes to the plan of care;¶
(f) Clients may refuse treatment;¶
(g) Clients shall be offered nourishment;¶
(h) Clients shall be informed of screening requirements and referrals to services determined necessary; and¶
(i) Information on how and where to file a complaint.¶
(4) A birthing center shall:¶
(a) Provide intrapartum and postpartum care described in sections (6) and (7) of this rule. ¶
(b) Assess the client's risk status throughout pregnancy, labor, and delivery in accordance with OAR 333-077-0125 to determine if care and services in a birthing center, including delivery, is appropriate. ¶
(c) Consult with a provider of perinatal care or other specialty provider in accordance with OAR 333-077-0125. ¶
(d) Provide dietary services in accordance with OAR 333-077-0160. ¶
(5) A birthing center that provides prenatal care shall perform regular, periodic prenatal exams and assessments of client and fetus risk status. A prenatal exam shall include at a minimum:¶
(a) Physical exam;¶
(b) Urinalysis and other laboratory screenings as determined necessary by the clinical provider; ¶
(c) Discussions about the client's health and newborn's health including good nutrition and how to reduce pregnancy complications and newborn's risk for complications; ¶
(d) Fetal health assessment; and¶
(e) In third trimester, discussions about preparing for childbirth and classes available;¶
(6) Intrapartum care provided by a birthing center shall include, but is not limited to:¶
(a) Periodic assessment of the client's physical health and emotional and psychological needs including but not limited to:¶
(A) Monitoring of vital signs;¶

(B) Urinalysis if indicated;¶
(C) Pain assessment; and¶
(D) Frequency of contractions.¶
(b) Periodic assessment of the fetus's health including but not limited to:¶
(A) Monitoring fetal heart rate and fetal movement; and¶
(B) Abdomen palpation to determine fetal lie and presentation.¶
(c) Comfort measures including but not limited to:¶
(A) Physical assistance;¶
(B) Emotional support; and¶
(C) Pain relief methods.¶
(d) Companionship during labor and childbirth with a client's companion of choice.¶
(7) Postpartum care shall consist of periodic assessment of the client's health and newborn's health. ¶
(a) The client health assessment includes but is not limited to:¶
(A) Physical exam;¶
(B) Laboratory screening tests, if applicable;¶
(C) Education in child care including breast or chest feeding, immunization, and referral to sources of pediatric care; ¶
(D) Provision of, or referral to, family planning services; and¶
(E) Referral to newborn screenings as required in OAR 333-077-0170 if screenings are not provided by the birthing center.¶
(b) The newborn health assessment includes but is not limited to:¶
(A) Physical exam;¶
(B) Laboratory screening tests, if applicable; and¶
(C) Screenings for newborns in accordance with OAR 333-077-0170.¶
(8) A clinical provider may use telemedicine to provide prenatal and postpartum care to clients after completion of an initial, in-person assessment if no risk factors or complications were identified. ¶
(a) Telemedicine may be conducted through electronic and telecommunication technologies such as video communication, teleconference, landline or wireless communications. Real-time communication between the clinical provider and the client is required. ¶
(b) A clinical provider must ensure that an in-person assessment is completed with the client at least two times between 28 to 36 weeks, and two times between 36 weeks to 39 weeks, 6 days. ¶
(c) Telemedicine may not be conducted after 39 weeks, 6 days. ¶
(9) A clinical provider may use a birthing center for both primary care clients and birthing center clients. Client files must be distinct and maintained separately.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

ADOPT: 333-077-0110

RULE SUMMARY: Adopt OAR 333-077-0110
Specifies that 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.

CHANGES TO RULE:

333-077-0110
Admission and Discharge
(1) A birthing center shall only admit a client for whom medical history, physical examination, laboratory screening, and risk assessments do not exclude them from receiving care and services including delivery in a birthing center in accordance with OAR 333-077-0125. ¶
(2) After an assessment, a client who meets any exclusion factor, or a client or newborn who meet risk factor criteria or a complication specified in OAR 333-077-0125, shall be referred to an appropriate health care provider or facility. ¶
(3) Generally, a client and newborn shall be discharged within 24 hours after birth in accordance with written policies and procedures. If the client or newborn are not in satisfactory condition, or the client or newborn meet any of the risk factor criteria specified in OAR 333-077-0125, arrangements shall be made to transfer to hospital-based care in accordance with OAR 333-077-0120. ¶
(4) A discharge plan shall be developed and communicated to the client and documented in the medical record. ¶
(a) The discharge plan shall include, at a minimum, provisions for newborn screenings and follow-up care for both the client and newborn. ¶
(b) The plan shall clarify that a newborn follow-up visit is necessary at two weeks and again between 6-8 weeks.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

ADOPT: 333-077-0120

RULE SUMMARY: Adopt OAR 333-077-0120

Specifies that 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. It specifies minimum requirements for the policy. The rule further acknowledges that imminent fetal delivery may delay or preclude transfer prior to birth.

CHANGES TO RULE:

333-077-0120
Client or Newborn Transfer
(1) A birthing center shall have a policy for essential life saving measures, stabilization, and immediate transfer to hospital-based care, of a client or newborn requiring medical care that exceeds the capabilities of the birthing center. ¶
(2) The policy for essential life saving measures must address at a minimum the following: ¶
(a) Circumstances warranting transfer, including but not limited to:¶
(A) The risk factor criteria specified in OAR 333-077-0125; and¶
(B) The person responsible for making the transfer decision. ¶
(b) Documentation and transfer of information required for proper care and treatment of the client being transferred; ¶
(c) Arrangement for immediate emergency transport of the client including communication with the receiving facility; and¶
(d) Annual staff training requirements for emergency and non-emergency transfer of clients and newborns. ¶
(3) Imminent fetal delivery may delay or preclude actual transfer prior to birth.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

ADOPT: 333-077-0125

RULE SUMMARY: Adopt OAR 333-077-0125

Requires a clinical provider at the birthing center to assess 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 based on adopted risk factor tables. The rule notes that that the risk factors identified in tables are not comprehensive and other conditions may arise that may require further consultation or transfer to a hospital. The rule requires that an in-person risk assessment be completed within the first 21 days after the first prenatal care visit. 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 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 and the rule specifies requirements for documentation. Under this new rule, 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.

CHANGES TO RULE:

333-077-0125
Risk Status Assessment and Consultation Requirements
(1) As used in this rule, "provider of perinatal care" means a physician or certified nurse midwife as those terms are defined under OAR 333-077-0010, a physician associate licensed under ORS chapter 677, a nurse practitioner licensed under ORS chapter 678, or a licensed direct entry midwife licensed under ORS chapter 687. ¶
(2) A clinical provider at a birthing center shall assess a client's risk status throughout pregnancy, labor, and delivery to determine if care and services including delivery in a birthing center is appropriate based on the criteria for exclusion, risk factor criteria specified in Tables I and II, or any consultation conducted based on the criteria specified in Tables I and II. The list of exclusion and risk factor criteria is not comprehensive, and other physical, behavioral health, obstetric, or fetal conditions may arise that require consultation or transfer to hospital-based care. Having multiple risk conditions requiring consultation may increase the risk sufficiently to indicate the need to transfer care. ¶
(3) An initial, in-person risk assessment shall be performed within 21 calendar days of the initial prenatal care visit and updated throughout the pregnancy, labor, and delivery. ¶
(4) Appropriate referral or transfer to hospital-based care shall occur promptly if the client, fetus or newborn meet any one criteria for exclusion, or risk factor criteria or complication identified in Tables I through III at any time, including but not limited to during an initial risk assessment, a periodic risk assessment, or if discovered during a consultation conducted in accordance with section (5) of this rule. ¶
(5) A clinical provider at the birthing center shall consult with a provider of perinatal care if the client or fetus meet any one of the consultation criteria specified in Tables I through III. ¶
(a) The consulted provider of perinatal care must have direct experience handling complications of the risk(s) present, as well as the ability to confirm the indication for consult which includes, but is not limited to, confirmation of a diagnosis and recommendation(s) regarding management of medical, obstetric, or fetal problems or conditions. ¶
(b) The consulted provider of perinatal care may not be an owner or employee of the birthing center. ¶
(c) A birthing center shall include the client during the consultation, if possible. If the client is unable to participate during the consultation, the birthing center shall notify the client as soon as practicable, but not later than the next appointment, about any findings and recommendations from the consulted provider of perinatal care.¶
(6) The clinical provider at the birthing center shall implement outcomes of the consultation and any decisions made regarding the plan of care and document the following information within seven calendar days of the consultation:¶
(a) Who participated in the consultation;¶
(b) Information shared with the consulted provider of perinatal care;¶
(c) Any findings and recommendations from the consulted provider of perinatal care;¶
(d) Discussions with the client during or after the consultation about the findings and recommendations;¶

(e) Decisions made by the clinical provider as to whether the client is no longer suitable for care at the birthing center;¶
(f) Decisions made by the client for continued care;¶
(g) Informed consent from the client if the client decides to continue care at the birthing center; and ¶
(h) Plan of care.¶
(7) A client who must be referred or transferred to hospital-based care in accordance with section (4) of this rule, or after consultation under section (5) of this rule is referred or transferred to hospital-based care, may continue to receive prenatal care from the birthing center if: ¶
(a) The client provides informed consent to continue to receive prenatal care after being reasonably informed of: ¶
(A) Known material risk(s);¶
(B) Possible adverse outcomes; and¶
(C) Risk of adverse outcomes.¶
(b) The client acknowledges that the birth will not take place at the birthing center; and¶
(c) The information contained in section (6) and subsection (7)(a) of this rule is documented in the client's medical record. ¶
(8) These rules do not apply to decisions regarding eligibility, prior authorization, coverage determination, or payment from Medicaid, Medicare, or other reimbursement for care provided at a birthing center.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

RULE ATTACHMENTS MAY NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

Table I
OAR 333-077-0125

MEDICAL HISTORY or OBSTETRIC HISTORY that Requires Transfer or Consultation

Conditions in red boxes indicate high-risk conditions that, when present on intake, will require the transfer of a client to hospital-based care.

Conditions in the yellow boxes indicate potentially risky conditions that require consultation with a provider of perinatal care[1] as defined under OAR 333-077-0125.

The list of high-risk conditions and potentially risky conditions is not comprehensive, and other physical, behavioral health, obstetric, or fetal conditions may arise that require consultation or transfer to hospital-based care. Having multiple risk conditions requiring consultation may increase the risk sufficiently to indicate the need to transfer care.

Condition	Criteria
Delivery history and uterine conditions	• Conception occurred less than 12 months following surgery or uterine procedure • Absence of ultrasound to rule out placenta previa or placental placement to the surgical site • History of two or more Cesareans sections without a prior successful vaginal delivery • History of myomectomy which invaded the endometrium • History of a known uterine perforation • History of cesarean section which included classical incision • History of cesarean section and complications including postoperative infection, diabetes, or steroid use • Uterine rupture • Hysterotomy, other than cesarean
	• Prior myomectomy
Diabetes mellitus	• Type 1 or Type 2; currently requiring oral medication or insulin
Endocrine conditions	• Significant endocrine conditions other than diabetes (e.g. hyperthyroidism)
Fetal demise/prior still birth	• Prior stillbirth/neonatal death

[1] OAR 333-077-0125 – Provider of perinatal care means a physician or certified nurse midwife as those terms are defined under OAR 333-077-0010, a physician associate licensed under ORS chapter 677, a nurse practitioner licensed under ORS chapter 678, or a a licensed direct entry midwife licensed under ORS chapter 687.

Hematologic disorders	• Maternal bleeding disorder
	• Hemoglobinopathies • History of thrombosis or thromboembolism • History of postpartum hemorrhage requiring transfusion or other advanced treatment (e.g. Bakri balloon)
Hypertensive disorders	• Eclampsia with eclamptic seizure
	• HELLP Syndrome • Pre-eclampsia requiring preterm birth
Infectious conditions	• HIV; positive status
Neonatal encephalopathy in prior pregnancy	• Neonatal encephalopathy in prior pregnancy
Neurological disorders	• Neurological disorders or active seizure disorders that would impact maternal or neonatal health (e.g. epilepsy, myasthenia gravis, previous cerebrovascular accident)
Perineal laceration or obstetric anal sphincter injury	• Fourth-degree laceration without satisfactory functional recovery
Placental conditions	• Placenta accreta • Placenta increta • Placenta percreta
	• Retained placenta requiring surgical removal
Psychiatric conditions	• History of postpartum mood disorder with high risk to the infant (e.g. psychosis) • Schizophrenia, other psychotic disorders, bipolar I disorder or schizotypal disorders
Pulmonary disease	• Chronic pulmonary disease (e.g. cystic fibrosis)
Renal disease	• Renal disease requiring supervision by a renal specialist • Renal failure

TABLE II
OAR 333-077-0125

Conditions of CURRENT PREGNANCY that Require Transfer or Consultation

Conditions highlighted in red boxes indicate high-risk conditions that, when condition develops, will require the transfer of a client to hospital-based care.

Conditions in the yellow boxes indicate potentially risky conditions that require consultation with a provider of perinatal care[1] as defined under OAR 333-077-0125.

The list of high-risk conditions and potentially risky conditions is not comprehensive, and other physical, behavioral health, obstetric, or fetal conditions may arise that require consultation or transfer to hospital-based care. Having multiple risk conditions requiring consultation may increase the risk sufficiently to indicate the need to transfer care.

Abnormal bleeding in pregnancy	• Antepartum hemorrhage, recurrent • Hemorrhage (hypovolemia, shock, need for transfusion, vital sign instability)
Amniotic fluid	• Oligohydramnios • Polyhydramnios
Amniotic membrane rupture	• Before 36 weeks 0 days
	• Pre-labor rupture > 24 hours
Cancer	• Active gynecologic cancer
Cardiovascular disease	• Cardiovascular disease-causing functional impairment
Connective tissue disorders	• Systemic lupus erythematous • Scleroderma • Rheumatoid arthritis • Any collagen-vascular disease
Gestational diabetes	• Requiring medication or uncontrolled
Hematologic conditions	• Hemoglobin < 8.5 g/dL at admission for labor • Thrombosis, suspected or diagnosed • Thromboembolism, suspected or diagnosed • Thrombocytopenia (platelets < 100,000)

[1] OAR 333-077-0125 – Provider of perinatal care means a physician or certified nurse midwife as those terms are defined under OAR 333-077-0010, a physician associate licensed under ORS chapter 677, a nurse practitioner licensed under ORS chapter 678, or a licensed direct entry midwife licensed under ORS chapter 687.

<table>
<tr><td rowspan="2">Fetal growth</td><td>Uteroplacental insufficiency
Intrauterine growth restriction (IUGR) – fetal weight less than 5th percentile using ethnically-appropriate growth table, or concerning reduced growth velocity on ultrasound</td></tr>
<tr><td>Inappropriate uterine growth (size-date discrepancy). (An ultrasound read by a qualified physician constitutes a consultation.)</td></tr>
<tr><td>Fetal monitoring or movement</td><td>Repetitive or persistent abnormal fetal heart rate pattern</td></tr>
<tr><td>Fetal presentation</td><td>Non-cephalic
Breech</td></tr>
<tr><td rowspan="2">Gestational age</td><td>Labor or premature rupture of membranes at <36 weeks 0 days
Pregnancy ≥42 weeks (unless already in active labor at 41 weeks 6 days)</td></tr>
<tr><td>Expected delivery date uncertain</td></tr>
<tr><td>Hepatic disorders</td><td>Disorders including uncontrolled intrahepatic cholestasis of pregnancy or abnormal liver function tests</td></tr>
<tr><td>Hyperemesis gravidarum</td><td>Refractory hyperemesis gravidarum</td></tr>
<tr><td>Hypertensive disorders</td><td>Eclampsia
Hypertension at or above 140 systolic or at or above 90 diastolic on two (2) separate occasions that are more than four (4) hours apart, or hypertension at or above 160 systolic or at or above 110 diastolic on one (1) occasion.
Pre-existing or chronic hypertension
Pre-eclampsia</td></tr>
<tr><td rowspan="2">Infectious Conditions</td><td>Diagnosed Chorioamnionitis
Genital herpes; primary outbreak at time of labor
Hepatitis B, positive status
HIV; positive status
Rubella; anytime during pregnancy
Shingles; active at labor
Syphilis; positive status or unknown
Varicella; active at labor
Maternal infection postpartum (e.g., endometritis, sepsis, wound) requiring hospital treatment)
Two (2) temperatures at 100.4 degrees Fahrenheit or 38 degrees Celsius or greater within one (1) hour or one (1) temperature at 102.2 degrees Fahrenheit or 39 degrees Celsius or greater.</td></tr>
<tr><td>Toxoplasmosis</td></tr>
</table>

	• CMV
Isoimmunization	• Blood group incompatibility and/or Rh sensitization in current pregnancy
Labor management	• Induction; pharmacological • Lack of adequate progress in 2nd stage with cephalic presentation.
Miscarriage/non-viable pregnancy	• Molar
Multiple gestations	• Multiple gestations
Perineal laceration or obstetric anal sphincter injury	• 3rd degree requiring hospital repair or beyond expertise of attendant • 4th degree • Enlarging hematoma
Placental Conditions	• Abruption • Low lying with 2 cm or less of cervical os at term • Previa • Vasa previa • Retained placenta > 60 minutes
Psychiatric Conditions	• Maternal mental illness requiring psychological or psychiatric intervention • Patient currently taking psychotropic medications
Substance Use	• Drug or alcohol misuse with high risk factor for adverse effects to fetal or maternal health
Umbilical cord	• Prolapse
Uterine Conditions	• Uterine rupture • Uterine inversion
	• Uterine prolapse • Anatomic anomaly (e.g. bicornuate, large fibroid impacting delivery

Table III
OAR 333-077-0125

Condition of NEWBORN AFTER DELIVERY that Requires Transfer or Consultation

Conditions highlighted in red boxes indicate high-risk conditions that, when condition develops, will require the transfer of a client to hospital-based care.

Conditions in the yellow boxes indicate potentially risky conditions that require consultation with a provider of perinatal care as defined under OAR 333-077-0125.

The list of high-risk conditions and potentially risky conditions is not comprehensive, and other physical, behavioral health, obstetric, or fetal conditions may arise that require consultation or transfer to hospital-based care. Having multiple risk conditions requiring consultation may increase the risk sufficiently to indicate the need to transfer care.

Condition	Criteria
Apgar	• Low Apgar score < 5 at 5 minutes or < 7 at 10 minutes
Birth injury	• Significant birth injury • Enlarging cephalohematoma
	• Excessive bruising
Blood glucose	• Hyperglycemia unresponsive to treatment • Hypoglycemia unresponsive to treatment
Congenital anomaly	• Unexpected and life-threatening
	• Expected and documented, life-threatening
Gastrointestinal	• Persistent projectile or bilious vomiting • Emesis of fresh blood
Infection	• Persistent inability to maintain temperature between 97 to 100 degrees Fahrenheit or 36 to 37 degrees Celsius. • Evident or suspected infection
Neurological	• Persistent, unexplained hypotonia • Seizures
Respiratory	• Central Cyanosis • Unresolved Pallor
	• Heart rate less than 80 or greater than 160 (at rest) without improvement. • Persistent cardiac murmur • Respiration rate greater than 100 within the first two hours postpartum, and greater than 80 thereafter, lasting more than one hour without improvement.
Weight	• Weight less than 2,270 grams (five pounds)

AMEND: 333-077-0130

RULE SUMMARY: Amend OAR 333-077-0130 (Renumbered from 333-076-0690)

Amendments clarify and add additional requirements for information that must be documented in the client medical record including but not limited to collection of demographic information, examinations, laboratory results, client disclosures, medical history, risk assessments, emergency planning, necessary evaluations, and discharge summary. A medical record for a newborn or stillborn is also required and the rule identifies what must documented for the newborn including but not limited to required newborn care and screening. The rule requires that specific information accompany the parental or newborn client in the case of a transfer. Medical records must be easily retrievable and stored to protect privacy. The rule specifies requirements for how long a medical record must be kept and requirements for keeping records if the birthing center is sold or permanently closed. The rule requires a birthing center to measure and evaluate medical record documentation including timeliness.

CHANGES TO RULE:

333-077-0130
~~Birthing Centers: Health and~~ Medical Records ¶

~~Health and Clin~~(1) A medical record shall be maintained for each client and newborn admitted for care.¶
(2) Med~~ical R~~records must be ~~developed according to procedures outlined in the Policy and Procedures Manual as a legal record and an instrument for the continuity of care and must include~~completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information. Each client and newborn medical record must contain sufficient information to clearly identify the client.¶
(3) A legible, reproducible medical record shall include at least the following (if applicable):¶
(~~1~~a) ~~Contents - The records of each client must contain:¶~~
~~(a) Demographic data, i~~For the client: ¶
(A) Race, ethnicity, preferred spoken and written language, disability status, sexual orientation, and gender identity that meets the requirements of ORS 413.164 and OAR chapter 950, division 30; ¶
(B) Initial prenatal physical exam~~ination, l~~;¶
(C) Laboratory tests and ~~evaluation of risk statu~~results;¶
(~~b~~D) ~~Continuous~~Regular periodic prenatal and intrapartum examinations and ~~evaluation~~assessments of risk status in accordance with OAR 333-077-0100 and OAR 333-077-0125;¶
(~~c~~E) A signed ~~informed consent (refer also to~~disclosure in accordance with OAR 333-07~~6~~7-0~~670(12))~~100;¶
(~~d~~F) ~~H~~Client history, physical exam~~ination~~ and risk assessment on admission to the ~~C~~birthing center in labor (including assessment of ~~mother and fetus);¶~~
~~(e) Continuous~~fetus);¶
(G) Regular periodic assessment (including assessment of the ~~mother and~~ fetus) during labor and delivery in accordance with OAR 333-077-0100;¶
(~~f~~H) Labor summary;¶
(~~g~~I) The emergency transport plan ~~for the client;¶~~
~~(h) Physical assessment of newborn, including Apgar scores and vital signs~~(including the emergency transport plan for the newborn client);¶
(~~i~~J) Post-partum evaluation ~~of the mother~~;¶
(~~j~~K) Discharge summary ~~for mother and newborn~~;¶
(~~k~~L) Documentation of assessments, consultation, referral, ~~and/~~or transfer;¶
(~~l~~M) Documentation of disclosures pursuant to ORS 441.098;¶
(N) Signed documents as may be required by law; and¶
(~~m~~b) ~~Records of~~For the newborn ~~and~~or stillborn ~~infants must include, in addition to the requirement for medical records, the following information~~delivery:¶
(A) Date and hour of birth~~, b~~;¶
(B) Birth weight ~~and l~~; ¶
(C) Length of infant~~, p~~; ¶
(D) Period of gestation~~, s~~;¶
(E) Sex~~, and condition of infant on delivery~~ssigned at birth;¶
(F) Initial physical assessment and condition on delivery, including Apgar scores and vital signs;¶
(~~B~~G) ~~Mother~~Client's name;¶

(CH) Record of ophthalmic prophylaxis and Vitamin K administration or refusal of same; and¶
(I) Record of newborn hearing and newborn metabolic screening, or record of referral to screenings if screenings are not provided by the birthing center;¶
(DJ) Progress notes including:¶
(i) Temperature, weight and feeding data;¶
(ii) Number, consistency and color of stoolsStool output;¶
(iii) Urinary output;¶
(iv) Condition of eyes and umbilical cord;¶
(v) Condition and color of skin; and¶
(vi) Motor behavior; and¶
(K) Discharge summary.¶
(24) All entries in a client's labor record must be promptly dated, timed, and authenticated.: ¶
(a) Entries made 48 hours after the care has been provided must be identified as an addendum or an amended entry and must include the date and time of entry and the clinical providers initials.¶
(b) Verification of an entry requires use of a unique identifier, i.e.for example, signature, code, thumbprint, voice print or other means, that allows identification of the individual responsible for the entry.¶
(3c) A single signature or authentication of the responsible practitionerclinical provider or other individual authorized within the scope onf the clinir professional license on the medical record does not suffice to cover the entire content of the record.¶
(45) The completion of the clinmedical record must beis the responsibility of the attending practitionclinical provider.¶
(56)(a) The Cbirthing center will ensure that the prenatal and intrapartal records are available at the time of admission and, in the event of transfer to the care of another clinician or health care facility, the birthing center must ensure the following information accompanies the client or newborn client to the care of another clinician or hospital-based care: medical history, prenatal flow sheet, diagnostic studies, laboratory findings, and client and newborn care notes through time of transfer.¶
(6b) Storage - The records will be stored in such a way as toIn cases of emergency, at the time of transfer, the birthing center must provide the information specified in subsection (6)(a) of this rule to the hospital-based care or another clinician, including notes for care provided during the emergency. If notes are not available, an oral summary of care during the emergency must be made available to the hospital-based care or responding EMS provider(s). ¶
(7) Medical records will be stored in such a way as to comply with state and federal privacy laws and minimize the chance of their destruction by fire or other source of loss or damage and to ensure prevention of access by unauthorized persons.¶
(78) RMedical records are the property of the Cbirthing center, and will be kept confidential unless released by the permission of the client. An exception is that they may be reviewed by representativesThe medical record, either in original or electronic form, shall not be removed from the birthing center except where necessary for a judicial or administrative proceeding. Authorized personnel of the Division, and will be provided Oregon Health Authority (Authority) shall be permitted to review medical records. If a birthing copy form to such representatives on requestenter uses off-site storage for medical records, arrangements must be made for prompt delivery of these records to the birthing center when needed for client care or other activities.¶
(89) All clinical records must be kept for a period of at least twenty-oneseven years after the date of discharge for the birthing client and 21 years after the date of last discharge for the newborn client. Original clinmedical records may be retained on paper, microfilm, electronic, or other media.¶
(910) If a Cbirthing center changes ownership, all clinmedical records in original, electronic, or microfilmother form must remain in the Centerbirthing center or off-site storage, and it must be the responsibility of the new owner to protect and maintain these records.¶
(101) If a Bbirthing Ccenter must beis permanently closed, its clinmedical records may be delivered and turned over to any other health care facility in the vicinity willing to accept and mainretain the same as provided in section (89) of this rule.¶
(11) If a qualified clinical record practitioner, RHIA (Registered Health Information Administrator) or RHIT (Registered Health Information Technician A birthing center which permanently closes shall follow the procedures for notifying the Authority and public notice requirements regarding disposal of medical records under OAR 333-077-0045.¶
(12) A current written policy on the release of medical record information including client access to the medical record shall be maintained in the facility.¶
(13) iAs not the Director of the Clinpart of its quality assessment and performance improvement program, a birthing center shall measure and evaluate its medical Rrecords Department, the Division may require the Center to obtain periodic and at least annual consultation from a qualified clinical records consultant, RHIA/RHIT. The

visits of the clinical records consultant must be of sufficient duration and frequency to rev documentation of care including timeliness of documentation. The following factors shall be considered during an evaluation:¶
(a) Confidentiality of the record;¶
(b) Records are easily retrievable;¶
(c) Quality, legibility and accuracy of the information in the record;¶
(d) Documentation of all requirements specified in these rules;¶
(e) All entries are dated and timed; and¶
(f) The timeliness of the entry.¶
(14) A birthing center shall implement performance improvement activities based on its medical record evaluation.¶
(15) A birthing center is encouraged to consult with a qualifiewd clinical record systems and assure quality records of the clients. Contract for such services must be available to the Divisionpractitioner to conduct its review.¶
(16) As used in this rule, "qualified clinical record practitioner" means a Registered Health Information Administrator (RHIA) or Registered Health Information Technician (RHIT).
Statutory/Other Authority: ORS 441.025, 442.015
Statutes/Other Implemented: 442.015, ORS 441.025

ADOPT: 333-077-0140

RULE SUMMARY: Adopt OAR 333-077-0140

Specifies that a birthing center is limited to providing procedures that are directly related to pregnancy, labor, and delivery care, and that are normally accomplished during uncomplicated childbirth such as episiotomy and repair. Services performed must be within the provider's scope of practice.

CHANGES TO RULE:

333-077-0140
Surgical Services
Surgical services may be performed but are limited to procedures pertaining directly to pregnancy, labor, and delivery care, and that are normally accomplished during uncomplicated childbirth such as episiotomy and repair. Procedures performed must be consistent with the individual clinical provider's license and scope of practice. Tubal ligation or abortion shall not be performed.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

ADOPT: 333-077-0145

RULE SUMMARY: Adopt OAR 333-077-0145

Requires that a birthing center provide or make available laboratory services using a licensed clinical laboratory that is in the facility or through a written contract. The birthing center must maintain a list of available tests and procedures. Laboratory findings for a client must be documented in the medical record.

CHANGES TO RULE:

333-077-0145
Laboratory Services
(1) A birthing center shall provide or shall make available laboratory services using a licensed clinical laboratory in the facility or through a written contract.¶
(a) A list of available tests and procedures shall be maintained by the birthing center.¶
(b) A written report of laboratory findings shall be recorded in the client's medical record in accordance with OAR 333-077-0130. ¶
(2) The licensed clinical laboratory shall meet the requirements under ORS chapter 438 and OAR chapter 333, division 24.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

ADOPT: 333-077-0150

RULE SUMMARY: Adopt OAR 333-077-0150

Requires a birthing center to have a system to keep a list of and monitor all prescription and non-prescription medicine, I.V. fluids and additional supplies. The system must include at a minimum a way to: identify, store, and secure all medicine that is outdated, misbranded, ruined, or otherwise unfit for use and stored in a separate location from usable medicine; and store and secure controlled substances. When a pharmacy is not on the premises, a birthing center may only stock quantities of prescription medication when the drugs have been obtained for dispensing or administering to a client by a provider or other individual authorized by their scope of practice. The rule requires a birthing center to comply with federal and state requirements relating to disposing expired medication. Prescription medications must be ordered by a clinical provider or other individual within the scope of their professional license. Dispensing of prescription medicine must be completed by a provider or individual authorized by their scope of practice or may be delegated if certain criteria are met. Written prescriptions or orders must be maintained by the birthing center. All medications including non-prescription or nutritional supplements must be clearly labeled with the drug name, dosage, and expiration date. A birthing center may not administer any general, spinal, caudal, or epidural anesthesia. Labor may not be induced, stimulated, or augmented with any drug during the first or second stages of labor. Drugs may be administered within a provider's scope of practice to reduce labor as a temporary measure until referral or transfer of the client is complete. Nitrous oxide may be prescribed and dispensed to a birthing center client under specified criteria in the rule.

CHANGES TO RULE:

333-077-0150
Pharmacy and Anesthetic Services
(1) A birthing center shall have a system to inventory and monitor all prescription and non-prescription medications, intravenous fluids, and ancillary supplies. The system shall include, but is not limited to: ¶
(a) Identification, storage and security of all medications, fluids and controlled substances that are deteriorated, outdated, misbranded, adulterated or otherwise unfit for use that are readily identifiable as defective and stored in a separate location from usable products; and¶
(b) Storage and security of medications including controlled substances that meet the requirements of the Oregon Board of Pharmacy in OAR chapter 855, division 41 and the U.S. Drug Enforcement Agency found in 21 CFR 1301.75(b). ¶
(2) In a birthing center that does not have a pharmacy on the premises, stock quantities of prescription drugs, including local anesthetics, shall be stored on the premises only when such drugs have been obtained for dispensation or administration to respective clients by a clinical provider or other individual authorized within the scope of their professional license to dispense or administer such drugs. Prescribed drugs already prepared for clients in the birthing center may also be stored on the premises.¶
(3) Expired medications, including special prescriptions for clients who have left the birthing center, shall be disposed of by incineration or other equally effective method, except controlled substances, which shall be handled in the manner prescribed by the U.S Drug Enforcement Administration under 21 CFR 1317 and the Oregon Board of Pharmacy under OAR 841-041-1046. ¶
(4) Drugs shall not be administered to clients unless ordered by a clinical provider or other individual authorized within the scope of their professional license to prescribe drugs. Such orders shall be in writing and signed by the clinical provider or other authorized individual. An electronic signature or other authentication method is acceptable. ¶
(5) Prescription drugs dispensed by a clinical provider or other individual authorized within the scope of their professional license shall be personally dispensed by the provider or other individual authorized within the scope of their professional license. Dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by the clinical provider or other individual and where no independent judgement of the staff assistant is required.¶
(a) The dispensing clinical provider or individual shall label prescription drugs with the following information:¶
(A) Name of client;¶
(B) The name and address of the dispensing physician or nurse practitioner;¶
(C) Date of dispensing;¶
(D) The name of the drug. If the dispensed drug does not have a brand name, the prescription label shall indicate

the generic name of the drug dispensed along with the name of the drug distributor or manufacturer, its quantity per unit, and the directions for its use stated in the prescription. However, if the drug is a compound, the quantity per unit need not be stated;¶
(E) Cautionary statements, if any, as required by law; and¶
(F) When applicable, an expiration date after which the client should not use the drug.¶
(b) Prescription drugs shall be dispensed in containers complying with OAR 855-043-0545.¶
(6) A birthing center shall maintain written prescriptions or orders signed by a clinical provider or other individual legally authorized to prescribe for all drugs administered to clients within the birthing center.¶
(7) All medications, including non-prescription drugs and nutritional supplements, shall be clearly labeled with the drug name, dosage, and expiration date. ¶
(8) General, spinal, caudal, or epidural anesthesia shall not be administered in the birthing center. ¶
(9) Labor shall not be induced, stimulated, or augmented with any drug during the first or second stages of labor. Drugs may be administered within the individual clinical provider's scope of practice to inhibit labor, as a temporary measure, until referral or transfer of the client is complete.¶
(10) Nitrous oxide may be prescribed and dispensed in accordance with a clinical provider's scope of practice and in accordance with the following: ¶
(a) A client must be assessed for suitability and absence of contraindications;¶
(b) Informed consent must be obtained from the client that clearly identifies potential risks; ¶
(c) Clients must be educated in the use of the equipment and the nitrous shall be self-administered only. No assistance from birthing center staff or from other individuals is allowed; ¶
(d) The nitrous oxide concentration must not exceed 50 percent and shall be administered through a scavenging system with a demand valve in a well-ventilated room;¶
(e) Clients self-administering nitrous oxide shall be continuously monitored for adverse effects by a trained clinical provider;¶
(f) Equipment shall be sterilized and stored in accordance with policies adopted pursuant to OAR 333-077-0090; and¶
(g) Staff shall be trained in the use of nitrous oxide in accordance with policies adopted pursuant to OAR 333-077-0090.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

ADOPT: 333-077-0160

RULE SUMMARY: Adopt OAR 333-077-0160

Specifies requirements for a birthing center to provide food to clients and family members. It requires the birthing center to be able to store, refrigerate, and reheat food to meet the needs of the client. The rule requires that certain conditions be met including refrigerator use and temperature. Any food or beverage brought to the birthing center by clients or family members must be 'ready-to-eat,' labeled with client's name, and dated. Food or beverage served by the birthing center must be commercially prepared, individually packaged, single serving foods. Only single service utensils may be used. A birthing center may arrange for food services through an external vendor to prepare or deliver food. All counters, shelves, tables, refrigerators, sinks, cutting boards, appliances and other equipment must be kept clean and in good repair. Surfaces that come in contact with food must be washed, rinsed, and sanitized after each use. If a birthing center chooses to provide food services prepared by the birthing center, it must meet other Food Sanitation Rules.

CHANGES TO RULE:

333-077-0160
Dietary Services
(1) As used in this rule, "potentially hazardous food" means any food or beverage that contains milk or milk products, eggs, meat, fish, shellfish, poultry, cooked rice or beans, and all other previously cooked foods. ¶
(2) A birthing center shall make dietary services available to provide clients and family members with nutritious liquids, snacks, or other foods. ¶
(3) A birthing center must be able to store, refrigerate and reheat food to meet the needs of a client. ¶
(a) Food shall be stored in a space used only for food, beverages, and single-service utensils;¶
(b) At least one refrigerator, in good operating condition, shall be on-site that is adequate to store all potentially hazardous foods. ¶
(A) A thermometer in working condition shall be affixed to the door, or the front edge of the top shelf, of each refrigerator. ¶
(B) Refrigerators equipped with a temperature gauge visible from the exterior are acceptable. ¶
(c) Any food or beverage brought to the birthing center by the client or a client's family member shall be 'ready to eat' and labeled with the client's name and dated.¶
(d) All food or beverage products served by the birthing center shall be commercially-prepared, individually-packaged, single-serving foods.¶
(e) All food, once removed from the kitchen for service, shall be discarded.¶
(f) Leftover prepared food which has not been served shall be labeled and dated, rapidly cooled, and used within 36 hours. ¶
(4) A birthing center may make arrangements with an external vendor to prepare or deliver food to the birthing center. All catered or delivered foods shall be:¶
(a) Prepared by a licensed food establishment or in a kitchen approved by the Oregon Health Authority or local public health authority; and¶
(b) Delivered in a safe, sanitary manner with food maintained at the required temperature specified in this rule. ¶
(5) All potentially hazardous food shall be kept at 41 degrees Fahrenheit or below, or 135 degrees Fahrenheit or above. ¶
(a) Foods requiring refrigeration after preparation shall be rapidly cooled to a temperature of 41 degrees F or below. ¶
(b) Refrigerated storage space at 41 degrees Fahrenheit or less shall be used to store meals which contain potentially hazardous food.¶
(c) Foods that have been cooked, and then refrigerated, shall be reheated rapidly to at least 165 degrees F before being served or placed in a hot food storage unit. ¶
(6) Only single service utensils shall be used. ¶
(7) All counters, shelves, tables, refrigeration equipment, sinks, drain boards, dish tables, cutting boards, appliances and other equipment used for food service shall be kept clean and in good repair.¶
(8) Food contact surfaces and equipment shall be washed, rinsed and sanitized after each use. ¶
(9) A birthing center that provides food services prepared on-site and to the public shall meet the requirements of the Food Sanitation Rules, OAR 333-150-0000.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

ADOPT: 333-077-0170

RULE SUMMARY: Adopt OAR 333-077-0170

Various newborn screenings and care are required under this new rule 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.

CHANGES TO RULE:

333-077-0170
Newborn Care and Screening
(1) A birthing center shall ensure that all newborns are given Vitamin K at birth in accordance with OAR 333-021-0800, the purpose of which is to protect newborns against Vitamin K deficiency bleeding. ¶
(2) A birthing center shall ensure that every newborn delivered in the birthing center is tested for metabolic diseases as required by OAR 333-024-1020. ¶
(3) A birthing center shall ensure that every newborn delivered in the birthing center receives a newborn hearing screening test or referral as required by OAR chapter 333, division 20. ¶
(4) The birthing center must ensure that a newborn is evaluated and treated who is at risk for gonococcal ophthalmia neonatorum in accordance with OAR 333-019-0036. ¶
(5) A birthing center must perform pulse oximetry screening on every newborn delivered at the birthing center before discharging the newborn in conformance with the following requirements: ¶
(a) The pulse oximetry screening must be performed using evidence-based guidelines such as those recommended by Strategies for Implementing Screening for Critical Congenital Heart Disease, AR Kemper et al., Pediatrics 2011;128(5): e1259-1267. ¶
(b) The birthing center must have policies and procedures based on the guidelines required by subsection (a) of this section for: ¶
(A) Determining what is considered a positive screening result; and ¶
(B) Determining what follow-up services, treatment or referrals must be provided if a newborn has a positive screening result. ¶
(c) A Federal Drug Administration (FDA) approved motion tolerant pulse oximeter must be used. ¶
(d) The pulse oximetry screening must be performed no sooner than 24 hours after birth or as close to discharge of the newborn as possible. ¶
(e) Before performing pulse oximetry screening on a newborn, birthing center staff must have received training on how to correctly operate the pulse oximeter and the policies and procedures associated with the screening. The birthing center must document this training. ¶
(f) If a newborn is admitted to hospital-based care as the result of a transfer from the birthing center before a pulse oximetry screening is performed, the hospital-based care from which the newborn is discharged to home is responsible for performing the screening. ¶
(g) The birthing center must provide the following notifications and document them in the newborn's medical record: ¶
(A) Prior to the pulse oximetry screening, notify a client or legal representative of the newborn about the reasons for the screening and the risks and consequences of not screening. ¶
(B) Following the pulse oximetry screening, notify the health care provider responsible for the newborn and the newborn's primary care provider of the results of the screening. ¶
(C) Following the pulse oximetry screening and prior to discharge, notify a client or legal representative of the newborn of the screening result, an explanation of its meaning and, if it is a positive screening result, provide information about the importance of timely diagnosis and intervention. ¶
(h) A client or legal representative of a newborn may decline pulse oximetry screening and, if screening is declined, the birthing center must document the declination in the newborn's medical record. ¶
(i) Following the pulse oximetry screening, the birthing center, in accordance with the applicable standard of care, must provide any appropriate follow-up services or treatment for the newborn if necessary or provide a referral to a client or legal representative of the newborn for follow-up services or treatment if necessary. ¶
(j) The birthing center must document in the newborn's medical record that the screening was performed, the screening result, the names of the health care providers who were notified of the screening result, and any follow-up services or treatment or referral for services or treatment. ¶
(k) No newborn may be refused screening because of the inability of a client or legal representative to pay for the screening. ¶
NOTE: The document referenced in section (5) of this rule is available upon request by contacting the Health Care

Regulation and Quality Improvement section at mailbox.hclc@odhsoha.oregon.gov
Statutory/Other Authority: ORS 441.025, ORS 433.285, ORS 433.318, ORS 433.323
Statutes/Other Implemented: ORS 441.025, ORS 433.285, ORS 433.306, ORS 433.318, ORS 433.321

ADOPT: 333-077-0180

RULE SUMMARY: Adopt OAR 333-077-0180

Requires a birthing center to have and to maintain appropriate equipment and other supplies required to provide care for a client and newborn and to be able to provide emergency procedures in a life-threatening event. The rule identifies minimum equipment requirements. The rule also prescribes that a birthing center must implement a system to ensure that all equipment and supplies are regularly maintained, tested, and that there enough supplies to meet the needs of clients. A birthing center must implement appropriate infection control procedures.

CHANGES TO RULE:

333-077-0180
Equipment and Supplies
(1) A birthing center shall have and maintain appropriate equipment and all ancillary supplies necessary to provide care for a client and newborn and to initiate emergency procedures in life threatening events to client and newborn including, but not limited to: ¶
(a) A bed suitable for labor, birth, and recovery;¶
(b) Suction equipment; ¶
(c) Fetal monitoring equipment;¶
(d) Equipment or supplies for monitoring and maintaining optimum body temperature of a newborn;¶
(e) Sterile suturing equipment and supplies;¶
(f) Oxygen with flow meter and positive pressure mask;¶
(g) Blood pressure equipment;¶
(h) Resuscitation equipment; ¶
(i) Intravenous equipment and fluids;¶
(j) Newborn scale; ¶
(k) Medications identified in protocols approved by the governing body to meet emergency needs of a client and newborn in the birthing center, and during transport to acute care setting; and¶
(l) Equipment for performing standard screenings and laboratory tests.¶
(2) A birthing center shall have a system to monitor all equipment and supplies that includes, but is not limited to:¶
(a) Regular maintenance and testing; and¶
(b) Sufficient inventory availability to meet the needs of clients.¶
(3) A birthing center shall apply appropriate infection control procedures for cleaning, disinfection, and sterilization of equipment in accordance with OAR 333-077-0190.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

ADOPT: 333-077-0190

RULE SUMMARY: Adopt OAR 333-076-0190

Requires a birthing center to establish and maintain an infection control program for the control and prevention of infections. The program must be managed by a qualified individual and overseen by a committee that will be responsible for investigating, controlling, and preventing infections in the birthing center. Written infection control policies must be adopted and reviewed annually. The rule specifies minimum requirements that must be addressed in the policy including annual training for volunteers and staff on the cause, transmission, and prevention of infections. A birthing center must have a Tuberculosis infection control plan that includes employee assessment and screening. A birthing center must comply with rules about the control of communicable diseases and infectious waste management, including the safe management and transport of placentas. A birthing center must comply with bloodborne pathogen standards and infection control training requirements established by the Oregon Occupational Safety and Health Division. Infection control procedures for cleaning, disinfecting and sterilizing client care equipment must be established in accordance with CDC guidelines.

CHANGES TO RULE:

333-077-0190
Infection Control
(1) A birthing center shall establish and maintain an active facility-wide infection control program for the control and prevention of infection. The program shall be managed by a qualified individual and overseen by a multi-disciplinary committee which shall be responsible for investigating, controlling, and preventing infections in the facility. ¶
(2) A birthing center shall be responsible for developing written policies and for annual review of such policies, relating to at least the following: ¶
(a) Identification of existing or potential infections in clients, newborns, employees, clinical staff, and clinical providers with birthing center privileges; ¶
(b) Control of factors affecting the transmission of infections and communicable diseases; ¶
(c) Provisions for orienting and educating all volunteers, employees, clinical staff, and clinical providers with birthing center privileges on the cause, transmission, and prevention of infections on an annual basis; and¶
(d) Collection, analysis, and use of data relating to infections in the birthing center.¶
(3) A birthing center shall have a tuberculosis (TB) infection control plan that includes employee assessment and screening for protecting clients and staff from TB in accordance with OAR 333-019-0041.¶
(4) A birthing center shall comply with OAR chapter 333, division 19 for the control of communicable diseases and division 56 relating to infectious waste management, including the safe management and transport of placentas. ¶
(5) A birthing center shall comply with the OR-OSHA bloodborne pathogens standards and infection control training requirements, OAR 437-002-0360(26). The birthing center shall ensure that all staff with potential occupational exposure to bloodborne pathogens participate in a training program at the time of initial assignment and annually thereafter. ¶
(6) A birthing center shall establish infection control procedures for cleaning, disinfection, and sterilization of client care equipment, unless only pre-packaged and pre-sterilized items are used, and cleaning and disinfecting the health care environment in accordance with the U.S. Centers for Disease Control and Prevention (CDC), "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 - Update: May 2019" adopted by reference. ¶
NOTE: The CDC guideline referenced in section (6) of this rule is available upon request by contacting the Health Care Regulation and Quality Improvement section at mailbox.hclc@odhsoha.oregon.gov.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

ADOPT: 333-077-0200

RULE SUMMARY: Adopt OAR 333-077-0200

Requires a birthing center to ensure the implementation of a an effective, facility-wide quality assessment and performance improvement program to ensure that services are meeting quality standards and to maintain and improve client health and safety and reduce medical errors. The rule specifies that a 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 a birthing center. Written documentation of quarterly activities is required. A birthing center must develop and implement facility-wide preventive strategies after an analysis of the causes of an adverse event and must train staff to ensure they are familiar with identified preventive strategies. The rule further states that a birthing center must set priorities for its performance improvement activities.

CHANGES TO RULE:

333-077-0200
Quality Assessment and Performance Improvement
(1) The governing body of a birthing center must ensure that there is an effective, facility-wide quality assessment and performance improvement program that demonstrates measurable improvement in client health outcomes and improves client safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors. ¶
(2) The birthing center must measure, analyze, and track quality indicators, adverse client and newborn events including deaths, infection control, and other aspects of performance that includes care and services furnished in a birthing center. Written documentation of quality assessment and performance improvement activities shall be recorded at least quarterly. ¶
(3) After an analysis of the causes for adverse events, the birthing center must develop and implement facility-wide preventive strategies and ensure that staff are trained in and familiar with these strategies. ¶
(4) The birthing center must set priorities for its performance improvement activities that: ¶
(a) Focus on high risk, high volume, and problem prone areas; ¶
(b) Consider incidence, prevalence, and severity of problems in those areas; and¶
(c) Affect health outcomes, client safety and quality of care.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

ADOPT: 333-077-0210

RULE SUMMARY: Adopt OAR 333-077-0210

Outlines requirements to ensure that the environment where a client receives care is functional, clean, sanitary, safe, and comfortable. The building and equipment must be kept clean and in good repair. Linen must be properly cleaned, and garbage appropriately disposed. Measures must be taken to prevent the entry of rats, mice, flies, and other insects. An emergency preparedness plan must be developed and maintained in the event of an emergency. The rule specifies minimum requirements for the plan including 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. The policy must include a system to track staff and clients in the care of the birthing center, responsibilities of staff for safe evacuation of clients and newborns, a means to shelter in place, system for documenting, securing, and maintaining records, and arrangements with other health care providers or facilities. An emergency preparedness orientation and training program must be maintained and evaluated every year. A birthing center must conduct at least two drills every year that document and demonstrate the staff have practiced specific duties and assignments in the emergency preparedness plan.

CHANGES TO RULE:

333-077-0210
Facility Safety and Emergency Preparedness
(1) The environment in which client care described in OAR 333-077-0100 is furnished must afford a functional, clean, sanitary, safe, and comfortable setting for clients, staff, and the public. ¶
(a) The building and equipment must be kept clean and in good repair.¶
(b) Provisions shall be made for the proper cleaning of linen and other washable goods and proper disposal of all refuse.¶
(c) All garbage and refuse shall be stored and disposed of in a manner that will not create a nuisance, public hazard, or infection risk. ¶
(d) Measures shall be taken to prevent the entry of rodents, flies, and other insects. Adequate measures include but are not limited to preventing their entry through doors, windows, or other outside opening. ¶
(2) A birthing center shall develop and maintain an emergency preparedness plan for the protection of all individuals in the event of an emergency, in accordance with this rule and the regulations specified in Oregon Fire Code (OAR chapter 837, division 40). The emergency preparedness plan must:¶
(a) Be based on a risk assessment that seeks to identify all potential hazards, assess vulnerabilities, and analyze potential impacts; ¶
(b) Include strategies for addressing emergency events identified by the risk assessment;¶
(c) Address client or newborn population including, but not limited to, the type of services the birthing center has the ability to provide in an emergency and continuity of operations; and¶
(d) Include the contact information for local emergency management. Each facility shall have documentation that the local emergency management office has been contacted and that the facility has a list of local hazards identified in the county hazard vulnerability analysis.¶
(3) A birthing center shall develop an emergency preparedness policy pursuant to OAR 333-077-0090 which must be based on the emergency preparedness plan specified in section (2) of this rule. The emergency preparedness policy shall be reviewed and updated at least annually and include, but not be limited to, the following: ¶
(a) A system to track the location of on-duty staff and sheltered clients or newborns in the care of the birthing center during and after an emergency. If on-duty staff and clients or newborns are relocated during the emergency, the birthing center must document the specific name and location of the receiving facility or other location;¶
(b) Safe evacuation from the birthing center which includes staff responsibilities and needs of the clients or newborns;¶
(c) A means to shelter in place for clients, newborns, staff, and volunteers who remain in the birthing center, including the availability of sufficient supplies for a minimum of two days;¶
(d) A system of documentation that preserves client and newborn information, protects confidentiality of client and newborn information, and secures and maintains the availability of records;¶
(e) Arrangements with other health care facilities or providers to receive clients or newborns in the event of limitations or cessation of operations; and ¶
(f) Continued access to medical supplies and equipment.¶

(4) A birthing center must develop and maintain an emergency preparedness communication plan which includes, but is not limited to, the following:¶
(a) Names and contact information for staff, volunteers, entities providing services under arrangement, and client clinicians;¶
(b) Contact information for federal, state, and local emergency preparedness staff and other sources of assistance;¶
(c) Primary and alternate means of communication with staff and federal, state, or local emergency management agencies;¶
(d) A method for sharing information and medical documentation for clients or newborns under the birthing center's care, as necessary, with other health care facilities or providers to maintain continuity of care; and¶
(e) A means to release Health Insurance Portability and Accountability Act (HIPAA) compliant, client or newborn information in the event of an evacuation.¶
(5) A birthing center shall maintain an emergency preparedness orientation and training program based on the emergency preparedness policy and plans. The training and orientation program must be evaluated and updated at least annually and include, but not limited to, the following:¶
(a) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers consistent with their roles;¶
(b) Provide emergency preparedness training annually;¶
(c) Demonstrate staff knowledge of emergency procedures including informing clients on what to do, where to go, and whom to contact in the event of an emergency. ¶
(6) The birthing center shall conduct at least two drills every year that document and demonstrate that clinical staff, contractors, and volunteers have practiced specific duties and assignments, as outlined in the emergency preparedness plan.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

AMEND: 333-077-0220

RULE SUMMARY: Amend OAR 333-077-0220 (Renumbered from 333-076-0710)

Specific building requirements when a new facility is being built or when an existing facility is proposing new alterations or additions are amended. At the time of initial licensure, 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. A birthing center must continue to meet all building standards including structural, mechanical, electrical, plumbing, and fire and life safety codes. The rule further specifies 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. The rule allows a birthing center to request a waiver from physical environment standards under certain conditions.

CHANGES TO RULE:

333-077-0220
~~Birthing Centers: Physical Facility~~Physical Environment ¶

(1) ~~Design - The Center may be an adaptation of a house. It must include birthing rooms of adequate size to meet the needs to accomplish the procedures specified in the Policies and Procedures and must meet applicable codes for ordinary construction and for water supply and sewage disposal. The building and equipment must be kept clean and in good repair. The C~~As used in this rule:¶
(a) "Area" means a particular space or surface serving a defined function. An 'area' exists as a small portion of an overall 'room' or space. ¶
(b) "Authorities having jurisdiction" means an organization, office, or individual responsible for enforcing the requirements of a code or standard, or for approving equipment, materials, an installation, or a procedure. ¶
(c) "Room" means a space enclosed by hard walls and having a door.¶
(2) At the time of initial licensure, a birthing center must meet the physical environment requirements in these rules including any applicable local, state, or federal building and specialty codes in effect at the time of initial licensure. ¶
(3) Subsequent modifications to a facility after initial licensure must comply with these rules and any applicable building or specialty codes in effect at the time of the modification.¶
(4) A licensed birthing center must continue to meet all applicable building and physical environment standards, including but not limited to structural, mechanical, electrical, plumbing, fire and life safety codes that were in effect at the time of licensure, or the standards that applied at the time of a major alteration or new construction as required by this rule. Each instance of non-compliance with a building or physical environment standard or code is a separate violation. ¶
(5) For an existing licensed birthing center, only the portion of the building that is being altered or renovated, and any impacted ancillary areas required to ensure full functionality of the birthing center, must ~~include:¶~~
~~(a) Toilet facilities for staff, mothers and famili~~meet the requirements in this rule. ¶
(6)(a) On or after [insert time period from effective date of this rule], any person proposing to construct a new birthing center, or proposing to make certain alterations or additions to an existing birthing center, must before commencing new construction, alterations, or additions, comply with OAR chapter 333, division 675 and these rules~~;~~.¶
(b) ~~Bath~~A faciliti~~es;¶~~
~~(c) Hand washing facilities and single use towel disp~~y may choose to comply with the revised standards on or after [insert filing date of new rule.] ¶
(7) An applicant or a licensed birthing center must comply with the following requirements: ¶
(a) The birthing cen~~s~~ter~~s adjacent or closely available to all examining or birth rooms;~~ shall be classified as an outpatient clinic business occupancy pursuant to 2019, Oregon Structural Specialty Code (OSSC). A client must be capable of promptly evacuating the birthing center in an emergency, such as fire, to a safe place based upon the services offered. ¶
(~~d~~b) ~~Examination areas;~~Security and safety: ¶
(~~e~~A) ~~Laundry facilities (unless laundry is done elsewhere);~~All exterior and interior surfaces, furnishings, fixtures, and equipment shall be kept clean and in good repair.¶
(B) Hallways, doors, and stairs shall be sized and arranged to accommodate emergency transport. ¶
(~~f~~i) ~~Kitchen facilities;¶~~
~~(g) Adequate storage areas for emergency equipment;¶~~
~~(h) Separate storag~~Hallways and stairs shall be a minimum of 36 inches clear excluding minor encroachments such

as stair handrails. ¶
(ii) Doors shall be sized to provide a minimum clear opening of 32 inches. ¶
(iii) Stairs shall be provided with handrails and emergency egress lighting.¶
(C) Smoke alarms are required within each birthing room, outside of each birthing room but in immediate vicinity, and on each occupiable for clean/sterile supplies and equipment;¶
(i) Storage areas for laboratory equipment and sterilizing, if applicable;¶
(j) Space for resuscitation of the newborn; andloor. Additional locations may be required by other authorities having jurisdiction.¶
(D) Fire extinguishers shall be placed within 20 feet of each birthing room, kitchen, and laundry equipment (measured along path of travel) in a readily accessible location. Fire extinguishers shall be installed, inspected, and serviced as required by the authorities having jurisdiction. Additional locations and provisions may be required by other authorities having jurisdiction. ¶
(kE) Reception and family facilities.¶
(2) Client Environment:¶
(a) There must be provided for each client a good bed, mattrEmergency egress lighting shall be provided.¶
(F) Exit routes shall be free of obstructions. Areas outside of exit routes shall not place any obstructions (chairs, birthing balls, or similar) that may impede emergency medical services (EMS) access to clients or newborns.¶
(G) Combustibles, flammabless, and pillow with protective coverage, and necessary bed coverings;refuse shall not be stored within three feet of heating sources such as furnaces, fireplaces, stoves, hot water heaters, and open flames.¶
(H) All electrical outlets accessible to the public shall be of the tamper resistant type. ¶
(bI) No towels, wash cloths, bath blankets, or other linen which comes directly in contact with the client will be interchangeable from one client to another unless it is first laundered;¶
(c) The use of torn or unclean bed linenGround fault circuit interrupter (GFCI) protection shall be provided at all electrical receptacles that serve kitchens, toilet rooms, bathrooms, and where outlets are within six feet of any other water source. ¶
(J) The use of extension cords is prohibited except: ¶
(i) In response to emergencies such as power failure for the duration of the emergency as long as risk of injury is minimized wherever possible. ¶
(ii) Relocatable power strips such as those used at computer work areas to power multiple items are allowed as long as they are UL listed, cords are not a tripping hazard, and the relocatable power strips are selected and installed per local and state fire prevention requirements. ¶
(K) Placing extension cords or placing equipment plug wiring under rugs is prohibited; and.¶
(dL) After the discharge of any client, the bed, bed furnishings, bedside furniture and equipment must be thoroughly cleaned andregular business hours, exterior doors shall be locked to preclude unscheduled access into the facility. Door locking functions shall not obstruct ability to freely exit the building. ¶
(c) Site and exterior: ¶
(A) Parking lots and exterior access walkways to building shall be provided with adequate lighting. ¶
(B) At least one entrance shall be accessible to persons with disabilities and shall be usable by persons in wheelchairs. ¶
(C) The entrance shall be clearly marked.¶
(d) Birthing suite: ¶
(A) Birthing areas shall have distinfected prior to reuse. Mattresses must be professionally renovated when necessaryct separation from unrelated facility traffic, including separation from exam rooms or other business functions. ¶
(B) Access to the birthing area shall be regulated for infant security.¶
(C) The maximum number of beds per birthing room shall be one unless approved by the Oregon Health Authority (Authority).¶
(3D) Provision must be made for the safe disposal of any bodily wastes that result from procedures performed in accordance with Centers for Disease Control and Prevention recommendations and state law.Each birthing room shall provide adequate space for laboring clients, labor support persons, and staff and provide: ¶
(i) Sufficient space and access for staff to function safely; and ¶
(ii) Not less than seven feet in any plan dimension with a minimum of 100 square feet.¶
(E) Within each birthing room, the newborn care area shall be located to provide the client and support person(s) direct visual observation of the newborn. The newborn care area shall provide adequate space for newborn resuscitation, stabilization, and examination. ¶
(F) Secure storage of emergency supplies for both the newborn and the client shall be provided within each birthing room. Any additional emergency equipment may be located outside the birthing rooms but must be secured and readily located for immediate access. ¶

(~~4~~G) ~~Fire and Safety - State and local fire and life-safety codes apply with specific attention to demonstr~~Emergency phone numbers shall be posted in each birthing room.¶
(H) Each birthing room shall provide a private bathroom that contains a toilet, handwash station with soap and single use paper or cloth towels that are stored in a contactless enclosed dispenser to prevent contamination~~ of adequate ingress and egress of occupants, placement of smoke alarms, emergency lighting, fire extinguishers or sprinkler systems, fire escape routes, and fire repo~~, and a shower or tub. Bathtubs intended for laboring or delivery may be located outside the private bathroom but within the birthing suite. ¶
(i) At least one birthing room bathroom shall be fully accessible in accordance with Oregon's adopted accessibility code, 2009 edition of ICC ANSI A117.1. Additional requirements and quantities of fully accessible birthing suites may be required by other authorities having jurisdiction. ¶
(ii) Non-accessible birthing ~~plans. The Center must have an emergency plan in effect on premises available to all staff. There must~~room bathroom tubs and showers shall include safety rails or grips to allow safe entrance, maneuvering, and exit. ¶
(iii) Thermometers shall be made available for monitoring bathtub water temperature. ¶
(I) Sharps disposal containers shall be ~~e~~provide~~nce of an annual fire inspection~~d in each birthing room. If mounted to the wall, the top of sharps disposal container shall be placed no higher than five feet, zero inches vertical dimension above floor.¶
(~~5~~J) ~~Emergency Access - Hallways and doorways must be so sized and arranged as to ensure the reasonable access of equipment in the event of the need for emergency transport~~For new construction or where seeking licensure of a previously unlicensed space, a handwash station is required in the birthing room. The handwash station must include soap and single use paper or cloth towels that are stored in a contactless enclosed dispenser to prevent contamination.¶
(K) For renovation work within existing licensed space, a hand sanitation dispenser may be provided in the birthing room in lieu of a handwash station.¶
(~~6~~L) ~~Emergency preparedness:¶~~
~~(a) The health care facility shall develop, maintain, update, train, and exercise an emergency plan for the prote~~If window(s) are provided within a birthing suite, the window(s) must include locks for infant security and shall have window coverings that provide privacy and control exterior light. ¶
(M) Supplemental portable lighting shall be available for laceration or episiotomy repair, newborn exam, and other similar purposes. Emergency ambient lighting shall be provided for the birthing room. Both must remain function~~ of all individuals in the event of~~al during a power loss. Supplemental and emergency~~, in accordance with the regulations as specified in Oregon Fire Code (OAR 837-040).~~ lighting need not be built-in; battery-powered lighting is allowed.¶
(e) Support areas for birthing center: ¶
(A) An examination room is not required. If provided, the examination room shall provide adequate space to accommodate clients, support persons, and staff. ¶
(~~A~~i) ~~The health care facility shall conduct at least two drills every year that document and demon~~For new construction or where seeking licensure of previously unlicensed space, a handwash station is required in the examination room. Handwash station shall include soap and single use paper or cloth towels that are stored in a contactless enclosed dispenser to prevent contamination. ¶
(ii) For renovation work within existing licensed space, a hand sanitation dispenser may be provided in the examination room in lieu of a handwash st~~rate that employee~~ion.¶
(iii) Sharps disposal containers sha~~ve practiced their specific duties and assignments, as outlined in the emergency preparedness plan.~~ll be provided in each examination room. If mounted to the wall, the top of sharps disposal container shall be placed no higher than five feet, zero inches vertical dimension above floor.¶
(B) Laundry service may be provided onsite or contracted. All laundry contaminated with bodily fluids shall be placed in bags in impervious receptacles. ¶
(~~b~~i) ~~The emergency plan shall inclu~~If laundry service is onsite, an area shall be provided th~~e contact information for local~~ at is large enough to accommodate the following: ¶
(I) Washer/extractor(s). Washers/extractors shall provide a temper~~gency management. Each facility shall have documentation that the local emergency management office has been contacted and that the facility has a list of local hazards identified in the~~ature of at least 160 degrees Fahrenheit for a minimum of 25 minutes or include use of a chemical disinfectant; ¶
(II) Dryer; ¶
(III) Storage shall be provided for laundry supplies. If laundry area is accessible to the public, all chemicals shall be secured within locked rooms or cabinetry; and ¶
(IV) Separate and distinct areas shall be provided for processing soiled and clean laundry. A handwash station with soap and single use paper or cloth towels that are stored in a contactless enclosed dispenser to prevent contamination shall be provided within 20 feet of soiled linen area (measured along path of travel).¶

(ii) If laundry service is co~~unty hazard vulnerability analysis~~racted, adequate storage of soiled laundry under staff control and protected from public access shall be provided.¶
(~~c~~C) ~~T~~A kitchen s~~ummary of the emergency pl~~hall be provided for staff, client, and support person use that includes:¶
(i) A sink with soap and s~~hall be sent to the Authority within one year of the filing of this rule. New facilities that have submitted licensing documents to the state before this provision goes into effect will have one year from the date o~~ingle use paper or cloth towels that are stored in a contactless enclosed dispenser to prevent contamination. ¶
(ii) A worksurface. ¶
(iii) Means to keep food cold. Refrigerators for food cannot contain birth center medications, placentas, or laboratory specimens.¶
(iv) Means to heat food. Means for heating food shall be located or monitored to preclude tampering by children. ¶
(v) Commercial-grade cooking equipment and appliances may be required by other authorities having jurisdiction.¶
(vi) Storage of dangerous or sharp utensils and equipment shall be secured to preclude access by children. ¶
(vii) Toilet rooms cannot directly open to rooms where food is being prepared.¶
(viii) If ~~license application to submit their plan. All other new facilities shall have a plan prior to licensing. The Authority shall request updated plans as needed.¶~~
~~(d) The emergency plan shall address all local hazards that have been identified by local emergency management and may include, but is not limited to, the following:¶~~
~~(A) Chemical emergencies;¶~~
~~(B) Dam failure;¶~~
~~(C) Earthquake;¶~~
~~(D) Fire;¶~~
~~(E) Flood;¶~~
~~(F) Hazardous material;¶~~
~~(G) Heat;¶~~
~~(H) Hurricane;¶~~
~~(I) Landslide;¶~~
~~(J) Nuclear power plant emergency;¶~~
~~(K) Pandemic;¶~~
~~(L) Terrorism; or¶~~
~~(M) Thunderstorms.¶~~
~~(e) The emergency plan shall address the availability of sufficient supplies for staff and patients to shelter in place or at an agreed upon alternative location for a minimum of two days, in coordination with local emergency management, under the following conditions:¶~~
~~(A) Extended power outage;¶~~
~~(B) No running water;¶~~
~~(C) Replacement of food or supplies is unavailable;¶~~
~~(D) Staff members do not report to work as scheduled; and¶~~
~~(E) The patient is unable to return to the pre-treatment shelter.¶~~
~~(f) The emergency plan shall address evacuation, including:¶~~
~~(A) Identification of individual positions' duties while vacating the building, transporting, and housing residents;¶~~
~~(B) Method and source of transportation;¶~~
~~(C) Planned relocation sites;¶~~
~~(D) Method by which each patient will be identified by name and facility of origin by people unknown to them;¶~~
~~(E) Method for tracking and reporting the physical location of specific patients until a different entity resumes responsibility for the patient; and¶~~
~~(F) Notification to the Authority about the status of the evacuation.¶~~
~~(g) The emergency plan shall address the clinical and medical needs of the patients, including provisions to provide:¶~~
~~(A) Storage of and continued access to medical records necessary to obtain care and treatment of patients, and the use of paper forms to be used for the transfer of care or to maintain care on-site when electronic systems are not available.¶~~
~~(B) Continued access to pharmaceuticals, medical supplies, and equipment, even during and after an evacuation; and¶~~
~~(C) Alternative staffing plans to meet the needs of the patients when scheduled staff members are unavailable. Alternative staffing plans may include, but is not limited to, on-call staff, the use of travelers, the use of management, or the use of other emergency personnel.¶~~

~~(h) The emergency plan shall be made available as requested by the Authority and during licensing and certification surveys. Each plan will be re-evaluated and revised as necessary or when there is a significant change in the facility or population of the health care facility~~ is provided in the birthing center for therapeutic purposes or for consumption, it shall be self-dispensing to preclude possible contamination. Self-dispensing ice can be provided via refrigerator in-door dispenser or countertop ice dispenser as long as scoops are not used and hands cannot easily contact the ice.¶
(D) Medications and ancillary supplies:¶
(i) Medications, needles, and prescription pads shall be secure and lockable to preclude unauthorized use. ¶
(ii) Sharps disposal containers shall be provided near the medical supplies. If mounted to the wall, the top of sharps disposal container shall be placed no higher than five feet, zero inches vertical dimension above floor.¶
(iii) If medication refrigerator(s) are included, they shall not store any food, placentas, or laboratory specimens. ¶
(iv) Medication refrigerators shall include a temperature gauge. ¶
(v) A handwash station with soap and single use paper or cloth towels that are stored in a contactless enclosed dispenser to prevent contamination shall be provided within 20 feet of where medications are opened for handling or dispensing (measured along path of travel).¶
(E) Storage shall be provided to meet the needs of the birthing center. A minimum area of 10 square feet per birthing room shall be provided in the birthing center to store all necessary items for immediate use and for satisfactory function of the overall facility. Designated separate and distinct storage room or areas shall include clean supplies, office supplies, and soiled materials holding. The 10 square feet is a cumulative total for both clean supplies and soiled materials holding and need not be provided in one assigned location nor within the birthing room. Use of closets, furniture like armoires, built-in casework, and storage rooms on different floors is acceptable as long as those locations meet or exceed the minimum required cumulative total. Utility and storage areas shall be designated for use as "clean" or "dirty" as these items must remain separate.¶
(i) Designated space(s) shall be provided and sized for holding of soiled materials that is under staff control and protected from public access. These soiled holding spaces are included in the calculated minimum required cumulative total for storage. ¶
(I) Biohazard waste must be placed in clearly marked bags or containers and in accordance with OAR 333-077-0190(4). ¶
(II) A handwash station with soap and single use paper or cloth towels that are stored in a contactless enclosed dispenser to prevent contamination shall be provided within 20 feet of soiled material holding space(s) (measured along path of travel).¶
(ii) Flammable liquids storage (such as hand sanitizer) exceeding five gallons shall be placed in a hazardous materials storage cabinet.¶
(iii) All storage items need to be located below 24 inches of the ceiling or structure if the building is non-sprinklered or 18 inches below the sprinkler head deflector if the building is sprinklered.¶
(F) Equipment.¶
(i) A means for sterilizing equipment shall be provided in accordance with OAR 333-077-0190 (6).¶
(ii) A means for oxygen supplementation and vacuum or suction of airways shall be provided. ¶
(iii) If portable medical gas (includes oxygen and nitrous oxide) tanks are utilized:¶
(I) Storage of cylinders not in use shall be 20 feet distance or greater separation from other flammables, combustibles, open electrical equipment, motor-driven equipment, kitchens, furnaces, fireplaces, candles, or any other open flame. ¶
(II) Cylinders not in use must be held within stands or chained to non-movable partitions to preclude tipping or falling. ¶
(III) If the volume of cylinders not in use is less than 300 cubic feet (12 or fewer E-size cylinders), no special room construction and fire protection is required for licensure purposes. Additional requirements may be required by other authorities having jurisdiction.¶
(IV) Cylinders shall be identified as empty or full. Empty and full cylinder storage shall be in separate locations.¶
(V) The door(s) to any rooms containing cylinders shall include signage that states "CAUTION: OXIDIZING GAS(ES) STORED WITHIN. NO SMOKING"¶
(f) Support areas for visitors:¶
(A) Toilet facilities shall be made available for staff and support persons that are not located within the birthing room. Each toilet room shall contain a toilet, a handwash station with soap, and single use paper or cloth towels that are stored in a contactless enclosed dispenser to prevent contamination. ¶
(i) At least one staff and support person use toilet room shall be fully accessible in accordance with Oregon's adopted accessibility code, 2009 edition of ICC ANSI A117.1. ¶
(ii) Additional requirements and quantities of fully accessible toilet rooms may be required by other authorities having jurisdiction. ¶
(B) A reception and waiting area shall be provided, including a play area for children.¶

(C) A telephone shall be made available to the client and support persons to access emergency assistance. Hard-wired "land" line, VoIP, cellular phone, or similar are all acceptable options as long as service is reliable. Signage shall be posted notifying that a phone is available for use with emergency numbers listed.¶
(g) Support areas for staff. ¶
(A) Staff work stations may be provided within the birthing room but an additional staff work area shall be located outside of birthing room(s). ¶
(B) An area or room shall be provided for staff to discuss clients' protected health information and this need not be on the same floor as the birthing room(s). ¶
(C) Storage of medical records whether paper copy or digital shall be secure and lockable from public access.¶
(h) Materials and finishes:¶
(A) Materials and finishes shall be appropriate for a birthing center. ¶
(B) Materials and finishes shall be wear-resistant and selected to withstand the type and frequency of cleaning or disinfection methods that occurs within each space. ¶
(i) Flooring finishes shall accommodate suitable cleaning methods for the spaces they serve. ¶
(ii) The use of carpeting shall be limited to rooms and spaces where risk of soiling with bodily fluids is minimal. Throw rugs or similar are allowed as long as their size allows regularly washing. Throw rugs that do not lie flat are prohibited.¶
(iii) Floor finishes in wet locations such as toilet rooms, bathrooms, kitchen, laundry, and any areas immediately within handwash station locations shall be slip-resistant. ¶
(iv) Bathrooms and areas surrounding bathtubs shall have floors and walls that have a smooth, hard, nonabsorbent finish. ¶
(8) Oregon Health Authority, Facility, Planning and Safety (FPS) issuance of final project approval is a prerequisite for licensure. FPS final project approval shall not be issued until the certificate of occupancy or permit sign-off issued by the local jurisdiction is submitted to the Authority documenting approval of work. ¶
(9) A request to waive physical environment standards in this rule will only be considered for portions of a structure, space, or system if the birthing center's operations and patient safety are not jeopardized. Waivers for physical environment standards may be granted to minimize restrictions on improvements where total compliance would create an unreasonable hardship and would not substantially improve safety.¶
NOTE: The codes referenced in this rule are available upon request by contacting the Health Care Regulation and Quality Improvement, Facility Planning and Safety program at mailbox.fps@odhsoha.oregon.gov.
Statutory/Other Authority: ORS 441.020, ORS 442.015
Statutes/Other Implemented: ORS 44~~2~~1.0~~15~~20, ORS 44~~1.020~~2.015

ADOPT: 333-077-0230

RULE SUMMARY: Adopt OAR 333-077-0230

Specifies what is considered a violation.

CHANGES TO RULE:

333-077-0230
Violations
In addition to non-compliance with any law that governs a birthing center, it is a violation to: ¶
(1) Refuse to cooperate with an investigation or survey, including but not limited to failure to permit Oregon Health Authority (Authority) staff access to the birthing center, its documents or records; ¶
(2) Fail to submit a plan of correction or implement an approved plan of correction; ¶
(3) Fail to comply with all applicable laws, lawful ordinances and rules relating to safety from fire; ¶
(4) Refuse or fail to comply with an order issued by the Authority; ¶
(5) Refuse or fail to pay a civil penalty; ¶
(6) Fail to comply with rules governing the storage of medical records following the closure of a birthing center; or¶
(7) Knowingly allow a licensed clinical provider to practice outside their scope of practice.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025

ADOPT: 333-077-0240

RULE SUMMARY: Adopt OAR 333-077-0240

Specifies that if during an investigation Oregon Health Authority (Authority) staff document a violation of laws, it may issue a statement of deficiencies. The rule allows the birthing center to dispute findings and request an informal conference. Plans of corrections must be submitted to the Authority and a birthing center must correct all deficiencies within 60 days from the date of the exit conference. The Authority shall determine if the plan of correction is acceptable. The Authority may propose to deny, suspend, or revoke the birthing center's license or impose civil penalties for failing to come into compliance.

CHANGES TO RULE:

333-077-0240
Informal Enforcement
(1) If, during an investigation or survey Oregon Health Authority (Authority) staff document violations of birthing center licensing laws, the Authority may issue a statement of deficiencies that cites the law alleged to have been violated and the facts supporting the allegation. ¶
(2) Upon receipt of a statement of deficiencies, a birthing center shall be provided an opportunity to dispute the Authority's survey findings but must still comply with sections (3) and (4) of this rule.¶
(a) If a birthing center desires an informal conference to dispute the Authority's survey findings, the birthing center shall advise the Authority in writing within 10 business days after receipt of the statement of deficiencies. The written request must include a detailed explanation of why the birthing center believes the statement of deficiencies is incorrect.¶
(b) A birthing center may not seek a delay of any enforcement action against it on the grounds the informal dispute resolution has not been completed.¶
(c) If a birthing center is successful in demonstrating the deficiencies should not have been cited, the Authority shall reissue the statement of deficiencies, removing such deficiencies and rescinding or modifying any remedies issued for such deficiencies. The reissued statement of deficiencies shall state that it supersedes the previous statement of deficiencies and shall clearly identify the date of the superseded statement of deficiencies.¶
(3) A signed plan of correction must be received by the Authority within 10 business days from the date the statement of deficiencies was mailed to the birthing center. A signed plan of correction will not be used by the Authority as an admission of the violations alleged in the statement of deficiencies. ¶
(4) A birthing center shall correct all deficiencies within 60 days from the date of the exit conference, unless an extension of time is requested and granted from the Authority. A request for such an extension shall be submitted in writing and must accompany the plan of correction. ¶
(5) The Authority shall determine if a written plan of correction is acceptable. If the plan of correction is not acceptable to the Authority, the Authority shall notify the birthing center administrator or the administrator's designee in writing and request that the plan of correction be modified and resubmitted no later than 10 working days from the date the letter of non-acceptance was mailed to the administrator. ¶
(6) If the birthing center does not come into compliance by the date of correction reflected on the plan of correction or 60 days from date of the exit conference, whichever is sooner, the Authority may propose to deny, suspend, or revoke the birthing center license, or impose civil penalties in accordance with ORS chapter 183.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025, ORS 441.015, ORS 441.030

ADOPT: 333-077-0250

RULE SUMMARY: Adopt OAR 333-077-0250
Specifies that if the Oregon Health Authority (Authority) finds substantial failure to comply with rules and regulations, it may issue a Notice of Proposed Nonrenewal, Revocation or Suspension in accordance with Oregon law. A Notice of Emergency License Suspension may be issued if the Authority finds a serious danger to public health or safety.

CHANGES TO RULE:

333-077-0250
Formal Enforcement
(1) If during an investigation or survey the Oregon Health Authority (Authority) finds substantial failure to comply with birthing center licensing laws, the Authority may issue a Notice of Proposed Nonrenewal, Revocation or Suspension in accordance with ORS 183.411 through 183.470. ¶
(2) If the Authority finds a serious danger to public health or safety, it may issue a Notice of Emergency License Suspension under ORS 183.430(2). ¶
(3) If the Authority revokes a birthing center license, the final order shall specify when the birthing center may reapply for a license.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.025, ORS 183.430, ORS 441.015, ORS 441.030

ADOPT: 333-077-0260

RULE SUMMARY: Adopt OAR 333-077-0260

Identifies that the Oregon Health Authority (Authority) may issue civil penalties in accordance with Oregon law not to exceed $500 per day per violation for a birthing center that violates rules and regulations.

CHANGES TO RULE:

333-077-0260
Civil Penalties
(1) A licensee that violates a birthing center licensing law, including OAR 333-077-0230 is subject to the imposition of a civil penalty not to exceed $500 per day per violation. ¶
(2) In determining the amount of a civil penalty, the Oregon Health Authority (Authority) shall consider whether: ¶
(a) The Authority made repeated attempts to obtain compliance; ¶
(b) The licensee has a history of noncompliance with birthing center licensing laws; ¶
(c) The violation poses a serious risk to the public's health; ¶
(d) The licensee gained financially from the noncompliance; and ¶
(e) There are mitigating factors, such as a licensee's cooperation with an investigation or actions to come into compliance. ¶
(3) The Authority shall document its consideration of the factors in section (2) of this rule. ¶
(4) Each day a violation continues is an additional violation. ¶
(5) A civil penalty imposed under this rule shall comply with ORS 183.745.
Statutory/Other Authority: ORS 441.025
Statutes/Other Implemented: ORS 441.990