Secretary of State

STATEMENT OF NEED AND FISCAL IMPACT

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

Oregon Health Authority- Public Health Division	333
Agency and Division	Administrative Rules Chapter Number

Freestanding Birthing Center Licensure Requirements

Rule Caption

Statutory Authority: ORS 441.025, 433.285, 433.318 and 433.323

Other Authority:

Stats. Implemented: ORS 183.430, 433.306, 433.318, 433.285, 433.306, 433.318, 433.321, 441.015 – 441.098, 441.990, 441-991 and 442.015

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 Resources and Services Administration (HRSA), and the Administration on Children and Families (ACF), was a four-year initiative from 2013 to 2017 to "test and evaluate enhanced prenatal care interventions for women enrolled in Medicaid or the Children's Health Insurance Program who were at risk for having a preterm birth. The goal of the initiative was to determine if these approaches to care could reduce the rate of preterm births, improve the health outcomes of pregnant women and newborns, and decrease the anticipated total cost of medical care during pregnancy, delivery and over the first year of life for children born to mothers in Medicaid or CHIP." Findings from this initiative as stated in the Strong Start for Mothers and Newborn Evaluation: Year 5 Project Synthesis[2], include:

- Participant focus groups gave voice to the experiences of pregnant and postpartum women, who overwhelmingly said that they appreciated the extra time, support, and education Strong Start provided. Most women with prior pregnancies said they were more satisfied with their prenatal and delivery 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 by Birth Centers experiencing the lowest risk levels. Birth Center participants had dramatically lower rates of preterm birth (4.5 percent) than

[1] Centers for Medicare and Medicaid Services, Strong Start for Mothers and Newborns Initiative: Enhanced Prenatal Care Models: 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 Finings, October 2018: https://downloads.cms.gov/files/cmmi/strongstart-prenatal-finalevalrpt-v1.pdf

women served by either Group Prenatal Care (12 percent) or Maternity Care Homes (12.9 percent). Similarly, rates of low birthweight among Birth Center participants were much lower (3.6 percent) than for Group Prenatal Care and Maternity Care Home participants (10 percent and 10.5 percent, respectively). Finally, Cesarean section (C-section) deliveries for Strong Start participants were, by far, lowest for women in Birth Centers (13 percent). In contrast, 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% Asian, 7.6% 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 persons despite having risk factor(s) that would otherwise require a birth to occur in a hospital-based care setting. Pregnant persons from marginalized communities with risk factors would potentially benefit from access to additional prenatal care support. Additionally, based on community feedback and equity analysis current rules will remain in effect allowing a freestanding birthing center to offer a vaginal birth after cesarean (VBAC) if certain safety conditions are met. Similarly, these individuals from marginalized communities would have continued access to VBAC in this setting. Risk factors have been identified that require a freestanding birthing center to consult with a perinatal provider that are not required under current rule. The purpose of the consultation is to help inform the health and safety of a client to give birth in a freestanding birthing center versus transferring to a hospital-based care setting. Consultation based on risk factors is not required under existing rules, however, the OHA notes that existing regulations for licensed Direct Entry Midwives already require consultation for certain conditions or risk factors. There are no similar requirements for Naturopathic Physicians or 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 Maternal Mortality and Morbidity Review Committee (MMMRC)[3], over the past 10 years, the number of Oregon maternal deaths per year has ranged from four to 12. However, the current method of case finding may undercount actual deaths by as much as one-third. It is also important to note that for every woman who dies, there are approximately 50 who suffer severe maternal morbidity--very severe complications of pregnancy, labor, and delivery that bring them close to death. Oregon's maternal death

[3] Oregon Health Authority, Healthy People and Families, Maternal and Children Health, Maternal Mortality and Morbidity Review Committee webpage: https://www.oregon.gov/oha/ph/healthypeoplefamilies/datareports/pages/maternal-mortality-morbidity-review-committee.aspx

rate, measured as the number of maternal deaths per 100,000 live births, varies from year to year due to the 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 (MMMRC), Biennial 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 condition.
- Ensure pregnant and postpartum people with histories of substance use disorders obtain the services they need to manager their condition.

Current rules do not require that birthing persons experiencing a behavioral health condition must be transferred to hospital-based care; however, under the proposed rules, a freestanding birthing center would be required to consult with a perinatal care provider. The addition of this requirement 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 the infant" are required to be transferred to hospital-based care. This condition will continue to require hospital-based care under the proposed rules which was supported by 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 attend births other than what is already allowed under Oregon law. Birthing centers are primarily operated by licensed direct entry midwives,

[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/January2023BiennielReportMMRCFinal.pdf

naturopathic physicians, and certified nurse midwives. The proposed rules added chiropractic physicians who also have a certification for natural childbirth under their scope of practice. The OHA recognizes that there is a critical need for more culturally diverse providers who can attend births and supports efforts of licensing boards in their aim to increase culturally diverse provider options. According to data obtained from the health licensing regulatory boards, there are:

- 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 informs Oregon's efforts to ensure culturally and linguistically responsive care for all. One of the key findings is that Oregon must improve the diversity of health care providers in order to achieve the strategic goal of eliminating health inequities. This report recommends reducing barriers to entry and advancement for persons of color in the workforce and increase investments in training, recruiting, and retaining health care workers. It further concludes that "in order to stabilize, expand, and diversify Oregon's health care workforce so that it can deliver culturally responsive, effective health care services to all: 1) some professions need increased compensation to attract new individuals and increase retention; 2) Many professions with unclear career pathways need better, focused 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 American; 4.2% identify s 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 American; 4.6% identify 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 American; 3.1% identify as

[5] Oregon State University, College of Public Health and Human Sciences, Oregon's Health Care Workforce Needs Assessment 2023, February 2023; Prepared for the Oregon Health Authority, Oregon Health Policy Board

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 specific race, 47 were 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 other than English among licensed providers (about 10%). The next most common languages spoken are Chinese (including Mandarin and Cantonese), Tagalog, Vietnamese, French, and Russian. Less than 1% of the licensed health care providers are native speakers or have advanced proficiency in each of those languages. Thus, many patients who speak a language other than English need the assistance of a Health Care Interpreter. ORS 413.559 and rules adopted thereunder require that health care providers, including health care facilities defined under ORS 442.015, must work with a health care interpreter from the health care interpreter registry for persons who prefer to communicate in a language other than English. The proposed rules reiterate this requirement.

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:
    - 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).
    - 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:
    - 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.
    - Job descriptions for each position and annual performance evaluations.
    - Threats against clients or newborns.
    - Visitor conduct and control.
    - Client grievance procedures.
    - Storage and maintenance of equipment.
    - Financial interest notification.
    - Health care interpreter services.
- Additional requirements for client services that may result in additional costs include:
    - Required client orientation and disclosures.
    - Consultation with perinatal provider for specified risk factors.
    - Risk assessment within 21 days of first prenatal care visit.
    - Allows telemedicine, however, requires certain number of in-person assessments.
    - 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:
    - 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.
    - 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.
    - 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.
    - 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.

- 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.
- 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.
- Toilet rooms must not open to rooms where food is being prepared, and may require thoughtful space planning layout.
- Requiring birthing rooms to be a minimum size may require additional space.
- Newborn care area under direct visual observation of client may require thoughtful space planning layout.
- Requiring 10 square feet of storage for every birthing room, may require additional space.
- Adding a children's play area to the waiting room, may require additional space.
- Providing staff work area, may require additional space.

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):

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. Cost of compliance effect on small business (ORS 183.336):

a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule:

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. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:

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. Equipment, supplies, labor and increased administration required for compliance:

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.

How were small businesses involved in the development of this rule?

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.

Administrative Rule Advisory Committee consulted?:

Yes. Licensed freestanding birthing centers, special interest associations, the Board of Direct Entry Midwifery, State Board of Nursing, and Oregon Midwifery Council were all represented on the RAC. A consumer representative as well as a neonatologist, OB/GYN hospitalist, and a representative from the Birth Justice Policy Committee also participated.

If not, why?: