

PROPOSAL

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FINAL ACTION

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Inclusive of Non-Substantive Changes Made at Final Action

Italic underline text indicates new text at the time of final action; double bold brackets indicate a deletion made at final action.

Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 05 FREESTANDING AMBULATORY CARE FACILITIES

10.05.02 Freestanding Birthing Centers

Authority: Health-General Article, §19-3B-01 et seq., Annotated Code of Maryland

Notice of Proposed Action

[25-068-P]

The Secretary of Health proposes to amend Regulations **.01**, **.03—~~.08~~**, **.10—~~.12~~**, propose new Regulations **.02**, **.08**, and **.10**, and recodify existing Regulations **.02—~~.06~~**, **.07**, and **.08—~~.12~~** to be Regulations **.03—~~.07~~**, **.09**, and **.11—~~.15~~** respectively of **COMAR 10.05.02 Freestanding Birthing Centers**.

Statement of Purpose

The purpose of this action is to set minimum, reasonable standards for licensure of Freestanding Birthing Centers in Maryland. OHQC is proposing changes to 10.05.02 because of the need to:

- (1) Incorporate more recent definitions and references;
- (2) Add template language to clarify the enforcement process and protect a facility's right for an informal dispute resolution (existing authority and process has not changed); and
- (3) Reflect current standards of care and strengthen quality and safety protocols.

This chapter is intended to maximize safety and quality of perinatal care services (services before, during, and after birth) in a non-hospital, non-residential setting. Revisions will support the opening of freestanding birth centers (there currently are none in operation) which would improve access to perinatal services for pregnant birthing persons.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Jordan Fisher Blotter, Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 W. Preston Street, Room 534, Baltimore, Maryland 21201, or call 410-767-0938, or email to mdh.regs@maryland.gov. Comments will be accepted through June 16, 2025. A public hearing has not been scheduled.

.01 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) (text unchanged)

(2) "Certified nurse midwife" [means a registered nurse who is certified:] *has the meaning stated in COMAR 10.27.05.01.*

[(a) By the American College of Nurse Midwives Certification Council; and

(b) To practice nurse midwifery in this State by the Board.]

(3) (text unchanged)

(4) *"Immediate action" means all actions the freestanding birthing center has taken or will take to immediately address the noncompliance that resulted in or made serious injury, serious harm, serious impairment, or death likely.*

(5) *Immediate Jeopardy.*

(a) "Immediate jeopardy" means a situation in which immediate corrective action is necessary because the freestanding birthing center's noncompliance with one or more licensure requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the freestanding birthing center or to the health or safety of the general public.

(b) "Immediate jeopardy" consists of three components:

- (i) Noncompliance with this chapter;
- (ii) Serious injury, harm, or death; and
- (iii) The need for immediate action.

(6) "Informal dispute resolution (IDR)" means an informal process that provides a freestanding birthing center the opportunity to dispute one or more deficiencies cited in a written Statement of Deficiencies issued by the Department or the Department's designee related to a recent survey.

(7) "Licensed certified midwife" has the meaning stated in Health Occupations Article, §8-6D-01, Annotated Code of Maryland.

(8) "Licensed direct-entry midwife" has the meaning stated in COMAR 10.64.01.01.

[(4)] (9) "Midwifery" means the antepartum, intrapartum, and postpartum management and care of [women] birthing persons and their newborns.

(10) "Need for immediate action" means that immediate corrective action is necessary to remove the jeopardy.

[(5)] (11) "Newborn" means an infant in the first [48 hours] 28 days of life.

(12) "Noncompliance" means the freestanding birthing center is non-compliant with one or more licensure requirements of this chapter.

[(6)] (13) Normal Maternity.

(a) (text unchanged)

(b) Normal maternity does not include the use of drugs for induction or augmentation of labor, general and regional anesthesia, vacuum extractors, forceps, recorded electronic fetal monitors, cesarean section, surgical procedures other than episiotomy or perineal repair, intrapartum care provided prior to 36 weeks gestation, or intrapartum care provided after 42 weeks gestation.

[(7)] "Nurse midwife services" means those services permitted to be provided by individuals licensed to practice nurse midwifery under Health Occupations Article, Title 8, Subtitle 6, Annotated Code of Maryland.]

(14) "Office of Health Care Quality (OHCQ)" means the Office of Healthcare Quality of the Maryland Department of Health.

(15) "Plan of Correction" means a written plan submitted by the freestanding birthing center to the OHCQ which documents steps the freestanding birthing center will take to come into compliance with the licensure requirements.

(16) "Removal of the immediate jeopardy" means that the freestanding birthing center has implemented the removal plan, and the OHCQ has verified that all actions the freestanding birthing center took were effective in removing the likelihood that serious injury, serious harm, serious impairment, or death would occur or recur.

(17) "Serious injury, harm, or death" means a situation which has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the freestanding birthing center or to the health or safety of the general public.

(18) "Statement of Deficiencies" means the written notification that the OHCQ issues to the free standing birthing center that contains a listing of deficiencies cited that require correction.

.02 Incorporation By Reference.

In this chapter, the following document is incorporated by reference, National Fire Protection Association (NFPA) 101 Life Safety Code (2018 Edition), which is incorporated by reference in COMAR 29.06.01.06.

[.03].04 Licensing Procedure.

[A freestanding birthing center shall submit a nonrefundable fee of \$300 with an application for initial licensure or \$300 with an application for license renewal.]

A. An applicant shall submit:

- (1) An application on a written or electronic form provided by the Department;
- (2) All other reasonable documents as required by the Department; and
- (3) A business email address for the applicant or their organization.

B. License Application Administratively Closed.

(1) An application is not complete until the Department has received the completed license application and all required documents.

(2) After 180 calendar days from the date of initial receipt, the Department may deem an incomplete license application inactive and administratively close the application.

(3) An applicant whose application is administratively closed may reapply for a license by submitting a new application.

C. Voiding of License.

(1) Maryland State Department of Assessments and Taxation (SDAT).

(a) A freestanding birthing center shall remain in good standing with (SDAT).

(b) If the freestanding birthing center fails to return to good standing 60 calendar days after receipt of notification of noncompliance from SDAT or another government agency, the Department may void the freestanding birthing center's license.

(2) *Ceases the Provision of Services.*

(a) *A license is void if the freestanding birthing center ceases to provide services to patients for a period of 180 consecutive days.*

(b) *The owner shall immediately cease all use of the previously issued freestanding birthing center license when the license is voided.*

D. Current Business Email Address. A freestanding birthing center is required to maintain a current business email address on file with the OHCQ.

[.04] .05 [Surveys.] *Inspection by OHCQ.*

A.—C. (text unchanged)

D. Notice of Deficiencies.

(1) *If a survey identifies noncompliance with a requirement, the Secretary shall:*

(a) *Issue a written Statement of Deficiencies that cites each deficiency;*

(b) *Require the freestanding birthing center to submit an acceptable Plan of Correction within 10 calendar days of receipt of the Statement of Deficiencies;*

(c) *Notify the freestanding birthing center of any sanctions or that failure to correct the violation may result in sanctions; and*

(d) *Offer the freestanding birthing center the opportunity for IDR.*

E. Plan of Correction.

(1) *The freestanding birthing center shall submit a written Plan of Correction to the OHCQ that documents steps the licensee will take to come into compliance, including:*

(a) *How the freestanding birthing center will correct each deficiency;*

(b) *The date by which each deficient practice will be corrected;*

(c) *How the freestanding birthing center will prevent the deficient practice from recurring; and*

(d) *Who will be responsible for ensuring the deficiency will not reoccur.*

(2) *Failure to return an acceptable Plan of Correction within the allotted time frame may result in a sanction.*

(3) *A request for an IDR does not change the freestanding birthing center's requirement to submit a Plan of Correction for all deficiencies within 10 calendar days after receipt of the notice of deficiency.*

F. Immediate Jeopardy.

(1) *Declaration of Immediate Jeopardy.*

(a) *When the OHCQ identifies a situation in which immediate corrective action is necessary because the freestanding birthing center's noncompliance with one or more licensure requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the freestanding birthing center or to the health or safety of the general public, an immediate jeopardy will be declared.*

(b) *The OHCQ shall provide the freestanding birthing center with a written notice that includes a description of the situation that constitutes an immediate jeopardy.*

(2) *Removal Plan. The freestanding birthing center shall submit a written removal plan to the OHCQ that includes:*

(a) *The immediate action a freestanding birthing center will take to prevent serious harm from occurring or recurring;*

(b) *All actions to remove past, present, and future jeopardy; and*

(c) *The date by which the freestanding birthing center asserts the likelihood for serious harm to any recipient no longer exists.*

(3) *OHCQ's Review of the Removal Plan.*

(a) *The OHCQ shall review the freestanding birthing center's removal plan to determine that the removal plan, if implemented appropriately, will remove the likelihood that serious harm will occur, or recur.*

(b) *The OHCQ shall verify that the freestanding birthing center has implemented the removal plan.*

(4) *OHCQ's Approval of the Removal Plan. The OHCQ shall approve the removal plan after verifying that all actions the freestanding birthing center took were effective in removing the likelihood that serious injury, serious harm, serious impairment or death would occur or reoccur.*

(5) *Plan of Correction. If an immediate jeopardy is identified during a survey, the Plan of Correction must completely correct all noncompliance associated with the immediate jeopardy.*

G. Informal Dispute Resolution (IDR).

(1) *A freestanding birthing center may request an IDR to dispute one or more deficiencies in a Statement of Deficiencies.*

(2) *The freestanding birthing center shall submit the request for an IDR to the Department within 10 calendar days of receiving the Statement of Deficiencies.*

(3) *The written request for an IDR shall fully describe the disagreement with the Statement of Deficiencies and be accompanied by all evidence for the Department's consideration.*

(4) *At the discretion of the Department, the IDR may be held in person, by telephone, by video conference, or in writing.*

(5) *IDRs are informal in nature and are not attended by legal counsel representing the freestanding birthing center or the Department.*

(6) *The IDR process may not delay the effective date of any enforcement action.*

(7) *In the event a freestanding birthing center requests an IDR of a deficiency written by a designee of the Department, the Department shall request the designee to participate in the IDR process.*

(8) *There is no appeal of the Department's decision in an IDR.*

[.05] .06 Personnel.

A. (text unchanged)

B. Director of Midwifery Services. The administrator shall appoint a certified nurse midwife or licensed certified midwife as director of midwifery services who is responsible for the employment, training, and supervision of the licensed professional staff.

[C. A physician shall be on call and available to provide medical assistance to the freestanding birthing center whenever the center is treating a patient.]

[D.]C. [Medical Director] *Clinical Director.*

(1) The [medical] *clinical* director shall:

(a) *Be a certified nurse midwife;*

(b) *Be a licensed certified midwife; or*

(c) *Be a physician with:*

[a)] (i) (text unchanged)

(ii) *Appropriate experience in the care of pregnant and postpartum patients; and*

[(2)] Have staff privileges at a hospital licensed by this State; and]

[(3)] (d) (text unchanged)

(2) *The same individual may be clinical director and the director of midwifery services.*

[E.] D. Two licensed staff individuals in midwifery, one of whom shall be a certified nurse midwife or licensed certified midwife, shall:

[attend] (1) *Attend each birth; and*

I. They shall be] (2) *Be currently certified in:*

[(1)] (a) *Adult [CPR] cardiopulmonary resuscitation equivalent to the American Heart Association Class C basic life support; and*

[(2)] (b) *Neonatal [CPR] resuscitation by a course endorsed by the [equivalent to that of the] American Academy of Pediatrics and the American Heart Association.*

[.06] .07 [Protocols] Clinical Practice Guidelines.

A. The [medical] *clinical* director and director of [nurse] midwifery shall develop [protocols] *clinical practice guidelines* for the management of routine and emergency care of the patient and [her] *the* fetus or newborn during pregnancy, birth, and postpartum through discharge, whether through completion of the pregnancy or referral or transfer to other levels of care.

B. The [protocols] *clinical practice guidelines* shall include, *at a minimum*, procedures for the:

(1) *Transfer of patients or newborns for appropriate hospital obstetric and newborn care; [and]*

(2) *Monitoring of fetal heart tones consistent with the current standards of care; and*

[(2)] (3) *Use of ultrasound imaging that is:*

(a) (text unchanged)

(b) *Within the scope of practice for a:*

(i) *Physician; [or]*

(ii) *Certified nurse midwife[.]; or*

(iii) *Licensed certified midwife.*

[B.]C. The administrator shall:

(1) *Ensure that all [protocols] clinical practice guidelines are fully implemented by the clinical staff;*

(2) *Periodically review the [protocols] non-clinical policies and revise them when necessary; and*

(3) *Make the [protocols] clinical practice guidelines available to staff for reference on site at all times.*

D. *A licensed direct-entry midwife, certified nurse midwife, and licensed certified midwife practicing in a birthing center shall remain in compliance with applicable practice guidelines including but not limited to:*

(1) *Health Occupations Article, §8-6C-08, Annotated Code of Maryland;*

(2) *COMAR 10.64.01.10;*

(3) *COMAR 10.27.05.04; and*

(4) *COMAR 10.27.05.01(a)(8).*

.08 Consultation.

A licensed direct-entry midwife, licensed certified midwife, certified nurse midwife, or physician shall consult or collaborate with another health care practitioner who has the knowledge, skills, and expertise to manage a clinical issue, as needed or as required in Health Occupations Article, §8-6C-04, Annotated Code of Maryland.

[.07] .09 [Referral System.] Referrals.

[A freestanding birthing center shall have a system for consultation with and referral to a physician who is Board-certified in a specialty that provides services for pregnant and postpartum patients, or a physician who has appropriate experience in the care of pregnant and postpartum patients.] *A licensed direct-entry midwife, licensed certified midwife, certified nurse midwife, or physician shall refer and transfer patients with complications beyond their scope of practice to a health care practitioner with the knowledge, skills, and experience to manage the client.*

.10 Hospitalization.

A. A freestanding birthing center shall have a written procedure for the transfer of patients to a nearby hospital when care beyond the capabilities of the facility is required.

B. Procedures for emergency transfer to a hospital shall include, at minimum:

- (1) Written clinical practice guidelines related to emergency transfer procedures;
- (2) A mechanism for notifying the hospital of a pending emergency case;
- (3) A mechanism for arranging appropriate transportation to the hospital; and
- (4) Protocols for transmitting a copy of the patient's medical record to the hospital.

C. A freestanding birthing center shall conduct a transfer drill with staff that may be involved in patient transfers at least once a year.

[.08] .11 Quality Assurance Program.

A.—B. (text unchanged)

C. A freestanding birthing center shall conduct a quarterly review of all patients transferred to an emergency department or a hospital.

D. Process of Filing a Complaint. The freestanding birthing center shall have a written process that describes how patients are notified of how to file a complaint with the OHCQ and, if applicable, an accreditation organization.

[.10] .13 Fire Safety and Emergency Preparedness.

A. (text unchanged)

B. Power Outage. A freestanding birthing center shall have:

- (1) A written plan to address power outages; and
- (2) Annual staff training relating to power outages.

[B.] C. Evacuation.

- (1) (text unchanged)
- (2) A freestanding birthing center shall keep all personnel informed of their responsibilities under the plan and conduct a supervised evacuation [drills] *drill* at [regular intervals] *least once a year*.

[C. Transfer of Patients.

- (1) A freestanding birthing center shall have emergency transportation available at all times, as demonstrated by:
 - (a) A written agreement with an ambulance service;
 - (b) Evidence that the center has confirmed that municipal ambulance services are available; or
 - (c) When located on the grounds of an acute care hospital, a written protocol which describes emergency transportation by means other than ambulance.
- (2) A freestanding birthing center shall have a procedure for emergency communication with the ambulance service, or other emergency transportation mechanisms.]

[.11] .14 Equipment.

A. Equipment and furnishings shall be constructed of materials that are easily cleaned and maintained and shall include, at a minimum:

- (1) (text unchanged)
- (2) A transfer [incubator or] isolette or demonstrated capability of ready access to a transfer [incubator] *isolette*;
- (3)—(5) (text unchanged)
- (6) Adult and neonatal resuscitation equipment including, but not limited to, oxygen equipment for patient and newborn that is stored in accordance with Standards for Health Care Facilities, NFPA 99; and
- (7) (text unchanged)

B. (text unchanged)

[.12] .15 Health Record.

A. (text unchanged)

B. The health record of each patient shall contain documentation of all services provided while the patient and [her] *the* fetus or newborn are under the care of the freestanding birthing center, including reports by outside providers who have examined or treated the patient at the request of the center.

C. (text unchanged)

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