

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	08/16/2016	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 9/30/2016

2. COMAR Codification

Title Subtitle Chapter Regulation

10 64 01 01-.19

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator

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5. Name of Person to Call About this Document

Shirley Devaris

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6. Check applicable items:

New Regulations

Amendments to Existing Regulations

 Date when existing text was downloaded from COMAR online: .

Repeal of Existing Regulations

Recodification

Incorporation by Reference of Documents Requiring DSD Approval

Reproposal of Substantively Different Text:

: Md. R

(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

Yes No

8. Incorporation by Reference

Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Sarah E.

Pendley, Assistant Attorney General, (telephone #410-767-3201) on June 19, 2016. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Van T. Mitchell

Title

Secretary

Telephone No.

410-767-6500

Date

August 16, 2016

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 64 BOARD OF NURSING — LICENSED DIRECT-ENTRY MIDWIVES

10.64.01 Practice of Licensed Direct-Entry Midwives

Authority: Health Occupations Article, §§8-205 and 8-6C, Annotated Code of Maryland
and Chapter 383, Acts of 2015

Notice of Proposed Action

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The Secretary of Health and Mental Hygiene proposes to adopt new Regulations .01—.19 under a new chapter, COMAR 10.64.01 Practice of Licensed Direct-Entry Midwives. This action was considered by the Board at its regular monthly meeting on May 25, 2016, notice of which was placed on the Board’s web site on April 1 and May 1, 2016, pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to provide all new regulations for licensing Direct-Entry Midwives including, but not limited to, requirements for licensure, scope of practice for mothers and newborns, limits on scope of practice, rules for transfer of care, discipline, required plan of care for each direct-entry midwife, renewal and continuing education requirements, regulation of the Direct-entry Midwife Advisory Committee, and reporting requirements.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

The Board has and will continue to incur expenses for licensing the Direct- Entry Midwives. The income from initial licensure and renewal is expected to cover the cost to the Board.

II. Types of Economic Impact.	Revenue (R+/R-)	Expenditure (E+/E-)	Magnitude
<hr/>			
A. On issuing agency:	(R+)		\$27,000
B. On other State agencies:	NONE		
C. On local governments:	NONE		

	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(-)	\$27,000
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	(+)	Indeterminable

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. It is assumed the approximately 30 midwives will apply for initial licensure. (30 licensees x \$900 initial licensure fee = \$27,000) The start-up cost to the Board of Nursing equals or might slightly exceed that amount.

D. See A. above.

F. There is a benefit to women in Maryland seeking to have a safe home birth. The licensed Direct-Entry midwives will be providing home birth services. There is no way to estimate how many home births will be attended by them or the savings for the mothers.

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 Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhnh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through October 31, 2016. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2017

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

No

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

The Board will rely on the license fee to cover the costs.

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

Small businesses do not regulate midwives. The small amount of equipment and supplies that they purchase for their practice will have a minimal effect on their suppliers.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 64 BOARD OF NURSING — LICENSED DIRECT-ENTRY MIDWIVES

10.64.01 Practice of Licensed Direct-Entry Midwives

Authority: Health Occupations Article, §§8-205 and 8-6C, Annotated Code of Maryland and Chapter 383, Acts of 2015

.01 Definitions.

A. In this chapter the following terms have the meanings indicated.

B. Terms Defined.

(1) "Accompany the patient to the hospital" means, in the case of a transfer of care to a hospital, the direct-entry midwife:

(a) If possible, will ride in the ambulance with the patient; or

(b) Travel by other means to the hospital.

(2) "ACME" means the Accreditation Commission for Midwifery Education, or a successor organization that is:

(a) An accrediting agency for nurse-midwifery and direct-entry midwifery education programs; and

(b) Approved by the United States Department of Education.

(3) "AIMM" means the Association of Independent Midwives of Maryland or a successor organization that is a professional organization representing independent midwives in the State.

(4) "Board" means the State Board of Nursing.

(5) "Committee" means the Direct-Entry Midwifery Advisory Committee established under Health Occupations Article, §8-6C-11, Annotated Code of Maryland.

(6) "Electronic device" means, but is not limited to, any of the following:

(a) Telephone;

(b) Telephone answering device;

(c) Facsimile machine, photocopier, and scanner for copying; and

(d) Computer.

(7) "Health care practitioner" means an individual certified or licensed under the Health Occupations Article, Annotated Code of Maryland as a:

(a) Nurse-midwife;

(b) Nurse practitioner; or

(c) *Physician.*

(8) *“Health care provider” means a health care practitioner or a hospital and the agents or employees of a health care practitioner or a hospital.*

(9) *“Hospital” has the meaning stated in Health General Article, §19–301, Annotated Code of Maryland.*

(10) *Licensed Direct-Entry Midwife.*

(a) *“Licensed direct-entry midwife” means an individual who has been granted a license under Health Occupations Article, Title 8, Annotated Code of Maryland, to practice direct-entry midwifery.*

(b) *“Licensed direct-entry midwife” does not include a licensed registered nurse certified as a nurse-midwife under the Health Occupations Article, Title 8, Annotated Code of Maryland.*

(11) *“Low-risk pregnancy” means a pregnancy, labor, and delivery and postpartum, newborn, and interconceptional care that does not include a condition that requires a mandatory transfer under Regulation .03 of this chapter.*

(12) *“MEAC” means the Midwifery Education and Accreditation Council, or a successor organization that is a national accreditation agency for midwifery education approved by the United States Department of Education.*

(13) *“NARM” means the North American Registry of Midwives, or a successor organization approved by the Board, that is an international certification agency that establishes and administers certification for the certified professional midwife credential.*

(14) *“Patient” means:*

(a) *A woman for whom a licensed direct-entry midwife performs services; and*

(b) *A woman’s newborn for the purpose of perinatal or postpartum care.*

(15) *“Postpartum period” means the first 6 weeks after delivery.*

(16) *“Practice direct-entry midwifery” means:*

(a) *Providing maternity care that is consistent with a midwife’s training, education, and experience;*

(b) *Identifying and referring patients who require medical care to an appropriate health care provider; and*

(c) *Includes the activities described in Regulation .02 of this chapter.*

.02 Scope of Practice.

The practice of direct-entry midwifery includes:

A. *Providing the necessary supervision, care, and advice to a patient during a low-risk pregnancy, labor, delivery, and postpartum period;*

B. *Newborn care authorized under Health Occupations Article § 8-6C-02, Annotated Code of Maryland, provided in a manner that is:*

(1) *Consistent with national direct-entry midwifery standards; and*

(2) *Based on the acquisition of clinical skills necessary for the care of pregnant women and newborns, including antepartum, intrapartum, and postpartum care.*

C. *Obtaining informed consent to provide services to the patient;*

D. *Discussing:*

(1) *Any general risk factors associated with the services to be provided;*

(2) *Any specific risk factors pertaining to the health and circumstances of the individual patient;*

(3) *Conditions that preclude care by a licensed direct-entry midwife; and*

(4) *The conditions under which consultation, transfer of care, or transport of the patient must be implemented;*

E. *Obtaining a health history of the patient, including a travel history, and performing a physical examination;*

F. *Developing a written plan of care specific to the patient, to ensure continuity of care throughout the antepartum, intrapartum, and postpartum periods that includes:*

(1) *A plan for the management of any specific risk factors pertaining to the individual health and circumstances of the individual patient; and*

(2) *A plan to be followed in the event of an emergency, including a plan for transportation;*

G. *Evaluating the results of patient care;*

H. *Consulting and collaborating with a health care practitioner regarding the care of a patient, and referring and transferring care to a health care provider, as required;*

I. *Referral of all patients, within 72 hours after delivery, to a pediatric health care practitioner for care of the newborn;*

J. *As approved by the Board, in accordance with Regulation .08 of this chapter:*

(1) *Obtaining and administering medications; and*

(2) *Obtaining and using equipment and devices;*

K. *Obtaining appropriate screening and testing, including laboratory tests, urinalysis, and ultrasound;*

L. *Providing prenatal care during the antepartum period, with consultation or referral as required;*

M. *Providing care during the intrapartum period, including*

(1) *Monitoring and evaluating the condition of the patient and fetus;*

(2) *At the onset of active labor notifying the pediatric health care practitioner, by any electronic device, that delivery is imminent;*

(3) *Performing emergency procedures, including:*

(a) Administering approved medications;
(b) Administering intravenous fluids for stabilization;
(c) Performing an emergency episiotomy; and
(d) Providing care while on the way to a hospital under circumstances in which emergency medical services have not been activated;

(4) Activating emergency medical services for an emergency; and
(5) Delivering in an out-of-hospital setting;

N. Participating in peer review as required under Regulation .16 of this chapter;

O. Providing care during the postpartum period, including:

(1) Suturing of first and second degree perineal or labial lacerations, or suturing of an episiotomy with the administration of a local anesthetic; and

(2) Making further contact with the patient within 48 hours, within 2 weeks, and at 6 weeks after the delivery to assess for:

(a) Hemorrhage;
(b) Preeclampsia;
(c) Thrombo-embolism;
(d) Infection; and
(e) Emotional well-being;

P. Providing routine care for the newborn for up to 72 hours after delivery, exclusive of administering immunizations, including:

(1) Immediate care at birth, including:

(a) Resuscitating as needed;
(b) Performing a newborn examination; and
(c) Administering intramuscular vitamin K and eye ointment for prevention of ophthalmia neonatorum;

(2) Assessing newborn feeding and hydration;

(3) Performing metabolic screening and reporting on the screening in accordance with COMAR 10.52.12;

(4) Performing critical congenital heart disease screening and reporting on the screening in accordance with COMAR 10.52.12;

(5) If unable to perform the screening required under §P(3) or (4) of this regulation, referring the newborn to a pediatric health care practitioner to perform the screening within 24 to 48 hours after delivery;

(6) Administering any other required newborn test, medication or treatment required by the Department if authorized by the formulary in Regulation .07 of this chapter; and

(7) Referring the infant to an audiologist for a hearing screening in accordance with COMAR 10.52.12;

Q. Within 24 hours after delivery, notifying a pediatric health care practitioner, by any electronic device, of the delivery;

R. Within 72 hours after delivery:

(1) Referring the newborn to a pediatric health care practitioner; and

(2) Transferring health records to the pediatric health care practitioner, including documentation of the performance of the screenings required under this regulation;

S. Providing the following care of the newborn beyond the first 72 hours after delivery:

(1) Weight checks and general observation of the newborn's activity, with abnormal findings communicated to the newborn's pediatric health care practitioner;

(2) Assessment of newborn feeding and hydration; and

(3) Breastfeeding support and counseling; and

T. Providing limited services to the patient after the postpartum period, including:

(1) Breastfeeding support and counseling; and

(2) Counseling and referral for all family planning methods.

.03 Scope of Practice — Prohibitions.

A. The practice of direct-entry midwifery does not include:

(1) Pharmacological induction or augmentation of labor or artificial rupture of membranes before the onset of labor;

(2) Surgical delivery or any surgery except an emergency episiotomy;

(3) Use of forceps or vacuum extractor;

(4) Except for the administration of a local anesthetic, administration of an anesthetic;

(5) Administration of any kind of narcotic analgesic; or

(6) Administration of any prescription medication not authorized in accordance with Regulation .07 of this chapter.

B. A licensed direct-entry midwife may not assume care or continue to take responsibility for a patient's pregnancy and birth care if a finding of any of the disorders or situations listed under §C of this regulation is found to be present:

(1) At the initial interview;

(2) During an examination of the patient;

- (3) While obtaining a patient history or at subsequent prenatal visits;
 - (4) As a result of a laboratory or other test; or
 - (5) After consultation with another health care practitioner.
- C. If any of the following disorders or situations exist, the licensed direct-entry midwife shall arrange for the orderly transfer of care to a health care practitioner:
- (1) Diabetes mellitus, including uncontrolled gestational diabetes;
 - (2) Hyperthyroidism treated with medication;
 - (3) Uncontrolled hypothyroidism;
 - (4) Epilepsy with seizures or antiepileptic drug use during the previous 12 months;
 - (5) Coagulation disorders;
 - (6) Chronic pulmonary disease;
 - (7) Heart disease in which there are arrhythmias or murmurs except when, after evaluation, it is the opinion of a physician licensed under Health Occupations Article, Title 14, Annotated Code of Maryland, or a licensed nurse certified as a nurse-midwife or a nurse practitioner under Health Occupations Article, Title 8, Annotated Code of Maryland, that midwifery care may proceed;
 - (8) Hypertension, including pregnancy-induced hypertension (PIH);
 - (9) Renal disease;
 - (10) Except as otherwise provided in Health Occupations Article, §8-6C-04(a)(11), Annotated Code of Maryland, Rh sensitization with positive antibody titer;
 - (11) Previous uterine surgery, including a cesarean section or myomectomy;
 - (12) Indications that the fetus has died in utero;
 - (13) Premature labor (gestation less than 37 weeks);
 - (14) Multiple gestation;
 - (15) Noncephalic presentation at or after 38 weeks;
 - (16) Placenta previa or abruption;
 - (17) Preeclampsia;
 - (18) Severe anemia, defined as hemoglobin less than 10 g/dL;
 - (19) Uncommon diseases and disorders, including:
 - (a) Addison's disease;
 - (b) Cushing's disease;
 - (c) Systemic lupus erythematosus;
 - (d) Antiphospholipid syndrome;
 - (e) Scleroderma;
 - (f) Rheumatoid arthritis;
 - (g) Periarteritis nodosa;
 - (h) Marfan's syndrome; and
 - (i) Other systemic and rare diseases and disorders, as determined by the Department;
 - (20) AIDS/HIV;
 - (21) Hepatitis A through G and non-A through G;
 - (22) Acute toxoplasmosis infection, if the patient is symptomatic;
 - (23) Acute Rubella infection during pregnancy;
 - (24) Acute cytomegalovirus infection, if the patient is symptomatic;
 - (25) Acute Parvovirus infection, if the patient is symptomatic;
 - (26) Alcohol abuse, substance abuse, or prescription abuse during pregnancy;
 - (27) Continued daily tobacco use into the second trimester;
 - (28) Thrombosis;
 - (29) Inflammatory bowel disease that is not in remission;
 - (30) Primary herpes simplex virus, genital infection during pregnancy, or any active genital lesions at the time of delivery;
 - (31) Significant fetal congenital anomaly;
 - (32) Ectopic pregnancy;
 - (33) Pre-pregnancy body mass index (BMI) of less than 18.5 or 35 or more; or
 - (34) Post term maturity (gestational age 42 0/7 weeks and beyond).

.04 Required Consultation.

- A. A licensed direct-entry midwife shall consult with a health care practitioner and document:
- (1) The consultation;
 - (2) The recommendations of the consultation; and
 - (3) The discussion of the consultation with the client, if any of the following conditions are present during prenatal care:

(a) Significant mental disease, including depression, bipolar disorder, schizophrenia, and other conditions that impair the ability of the patient to participate effectively in the patient's care or that require the use of psychotropic drugs to control the condition;

(b) Second or third trimester bleeding;

(c) Intermittent use of alcohol into the second trimester;

(d) Asthma;

(e) Diet-controlled gestational diabetes;

(f) History of genetic problems, intrauterine death after 20 weeks' gestation, or stillbirth;

(g) Abnormal Pap smear;

(h) Possible ectopic pregnancy;

(i) Tuberculosis;

(j) Controlled hypothyroidism, being treated with thyroid replacement and euthyroid, and with thyroid test numbers in the normal range;

(k) Rh sensitization with positive antibody titer;

(l) Breech presentation between 35 and 38 weeks;

(m) Transverse lie or other abnormal presentation between 35 and 38 weeks;

(n) Premature rupture of membranes at 37 weeks or less;

(o) Small for gestational age or large for gestational age fetus;

(p) Polyhydramnios or oligohydramnios;

(q) Previous LEEP procedure or cone biopsy;

(r) Previous obstetrical problems, including uterine abnormalities, placental abruption, placenta accreta, obstetric hemorrhage, incompetent cervix, or preterm delivery for any reason;

(s) Post-term maturity (41 0/7 to 6/7 weeks gestational age);

(t) Inflammatory bowel disease, in remission; or

(u) Primary herpes simplex virus, infection or any active infection at time of delivery.

B. Any changes in the plan of care following a consultation in accordance with §A of this regulation shall be documented in the patient's plan of care.

.05 Required Transfer of Care.

A. Except for §A(3) of this regulation, a licensed direct-entry midwife shall arrange immediate emergency transfer to a hospital if:

(1) The patient requests transfer; or

(2) The patient or newborn is determined to have any of the following conditions during labor, delivery, or the immediate postpartum period:

(a) Unforeseen non-cephalic presentation;

(b) Unforeseen multiple gestation;

(c) Non-reassuring fetal heart rate or pattern, including:

(i) Tachycardia

(ii) Bradycardia;

(iii) Significant change in baseline; or

(iv) Persistent late or severe variable decelerations;

(d) Prolapsed cord;

(e) Unresolved maternal hemorrhage;

(f) Retained placenta;

(g) Signs of fetal or maternal infection;

(h) Patient with a third or fourth degree laceration or a laceration beyond the licensed direct-entry midwife's ability to repair;

(i) Apgar of less than seven at 5 minutes;

(j) Obvious congenital anomalies;

(k) Need for chest compressions during neonatal resuscitation;

(l) Newborn with persistent central cyanosis;

(m) Newborn with persistent grunting and retractions;

(n) Newborn with abnormal vital signs;

(o) Gross or thick meconium staining, when discovered; or

(p) Newborn with excessive dehydration due to inability to feed.

(3) If transfer is not possible because of imminent delivery, the licensed direct-entry midwife shall consult with a health care provider for guidance on further management of the patient and to determine when transfer may be safely arranged, if required.

B. A licensed direct-entry midwife shall immediately transfer the care of a patient to a health care provider for the treatment of any significant postpartum morbidity, including:

(1) Uncontrolled postpartum hemorrhage;

(2) Preeclampsia;

- (3) Thrombo-embolism;
- (4) An infection; or
- (5) A postpartum mental health disorder.

C. A licensed direct-entry midwife who is required to transfer care of a patient under this regulation may continue other aspects of postpartum care in consultation with the treating health care practitioner.

.06 Assistant for Home Birth.

At the time of delivery, a licensed direct-entry midwife shall be assisted by a second individual who has:

A. Completed the American Academy of Pediatrics/American Heart Association Neonatal Resuscitation Program (NRP) within the previous 2 years; and

B. The skills and equipment necessary to perform a full resuscitation of the newborn in accordance with the principles of NRP.

.07 Licensed Direct-Entry Midwifery Formulary, Equipment, and Medical Devices.

A. As approved by the Board, in accordance with Health Occupations Article §8-6C-02(b)(8), Annotated Code of Maryland, a licensed direct-entry midwife may:

- (1) Obtain and administer medications; and
- (2) Obtain and use equipment and devices for the practice of midwifery;

B. The following medications are approved by the Board:

- (1) Vitamin K1 (phyloquinone, phytonadione);
- (2) Rho D immune globulin;
- (3) Oxytocin (Pitocin);
- (4) Methylergonovine (Methergine);
- (5) Misoprostol (Cytotec);
- (6) Erythromycin ophthalmic ointment USP (0.5%);
- (7) Oxygen;
- (8) Local anesthetics (lidocaine HCl, cetacaine, novacaine (procaine));
- (9) Epinephrine;
- (10) Penicillin;
- (11) Cefazolin;
- (12) Sterile H2O Papules; and
- (13) Intravenous Fluids including Lactated Ringer's and normal saline.

D. The following devices are approved by the Board:

- (1) Fetal heart rate dopplers;
- (2) Syringes;
- (3) Needles;
- (4) Phlebotomy equipment;
- (5) Suture and suturing equipment or supplies;
- (6) Urinary catheters;
- (7) Intravenous equipment;
- (8) Amnihooks;
- (9) Airway suction devices;
- (10) Electronic fetal monitoring equipment;
- (11) Toco monitoring equipment;
- (12) Neonatal and adult resuscitation equipment;
- (13) Glucose monitoring equipment;
- (14) Centrifuge;
- (15) Hemoglobin/hematocrit monitoring equipment;
- (16) Pulse oximeters, adult and neonatal;
- (17) Birth Supplies including medical grade birthing tubs and birthing stools;
- (18) Blood pressure equipment;
- (19) Urinalysis supplies;
- (20) Stethoscopes, adult and neonatal;
- (21) Sterile surgical instruments;
- (22) Speculums;
- (23) Eldon Cards;
- (25) Nitrazine paper, amniswabs and other amniotic fluid detection equipment;
- (26) Thermometers;
- (27) Laboratory specimen collection equipment;
- (28) Sterilization supplies and equipment;
- (29) Equipment and devices for critical congenital heart screening;
- (30) Equipment and devices for hearing screening;
- (31) Supplies to collect newborn metabolic screening;

- (32) Other equipment and devices as approved by the Board;
- (33) Breast Pumps;
- (34) Compression stockings and belts;
- (35) Maternity belts; and
- (36) Diaphragms and Cervical caps.

.08 License Required and Exceptions.

A. An individual shall be licensed by the Board before the individual may practice direct-entry midwifery in the State.

B. This regulation does not apply to:

- (1) An individual who assists at a birth in an emergency;
- (2) An individual who is licensed as a health care practitioner whose scope of practice allows the individual to practice direct-entry midwifery; or
- (3) A student who is practicing direct-entry midwifery while engaged in a Board approved clinical midwife educational experience under the supervision of a licensed direct-entry midwife.

.09 Patient's Refusal to Transfer Care.

A. If a patient chooses to give birth at home in a situation prohibited by this chapter or in which a licensed direct-entry midwife recommends transfer, the licensed direct-entry midwife shall:

- (1) Transfer care of the patient to a health care practitioner;
- (2) Complete the standard form developed under Regulation .10 of this chapter:
 - (a) Submit the completed form to the accepting health care practitioner; and
 - (b) Cease to take responsibility for the patient's pregnancy care within 1 week after the transfer.

B. If birth is imminent and the patient refuses to be transferred after the licensed direct-entry midwife determines that a transfer is necessary, the licensed direct-entry midwife shall:

- (1) Call 9-1-1 and remain with the patient until emergency services personnel arrive; and
- (2) Transfer care and give a verbal report of the care provided to the emergency medical services providers.

.10 Plan of Care.

A. A licensed direct-entry midwife shall develop a general written plan for:

- (1) Emergency transfer of a patient, a newborn, or both;
- (2) Transport of a newborn to a newborn nursery or neonatal intensive care nursery; and
- (3) Transport of a patient to an appropriate hospital with a labor and delivery unit.

B. The Committee shall review and recommend approval to the Board of the plan required under §A of this regulation.

C. The plan required under §A of this regulation shall be provided to any hospital identified in the plan approved by the Committee.

D. In addition to the general written plan required under §A of this regulation, a licensed direct-entry midwife shall prepare a plan that is specific to each patient and share the plan with the patient.

E. The plan required under §D of this regulation shall:

- (1) Include procedures and processes to be undertaken in the event of an emergency for the mother, the newborn, or both;
- (2) Identify the hospital nearest to the address of the planned home birth that has a labor and delivery unit;
- (3) Include a care plan for the newborn; and
- (4) Identify the pediatric health care practitioner who will be notified after delivery in accordance with Regulation .02 of this chapter to receive the transfer of care of the newborn.

F. Each direct-entry midwife shall use the standard form approved by the Board for all cases in which a transfer occurs during prenatal care, labor, or postpartum.

G. After a decision to transport a patient has been made, the licensed direct-entry midwife shall:

- (1) Call the receiving health care provider;
- (2) Inform the health care provider of the incoming patient;
- (3) Accompany the patient to the hospital; and
- (4) On arrival at the hospital, provide to the staff of the hospital:
 - (a) The standard form developed under §D of this regulation;
 - (b) The complete medical records of the patient and newborn; and
 - (c) A verbal summary of the care provided to the patient and newborn by the licensed direct-entry midwife.

.11 Informed Consent Agreements.

A. Before initiating care, a licensed direct-entry midwife shall obtain a signed copy of the Board-approved standardized informed consent agreement.

B. The agreement developed under §A of this regulation shall include acknowledgment by the patient of receipt, at a minimum, of the following:

- (1) The licensed direct-entry midwife's training and experience;

- (2) Instructions for obtaining a copy of the regulations under this chapter
- (3) Instructions for obtaining a copy of the NARM certification requirements;
- (4) Instructions for filing a complaint with the Board;
- (5) Notice of whether the licensed direct-entry midwife has professional liability insurance coverage;
- (6) A description of the procedures, benefits, and risks of home births, including those conditions that may arise during delivery; and
- (7) Any other information that the Board requires.

.12 Required Reports.

A. Annually, beginning October 1, 2016, a licensed direct-entry midwife shall submit a report to the Committee, in a form specified by the Board, the following information regarding cases in which the licensed direct-entry midwife assisted during the previous fiscal year ending June 30, when the intended place of birth was an out of hospital setting:

- (1) The total number of patients served as primary caregiver at the onset of care;
- (2) The number, by county, of live births attended as primary caregiver;
- (3) The number, by county, of cases of fetal demise, infant deaths, and maternal deaths attended as primary caregiver at the discovery of the demise or death;
- (4) The number of women whose primary care was transferred to another health care practitioner during the antepartum period and the reason for the transfer;
- (5) The number, reason for, and outcome of each nonemergency hospital transfer during the intrapartum or postpartum period;
- (6) The number, reason for, and outcome of each urgent or emergency transport of an expectant mother in the antepartum period;
- (7) The number, reason for, and outcome of each urgent or emergency transport of an infant or mother during the intrapartum or immediate postpartum period;
- (8) The number of planned out-of-hospital births at the onset of labor and the number of births completed in an out-of-hospital setting;
- (9) A brief description of any complications resulting in the morbidity or mortality of a mother or a neonate; and
- (10) Any other information required by the Board in this chapter.

B. The Board shall send a written notice of noncompliance to a licensee who fails to meet the reporting requirements under §A of this regulation.

C. A licensed direct-entry midwife who fails to comply with the reporting requirements under this regulation may not be allowed to renew their license until the information required under §A of this regulation is reported.

D. The Committee shall maintain the confidentiality of any report submitted under §A of this regulation.

E. In addition to the report required under this regulation, a licensed direct-entry midwife shall be subject to the same State reporting requirements as other health care practitioners who provide care to individuals in accordance with the Health General and Health Occupations Articles, Annotated Code of Maryland and the Code of Maryland Regulations.

F. A licensed direct-entry midwife attending an out-of-hospital delivery shall:

- (1) For any live birth, complete and submit a birth certificate in accordance with Health General Article, §4-208, Annotated Code of Maryland; and
- (2) For any death, make all medical records available and communicate relevant circumstances of the death to the individual responsible for completing the certificate of death under Health General Article, §§4-212 and 213, Annotated Code of Maryland.

.13 Direct-Entry Midwifery Advisory Committee.

A. There is a Direct-Entry Midwifery Advisory Committee within the Board.

B. Committee Appointments

- (1) The Committee shall consist of seven members appointed by the Board, in accordance with the following.
 - (a) Three shall be licensed direct-entry midwives;
 - (b) Two shall be licensed registered nurses certified as nurse-midwives;
 - (c) One shall be a representative of the Maryland Hospital Association; and
 - (d) One shall be a consumer member who meets the requirements stated in
- (2) AIMM List.
 - (a) The Board shall appoint the licensed direct-entry midwife members of the Committee from a list of qualified individuals submitted to the Board by AIMM.
 - (b) The Board may request an additional list of qualified individuals from AIMM if the initial list is determined to be inadequate.

C. General Requirement for Committee Membership. A member of the Committee shall be a:

- (1) Citizen of the United States; and
- (2) Resident of the State.

D. Additional Requirements for a Licensed Direct-Entry Midwife Member. A licensed direct-entry midwife member of the Committee:

- (1) Shall meet the licensure requirements of Regulation .15 of this chapter; and

(2) *May not be a licensed registered nurse who is certified as a nurse–midwife.*

E. Additional Requirements for the Consumer Member.

(1) *The consumer member shall be a member of the general public.*

(2) *The consumer member may not be or ever have been;*

(a) *A licensed direct–entry midwife;*

(b) *A licensed registered nurse certified as a midwife;*

(c) *A health care practitioner who is directly involved with pregnancy or labor; or*

(d) *In training to be a:*

(i) *Licensed direct–entry midwife;*

(ii) *Licensed registered nurse certified as a midwife; or*

(iii) *Health care practitioner who is directly involved with pregnancy or labor;*

(3) *The consumer member may not have a household member who is:*

(a) *A licensed direct–entry midwife;*

(b) *A licensed registered nurse who is certified as a nurse–midwife;*

(c) *A health care practitioner who is directly involved with pregnancy or labor; or*

(d) *In training to be a:*

(i) *Licensed direct–entry midwife;*

(ii) *Licensed nurse who is certified as a nurse–midwife; or*

(iii) *A health care practitioner who is directly involved with pregnancy or labor;*

(4) *The consumer member may not:*

(a) *Participate or ever have participated in a commercial or professional field related to the practice of direct–entry midwifery;*

(b) *Have a household member who participates in a commercial or professional field related to the practice of direct–entry midwifery; or*

(c) *Have, or have had within 2 years before appointment, a substantial financial interest in a person who is regulated by the Board.*

F. Committee Chair. *The Committee shall elect a chair from among its members to a 2–year term.*

G. Terms.

(1) *The term of a Committee member is 4 years.*

(2) *The terms of the members are staggered as required by the terms provided for members of the Committee on October 1, 2015.*

(3) *At the end of a term, a member continues to serve until a successor is appointed and qualifies.*

(4) *A member who is appointed after a term has begun serves only for the rest of the term and until a successor is appointed and qualifies.*

(5) *A member may not serve more than two consecutive full terms.*

(6) *To the extent practicable, the Board shall fill any vacancy on the Committee within 60 days of the date of the vacancy.*

H. Committee Meetings.

(1) *A majority of the full authorized membership of the Committee is a quorum.*

(2) *In addition to any other meeting requirements of Health Occupations Article, §8-6C-11, Annotated Code of Maryland, the Committee shall meet:*

(a) *At the request of the executive director of the Board; and*

(b) *As necessary to conduct Board or Committee business.*

I. Member Compensation. *In accordance with the Health Occupations Article, §8-6C-11, Annotated Code of Maryland, each member of the Committee is entitled to:*

(1) *Compensation, at a rate determined by the Board, for each day, or part of a day, on which the member is engaged in the duties of the Committee; and*

(2) *Reimbursement for expenses under the Standard State Travel Regulations.*

J. Removal of a Committee Member. *The Board may remove a member:*

(1) *For incompetence or misconduct; or*

(2) *Who is absent from two successive Committee meetings without adequate reason.*

.14 Committee Duties.

A. The Committee shall:

(1) *Review applications for licensure as a licensed direct–entry midwife and make recommendations to the Board regarding applicants;*

(2) *Maintain a list of all licensed direct–entry midwives;*

(3) *Make recommendations to the Board regarding continuing education requirements for licensed direct–entry midwives;*

(4) *Review advertising by licensed direct–entry midwives and by institutions that offer a direct–entry midwife program and make recommendations to the Board, as necessary;*

(5) *Advise the Board on matters relating to the practice of direct–entry midwifery;*

(6) Collect the reports required to be submitted by each licensed direct-entry midwife under Regulation .12 of this chapter;

(7) Make recommendations to the Board regarding regulations relating to the practice of direct-entry midwifery that are necessary to carry out the provisions of this chapter;

(8) At the request of the Board, investigate complaints against licensed direct-entry midwives; and

(9) Keep a record of the Committee's proceedings.

C. Annually, beginning November 1, 2016, submit to the Board a report to the Board, without any personal identifying information, that includes, but is not limited to:

(1) A summary of the information included in reports submitted to the Committee by licensed direct-entry midwives under Regulation .12 of this chapter; and

(2) Any other information identified by the Board.

D. Annually, beginning December 1, 2016, the Board shall submit to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee, in accordance with State Government Article, §2-1246, Annotated Code of Maryland, a report to include the following:

(1) The report submitted to the Board under §C of this regulation;

(2) Any Committee recommendations regarding the continuation and improvement of the licensure of licensed direct-entry midwives in the State;

(3) Any recommendations regarding expanding the scope of practice of licensed direct-entry midwives; and

(4) Any recommendations, including recommendations for legislation, regarding the scope of practice of licensed direct-entry midwives to include vaginal birth after cesarean delivery.

.15 Qualifications of Applicants for Initial Licensure.

A. An applicant shall:

(1) Be of good moral character;

(2) Be a high school graduate or have completed equivalent education;

(3) Be 21 years old or older;

(4) Hold a current cardiopulmonary resuscitation (CPR) certification issued by the American Red Cross or the American Heart Association; and

(5) Have completed in the past 2 years the American Academy of Pediatrics or American Heart Association Neonatal Resuscitation Program (NRP).

(6) Hold a current valid Certified Professional Midwife credential granted by NARM; and

(7) Have completed a midwifery education program as describe in §B of this regulation.

B. Midwifery Education Program. The applicant shall:

(1) Have completed a midwifery education program that is accredited by MEAC or ACME; or

(2) If the applicant was certified by NARM as a certified professional midwife on or before January 15, 2017, through a non-MEAC accredited program, but otherwise qualifies for licensure, provide:

(a) Verification of completion of NARM-approved clinical requirements; and

(b) Evidence of completion, in the past 2 years, of an additional 50 hours of continuing education units approved by the Board and accredited by MEAC, the American College of Nurse Midwives, or the Accrediting Council for Continuing Medical Education, which included:

(i) 14 hours of obstetric emergency skills training such as a Birth Emergency Skills Training (BEST) or an Advanced Life Saving in Obstetrics (ALSO) course; and

(ii) 36 hours of pharmacology, lab interpretation of pregnancy, antepartum complications, intrapartum complications, postpartum complications, and neonatal care courses.

.16 Applications for Licenses and Issuance of Licenses.

A. To apply for a license to practice direct-entry midwifery an applicant shall submit:

(1) To a criminal history records check (CHRC) in accordance with Health Occupations Article, §8-303, Annotated Code of Maryland;

(2) A completed application to the Board on the form that the Board requires; and

(3) Written, verified evidence that the requirement submissions to a CHRC in accordance with Health Occupations Article, §8-303, Annotated Code of Maryland, is being met;

(4) Any documentation requested from the applicant by the Board including, but not limited to:

(a) An official certified or true test court documents; and

(b) A signed and dated explanation, written by the applicant, regarding the facts and circumstances, outcome, and current status of any criminal history record information received by the Board:

(i) Under §A(1) of this regulation;

(ii) In an answer to a question on the Board's application form; and

(iii) Any other source; and

(iv) Any additional documentation requested by the Board if the documentation received from the applicant under §A(4) of this regulation is incomplete or insufficient; and

(5) The initial application fee specified in Regulation .18 of this chapter.

B. If an application is not complete when initially submitted to the Board by the applicant, the applicant shall have no longer than 12 months from the date the application is received by the Board to:

- (1) Complete the application; and*
- (2) Provide all information and documentation required in §A of this regulation.*

C. If an applicant fails to provide to the Board a complete application and any additional documentation requested by the Board under §A of this regulation within 12 months from the date the application is received by the Board, the application shall be void and the Board will no longer consider the applicant for licensure.

D. To pursue licensure after an application has become void under §C of this regulation, the applicant shall:

- (1) Submit a new application on the form required by the Board;*
- (2) Meet all of the requirements for licensure established in this chapter; and*
- (3) Pay the required fees under Regulation .18 of this chapter.*

E. A license may not be issued until the Board has:

- (1) Received and reviewed the CHRC; and*
- (2) Has approved the application.*

.17 Term and Renewal of License and Reinstatement of License.

A. A license issued under this regulation authorizes the licensee to practice direct-entry midwifery while the license is active.

B. A license:

- (1) Expires on October 28 every odd-numbered year;*
- (2) Is valid for 2 years, except for an initial license issued before the next renewal date;*
- (3) Issued for less than the full 2-year period, shall be renewed at the next annual renewal date;*
- (4) May be renewed for an additional term if the applicant:*
 - (a) Meets the renewal requirements under §B(4)(c) of this regulation :*
 - (b) Pays to the Board a renewal fee specified in Regulation 18 of this chapter; and*
 - (c) Submits to the Board:*
 - (i) A renewal application on the form that the Board requires; and*
 - (ii) Satisfactory evidence of compliance with any continuing education or other competency requirements for license renewal.*

C. In addition to all other qualifications and requirements established by the Board for license renewal, the renewal applicant shall submit proof of completion of:

- (1) 20 accredited and Board-approved continuing education units to be completed in the 2 years preceding the renewal date;*
- (2) 4 hours of peer review in the 2 years before the renewal date in accordance with NARM standards for official peer review; and*
- (3) Submission of the annual reports required under Regulation .12 of this chapter.*

D. The Board shall renew the license of each licensee who meets the requirements of this regulation.

E. A renewal applicant shall be placed on inactive status if the licensee:

- (1) Fails to provide satisfactory evidence of compliance with any continuing education requirements under this regulation for license renewal; or*
- (2) Fails to submit the annual report required under Regulation .12 of this chapter.*

F. If the renewal applicant fails to submit the required documents within 1 year of the renewal date, the status of the license shall be changed to non-renewed.

G. The Board shall place a licensee on inactive status at the request of the licensee if the licensee submits to the Board:

- (1) A completed application for inactive status on the form required by the Board; and*
- (2) The fee for inactive status specified in Regulation .18 of this chapter.*

H. The Board shall reactivate the license of a licensee who has requested inactive status if the licensee:

- (1) Complies with any continuing education and data reporting requirements established by the Board for this purpose;*
- (2) Pays to the Board a reactivation fee specified in Regulation .18 of this chapter; and*
- (3) Is otherwise entitled to be licensed in accordance with this regulation.*

I. The Board shall reinstate the license of an individual who has failed to renew the license for any reason if the individual:

- (1) Is otherwise entitled to be licensed in accordance with this regulation;*
- (2) Complies with any continuing education and data reporting requirements established by the Board for this purpose;*
- (3) Submits a completed application for reinstatement to the Board;*
- (4) Pays to the Board the fee for reinstatement;*
- (5) Completes a criminal history record check in accordance with Health Occupations Article, §8-303, Annotated Code of Maryland, for a license that has expired or lapsed for more than 1 year; and*
- (6) Applies to the Board for reinstatement of the license within 5 years after the license expires.*

J. The Board may not reinstate the license of a licensed direct-entry midwife who fails to apply for reinstatement of the license within 5 years after the license expires. The individual may become licensed by meeting the current requirements for obtaining a new license as set forth in:

- (1) Health Occupations Article, §§8-6C-13—8-6C-16, Annotated Code of Maryland; and
- (2) This chapter.

K. A licensee shall submit to an additional criminal history records check every 12 years. The Board may not renew a license if the criminal history record information required by this section has not been received.

.18 Fees.

- A. The fees listed in this regulation are not refundable.
- B. An initial license shall only be valid until the next renewal period.
- C. The fees are as follows:
 - (1) Initial application fee \$900;
 - (2) Biennial renewal \$800;
 - (3) Reactivation fee \$800;
 - (4) Reinstatement Fee \$900; and
 - (5) Inactive Status Fee \$100.

.19 Prohibited Acts.

- A. Unless authorized to practice direct-entry midwifery, an individual may not represent to the public by title, description of service, method, procedure, or otherwise, that the individual is authorized to practice direct-entry midwifery in the State.
- B. A licensee may not advertise in a manner that is unreasonable, misleading, or fraudulent.
- C. Unless authorized to practice direct-entry midwifery, an individual may not use the abbreviation "LDEM" or use the designation "licensed direct-entry midwife".
- D. Unless authorized to practice direct-entry midwifery or certified as a registered nurse midwife under the Health Occupations Article, Title 8, Annotated Code of Maryland, an individual may not use the designation "midwife".

VAN T. MITCHELL

Secretary of Health and Mental Hygiene

**FEE JUSTIFICATION FOR
PROPOSED COMAR 10.64.01**

(1) Explain/justify why an increase or decrease is necessary:

The Board of Nursing will be regulating a new discipline: Licensed Direct-Entry Midwives. This is a new fee proposal for initial, renewal, and reinstatement of a license for a licensed direct-entry midwife.

(2) How much money is needed to operate effectively or to eliminate an operating fund deficit?

It is estimated that there are approximately 30 direct-entry midwives who will be applying for an initial license. The cost to the Board for their initial licensure will be approximately \$27,000. This estimated expense includes time spent by staff working with the advisory committee in the last year to develop consent forms, regulations, data collection forms, application forms, the care plan, meeting with stakeholders, and developing the formulary for medications and equipment. Additionally, the Board will have to add to its existing computer licensing program to add the direct-entry midwives. All applications and supporting documents will have to be scanned into the Board's data base. Staff is responsible for staffing meetings and arranging the meetings. Biennial renewal fees have been based on the time it will take to review reports and continuing education requirements, scan them into the Board's license program and hand-enter them into the data base. Presently it will be less costly to hand-enter 30 applications or renewals into the Board's licensure data base than to develop an additional on-line application program. The estimated cost is \$24,000 for renewals. The cost of investigating complaints and prosecuting has not been included in these computations. There may have to be an adjustment of fees if the Board receives several complaints a year

(3) In what year was the most recent fee increase?

N/A.

(4) Is the fee revenue retained by the Proposing Unit or passed through to a national organization that administers a uniform licensing exam?

The fee will be retained by the proposing unit, paid to the General Fund and then paid into the Board's Special Fund.

(5) Describe any measures taken to mitigate the need for increased revenue:

N/A.

(6) Describe any special circumstances that have had an adverse impact on the Proposing Unit's operating expenses.

The Board has used existing staff to work with the Advisory Committee. This has added to staff duties because staff has had to maintain a record of proceedings, develop regulations, meet with the advisory committee and prepare forms. Board counsel has also spent many hours working with the Advisory Committee. Temporary and contract staff was used when available.

(7) Describe any consideration given by the Proposing Unit as to the hardship a fee increase may have on the regulated profession.

The fee was discussed on several occasions with the midwives during the legislative session and later at Advisory meetings. The midwives realize that the fees have to cover costs and have repeatedly expressed their expectation that the fee could be as high as \$1,000. The Board has limited its expenditures to use of internal staff. However, one additional contract officer will be needed to enable the Board to quickly and efficiently license these individuals, establish renewal policies, and collect the data for the required reports.

(8) Describe any efforts to solicit the opinions of licensees regarding the Proposing Unit's effectiveness and performance.

The Advisory Committee met on March 31, 2016, and proposed an initial license fee of \$900 and a biennial renewal fee of \$800. The Direct Entry Midwives proposed these fees after taking into consideration the time spent by staff and the use of Board resources for an initial license, the time preparing reports annually, and reviewing credentials every two years for renewal applicants. A comparative study was done for fees of similar boards in other states. Maryland is at the upper end of the fee range from other states. Maryland Health Occupation renewal fees range from \$146.00 (licensed nurses) to \$1,050.00 (Podiatrists). Most renewal fees cluster around the \$300.00 level. The smaller Boards tend to have higher fees.