

Department of Legislative Services
 Maryland General Assembly
 2015 Session

FISCAL AND POLICY NOTE

Senate Bill 105 (Senators Middleton and Conway)
 Education, Health, and Environmental Affairs

Maryland Home Birth Safety Act

This bill establishes the Direct-Entry Midwifery Advisory Committee within the State Board of Nursing (BON) and procedures for obtaining and renewing a license to practice direct-entry midwifery. The bill provides for the membership of the advisory committee, the application process, enforcement and hearing procedures, and fees associated with licensure. BON must adopt regulations related to the practice of direct-entry midwifery by June 1, 2016.

The bill takes effect June 1, 2015. Provisions regarding (1) the required consultation with a health care practitioner; (2) the emergency transfer of a patient to a hospital or other health care provider; and (3) instances where a certified direct-entry midwife may not undertake the care of patients, terminate on the effective date of specified regulations adopted by BON.

Fiscal Summary

State Effect: Special fund expenditures increase by \$108,600 in FY 2016 for BON to establish regulations, establish the committee, upgrade computer systems, and prepare to license certified direct-entry midwives beginning in FY 2017. Special fund revenues increase beginning in FY 2017 from new licensing fee revenues. Future year expenditures reflect inflation and elimination of one-time costs. General fund revenues may increase minimally due to the bill’s civil penalties.

(in dollars)	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
SF Revenue	\$0	-	-	-	-
SF Expenditure	\$108,600	\$44,100	\$4,100	\$4,100	\$4,200
Net Effect	(\$108,600)	(\$44,100)	(\$4,100)	(\$4,100)	(\$4,200)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: None.

Small Business Effect: Meaningful.

Analysis

Bill Summary:

The Practice of Direct-Entry Midwifery

“Practice direct-entry midwifery” is defined as providing primary maternity care that is consistent with a midwife’s training, education, and experience to parents throughout the childbearing cycle as well as identifying and referring patients who require medical care to an appropriate health care provider. “Practice direct-entry midwifery” includes (1) providing the necessary supervision, care, and advice to a patient during a low-risk pregnancy, labor, delivery, and postpartum period and (2) newborn care that is consistent with national direct-entry midwifery standards and based on the acquisition of clinical skills necessary for the care of pregnant woman and newborns, including antepartum, intrapartum, and postpartum care. The practice of direct-entry midwifery encompasses:

- obtaining informed consent to provide services;
- obtaining a health history, including a physical examination;
- developing a written plan of care for each patient;
- evaluating the results of patient care;
- consulting and collaborating with, and referring and transferring care to, a health care practitioner as required;
- referring all patients, prior to delivery, to a pediatric care provider;
- as recommended by the committee and approved by BON, obtaining and administering specified medications and obtaining and using appropriate equipment and devices;
- obtaining appropriate screening and testing, including laboratory tests, urinalysis, and ultrasound;

- providing prenatal care during the antepartum period, with consultation and referral as required;
- providing care during the intrapartum period, including monitoring and evaluating the conditions of the patient and fetus as well as performing specified emergency procedures and delivering in an out-of-hospital setting;
- participating in peer review;
- providing care during the postpartum period, including (1) with the administration of local anesthesia, suturing specified lacerations and performing an episiotomy and (2) making further contact with the patient at periodic intervals to assess specified risks;
- providing routine care to the newborn for 72 hours after delivery, exclusive of administering immunizations, including immediate care at birth (including resuscitation), performing a newborn examination, and administering intramuscular vitamin K and eye ointment;
- performing critical congenital heart disease screening between 24 and 48 hours after delivery or, if unable to perform the screening, referring the newborn to a health care provider;
- notifying a pediatric care provider of delivery, transferring health records, and recommending to the patient that the newborn be seen by a pediatric care provider within 24 hours of delivery;
- after the first 72 hours following delivery, providing (1) weight checks and general observation of the newborn with abnormal findings reported to the pediatric care provider; (2) referral for metabolic and congenital heart disease screening; and (3) breastfeeding support; and
- providing limited services to the patient after the postpartum period, including (1) breast feeding support and (2) counseling and referral related to family planning methods.

The practice of direct-entry midwifery does *not* include (1) induction or augmentation of labor with pharmaceuticals; (2) surgical delivery or any surgery except an emergency episiotomy; (3) use of forceps or vacuum extractor; (4) administration of an anesthetic,

other than a local anesthetic; (5) administration of any kind of narcotic pain reliever; or (6) administration of any prescription medication that violates the provisions of the bill.

At the time of delivery, a certified direct-entry midwife must be assisted by a second individual who has completed neonatal resuscitation training and has the skills and equipment necessary to perform a full resuscitation of a newborn.

State Board of Nursing Regulations

BON must adopt regulations for the licensure of certified direct-entry midwives and for the practice of direct-entry midwifery by June 1, 2016. BON must adopt regulations regarding approved types of equipment and devices as well as the administration of medications. BON has to establish reasonable fees for the issuance and renewal of licenses and other services it provides to licensed certified direct-entry midwives.

BON must develop initial, renewal, and inactive status application forms. In consultation with stakeholders, BON must also develop a form for use in all cases in which a transfer occurs during labor.

The Direct-Entry Midwifery Advisory Committee

The bill establishes a Direct-Entry Midwifery Advisory Committee within BON. BON is to appoint the seven members of the committee, with membership subject to numerous specified conditions based on position, experience, credentials, and other factors. The bill provides for the chairmanship, the length and number of terms, removal of members, and other procedures such as the constitution of a quorum and the filling of vacancies on the committee. Committee members are entitled to compensation and reimbursement for standard travel expenses.

The committee must review applications for licensure, make recommendations on applicants, and review advertising by certified direct-entry midwives and institutions that offer a midwifery program. The committee must make recommendations to BON on multiple issues, including regulations that define specific conditions requiring transfer of care to or consultation with a health care professional and conditions under which a certified direct-entry midwife may not undertake the care of a specified patient. The committee must maintain a list of all certified direct-entry midwives; at the request of BON, investigate complaints; keep records of proceedings; collect annual summary reports from the licensees and then submit an annual report to BON; and advise BON on matters relating to the practice of direct-entry midwifery.

The committee is also required to create a standardized informed consent document outlining the procedures, risks, and benefits of out-of-hospital birth to be used by all certified direct-entry midwives.

Licensure Requirements and Application Procedures

Generally, an individual must be licensed by BON before the individual may practice direct-entry midwifery in the State. Exempt are individuals assisting at a birth in an emergency, licensed health care practitioners authorized to practice direct-entry midwifery, or students practicing direct-entry midwifery under the supervision of a certified direct-entry midwife. An applicant for licensure must:

- be age 21 or older and of good moral character;
- be a high school graduate or have completed equivalent education;
- submit to a criminal history records check (CHRC);
- be certified to perform cardiopulmonary resuscitation;
- hold a current neonatal resuscitation certification;
- hold a valid Certified Professional Midwife (CPM) credential granted by the North American Registry of Midwives (NARM); and
- have completed a midwifery education program accredited by the Midwifery Education and Accreditation Council (MEAC) or the Accreditation Commission for Midwifery Education.

If the applicant was certified as a CPM on or before January 15, 2017, through a non-MEAC accredited program, but otherwise qualifies for a license, the applicant must provide (1) verification of completion of NARM-approved clinical requirements and (2) evidence of completion, in the past five years, of an additional 40 hours of accredited and board-approved continuing education units, including at least 8 hours of pharmacology and 14 hours of obstetric emergency skills training.

BON may waive the education and training requirements for an individual licensed in another state if the other state's licensure requirements are substantially equivalent to Maryland's and the applicant otherwise meets the qualifications for licensure.

If the CHRC reveals that a crime has been committed, BON must consider the age at which the crime was committed, the circumstances surrounding the crime, the length of time that has passed since the crime, subsequent work history, employment and character references, and other evidence that demonstrates that the applicant does not pose a threat to the public health or safety. BON may not issue a license if the CHRC has not been received. A licensee must submit to an additional CHRC every 12 years.

BON must issue a license to any applicant who meets the requirements of the bill and pays the required license fee. A license may not be renewed for a term longer than two years. At least three months before a license expires, BON must send a renewal notice to the licensee, which must state the date on which the current license expires, the date by which the renewal application must be received, and the amount of the renewal fee.

Among other requirements, a renewal applicant must provide satisfactory evidence of compliance with any continuing education or other competency requirements. BON must require 20 continuing education units to be completed every two years, of which 4 units must relate to peer review. If a licensee fails to provide evidence of compliance with continuing education requirements, BON must place the licensee on inactive status. The licensee must also submit data on every patient who consents to participate in the Midwife Alliance of North America (MANA) statistical data program on any form prescribed by MANA in accordance with MANA's policies and procedures.

BON must also place a licensee on inactive status if the licensee submits an application for inactive status and pays an inactive status fee. BON must reactivate a licensee on inactive status if (1) the licensee complies with any continuing education requirement; (2) pays the reactivation fee; and (3) is otherwise entitled to be licensed. Likewise, BON must reinstate a licensee who has failed to renew a license if the individual (1) is otherwise entitled to be licensed; (2) complies with continuing education requirements; (3) pays a reinstatement fee; and (4) applies for reinstatement within five years after the license has expired. In the case of any expired or lapsed license that has been expired or lapsed for more than one year, the individual must complete a CHRC.

An individual may not represent that he or she is authorized to practice direct-entry midwifery, unless authorized to do so. Additionally, a licensee may not advertise in a manner that is unreasonable, misleading, or fraudulent. Unless authorized to practice direct-entry midwifery, a person may not use the designation "CDEM" or "certified direct-entry midwife." Unless an individual is authorized to practice direct-entry midwifery or is a certified nurse-midwife, a person may not use the designation "midwife."

Enforcement and Hearing Procedures

The bill establishes grounds under which BON may deny a license to an applicant; reprimand a licensee; place a licensee on probation; or suspend or revoke a license. Before BON takes disciplinary action, it must give the person an opportunity for a hearing, unless the Administrative Procedure Act provides otherwise. If BON finds grounds to suspend or revoke a license, to reprimand a licensee, or to place a licensee on probation, BON may impose a penalty of up to \$5,000 in lieu of or in addition to suspending or revoking the license, reprimanding the licensee, or placing the licensee on probation.

A person who violates any provision of the bill is guilty of a misdemeanor and on conviction is subject to a fine of up to \$5,000 and/or imprisonment for up to one year.

Practice Requirements, Informed Consent, and Liability

Before initiating care, a certified direct-entry midwife must obtain a signed copy of a standardized informed consent agreement developed by the committee. An additional informed consent agreement must include acknowledgments of (1) the certified direct-entry midwife's training and experience; (2) instructions for obtaining a copy of the regulations adopted by BON; (3) instructions for obtaining a copy of NARM certification requirements; (4) notice of whether the certified direct-entry midwife has professional liability insurance coverage; (5) instructions for filing a complaint with BON; and (6) a description of the procedures, benefits, and risks of home births.

If a patient is determined to have any of 19 specified conditions present during prenatal care, a certified direct-entry midwife must consult with a health care practitioner (licensed physician, certified nurse-midwife, certified nurse practitioner, or licensed physician assistant). Additionally, care of a patient and/or a newborn must be transferred to a hospital if the patient requests transfer or any of 15 specified conditions occur during labor, delivery, or the postpartum period. Likewise, a certified direct-entry midwife may *not* undertake the care of a patient or must immediately refer and transfer the care of a patient to a health care provider if the patient is determined to have any of 31 specified conditions.

If a patient chooses to give birth at home in a situation prohibited by law or in which a certified direct-entry midwife recommends transfer, the certified direct-entry midwife is required to transfer the patient and the patient's family to an alternative care provider and cease to take responsibility for the patient's pregnancy care within one week after providing the referral. If birth is imminent, and the patient refuses to be transferred, the

certified direct-entry midwife must call 9-1-1 and remain with the patient until emergency services personnel arrive.

A certified direct-entry midwife may not offer a trial of labor to a patient who has had a delivery by cesarean section unless the patient (1) had a low transverse incision; (2) at the onset of labor, at least 18 months will have elapsed since the cesarean section; (3) the certified direct-entry midwife has recommended that the patient consult with a health care practitioner about the patient's level of risk; and (4) the certified direct-entry midwife has obtained written informed consent that specifies the risks of vaginal birth after cesarean section when performed in an out-of-hospital setting.

A certified direct-entry midwife must develop a general written plan for (1) emergency transport of a patient, 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. The committee must review and approve the plan provided by each certified direct-entry midwife. The plan must be provided to any hospital identified in the plan.

In addition to the general written plan, a certified direct-entry midwife must prepare a plan that is specific to each patient and share it with that patient. The certified direct-entry midwife must use the uniform form developed by BON for use with all transfers during labor.

A certified direct-entry midwife engaged in the private practice of direct-entry midwifery must display a notice, written in plain language, which explains the U.S. Centers for Disease Control and Prevention's guidelines on universal precautions, conspicuously in each office where the licensee is engaged in practice.

Except for any willful or grossly negligent act, any health care provider (licensed physician, certified nurse-midwife, certified nurse practitioner, licensed physician assistant, hospital, or an agent or employee of such), emergency room personnel who work at hospital, or emergency medical technicians or ambulance personnel may not be held civilly liable for an action arising from an injury resulting from an act or omission of a certified direct-entry midwife, even if the person consulted with, or accepted a referral from, the certified direct-entry midwife. A health care practitioner (licensed physician, certified nurse-midwife, certified nurse practitioner, or licensed physician assistant) who consults with a certified direct-entry midwife but who does not examine or treat a patient of the certified direct-entry midwife may not be deemed to have created a physician-patient relationship with the patient.

Direct-Entry Midwifery Formulary Workgroup

Uncodified language in the bill requires the committee, with the approval of BON, to convene a workgroup consisting of specified stakeholders to study and develop a midwifery formulary. The workgroup must (1) review midwifery formularies developed in other states; (2) make recommendations regarding the establishment of a midwifery formulary council; and (3) make recommendations regarding the establishment of a midwifery formulary, including the types of medications, equipment, and devices to be included and the method by which future medications, equipment, and devices will be included. By June 1, 2016, the workgroup must report its findings and recommendations to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee.

BON Reporting Requirement

By December 1, 2018, BON must, in consultation with the Direct-Entry Midwifery Advisory Committee, report to specified legislative committees, for licensure years 2016 through 2018, (1) the number of certified direct-entry midwives in the State; (2) the number and circumstances of all healthy and adverse birth outcomes attended by certified direct-entry midwives as well as births where a transfer or transport was made; and (3) recommendations for the continuation and improvement of the licensure of certified direct-entry midwives.

Sunset Review and Program Evaluation

The bill subjects the new licensure program to periodic review under the Maryland Program Evaluation Act, as with other health occupations boards, with a termination date of July 1, 2023 (consistent with that for BON).

The bill also subjects the advisory committee to a full evaluation, without the need for a preliminary evaluation, in 2021 (consistent with the evaluation timeline for BON).

Current Law/Background: The profession of midwifery includes direct-entry midwives and nurse-midwives. BON provides advanced practice registered nurse certification to nurse-midwives, who must also be licensed registered nurses. Under board regulations, an applicant for certification as a nurse-midwife must hold a current license to practice registered nursing in Maryland and complete a program in a clinical nurse specialty area accredited by a national certifying body that is specified or recognized by the board. As of June 2010, certified nurse-midwives in Maryland are no longer required to have a physician sign a collaborative agreement to provide clinical support to their attended births, and as of September 2014, certified nurse-midwives in

Maryland are no longer required to give BON a copy of a collaborative plan that lists a physician to whom they would transfer a patient in case of an emergency. Certified nurse-midwives are now considered independent practitioners. According to MANA, nurse-midwives are authorized to practice in all 50 states and the District of Columbia.

Direct-entry midwifery refers to an educational path that does not require prior nursing training to enter the profession. NARM issues the national, competency-based CPM credential. As of January 2015, more than 2,600 midwives nationally held CPM certification. CPMs offer primary maternity care to women in private homes or birth center-based practices. The CPM credential allows multiple routes of entry into the profession. Aspiring midwives can attend a midwifery program or school or apprentice with a qualified midwife and complete an evaluation process that verifies an individual's experience and skills. Individuals must then sit for the NARM written examination. Recertification is required every three years and includes a continuing education requirement.

Although NARM offers certification as a CPM, CPMs are guided by the National Association of Certified Professional Midwives (NACPM) Standards for Practice and the Midwives' Model of Care™ based on the fact that pregnancy and birth are normal life events. Midwife care includes (1) monitoring the physical, psychological, and social well-being of the mother throughout the childbearing cycle; (2) providing the mother with individualized education, counseling, and prenatal care; (3) continuous hands-on assistance during labor and delivery and postpartum support; (4) minimizing technological interventions; and (5) identifying and referring women who require obstetrical attention. According to NACPM, the application of this model has been proven to reduce the incidence of birth injury, trauma, and cesarean section.

More than one-half of all states (including Delaware and Virginia) recognize CPMs in statute. In 2007, the Washington state legislature commissioned a cost-benefit analysis from the Washington Department of Health on licensed midwifery care. That analysis found that licensed midwives save the State of Washington at least \$473,000 per biennium in cost offsets to Medicaid when women give birth at home or in freestanding birth centers. This was a conservative estimate that reflects only avoided costs associated with licensed midwives' lower cesarean section rates. When facility fees and medical procedures such as epidurals and continuous electronic fetal monitoring are factored into the equation, the actual savings to Medicaid biennially are approximately \$3.1 million. These savings occur with licensed midwives attending fewer than 2% of births in Washington state.

During the 2012 interim, the Department of Health and Mental Hygiene (DHMH) convened the Midwives Workgroup at the request of the House Health and Government

Operations Committee, with a report published in January 2013. The report noted that data on the number of CPMs and direct-entry midwives in Maryland is limited because they are not licensed to practice in the State. However, the percentage of U.S. births occurring at home increased between 2004 and 2009 after decreasing from 1990 to 2004. In Maryland, although there were 214 certified nurse-midwives licensed to practice in Maryland, fewer than half actually practiced full-scope midwifery, and only 4 were attending home births. Thus, 97% of all births attended by certified nurse-midwives in the State occur in hospitals.

The workgroup did not adopt consensus recommendations due to diverse views on how to best address the increased demand for licensed, safe home birth services in Maryland. DHMH did recommend further exploration into why so few certified nurse-midwives practice midwifery. Additionally, DHMH reaffirmed its support of the Joint Statement on Planned Home Births issued in 2012 (as endorsed by BON, the Maryland Association of County Health Officers, and the Maryland Affiliate of the American College of Nurse-Midwives), which states that (1) during the course of prenatal care, a pregnant woman considering a home birth should consult with a licensed physician or licensed certified nurse-midwife in order to be assessed as a candidate for a home birth; (2) to ensure the health and safety of the mother and infant, all planned home deliveries must be attended by a licensed physician or licensed certified nurse-midwife; and (3) it is unlawful for a physician or midwife to practice in Maryland without a valid Maryland license.

While the workgroup *did not* reach consensus, the report provides a wide range of options regarding the various charges of the workgroup. The options presented included, among many others:

- establishing an independent midwifery board for licensure, regulation, and oversight of midwives, including CPMs;
- adopting the certified professional credential as the model for licensure of direct-entry midwives in Maryland;
- requiring that NARM certification be the educational requirement for CPM licensure in Maryland; and
- requiring a minimum level of education and training for all midwives according to standards set by the American Midwifery Certification Board.

State Expenditures: BON advises that 25 individuals are likely to seek licensure under the bill's provisions, and that the total number of licensed individuals could increase to approximately 35 by 2020. Assuming approximately 25 individuals seek licensure, special fund expenditures increase by \$108,559 in fiscal 2016. This estimate reflects the cost of hiring one full-time contractual administrative officer (grade 14 equivalent) for

two years effective July 1, 2015, to assist BON with establishing regulations, establishing the committee, staffing the midwifery formula workgroup, and licensing certified direct-entry midwives. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses. The estimate includes \$50,000 to adapt existing licensure software to accommodate the licensing of certified direct-entry midwives. The estimate also includes \$12,000 for compensation and reimbursement for committee members. Committee compensation and reimbursement has been estimated at \$1,000 per meeting (including \$100 in compensation per member), with meetings occurring on a monthly basis for the first year.

Position	1
Salary and Fringe Benefits	\$41,689
Computer Programing Costs	50,000
Committee Compensation/Reimbursement	12,000
Operating Expenses	<u>4,870</u>
Total FY 2016 State Expenditures	\$108,559

BON advises that it will likely take at least nine months to develop regulations and that it will not issue licenses until the regulations are developed. Thus, in fiscal 2017, special fund expenditures increase by \$44,100, which reflects an ongoing contractual salary and committee compensation and reimbursement (assuming quarterly committee meetings). Once licenses are issued, to the extent complaints are received, special fund expenditures may increase further to hire a contractual investigator and an assistant Attorney General on a part-time basis to investigate complaints and take disciplinary actions as needed, though these duties may be absorbed by existing resources within BON. Any such cost has not been factored into this estimate.

State Revenues: Upon the bill’s effective date, June 1, 2015, individuals must be licensed to practice direct-entry midwifery in the State. However, because BON advises that it will not have the regulations promulgated until the June 1, 2016 deadline, special fund revenues for BON only increase beginning in fiscal 2017 once licensure begins.

The bill does not specify whether licensure is annual or biennial; however, it limits renewal to a term of no longer than two years. Thus, biennial licensure is assumed. Under the bill, the board is authorized to set *reasonable* fees for the issuance and renewal of licenses for certified direct-entry midwives sufficient to produce funds to approximate the cost of maintaining the licensure program. Based on projected expenditures and assuming that approximately 25 individuals will seek licensure, BON would need to charge *at least* \$6,108 (\$3,054 per year) to *cover* the expenditures of the board for the fiscal 2016 and 2017 biennial period. Additional revenues would be required to cover any necessary investigative services and communication with licensees. To the extent

that the number of licensed certified direct-entry midwives increases to 50 by the second biennial licensure renewal period (fiscal 2018 and 2019), licensure fees may be able to decrease to approximately \$164 (\$82 per year). BON currently oversees 383,000 licensees or certificate holders with 77 full-time regular and 4 contractual positions. BON's fund balance (reported by BON to be \$3.18 million as of February 2015) is sufficient to cover necessary costs associated with licensing certified direct-entry midwives as proposed in the bill at a fee that is more in line with fees charged nurses. The board charges \$110 for biennial renewal fees for registered nurses and licensed practical nurses.

Small Business Effect: Costs for certified direct-entry midwives, who must obtain licensure in order to practice in Maryland, increase significantly because of likely high licensure and renewal fees.

Additional Information

Prior Introductions: A similar bill, HB 1211 of 2014, received a hearing in the House Health and Government Operations Committee, but no further action was taken. Other legislation to regulate midwives has been considered in recent years. HB 1202 of 2013, which would have established a pilot program for CPMs to practice in Maryland, was heard by the House Health and Government Operations Committee but was withdrawn. HB 1056 of 2012, which would have established a separate board within DHMH to license midwives, was heard by the House Health and Government Operations Committee, but no further action was taken.

Cross File: HB 9 (Delegate Kelly) - Health and Government Operations.

Information Source(s): Department of Health and Mental Hygiene, Association of Independent Midwives of Maryland, Midwives Alliance of North America, National Association of Certified Professional Midwives, Department of Legislative Services

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