HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 1255 Childbirth
SPONSOR(S): Health & Human Services Committee, Health Quality Subcommittee, Mercado
TIED BILLS: **IDEN./SIM. BILLS:** SB 1764

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	15 Y, 0 N, As CS	Siples	McElroy
2) Health & Human Services Committee	16 Y, 2 N, As CS	Siples	Calamas

SUMMARY ANALYSIS

Midwifery is the practice of supervising a normal labor and childbirth, with the informed consent of the parent, advising the parents as to the progress of childbirth, and rendering prenatal and postpartal care. The Department of Health (DOH) licenses and regulates the practice of midwifery in this state. The Council of Licensed Midwifery assists and advises DOH on midwifery, including the development of rules relating to regulatory requirements, including but not limited to training requirements, the licensure examination, responsibilities of midwives, emergency care plans, and reports and records to be filed by licensed midwives.

Informed consent generally requires a patient to confirm that they understand the risks and benefits of medical treatment and agree to undergo or participate in the medical treatment. Licensed midwives must obtain informed consent on a form developed by DOH. The form requires a licensed midwife to explain, among other things, the licensed midwife's services and qualifications and the nature of the risk of the procedures used by the licensed midwife. The informed consent form also expressly authorizes the midwife to provide midwifery services to the client.

CS/HB 1255 expands current statutory requirements for the DOH-developed informed consent form for midwifery services. The bill requires the DOH form to inform the patient regarding:

- The option to obtain medical care from a licensed physician or certified nurse midwife;
- The licensure status of the license midwife and any disciplinary action taken against such license in the preceding five years;
- The number of patients for which the licensed midwife transferred care to a hospital or physician within the preceding five years;
- The number of adverse incidents reported to DOH by the licensed midwife within the preceding five years if such reports resulted in disciplinary action against the midwife's license;
- The licensed midwife's hospital admitting privileges; and
- The licensed midwife's professional liability insurance status.

The bill will have an insignificant, negative fiscal impact on DOH, which can be absorbed within current resources. The bill has no fiscal impact on local governments.

The bill provides an effective date of July 1, 2020.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Licensed Midwives

Midwifery is the practice of supervising a normal labor and childbirth, with the informed consent of the parent, advising the parents as to the progress of childbirth, and rendering prenatal and postpartal care.[1] The Department of Health (DOH) licenses and regulates the practice of midwifery in this state. The Council of Licensed Midwifery assists and advises DOH on midwifery, including the development of rules relating to regulatory requirements, including but not limited to training requirements, the licensure examination, responsibilities of midwives, emergency care plans, and reports and records to be filed by licensed midwives.[2]

An individual must graduate from an approved midwifery program and pass a licensure examination to be eligible for licensure as a midwife.[3] A licensed midwife must submit a general emergency care plan to DOH, which addresses consultation with other health care providers, emergency transfer protocols, and access to neonatal intensive care units and obstetrical units or other patient care areas with his or her application for licensure and licensure renewal.[4] A licensed midwife must also submit proof of professional liability coverage of at least $100,000, with an annual aggregate of at least $300,000.[5]

A licensed midwife must:[6]

- Accept only those patients who are expected to have a normal pregnancy, labor, and delivery;
- Provide collaborative prenatal and postnatal care, within a written protocol with a physician who maintains supervision for directing the specific course of treatment if a patient is not at low risk in her pregnancy;
- Ensure that each patient has signed the informed consent form developed by DOH;
- Administer medicinal drugs pursuant to a prescription issued by an allopathic or osteopathic physician;
- Prepare a written plan of action with the family to ensure continuity of medical care and to provide for immediate medical care if an emergency arises;
- Maintain appropriate equipment and supplies and instructing the patient and family regarding the preparation of the environment, if a home birth is planned;
- Instruct the patient in the hygiene of pregnancy and nutrition as it relates to prenatal care;
- Determine the progress of labor, and when birth is imminent, be immediately available until delivery is accomplished;
- Remain with the postpartal mother until the mother and neonate are stabilized;
- Instill a prophylactic into each eye of the newborn infant within one hour after birth for the prevention of neonatal ophthalmia;[7] and
- Ensure that the care of mothers and infants throughout the prenatal, intrapartal, and postpartal periods conforms to DOH rules and the state's public health laws.

[1] Section 467.003(8), F.S.
[2] Section 467.004, F.S.
[3] Section 467.011, F.S. Section 467.0125, F.S., provides for licensure by endorsement for applicants who hold a valid license to practice midwifery in another state.
[4] Section 467.017, F.S.
[5] Rule 64B24-7.013, F.A.C. An applicant does not have to submit proof of professional liability insurance if the applicant practices exclusively as an officer, employee, or agent of the federal government, practices only in conjunction with teaching duties at an approved midwifery school that provides such coverage on the applicant's behalf, or who does not practice midwifery in this state and provides proof of such.
[6] Section 467.015, F.S.
[7] Section 383.04, F.S.

Risk Assessment

A licensed midwife must assess the risk status of each potential patient to determine whether the licensed midwife can accept the patient or continue caring for the patient.[8] The licensed midwife must obtain a detailed medical history, perform a physical examination, and assess family circumstances along with social and psychological factors. DOH provides a scoring system, in rule, for these factors that assigns each factor a value of one to three.[9] For example, a heart disease assessed by a cardiologist which does not place the mother or fetus at any risk has a score of one and chronic hypertension has a score of three.

If the assessment results in a risk score of three or higher, the licensed midwife must consult with a physician who has obstetrical hospital privileges.[10] If there is a joint determination that the patient can be expected to have a normal pregnancy, labor, and delivery, the licensed midwife may provide services to the patient.[11]

Responsibilities during Pregnancy and Delivery

The Florida Administrative Code outlines the licensed midwife's responsibilities during the antepartum, intrapartum, and postpartum periods. During each of these periods, the licensed midwife must assess the patient for risk factors and either consult with or transfer the patient's care to a physician.

In the antepartum period, a licensed midwife must refer the patient for a consultation with a physician with hospital obstetrical privileges if one of the following occurs:

- Hematocrit of less than 33% at 37th week gestation or hemoglobin less than 11 gms/100 ml;
- Unexplained vaginal bleeding;
- Abnormal weight change defined as less than 12 or more than 50 pounds at term;
- Non-vertex presentation persisting past 37th week of gestation;
- Gestational age between 41 and 42 weeks;
- Genital herpes confirmed clinically or by culture at term;
- Documented asthma attack;
- Hyperemesis not responsive to supportive care; or
- Any other severe obstetrical, medical or surgical problem

A licensed midwife must transfer a patient if one of the following occurs:

- Genetic or congenital abnormalities or fetal chromosomal disorder;
- Multiple gestation;
- Pre-eclampsia;
- Intrauterine growth retardation;
- Thrombophlebitis;
- Pyelonephritis;
- Gestational diabetes confirmed by abnormal glucose tolerance test; or
- Laboratory evidence of Rh sensitization.

The licensed midwife may continue caring for the patient if the condition is resolved satisfactorily and the physician and licensed midwife determine that the patient is expected to have a normal pregnancy, labor, and deliver,.[12]

During the intrapartum period or labor, the licensed midwife must consult with a physician or refer or transfer a patient to a physician with hospital obstetrical privileges if one of the following occurs:[13]

[8] Rule 64B24-7.004, F.A.C.
[9] Rule 64B24-7.004(3), F.A.C.
[10] Rule 64B24-7.004(1), F.A.C.
[11] Id.
[12] Id.

- Premature labor, meaning labor occurring at less than 37 weeks of gestation;
- Premature rupture of membranes, meaning rupture occurring more than 12 hours before onset of regular active labor;
- Non-vertex presentation;
- Evidence of fetal distress;
- Abnormal heart tones;
- Moderate or severe meconium staining;
- Estimated fetal weight less than 2,500 grams or greater than 4,000 grams;
- Pregnancy induced hypertension;
- Failure to progress in active labor;
- Severe vulvar varicosities;
- Marked edema of cervix;
- Active bleeding;
- Prolapse of the cord;
- Active infectious process; or
- Other medical or surgical problems.

A licensed midwife may not perform any operative procedures other than clamping and cutting the umbilical cord, episiotomies, suturing to repair first and second degree lacerations, and artificial rupture of the membranes under certain conditions.[14] A licensed midwife may also not attempt to correct a fetal presentation and may not use artificial, forcible, or mechanical means to assist a birth.[15]

A licensed midwife must consult with physician or refer or transfer an infant under certain conditions, such as if the child has jaundice, respiratory problems, or major congenital anomalies.[16] The licensed midwife must consult with a physician or transfer a mother for emergency care if any postpartum complications arise, such as retained placenta or postpartum hemorrhage.[17] The licensed midwife must stay with the mother and infant for at least two hours after the birth or until the mother's and infant's conditions are stable, whichever is longer.[18]

Adverse Incident Reporting

A licensed midwife must submit an adverse incident report to DOH within 15 days of adverse incident occurring, providing a summary of the events that occurred. An adverse incident is an event over which the licensed midwife could exercise control and one of the following occurs:[19]

- A maternal death that occurs after delivery or within 42 days after delivery;
- A maternal patient is transferred to a hospital intensive care unit;
- A maternal patient experiences hemorrhagic shock or requires a transfusion of more than four units of blood or blood products;
- A fetal or newborn death, including a still birth, attributable to an obstetrical delivery;
- A newborn patient is transferred to a hospital neonatal intensive care unit (NICU) due to a traumatic birth injury; or
- A newborn patient is transferred to a hospital NICU within 72 hours after birth if the newborn remains in the NICU for more than 72 hours.

DOH must review the report and determine whether the incident involves conduct requiring disciplinary action against the midwife's license.[20]

---

[13] Rule 64B24-7.008(4), F.A.C.
[14] Rule 64B24-7.008(5), F.A.C.
[15] Rules 64B24-7.008(6) and 64B24-7.008(8), F.A.C.
[16] Rule 64B24-7.009(2), F.A.C.
[17] Rule 64B24-7.009(5), F.A.C.
[18] Rule 64B24-7.009(4), F.A.C.
[19] Section 456.0495, F.S.
[20] Id.

Informed Consent

Informed consent is the process by which a patient learns about and understands the purpose, benefits, and potential risks of a medical intervention, and then agrees to receive the treatment.[21] Informed consent generally requires the patient, or the patient's representative if the patient is incapacitated, to sign a statement confirming that they understand the risks and benefits of the treatment or procedure.[22]

A licensed midwife must obtain informed consent from the patient on a form developed by DOH.[23] The form explains that licensed midwives care for women who have normal, uncomplicated pregnancies and expect a normal delivery of a healthy newborn.[24] In signing the informed consent form, the patient acknowledges that:[25]

- The licensed midwife has explained her training and experience;
- The patient is aware of the benefits of natural childbirth relating to avoidance of potential injury resulting from either invasive procedures, anesthesia, or surgical intervention;
- In order to obtain care by the midwife, the patient must:
    - Provide a complete medical, health, and maternity history;
    - Review risk factors and other requirements with the midwife;
    - Maintain a regular schedule for prenatal visits; and
    - Make a plan for emergency care, with the assistance of the midwife, for unforeseen complications that may arise during pregnancy and delivery, as well as any pediatric care necessary for the baby;
- The licensed midwife provided the status of the midwife's malpractice insurance, including the amount of insurance; and
- The patient had an opportunity to review and discuss information contained in the informed consent form, including the conditions which require the midwife to refer or transfer care.

The form also requires the patient to expressly authorize the licensed midwife to perform maternity services that are within the scope of the midwifery license and provides that a copy of the statute and rules are available upon request.[26]

[21] William Schiel, Jr., MD, FACP, FACR, MedicineNet, *Medical Definition of Informed Consent*, (last rev. Dec. 2018), available at https://www.medicinenet.com/cosmetic_surgery_before_after_pictures_slideshow/article.htm (last visited January 22, 2020).
[22] Id.
[23] Section 467.016, F.S.
[24] Form DH-MQA 1047, Rev. 3/01, incorporated by reference in r. 64B24-7.005, F.A.C., available at http://www.floridahealth.gov/licensing-and-regulation/midwifery/resources/_documents/midwife-consent.pdf (last visited January 22, 2020).
[25] Id.
[26] Id.

Effect of Proposed Changes

CS/HB 1255 expands the requirements for informed consent for midwifery services and requires the form to include information on:

- The option to obtain medical care from a licensed physician or certified nurse midwife;
- The licensure status of the license midwife and any disciplinary action taken against such license in the preceding five years;
- The number of patients for which the licensed midwife transferred care to a hospital or physician within the preceding five years;
- The number of adverse incidents reported to DOH by the licensed midwife within the preceding five years if such reports resulted in disciplinary action against the midwife's license;
- The hospital admitting privileges of the licensed midwife; and
- The professional liability insurance status of the licensed midwife.

The bill also makes technical, non-substantive changes to improve readability.

The bill provides an effective date of July 1, 2020.

B. SECTION DIRECTORY:

Section 1: Amends s. 467.016, F.S., relating to informed consent.
Section 2: Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH will incur costs associated with undertaking rulemaking activities to revise the informed consent form, which can be absorbed within current resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Licensed midwives will have to print and make available revised informed consent forms.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

   DOH has sufficient rulemaking authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

   None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 12, 2020, the House and Human Services Committee adopted an amendment and reported the bill favorably as a committee substitute. The amendment required a licensed midwife to inform a patient of the midwife's licensure status and disciplinary history, and the numbers of patient transfers and adverse incident reports for the preceding five years.

This analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.