The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 1764
INTRODUCER:	Health Policy Committee and Senator Flores
SUBJECT:	Midwifery
DATE:	February 5, 2020
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Fav/CS**
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1764 amends s. 467.015, F.S., to establish additional requirements for midwives when participating in in-hospital or out-of-hospital births. The midwife must advise the patient of certain clinical outcomes and advise, but not require, the patient to consult an obstetrician for more information related to such clinical outcomes; measure and record vital signs upon initial contact with the patient; and transfer care to a hospital upon if specified complications occur.

The bill amends s. 467.016, F.S., to specify that the informed consent form developed by the Department of Health (DOH) is required to be used by a midwife only when providing an out-of-hospital birth. The bill also provides additional requirements on how the form must be signed and what information must be included on the form.

The bill takes effect July 1, 2020.

II. 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

[1] Section 467.003(8), F.S.

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, 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 that 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;
- If a patient is not at low risk in her pregnancy, provide collaborative prenatal and postnatal care, within a written protocol with a physician who maintains supervision for directing the specific course of treatment;
- Ensure that each patient has signed an informed consent form developed by the DOH;
- Administer medicinal drugs pursuant to a prescription issued by a practitioner licensed under ch. 458, F.S., or ch. 459, F.S.;
- 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.

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

[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.
[8] Rule 64B24-7.004, F.A.C.

must obtain a detailed medical history, perform a physical examination, and assess family circumstances along with social and psychological factors. The DOH provides a scoring system for the factors by rule, which assigns each factor a value of one to three.[9] For example, 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 a 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 percent 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.

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

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 delivery.[12]

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

- 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 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]

[12] Rule 64B24-7.007, F.A.C.
[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.

Adverse Incident Reporting

A licensed midwife must submit an adverse incident report to the DOH within 15 days of an 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.

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

Informed Consent

A licensed midwife must obtain informed consent from the patient on a form developed by the DOH.[21] The form explains that licensed midwives care for women who have normal, uncomplicated pregnancies and are expecting a normal delivery of a healthy newborn.[22] In signing the informed consent form, the patient acknowledges that:[23]

- 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; but not limited to the conditions which require the midwife to refer or transfer care.

[19] Section 456.0495, F.S.
[20] Id.
[21] Section 467.016, F.S.
[22] Form DH-MQA 1047, Rev. 3/01, incorporated by reference in Rule 64B24-7.005, F.A.C., *available at* http://www.floridahealth.gov/licensing-and-regulation/midwifery/resources/_documents/midwife-consent.pdf (last visited Jan. 30, 2020).
[23] Id.

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.[24]

III. Effect of Proposed Changes:

Section 1 amends s. 467.015, F.S., to require a midwife, whether providing an in-hospital or out-of-hospital birth, to:

- Upon acceptance of a patient into care, advise the patient of the clinical outcomes of births in low-risk patients during an out-of-hospital birth and any increased risks associated with an individual having a vaginal birth after having a caesarean section, a breech birth, or a multiple gestation pregnancy. The licensed health care practitioner providing out-of-hospital births shall further advise, but may not require, the patient to consult an obstetrician for more information related to such clinical outcomes and increased risks.
- Prepare a written plan of action with the patient or the patient's family, if any, to ensure continuity of medical care throughout labor and delivery and to provide for immediate medical care if an emergency arises.
- Upon initial contact with the patient during the intrapartal period, measure and record the vital signs of the mother and fetus to serve as a baseline during labor and delivery.
- Transfer care of the patient to a hospital with obstetrical services in accordance with the written emergency plan if any of the following occurs or presents during labor or delivery or immediately thereafter:
  - An unexpected nonvertex presentation of the fetus;
  - Indication that the mother's uterus has ruptured;
  - Evidence of severe and persistent fetal or maternal distress;
  - Pregnancy-induced hypertension;
  - An umbilical cord prolapse;
  - Active infectious disease process; or
  - Any other severe emergent condition.

Section 2 amends s. 467.016, F.S., to require a midwife to obtain informed consent using a form developed by the DOH only when participating in out-of-hospital births. The form must be signed by the practitioner and the patient and a copy of the signed form must be provided to the patient. The form must include:

- A statement advising the patient of the clinical outcomes of births in low-risk patients during an out-of-hospital birth and any increased risks associated with having a vaginal birth after having a caesarean section, a breech birth, or a multiple gestation pregnancy.
- A detailed statement explaining to the patient hospital admitting privileges and the requirements to obtain and maintain such privileges.
- Disclosure of each hospital and specific department, if any, where the health care practitioner providing out-of-hospital births has been granted admitting privileges, including the scope and duration of the admitting privileges, the current contact information for the specific hospital or department that has granted the health care practitioner admitting privileges, and a copy of documentation from the hospital or department providing proof of such admitting

[24] *Id.*

privileges. A health care practitioner providing out-of-hospital births who does not have admitting privileges at any hospital must explicitly state that fact on the form.

Section 3 provides that the bill takes effect July 1, 2020.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

The bill amends s. 467.015, F.S., relating to a list of responsibilities for midwives. The bill provides that a midwife must do everything on the list, regardless of whether the midwife is participating in an in-hospital or out-of-hospital birth. However, one aspect of the list is somewhat unclear because it provides a responsibility that "the licensed health care practitioner" must fulfill but only for out-of-hospital births. The latter aspect seems out of place in a list of responsibilities that must be observed in all cases, regardless of whether the birth is in-hospital or

out-of-hospital. And, the term "licensed health care practitioner" could pertain to any of numerous types of practitioners, as opposed to midwives specifically.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends sections 467.015 and 467.016 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy February 4, 2020:
The CS eliminates all provisions of the underlying bill except that the CS requires a midwife, whether participating in an in-hospital or out-of-hospital birth, to:

- Upon acceptance of a patient into care, advise the patient of the clinical outcomes of births in low-risk patients during an out-of-hospital birth and any increased risks associated with an individual having a vaginal birth after having a caesarean section, a breech birth, or a multiple gestation pregnancy. The licensed health care practitioner providing out-of-hospital births shall further advise, but may not require, the patient to consult an obstetrician for more information related to such clinical outcomes and increased risks.
- For written plans of action required under current law, prepare such plans with the patient and the patient's family, if any.
- Upon initial contact with the patient during the intrapartal period, measure and record the vital signs of the mother and fetus to serve as a baseline during labor and delivery.
- Transfer care of the patient to a hospital with obstetrical services in accordance with the written emergency plan if any of the following occurs or presents during labor or delivery or immediately thereafter:
  - An unexpected nonvertex presentation of the fetus;
  - Indication that the mother's uterus has ruptured;
  - Evidence of severe and persistent fetal or maternal distress;
  - Pregnancy-induced hypertension;
  - An umbilical cord prolapse;
  - Active infectious disease process; or
  - Any other severe emergent condition.

The CS changes the current law requirement for midwives to use an informed consent form to provide certain information to a patient. Under the CS, the informed consent form must be used only for out-of-hospital births and must be signed by the patient and the midwife, and a copy must be provided to the patient. The form must include, at a minimum:

- A statement advising the patient of the clinical outcomes of births in low-risk patients during an out-of-hospital birth and any increased risks associated with having a

vaginal birth after having a caesarean section, a breech birth, or a multiple gestation pregnancy.

- A detailed statement explaining to the patient hospital admitting privileges and the requirements to obtain and maintain such privileges.
- Disclosure of each hospital and specific department, if any, where the health care practitioner providing out-of-hospital births has been granted admitting privileges, including the scope and duration of the admitting privileges, the current contact information for the specific hospital or department that has granted the health care practitioner admitting privileges, and a copy of documentation from the hospital or department providing proof of such admitting privileges. A health care practitioner providing out-of-hospital births who does not have admitting privileges at any hospital must explicitly state that fact on the form.

B. Amendments:

None.