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:	SB 1764
INTRODUCER:	Senator Flores
SUBJECT:	Childbirth
DATE:	February 3, 2020
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Pre-meeting**
2.			AHS	
3.			AP	

I. Summary:

SB 1764 creates and amends multiple sections of law relating to the provisions of out-of-hospital births. The bill requires specified information on transfers to a hospital or other emergency department be included when issuing a certificate of live birth or a fetal death certificate.

The bill requires physicians, certified nurse midwives, and midwives to submit adverse incident reports related to out-of-hospital births to the Department of Health (DOH). The bill also establishes an adverse incident review panel within the DOH which must collaborate with experts in data collection and public health to identify any patterns or trends linking certain adverse incidents to any licensed health care practitioner providing planned out-of-hospital births, identify causes for such patterns or trends, and make recommendations for changes to address causes for adverse incidents identified in the panel's review.

The panel must submit its findings and recommendations to the DOH and the relevant boards by July 1 of each year. The bill requires the DOH to analyze specified data and submit its own findings and recommendations for policy changes to the Legislature by July 1 of each year.

The bill also creates a new section of law to establish requirements for health care practitioners who provide out-of-hospital birth services. Such requirements include continuing education, responsibilities of the health care practitioner, and informed consent. The bill establishes criminal and licensure penalties for fraudulent activities related to providing out-of-hospital births.

The bill takes effect July 1, 2020.

II. Present Situation:

Certificates of Birth and Fetal Death

Birth and fetal death certificates capture the name, location and specific type of facility where a delivery occurred. Facility type options are hospital, birthing center, clinic/doctor's office, home, or another designated place. On current birth and fetal certificates, home births are the only type that requires completion of an additional question of whether the home delivery was planned. The birth certificate also captures information as to whether the mother was transferred from another facility to the place where she delivered, or if the infant was transferred to another facility within 24 hours after delivery. The transfer information is currently recorded if a birthing facility or hospital is involved.

The attendant on the birth certificate is the person who was present at the time of delivery. The attendant is usually a health care clinician (i.e. physician, nurse, midwife) but can also include non-clinicians, such as a family member or any other person that was present at the time of the delivery. The certifier on the birth certificate is the person who attests to the facts presented on the birth certificate but may not have been present at the time of delivery. The attendant and the certifier may be the same person.

There is a minor difference on the certifier designation for the current fetal death certificate. The certifier on the fetal death certificate must be a physician who attests to the cause of death and the facts of delivery. The attendant on the fetal death certificate is the person who was present at the time of delivery. The attendant and the certifier may be the same person. However, if the attendant is not a physician, then the certifier must be a physician or a medical examiner.[1]

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.[2] 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, licensure examination, responsibilities of midwives, emergency care plans, and reports and records to be filed by licensed midwives.[3]

An individual must graduate from an approved midwifery program and pass a licensure examination to be eligible for licensure as a midwife.[4] 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.[5] A licensed

[1] See Department of Health, *House Bill 1255 Agency Analysis* (January 22, 2020) (on file with the Senate Committee on Health Policy).
[2] Section 467.003(8), F.S.
[3] Section 467.004, F.S.
[4] 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.
[5] Section 467.017, F.S.

midwife must also submit proof of professional liability coverage of at least $100,000, with an annual aggregate of at least $300,000.[6]

A licensed midwife must:[7]

- 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;[8] 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.[9] The licensed midwife 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.[10] 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.[11] 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.[12]

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[6] 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.
[7] Section 467.015, F.S.
[8] Section 383.04, F.S.
[9] Rule 64B24-7.004, F.A.C.
[10] Rule 64B24-7.004(3), F.A.C.
[11] Rule 64B24-7.004(1), F.A.C.
[12] Id.

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.

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.[13]

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:[14]

- 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;

[13] Rule 64B24-7.007, F.A.C.
[14] Rule 64B24-7.008(4), F.A.C.

- 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.[15] 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.[16]

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.[17] 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.[18] 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.[19]

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:[20]

- 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.

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

The DOH must review the report and determine whether the incident involves conduct requiring disciplinary action against the licensed midwife's license.[21]

Informed Consent

A licensed midwife must obtain informed consent from the patient on a form developed by the DOH.[22] The form explains that licensed midwives care for women who have normal, uncomplicated pregnancies and are expecting a normal delivery of a healthy newborn.[23] In signing the informed consent form, the patient acknowledges that:[24]

- 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.

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.[25]

III. Effect of Proposed Changes:

Section 1 amends s. 382.008, F.S., to require a certificate of fetal death to include the name, title, and professional license number of each physician, certified nurse midwife, or midwife who treated the mother of the fetus during pregnancy, labor, or delivery, or immediately thereafter if the fetal death occurred in association with a planned out-of-hospital birth, including a fetal death that occurs out-of-hospital or during a transfer or admission to a hospital, intensive care unit, or other similar facility. If the individual treating the mother is not appropriately licensed, the certificate must include the title and any license number used by the individual to represent licensure and a notation that the individual is not appropriately licensed.

Section 2 amends s. 382.013, F.S., to require a certificate of live birth to include:

- The intended place of birth;

[21] Id.
[22] Section 467.016, F.S.
[23] 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).
[24] Id.
[25] Supra note 23

- Whether the mother or newborn was transferred to an emergency care facility during labor, delivery, or within 72 hours of delivery;
- The name of and address of the transferring facility;
- The name, title, and professional license number of each physician, certified nurse midwife, or midwife who treated the mother or newborn during the pregnancy, labor, or delivery, or immediately thereafter; and
- If the individual treating the mother is not appropriately licensed, the title and any license number used by the individual to represent licensure and a clear notation that the individual is not appropriately licensed.

Section 3 amends s. 456.0495, F.S., to require an adverse incident report be provided to the DOH within 15 days of an event over which a physician, certified nurse midwife, or midwife could exercise control during a planned out-of-hospital birth that results in the transfer of a maternal patient or newborn from the out-of-hospital birth setting to a hospital during the prenatal, intrapartal, or postpartal period and which results in fetal or maternal morbidity or mortality. Additionally, the bill requires any health care practitioner who is required to report such adverse incidents to also report any adverse incidents the practitioner is aware of, including all related information which the practitioner has knowledge of, related to an out-of-hospital birth or attempted birth completed by an unlicensed individual who represented him or herself to be licensed. The DOH is required to investigate any such report of unlicensed activity and take appropriate action.

The bill establishes a review panel within the DOH, in consultation with the Boards of Medicine, Osteopathic Medicine, and Nursing and the Council of Licensed Midwifery, to review reported adverse incidents involving planned out-of-hospital births. The panel is composed of one obstetrical medical physician, one obstetrical osteopathic physician, one certified nurse midwife, one paramedic, and one midwife, each of whom must have experience in out-of-hospital births and be appointed by the applicable board or council. The State Surgeon General or his or her designee is required to serve as the chair and a nonvoting member of the panel and the panel is required to meet quarterly and as often as necessary to perform its duties. The panel may use any method of telecommunications to conduct its meetings and members serve without compensation but may be reimbursed for travel expenses and per diem.

Based on its review of reported adverse incidents, the panel must collaborate with experts in data collection and public health to identify any patterns or trends linking certain adverse incidents to any licensed health care practitioner providing planned out-of-hospital births, identify causes for such patterns or trends, and make recommendations for changes to address causes for adverse incidents identified in the panel's review. The panel's findings and recommendations must be reported to the DOH, the listed boards, and the Council of Licensed Midwifery by July 1 of each year.

The DOH, or its designee, is required, using data collected from adverse incident reports, certificates of live birth, certificates of fetal death, and information submitted by licensed midwives, to:

- Analyze data relating to the frequency and nature of adverse incidents in planned out-of-hospital births;

- Identify the rate of adverse incidents by the type of adverse incident and attending health care practitioners or unlicensed individuals;
- Identify any patterns or trends linking types of adverse incidents to attending health care practitioners or unlicensed individuals, and study causes for such patterns or trends;
- Compare the findings to any comparable research and data associated with out-of-hospital births available from other states; and
- Make recommendations for policy changes that may reduce the rate of adverse incidents in planned out-of-hospital births in this state.

The DOH must provide a deidentified report of its findings and any recommendations to the Governor and the Legislature, and publish such report on its website, by July 1 of each year.

Section 4 creates s. 456.0496, F.S., to establish new and additional requirements for out-of-hospital births.

Continuing Education

The bill requires a licensed health care practitioner[26] who provides out-of-hospital births to biennially take three hours of instruction on the risk of complications during pregnancy, labor, and delivery; and four hours of instruction on ethics and collaborative care, including informed consent, patient confidentiality, patient relationships, and transportation from a home or birth center to a hospital, and malpractice and negligence.

The DOH is required to prescribe by rule continuing education requirements as a condition of licensure renewal and approve the criteria for continuing education programs. In order to obtain DOH approval for a continuing education program, the program must:
- Have clinical relevance to practitioners providing out-of-hospital birth;
- Be at least 1 clock hour in duration;
- Have an organized structure with objectives and expected outcomes; and
- Requires that each presenter, instructor, or facilitator of the program is a recognized professional, such as a physician, nurse, certified nurse midwife, psychologist, or licensed midwife.

Responsibilities of a Health Care Practitioner Providing Out-of-Hospital Births

Health care practitioners providing out-of-hospital birthing services are required 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.

[26] Section 456.001, F.S., defines "health care practitioner" as any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part II or part III of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

- Prepare a written plan of action with the family to ensure continuity of medical care throughout labor and delivery and to provide for immediate medical care if an emergency arises. The family should have specific plans for medical care throughout the prenatal, intrapartal, and postpartal periods.
- If a home birth is planned, instruct the patient and family regarding the preparation of the home and ensure availability of equipment and supplies needed for delivery and infant care.
- Instruct the patient in personal hygiene and sanitary measures as they relate to pregnancy and in nutrition as it relates to prenatal care.
- Maintain equipment and supplies required for providing care during the intrapartum and immediate postpartum periods in an out-of-hospital setting.
- 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.
- Obtain informed consent using a form developed by the DOH. 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 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.

Penalties for Violations and Grounds for Discipline

The bill establishes that is a third degree felony to knowingly conceals or fraudulently misrepresent information or a requirement relating to the practice of out-of-hospital births. Additionally, such misrepresentation is grounds for the denial of a practitioner's license or other

disciplinary action.[27] The bill specifies that a first time violation for unprofessional conduct[28] in which no actual harm to the patient occurred is punishable by a citation issued from the relevant board or the DOH in accordance with s. 456.077, F.S.

Section 5 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:

SB 1764 may have an indeterminate negative fiscal impact on practitioners who perform out-of-hospital births due to the increased reporting and training requirements established by the bill.

C. Government Sector Impact:

The bill may have an indeterminate negative fiscal impact on the DOH due to the establishment of the adverse incident review panel, the requirements to provide reports, and the requirements to adopt specified rules.

[27] As specified in s. 456.072(2), F.S.
[28] As established in ss. 464.018(1)(h), 467.203(1)(f), 468.365(1)(f), and 478.52(1)(f), F.S.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 382.008, 382.013, and 456.0495.

This bill creates section 456.0496 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.