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 Rules

BILL:	CS/CS/SB 510
INTRODUCER:	Rules Committee; Health Policy Committee; and Senator Young and Mayfield
SUBJECT:	Reporting of Adverse Incidents in Planned Out-of-hospital Births
DATE:	January 18, 2018 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	**Fav/CS**
2.	Caldwell	Caldwell	GO	**Favorable**
3.	Rossitto-Van Winkle	Phelps	RC	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 510 requires physicians, certified advanced registered nurse midwives (ARNP-CNMs), and licensed midwives (LMs) to report to the Department of Health (DOH) adverse incidents occurring as a result of an attempted or completed, planned birthing center or out-of-hospital birth. The bill defines an adverse incident and, beginning July 1, 2018, requires the reporting within 15 days after the occurrence of the adverse incident. It further requires the DOH to review each adverse incident report and determine whether the incident involves conduct by the health care practitioner which is subject to disciplinary action, and to take disciplinary action if appropriate.

The bill takes effect upon becoming law.

II. Present Situation:

Childbirth Settings

The Legislature has recognized the need for a person to have the freedom to choose the manner, cost, and setting for childbirth.[1] There are three typical settings[2] from which a woman may

[1] *See* s. 467.002, F.S.

[2] *See* chs. 395, 383.30 – 383.335, and 467, F.S., and Rules 59A-11 and 64B24-7, F.A.C.

choose and plan for childbirth: at home, at a licensed birthing center, or at a hospital.[3,4] There are also four types of licensed health care practitioners from which a woman may choose to attend to her prenatally and at childbirth: a physician, physician assistant (PA), certified nurse midwife (ARNP-CNM), and a licensed midwife (LM).

Hospitals

Hospitals are licensed and regulated under ch. 395, F.S., and part II of ch. 408, F.S., by the Agency for Health Care Administration (ACHA). As of November 2, 2017, 147 hospitals provide obstetrical services.[5]

Section 395.0191, F.S., requires a hospital to establish rules and procedures to grant clinical privileges to provide, among other services, obstetrical and gynecological services by a physician licensed under ch. 458 or ch. 459, F.S., his or her respective PAs, and ARNP-CNMs certified under part I of ch. 464, F.S., if the hospital provides obstetrical services. All health care providers, agents, and employees of a hospital have an affirmative duty to report all adverse incidents occurring in the hospital to the hospital's risk manager within three business days after the occurrence.[6]

An "adverse incident," which must be reported to the hospital's risk manager, is an event over which health care personnel could exercise control, which is associated with medical intervention, and which results in:

- One of the following injuries:
  - Death;
  - Brain or spinal damage;
  - Permanent disfigurement;
  - Fracture or dislocation of bones or joints;
  - A limitation of neurological, physical, or sensory function which continues after discharge from the facility;
  - Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention to which the patient has not given his or her informed consent; or
  - Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;
- The performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;

[3] Ambulatory Surgical Centers (ASCs) and hospitals are facilities that are licensed and regulated under ch. 395, F.S., similarly. Although an ASC is not prohibited from providing birthing services, it is not a typical birth setting because patients are not authorized to stay in the ASC overnight. Accordingly, this analysis refers to hospitals only.
[4] *See* ss. 458.331(1)(t), 459.015(1)(w), 456.50(1)(g), and 766.202(7), F.S.; Rules 64B8-9.007 and 64B-15-14.006, F.A.C.
[5] Agency for Health Care Administration, FloridaHealthFinder.gov, *Facility/Provider Search Results*, based on an advanced search of facilities providing emergency obstetrical services, *available at* http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (last visited Nov. 2, 2017).
[6] Section 395.0197(1)(e), F.S.

- Required surgical repair of damage to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or
- A procedure to remove unplanned foreign objects left in a patient from a surgical procedure.[7]

Any of the following adverse incidents, whether occurring in the hospital or arising from health care prior to admission, must also be reported by the hospital to the AHCA within 15 calendar days after the occurrence:

- The death of a patient;
- Brain or spinal damage to a patient;
- The performance of a surgical procedure on the wrong patient;
- The performance of a wrong-site surgical procedure;
- The performance of a wrong surgical procedure;
- The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition;
- The surgical repair of damage resulting to a patient from a planned surgical procedure, in which the damage is not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or
- The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure.[8]

Birth Centers

Birth centers (not homes), ambulatory surgery centers, or hospitals, are places where women with normal, uncomplicated, low risk pregnancies may choose to have their babies.[9] Birth centers are licensed and regulated by the AHCA under ch. 383, F.S., and part II of ch. 408, F.S.; but the clinical staff in the birth centers may be physicians, PAs, ARNP-CNMs, or LMs,[10] who are licensed and regulated by the DOH.

Sections 383.330 through 383.335, F.S., establish minimum standards of care for birth centers. Standards require that, among other things:[11]

- Clinical staff is present during the entire labor and delivery at a licensed birthing center, at a ratio of 2 to 1;[12]
- A pregnant woman accepted for childbirth by a birth center is initially determined to be at low maternal risk and be regularly evaluated throughout the pregnancy; [13]
- The women receive specific prenatal,[14] intrapartum,[15,16] and postpartum care;[17]

[7] Section 395.0197(5), F.S. An annual report summarizing the adverse incidents must be submitted to the AHCA.
[8] Section 395.0197(7), F.S.
[9] Section 383.302(2), F.S.
[10] Section 383.302(3), F.S.
[11] Section 383.309, F.S.
[12] Rule 59A-11.005, F.A.C.
[13] Rule 59A-11.009, F.A.C.
[14] Rule 59A-11.012, F.A.C.
[15] Rule 59A-11.013, F.A.C.
[16] Merriam-Webster On-line Dictionary, *intrapartum* is defined as occurring during labor and delivery. *Available at*: https://www.merriam-webster.com/medical/intrapartum, (last visited Nov. 2, 2017). *See also* s. 467.003(5), F.S.
[17] Rule 59A-11.016, F.A.C.

- The mother and infant are discharged within 24 hours after birth, except in an unusual circumstance;[18,19]
- A postpartum examination of the mother is performed within 72 hours after delivery;
- The client is transferred to a hospital if unforeseen complications occur during labor;[20] and
- Each maternal death, newborn death, and stillbirth is reported to the medical examiner.[21]

There are no requirements for a birthing center to report adverse incidents to the AHCA or other regulatory entity. However, the birth center is required to audit clinical records at least every three months to evaluate the process and outcome of care;[22] and at least semiannually, to analyze statistics on the following:

- Maternal and perinatal morbidity and mortality;
- Maternal risk;
- Consultant referrals; and
- Transfers.[23]

The birthing center's governing body must examine the results of the record audits and statistical analyses and make such reports available for inspection by the public and licensing authorities.[24]

A written report of all transfers must be maintained and available for quality assurance review and agency inspection. The clinical staff, consultants, and governing body must review and evaluate the criteria, protocols, and emergency transfer reports annually. The findings of the evaluation shall be documented. [25] A report must also be submitted annually to the AHCA that includes:

- Number of deliveries, including birth weight;
- Number of clients accepted and length of stay;
- Number and type of surgical procedures performed;
- Maternal transfers, including reason and length of hospital stay;
- Infant transfers, including weight, days in hospital, and APGAR score at five and ten minutes;
- Newborn deaths; and
- Still/Fetal deaths.[26]

A birthing center's clinical records are confidential under s. 456.057, F.S., and exempt from disclosure under s. 119.07(1), F.S., except:

- Upon a signed patient release; or

[18] Section 383.318, F.S.
[19] *See* Rule 59A-11.016(6), F.A.C., The mother and infant are to be discharged from the birth center within 24 hours after the birth occurs except when the mother is in a deep sleep when the 24 hour period is completed; or the 24 hour period is completed during the middle of the night.
[20] Section 383.316, F.S.
[21] Section 383.327, F.S.
[22] Section 383.32, F.S.
[23] *Id.*
[24] Section 383.32(3) and (4), F.S., Rule 59A-11.005(8)(b), F.A.C. Clinical records that identify a patient are confidential in accord with s. 456.057, F.S.
[25] Section 383.316, F.S.
[26] Rule 59A-11.019, F.A.C., and the ACHA Form 3130-3004 (Feb. 2015).

- An AHCA review is made for a licensure survey or complaint investigation.[27]

Home Delivery for Childbirth

The home delivery setting for childbirth is not regulated. Nonetheless, the practices of the physicians, PAs,[28] ARNP-CNMs,[29] and LMs,[30] who may attend a women during an out-of-hospital or home delivery, are required to be licensed and are regulated by the DOH.[31]

Health Care Practitioners Who May Provide Childbirth Services

Physicians and PAs

A licensed physician may attend any childbirth in any setting, including home delivery, if he or she can do so with reasonable skill and safety, and within the standard of care. It is the physician's responsibility to determine whether a home delivery is appropriate, explain the procedure to the patient, and obtain the patient's informed consent.[32] A physician may also delegate any home delivery to his or her PA under his or her written protocol.[33] There are no specific laws or administrative rules that address the required perinatal care required, or adverse incident reporting, for a patient choosing home delivery by a physician or PA.[34]

Sections 458.351 and 459.026, F.S., require an allopathic and osteopathic physician, and his or her respective PAs, to report to the DOH, any adverse incident in an office practice setting within 15 days after the occurrence. The DOH reviews the incident and makes a determination of whether or not the conduct potentially involves conduct that may be subject to disciplinary action under s. 456.073, F.S.

Sections 458.351 and 459.026, F.S., define an "adverse incident" as an event over which a physician or licensee could exercise control and which is associated with a medical intervention which results in any of the following patient injuries:

- The death of a patient;
- Brain or spinal damage to a patient;
- The performance of a surgical procedure on the wrong patient;
- The performance of a:
  - Wrong-site surgical procedure;
  - Wrong surgical procedure; or
  - The surgical repair of damage to a patient from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented in the informed-consent process; if it results in death; brain or spinal damage; permanent disfigurement not including the incision scar; fracture or dislocation of bones or joints; a

[27] Section 383.32(3), F.S.
[28] *See* ss. 458.347 and 459.022, F.S.
[29] Section 464.012, F.S.
[30] *See* ch.467, F.S.
[31] *See* chs. 383 and 467, F.S., and Rules 59A-11 and 64B24-7, F.A.C.
[32] *See supra* note 3.
[33] *See supra* note 3; *See also* Rules 64B8-30.001 and 64B15-6.001, F.A.C.
[34] *See* chs. 458 and 459, F.S., and Rules 64B8-9 and 64B15-14, F.A.C.

limitation of neurological, physical, or sensory function; or any condition that required the transfer of the patient.
- A procedure to remove foreign objects remaining from a surgical procedure; or
- Any condition that required the transfer of a patient to a hospital from an ambulatory surgical center or any facility or any office maintained by a physician for the practice of medicine which is not licensed under ch. 395, F.S.

Physicians and PAs are also required to report adverse incidents that occur in a health care facility licensed under ch. 395, F.S.,[35] to the facility's risk manager.

ARNP-CNMs and LMs

An ARNP-CNM's scope of practice for pre-natal care, childbirth, and post-partum care is governed by his or her written protocol with the supervising physician.[36] Section 467.015, F.S., specifically defines a midwife's responsibilities as follows:
- Only accept and provide care for those mothers who are expected to have a normal pregnancy, labor, and delivery;
- Obtain a signed informed consent from the patient;
- Determine if the home is safe and hygienic for a home delivery, if applicable;
- Administer prophylactic ophthalmic medication, oxygen, postpartum oxytocin, vitamin K, rho immune globulin (human), and local anesthetic pursuant to a prescription issued by a doctor, and administer such other medicinal drugs as prescribed by a doctor;
- Prepare a written plan of action with the family to ensure continuity of medical care throughout labor and delivery, and provide for immediate medical care if an emergency arises;
- Instruct the patient and family regarding the preparation of the environment and ensure availability of equipment and supplies needed for delivery and infant care, if a home birth is planned;
- Instruct the patient in the hygiene of pregnancy and nutrition as it relates to prenatal care;
- Maintain appropriate equipment and supplies as defined by rule;
- Determine the progress of labor and, when birth is imminent, be immediately available until delivery is accomplished, including:
  - Maintaining a safe and hygienic environment;
  - Monitoring the progress of labor and the status of the fetus;
  - Recognizing early signs of distress or complications; and
  - Activating the written emergency plan when indicated; and
- Remain with the postpartal mother until the conditions of the mother and the neonate are stabilized.

A midwife may also provide collaborative prenatal and postpartal care to pregnant women not at low risk in their pregnancy, labor, and delivery, within a written protocol with a physician currently licensed under ch. 458 or ch. 459, F.S., if the physician maintains supervision for directing the specific course of medical treatment.[37]

[35] Section 395.0197(1)(e), F.S.
[36] *See* ss. 458.347(4), 459.022(4), and 464.012(4), F.S., and ch. 467, F.S.
[37] *Id.*.

An ARNP-CNM may also perform a home delivery under a written protocol with a supervising physician. Specific authorities in s. 464.012, F.S., relating to childbirth include:

- Managing a patient's labor and delivery, including performing an amniotomy, episiotomy, and perineal repair;
- Ordering, initiating, and performing appropriate anesthetic procedures;
- Performing postpartum examinations;
- Ordering appropriate medications;
- Providing family-planning services and well-woman care; and
- Managing the medical care of the normal obstetrical patient and the initial care of a newborn patient.

Section 467.015, F.S., permits LMs to accept mothers for prenatal, intrapartal, and postpartal care, but only if the mothers are expected to have a normal pregnancy, labor, and delivery; and for home delivery, only if the home is safe, hygienic, and meets the DOH standards.[38]

Section 467.019, F.S., requires a midwife to immediately report maternal and newborn deaths, and still births, to the medical examiner.

III. Effect of Proposed Changes:

CS/CS/SB 510 creates s. 456.0495, F.S., and defines the term "adverse incident" for this section to mean:

- An event over which a physician, ARNP-CNM, or LM could exercise control; and
- Which is associated with an attempted or completed planned out-of-hospital birth, that results in:
  - A maternal death that occurs during delivery or within 42 days after delivery;
  - The transfer of a maternal patient to a hospital intensive care unit;
  - A maternal patient who experiences hemorrhagic shock or who requires a transfusion of more than 4 units of blood or blood products;
  - A fetal or newborn death, including a stillbirth, associated with an obstetrical delivery;
  - A transfer of a newborn to a neonatal intensive care unit due to a traumatic physical or neurological birth injury, including any degree of a brachial plexus injury;
  - A transfer of a newborn to a neonatal intensive care unit within the first 72 hours after birth if the newborn remains in such unit for more than 72 hours; or
  - Any other injury as determined by department rule.

The bill requires a physician, ARNP-CNM, or LM who performs an attempted or completed planned out-of-hospital birth to report an adverse incident to the DOH within 15 days after the adverse incident occurs. The report must include a medical summary. This requirement begins July 1, 2018, to allow the DOH time to adopt rules, including developing the form for reporting.

The bill further requires the DOH to review each incident report to determine whether the incident involves conduct by a practitioner which subjects the practitioner to disciplinary action by the appropriate board or if there is no board, the DOH. The applicable board, or the DOH if

[38] Section 467.015, F.S., and Rule 64B24-7, F.A.C.

no such board exists, is required to take disciplinary action, if appropriate. The DOH must adopt rules to implement the section and develop a form for the reporting of adverse incidents.

The bill takes effect upon becoming law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

The bill requires physicians, ARNP-CNMs, and LMs to report adverse incidents during consensual private home births to a government agency which may violate the State and Federal Constitutions' Right to Privacy contained in Article I, section 23, of the Florida Constitution and inferred in Amendments IV and XIV of the U.S. Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Health care practitioners may experience administrative and potentially other costs as a result of reporting adverse incidents to the department.

C. Government Sector Impact:

The DOH may incur costs related to rulemaking.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 456.0495 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/CS by Rules on January 18, 2018:
The CS/CS delays the start date for the required reporting of adverse incidents to July 1, 2018.

CS by Health Policy on November 7, 2017:
The CS:

- Defines an adverse incident that is required to be reported to the DOH, rather than requiring the DOH to define adverse incidents by rule;
- Limits the professionals required to report adverse incidents associated with an attempted or completed, planned out-of-hospital birth to the DOH to physicians, ARNP-CNMs, and LMs;
- Substitutes the term newborn for infant as a technical correction; and
- Requires the DOH to review each incident report to determine if it involves conduct that might subject the practitioner to disciplinary action by the appropriate board or the DOH, and to take disciplinary action, if appropriate.

B. Amendments:

None.