

**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.)

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

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BILL: SB 510

INTRODUCER: Senator Young

SUBJECT: Health Care Practitioners

DATE: November 6, 2017

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	<b>Pre-meeting</b>
2.	_____	_____	GO	_____
3.	_____	_____	RC	_____

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**I. Summary:**

SB 510 requires licensed health care practitioners to report any adverse incidents occurring as the result of an attempted or completed, planned birthing center or out-of-hospital birth. The bill requires the Department of Health (DOH) to define an adverse incident and establish guidelines for reporting an adverse incident within 15 days after the incident to the DOH.

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.<sup>1</sup> There are three typical settings from which a women may *choose* and plan for childbirth: at home, at a licensed birthing center, or at a hospital.<sup>2,3</sup> There are also four types of licensed health care practitioners from which a women may *choose* to attend her prenatally and at child birth: a physician, physician assistant (PA), certified nurse midwife (ARNP-CNM), and a licensed midwife (LM).<sup>4</sup>

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<sup>1</sup> See s. 467.002, F.S.

<sup>2</sup> See chs. 395, 383.30 – 383.335, and 467, F.S., and Rules 59A-11 and 64B24-7, F.A.C.

<sup>3</sup> 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.

<sup>4</sup> 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.

### *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.<sup>5</sup>

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 chs. 458 or 459, F.S., his or her respective PAs, and ARNPs-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 to the hospital's risk manager within three business days after the occurrence.<sup>6</sup>

An "adverse incident," that 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;
- Required ~~the~~ 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.<sup>7</sup>

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;

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<sup>5</sup> 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).

<sup>6</sup> Section 395.0197(1)(e), F.S.

<sup>7</sup> Section 395.0197(5), F.S. An annual report summarizing the adverse incidents must be submitted to the AHCA.

- 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, where 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.<sup>8</sup>

### ***Birth Centers***

Birth centers are places, not a home, ambulatory surgery center, or hospital, where women with normal, uncomplicated, low risk pregnancies may choose to have their babies.<sup>9</sup> Birth centers are licensed and regulated by the AHCA under ch. 383, F.S., and part II ch. 408, F.S. The clinical staff in the birth centers may be physicians, PAs, ARNP-CNMs, or LMs;<sup>10</sup> and are licensed and regulated by the DOH.

Sections 383.330 through 383.335, F.S., establish minimum standards of care for birth centers. These include among other things:<sup>11</sup>

- Clinical staff to be present during the entire labor and delivery at a licensed birthing center, at a ratio of 2 to 1;<sup>12</sup>
- A pregnant women accepted for childbirth by a birth center be initially determined to be at low maternal risk, and be regularly evaluated throughout the pregnancy;<sup>13</sup>
- The women receive specific prenatal,<sup>14</sup> intrapartum,<sup>15,16</sup> and postpartum care;<sup>17</sup>
- The mother and infant must be discharged within 24 hours of birth, except under unusual circumstances;<sup>18,19</sup>
- A postpartum examination of the mother is required to be performed within 72 hours after delivery;
- If unforeseen complications occur during labor, the client must be transferred to a hospital;<sup>20</sup> and

<sup>8</sup> Section 395.0197(7), F.S.

<sup>9</sup> Section 383.302(2), F.S.

<sup>10</sup> Section 383.302(3), F.S.

<sup>11</sup> Section 383.309, F.S.

<sup>12</sup> Rule 59A-11.005, F.A.C.

<sup>13</sup> Rule 59A-11.009, F.A.C.

<sup>14</sup> Rule 59A-11.012, F.A.C.

<sup>15</sup> Rule 59A-11.013, F.A.C.

<sup>16</sup> 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.

<sup>17</sup> Rule 59A-11.016, F.A.C.

<sup>18</sup> Section 383.318, F.S.

<sup>19</sup> 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.

<sup>20</sup> Section 383.316, F.S.

- Each maternal death, newborn death, and stillbirth must be reported to the medical examiner.<sup>21</sup>

There are no requirements for a birthing center or the clinical staff 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;<sup>22</sup> and at least semiannually to analyze statistics on the following:

- Maternal and perinatal morbidity and mortality;
- Maternal risk;
- Consultant referrals; and
- Transfers.<sup>23</sup>

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.<sup>24</sup>

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.<sup>25</sup> 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.<sup>26</sup>

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
- An AHCA review for a licensure survey or complaint investigation.<sup>27</sup>

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<sup>21</sup> Section 383.327, F.S.

<sup>22</sup> Section 383.32, F.S.

<sup>23</sup> Id.

<sup>24</sup> 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.

<sup>25</sup> Section 383.316, F.S.

<sup>26</sup> Rule 59A-11.019, F.A.C., and the ACHA Form 3130-3004, February, 2015.

<sup>27</sup> Section 383.32(3), F.S.

### ***Home Delivery for Childbirth***

The home delivery setting for childbirth is not regulated. Nonetheless, the practices of the physicians, PAs,<sup>28</sup> ARNP-CNMs,<sup>29</sup> and LMs,<sup>30</sup> who may attend a woman during an out-of-hospital or home delivery, are licensed and regulated by the DOH.<sup>31</sup> There are no requirements for these health care practitioners to report adverse incidents occurring in a home delivery.

### **Health Care Practitioners Who May Provide Child Birth Services**

#### ***Physicians and PAs***

A licensed physician may attend any child birth 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 make the determination of whether a home delivery is appropriate, explain the procedure to the patient, and obtain the patient's informed consent.<sup>32</sup> A physician may also delegate any home delivery to his or her PA under his or her written protocol.<sup>33</sup> 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.<sup>34</sup>

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 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 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

<sup>28</sup> See ss. 458.347 and 459.022, F.S.

<sup>29</sup> Section 464.012, F.S.

<sup>30</sup> See ch.467, F.S.

<sup>31</sup> See chs. 383 and 467, F.S., and Rules 59A-11 and 64B24-7, F.A.C.

<sup>32</sup> Supra note 3.

<sup>33</sup> Id; See also Rules 64B8-30.001 and 64B15-6.001, F.A.C.

<sup>34</sup> See chs. 458 and 459, F.S., and Rules 64B8-9 and 64B15-14, F.A.C.

- 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.,<sup>35</sup> to the facility's risk manager.

### ***ARNP-CNMs and LMs***

An ARNP-CNM's scope of practice for pre-natal care, child birth, and post-partum care is governed by his or her written protocol with the supervising physician, s. 464.012, F.S., and ch. 467, F.S.<sup>36</sup>

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., 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;

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<sup>35</sup> Section 395.0197(1)(e), E.S.

<sup>36</sup> See ss. 458.347(4), 459.022(4), 464.012(4), F.S., and ch. 467, F.S.

- 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 LM may 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.<sup>37</sup> 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 chs. 458 or 459, F.S., if the physician maintains supervision for directing the specific course of medical treatment.<sup>38</sup>

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:

SB 510 creates s. 456.0495, F.S., to require the following health care providers to report any adverse incidents, as defined by the DOH rule, occurring as the result of an attempted or completed, planned birthing center or out-of-hospital birth:

- Acupuncturists,
- Allopathic Physicians;
- Osteopathic Physicians;
- Physician Assistants;
- Chiropractic Physicians;
- Podiatric Physicians;
- Naturopathic Physicians;
- Optometrists;
- Advanced Registered Nurse Practitioner;
- Registered Nurses;
- Licensed Practical Nurses;
- Certified Nursing Assistants;
- Pharmacists;
- Dentists;
- Dental Hygienists;
- Midwives;
- Speech and Language Pathologists;
- Nursing Home Administrators;
- Occupational Therapists;
- Respiratory Therapists;
- Dieticians;

<sup>37</sup> Section 467.015, F.S., and Rule 64B24-7, F.A.C.

<sup>38</sup> Id.

- Athletic Trainers;
- Electrolysisists;
- Massage Therapists;
- Clinical Laboratory Personnel;
- Medical Physicists;
- Opticians;
- Hearing Aid Specialists;
- Physical Therapists;
- Psychologists;
- Clinical Social Workers;
- Marriage and Family Counselors; and
- Mental Health Counselors.

The bill requires adverse incidents to be reported to the DOH within 15 days after the adverse incident. The DOH must adopt rules establishing a definition for an adverse incident, and guidelines for reporting adverse incidents, which must include, but are not limited to:

- Medical summary of the events;
- Maternal deaths that occur during delivery or within 42 days after delivery;
- Transfers of maternal patients to a hospital intensive care unit;
- Maternal patients who experience hemorrhagic shock or who require a transfusion of more than 4 units of blood or blood products;
- Fetal or infant deaths, including stillbirths, associated with obstetrical deliveries;
- Transfers of infants to a neonatal intensive care unit due to a traumatic physical or neurological birth injury, including any degree of a brachial plexus injury; and
- Transfers of infants to a neonatal intensive care unit within the first 72 hours after birth if the infant remains in such unit for more than 72 hours.

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 health care practitioners 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 22 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:**

The bill uses the term “infants” in the grant of rulemaking authority to the DOH for defining and reporting adverse incidents. Typically an “infant” refers to a baby in the age range from 30 days through 12 months; and “newborn” refers to a baby less than 1 month of age.<sup>39</sup>

**VIII. Statutes Affected:**

This bill creates section 456.0495 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.

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This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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<sup>39</sup> See for example s. 383.145(2) (d) and (g), F.S.; and the Steadman's Medical Dictionary, 28th Edition, published by Lippencott, Williams and Wilkins, 2005, defining an “infant” as a child between 1 month and 23 months of age; and “newborn” as a neonate, a baby less than 1 month of age.