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 448

INTRODUCER: Senator Harrell

SUBJECT: Advanced Birth Centers

DATE: February 8, 2019 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Favorable**
2.			CF	
3.			RC	

I. Summary:

SB 448 amends the Birth Center Licensure Act[1] and other related statutes to establish a new license type for advanced birth centers (ABCs). The bill defines an “advanced birth center” to mean a birth center that may perform trial of labor after cesarean deliveries for screened patients, planned low-risk cesarean deliveries, and anticipated vaginal deliveries between the 37th and the 41st weeks of gestation.

The bill applies most current-law requirements for birth centers to ABCs and establishes additional requirements specific to ABCs.

II. Present Situation:

Birth Centers

A birth center is any facility, institution, or place in which births are planned to occur away from the mother’s usual residence following a normal, uncomplicated, low-risk pregnancy, aside from an ambulatory surgical center, hospital, or part of a hospital.[2] Birth centers are licensed and regulated by the Agency for Health Care Administration (AHCA) under ch. 383. F.S., and part II of ch. 408, F.S.

Birth centers must have a governing body responsible for the overall operation and maintenance of the birth center.[3] The governing body must develop and make available to all staff, clinicians,

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[1] Sections 383.30-383.332, F.S.

[2] Section 383.302(2), F.S.; Section 383.302(8), F.S. defines “low-risk pregnancy” as a pregnancy which is expected to result in an uncomplicated birth, as determined through risk criteria developed by rule of the department, and which is accompanied by adequate prenatal care.

[3] Section 383.307, F.S.

consultants, and licensing authorities, a manual that documents the policies, procedures, and protocols of the birth center.[4]

A birth center may accept only those patients who are expected to have normal pregnancies and deliveries. Prior to being accepted for care, the patient must sign an informed consent form.[5] A mother and her infant must be discharged from a birth center within 24 hours after giving birth, except when:[6]

- The mother is in a deep sleep at the end of the 24-hour period, in which case the mother must be discharged as soon after waking as feasible; or
- The 24-hour period is completed during the middle of the night.

A birth center must file a report with the AHCA within 48 hours of the birth, describing the circumstances and the reasons for the decision, if a mother or infant must remain in the birth center for longer than 24 hours after the birth for a reason other than those listed above.[7]

The AHCA is required to adopt rules establishing minimum standards for birth centers, which ensure:[8]

- Sufficient numbers and qualified types of personnel and occupational disciplines are available at all times to provide necessary and adequate patient care and safety.
- Infection control, housekeeping, sanitary conditions, disaster plan, and medical record procedures are established and implemented that will adequately protect patient care and provide safety.
- Licensed facilities are established, organized, and operated consistent with established programmatic standards.

To maintain quality of care, a birth center is required to:[9]

- Have at least one clinical staff[10] member for every two clients in labor;
- Have a clinical staff member or qualified personnel[11] available on site during the entire time a client is in the birth center.
- Ensure that services during labor and delivery are provided by a physician, certified nurse midwife, or licensed midwife, assisted by at least one other staff member under protocols developed by clinical staff;
- Ensure that all qualified personnel and clinical staff are trained in infant and adult resuscitation;

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[4] Id.

[5] Section 383.31, F.S. The informed consent form must advise the patient of the qualifications of the clinical staff, the risks related to out-of-hospital births, the benefits of out-of-hospital births, and the possibility of referral or transfer if complications arise during pregnancy or childbirth with additional costs for services rendered (Rule 59A-11.010, F.A.C.)

[6] Section 383.318(1), F.S., and Rule 59A-11.016(6), F.A.C.

[7] Section 383.318(1), F.S.

[8] Section 383.309, F.S.; The minimum standards for birth centers are contained in Chapter 59A-11, F.A.C.

[9] Rule 59A-11.005(3), F.A.C.

[10] Section 383.302(3), F.S., defines “clinical staff” as individuals employed full-time or part-time by a birth center who are licensed or certified to provide care at childbirth.

[11] Rule 59A-11.002(6), F.A.C., defines “qualified staff” as an individual who is trained and competent in the services that he or she provides and is licensed or certified when required by statute or professional standard.

- Have qualified personnel or clinical staff who are able to perform neonatal resuscitation to be present during each birth;
- Maintain complete and accurate medical records;
- Evaluate the quality of care by reviewing clinical records;
- Review admissions with respect to eligibility, course of pregnancy and outcome, evaluation of services, condition of mother and newborn on discharge, or transfer to other providers; and
- Surveil infection risk and infection cases and promote preventive and corrective programs designed to minimize hazards.

Birth centers must ensure that their patients have adequate prenatal care and must maintain records of prenatal care for each client. Such records must be available during labor and delivery.[12]

A birth center may perform simple laboratory tests and collect specimens for tests that are requested pursuant to its protocol.[13] A birth center is exempt from the clinical laboratory licensure requirements under ch. 483, F.S., if the birth center employs no more than five physicians and its testing is conducted exclusively in connection with the diagnosis and treatment of patients of the birth center.[14]

Birth centers may perform surgical procedures that are normally performed during uncomplicated childbirths, such as episiotomies and repairs. Birth centers may not perform operative obstetrics or caesarean sections.[15]

Birth centers may not administer general and conduction anesthesia. Systemic analgesia and local anesthesia for pudendal block and episiotomy repair may be administered if procedures are outlined by the clinical staff and performed by personnel with statutory authority to do so.[16]

Birth centers may not inhibit, simulate, or augment labor with chemical agents during the first or second stage of labor unless prescribed by personnel with the statutory authority to do so and in connection with and prior to an emergency transport.[17]

Birth centers must provide postpartum care and evaluation that includes physical examination of the infant, metabolic screening tests, referral to pediatric care sources, maternal postpartum assessment, family planning, referral to secondary or tertiary care, and instruction in child care, including immunization, breastfeeding, safe sleep practices, and possible causes of Sudden Unexpected Infant Death.[18]

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[12] Section 383.312, F.S.
[13] Section 383.313, F.S.
[14] Id.
[15] Id.
[16] Id.
[17] Id.
[18] Section 383.313(3), F.S.

Birth centers must be designed to ensure adequate provision for birthing rooms, bath and toilet facilities, storage areas for supplies and equipment, examination areas, and reception or family areas.[19]

Birth centers must comply with provisions of the Florida Building Code and Florida Fire Prevention Code applicable to birth centers.[20] The AHCA may enforce the special-occupancy provisions of the Florida Building Code and the Florida Fire Prevention Code that apply to birth centers when conducting inspections.[21]

Birth centers must have the equipment necessary to provide low-risk maternity care and readily available equipment to initiate emergency procedures for mothers and infants during life-threatening events.[22] A birth center must transfer the patient to a hospital if unforeseen complications arise during labor.[23] Each facility must have an arrangement with a local ambulance service for the transport of emergency patients to a hospital, which must be documented in the facility's policy and procedures manual.[24]

Birth centers must submit an annual report to the AHCA that details, among other things:[25]

- The number of deliveries by birth weight;
- The number of maternity clients accepted for care and length of stay;
- The number of surgical procedures performed at the birth center by type;
- Maternal transfers, including the reasons for each transfer and whether it occurred intrapartum or postpartum, and the length of the subsequent hospital stay;
- Newborn transfers, including the reasons for each transfer, the birth weight, days in hospital, and Apgar score at five and ten minutes;[26]
- Newborn deaths; and
- Stillborn/fetal deaths.

Birth centers must have written consultation agreements with each consultant who has agreed to provide advice and services to the birth center.[27] A consultant must be a licensed medical doctor or licensed osteopathic physician who is either certified or eligible for certification by the American Board of Obstetrics and Gynecology, or has hospital obstetrical privileges.[28] Consultation may be provided onsite or by telephone.[29]

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[19] Section 383.308(1), F.S.
[20] Section 383.309(2), F.S.; Section 452 of the Florida Building Code provides requirements for birth centers.
[21] Id.
[22] Section 383.308(2)(a), F.S.
[23] Section 383.316, F.S.
[24] Id.
[25] Rule 59A-11.019, F.A.C., and AHCA Form 3130-3004, (Feb. 2015).
[26] Apgar is a quick test performed on a baby at 1 and 5 minutes after birth. The 1-minute score determines how well the baby tolerated the birthing process. The 5-minute score tells the health care provider how well the baby is doing outside the mother's womb. In rare cases, the test will be done 10 minutes after birth. See *Apgar Score*, Medline Plus, *available at* https://medlineplus.gov/ency/article/003402.htm (last visited on Feb. 7, 2019).
[27] Section 383.315(1), F.S.
[28] Section 383.302(4), F.S.
[29] Section 383.315(2), F.S.

Birth centers must adopt a protocol that provides information about adoption procedures. The protocol must be provided upon request to any birth parent or prospective adoptive parent of a child born in the facility.[30]

The AHCA may impose an administrative fine not to exceed $500 per violation per day for the violation of any provision of the Birth Center Licensure Act, part II of chapter 408, or applicable rules.[31] The AHCA may also impose an immediate moratorium on elective admissions to any birth center when it determines that any condition in the facility presents a threat to the public health or safety.[32]

Currently, there are 34 licensed birth centers in Florida.[33]

Out-of-Hospital Births at Birth Centers

Out-of-hospital births increased from 0.87 percent of U.S. births in 2004 to 1.36 percent 2012, its highest level since 1975.[34] In 2012, 66 percent of out-of-hospital births occurred at home and 29 percent occurred in a freestanding birth center.[35]

A 2013 study of 13,030 births at 79 birth centers in 33 states found that the cesarean section rate for women who entered labor planning a birth center birth was 6 percent compared to the national cesarean section rate of 27 percent.[36] Of the women who planned to give at a birth center, 4.5 percent were referred to a hospital before being admitted to the birth center, 11.9 percent transferred to the hospital during labor, 2.0 percent transferred after giving birth, and 2.2 percent had their babies transferred after birth. Fewer than 2 percent of the women required emergency transfer to a hospital.[37] Of the 1,851 women who transferred to hospitals during labor, 54 percent ended up with a vaginal birth, 38 percent had a cesarean, and 8 percent had a forceps or vacuum-assisted vaginal birth.[38] The study also found that 0.47 stillbirths per 1,000 women (0.047 percent) and 0.40 newborn deaths per 1,000 women (0.04 percent) occurred out of the births planned at the birth centers.[39]

The study also estimated $30 million in savings from the births that occurred at the birth centers, based on Medicare facility reimbursement rates at the time of the study.[40] The Medicare facility

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[30] Section 383.3105, F.S.
[31] Section 383.33, F.S.
[32] Id.
[33] See http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (last visited Feb. 7, 2019).
[34] Marian F. MacDorman, Ph.D., T.J. Mathews, M.S., and Eugene Declercq, Ph.D, *Trends in Out-of-Hospital Births in the United States, 1990–2012*, NCHS Data Brief No. 144 (March, 2014), *available at* https://www.cdc.gov/nchs/products/databriefs/db144.htm (last visited Feb. 7, 2017).
[35] Id.
[36] Susan Rutledge Stapleton, CNM, DNP, Cara Osborne, SD, CNM, and Jessica Illuzzi, M.D., M.S., *Outcomes of Care in Birth Centers: Demonstration of a Durable Model. Journal of Midwifery & Women's Health*, Vol. 58, No. 1, (January/February 2013), *available at* http://nacpm.org/documents/Birth%20Center%20Study%202013.pdf (last visited Feb. 7, 2019).
[37] Id.
[38] Id.
[39] Id.
[40] Id.

reimbursement for an uncomplicated vaginal birth in a hospital was $3,998 compared to $1,907 in a birth center.[41]

Practice of Pharmacy

The Florida Pharmacy Act regulates the practice of pharmacy in Florida and contains the minimum requirements for safe practice.[42] The Board of Pharmacy is tasked with adopting rules to implement the provisions of the chapter and setting standards of practice.[43] Any person who operates a pharmacy in Florida must have a permit. The following permits are issued by the Department of Health (DOH):

- *Community pharmacy* – A permit is required for each location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.[44]
- *Institutional pharmacy* – A permit is required for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.[45]
- *Nuclear pharmacy* – A permit is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under ch. 395, F.S., or the nuclear medicine facilities of such hospitals.[46]
- *Special pharmacy* – A permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold if the location does not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.[47]
- *Internet pharmacy* – A permit is required for a location not otherwise licensed or issued a permit under ch. 465, F.S., within or outside the state, which uses the Internet to communicate with or obtain information from consumers in Florida to fill or refill prescriptions or to dispense, distribute, or otherwise practice pharmacy in the state.[48]
- *Nonresident sterile compounding pharmacy* – A permit is required for a registered nonresident pharmacy or an outsourcing facility to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state.[49]
- *Special sterile compounding* – A separate permit is required for a pharmacy holding an active pharmacy permit that engages in sterile compounding.[50]

The DOH issues three different classes of permits for institutional pharmacies:[51]

- Institutional Class I: An Institutional Class I pharmacy is a pharmacy in which all medicinal drugs are administered from individual prescription containers to the individual patient and in

[41] Id.
[42] Chapter 465, F.S.
[43] Sections 465.005, 465.0155, and 465.022, F.S.
[44] Sections 465.003(11)(a)1. and 465.018, F.S.
[45] Sections 465.003(11)(a)2. and 465.019, F.S.
[46] Sections 465.003(11)(a)3. and 465.0193, F.S.
[47] Sections 465.003(11)(a)4. and 465.0196, F.S.
[48] Sections 465.003(11)(a)5. and 465.0197, F.S.
[49] Section 465.0158, F.S.
[50] Rules 64B16-2.100 and 64B16-28.802, F.A.C. An outsourcing facility is considered a pharmacy and need to hold a special sterile compounding permit if it engages in sterile compounding.
[51] Section 465.109, F.S.

which medicinal drugs are not dispensed on the premises. No medicinal drugs may be dispensed in a Class I Institutional pharmacy. A Special Closed System Pharmacy Permit, Special Parenteral and Enteral Pharmacy Permit, or Community Pharmacy Permit provides the individual patient prescriptions.

- Institutional Class II: An Institutional Class II pharmacy is a pharmacy that employs the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. An Institutional Class II pharmacy is required be open sufficient hours to meet the needs of the facility. A consultant pharmacist of record is also responsible for establishing a policy and procedure manual for the implementation of the general requirements set forth in Rule 64B16- 28.702 of the Florida Administrative Code.
- Modified Class II: Modified Institutional Class II pharmacies are those pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.

Ambulatory Surgical Centers

An ambulatory surgical center (ASC) is a non-hospital facility whose primary purpose is to provide elective surgical care in which the patient is admitted and discharged within the same working day and does not stay overnight.[52] ASCs are licensed and regulated by the AHCA under the same regulatory framework as hospitals.[53]

The AHCA is authorized to adopt rules for minimum standards for ASCs that ensure:[54]

- A sufficient number of qualified personnel within certain occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards

ASCs must comply with provisions of the Florida Building Code and Florida Fire Prevention Code applicable to ASCs.[55]

III. Effect of Proposed Changes:

SB 448 amends various sections of the Florida Statutes to create a new license type for advanced birth centers (ABCs).

Section 1 amends s. 383.30, F.S., to rename the "Birth Center Licensure Act" as the "Birth Center and Advanced Birth Center Licensure Act."

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[52] Section 395.002(3), F.S.
[53] Sections 395.001-.1065, F.S., and Part II, Chapter 408, F.S.
[54] Section 395.1055, F.S.; The minimum standards for ASCs are contained in Chapter 59A-5, F.A.C.
[55] Section 395.1063, F.S.; Section 451 of the Florida Building Code provides requirements for ASCs.

Section 2 amends s. 383.301, F.S., to apply existing legislative intent language for birth centers to ABCs and to specify that an ABC must obtain a license from the AHCA in order to operate.

Section 3 amends s. 383.302, F.S., to define the terms:
- "Advanced Birth Center" to mean means a birth center that may perform trial of labor after cesarean deliveries for screened patients who qualify, planned low-risk cesarean deliveries, and anticipated vaginal deliveries for laboring patients from the beginning of the 37th week of gestation through the end of the 41st week of gestation.
- "Medical director" to mean a person who holds an active unrestricted license as an allopathic physician under ch. 458, F.S., or osteopathic physician under ch. 459, F.S.

The bill also amends the definition of "consultant" to include allopathic and osteopathic physicians who are certified or eligible for certification by the American Osteopathic Board of Obstetrics and Gynecology. Additionally, the bill incorporates the term advanced birth center into other current-law definitions as appropriate.

Section 4 amends s. 383.305, F.S., to specify that an applicant for licensure as an ABC must pay a licensure fee for each application submitted. In addition to the requirements in the act, applicants for licensure as an ABC must comply with the requirements in part II of ch. 408, F.S.

Section 5 amends s. 383.307, F.S., to require that:
- Each ABC must have a governing body that is responsible for the overall operation of the ABC; and
- An ABC must have an adequate number of licensed personnel to provide clinical services as needed by mothers and newborns and sufficient qualified personnel to provide services to families and to maintain the ABC.

Section 6 creates s. 383.3081, F.S., to establish facility and equipment requirements for ABCs. ABCs must:
- Meet all facility and equipment requirements for birth centers established in s. 383.308, F.S.;
- Be operated and staffed 24 hours per day, 7 days per week;
- Employ two medical directors, one of whom must be a board-certified obstetrician and the other must be a board-certified anesthesiologist;
- Have at least one properly equipped and dedicated surgical suite for cesarean deliveries;
- Employ at least one registered nurse who is at the facility at all times and is able to stabilize and facilitate the transfer of patients and newborn infants;
- Enter into a written agreement with a blood bank for emergency services and have written protocols for the management of obstetrical hemorrhage. If a patient receives an emergency blood transfusion at the ABC, the patient must immediately be transferred to a hospital for further care.

Section 7 amends s. 383.309, F.S., to require that AHCA rules for ABCs must, at a minimum, be equivalent to the minimum standards for ASCs. Additionally, AHCA rules must include standards for quality of care, blood transfusions, and sanitary conditions for food handling and food service. The bill also restricts the AHCA from adopting any rule governing the design, construction, erection, alteration, modification, repair, or demolition of ABCs. These functions

are preempted to the Florida Building Commission and the State Fire Marshall through the maintenance of the Florida Building Code and the Florida Fire Prevention Code, respectively. An ABC must, at a minimum, comply with the Florida Building Code and Florida Fire Prevention Code standards for ASCs.

Section 8 amends s. 383.3105, F.S., to require each ABC to adopt a protocol that, at a minimum, provides for staff to be knowledgeable of the waiting periods, revocation, and contents of the consent to adoption in s. 63.082(4), F.S., and that describes the supportive and unbiased manner in which staff must interact with birth and prospective adoptive parents. The protocol must be written and be provided upon request to any birth or prospective adoptive parent.

Section 9 amends s. 383.311, F.S., to require that each ABC fully inform clients and their families of the ABC's policies and procedures.

Section 10 amends s. 383.312, F.S., to require that an ABC provide each of its clients with adequate prenatal care, as defined by the AHCA, and to require that serological tests are administered as required by ch. 383, F.S. Records of prenatal care must be maintained for each client and must be available during labor and delivery.

Section 11 amends s. 383.313, F.S., to specify that the laboratory and surgical services standards in that section apply only to birth centers.

Section 12 creates s. 383.3131, F.S., to establish laboratory and surgical services requirements specific to ABCs. An ABC:

- Must have a clinical laboratory on site. The clinical laboratory must:
  - At a minimum, be capable of providing laboratory testing for hematology, metabolic screening, liver function, and coagulation studies.
  - Be appropriately certified by the federal Centers for Medicare & Medicaid Services.
- May collect specimens for required tests.
- May perform laboratory tests as defined in rule by the AHCA.
- In addition to surgical services that may be performed during an uncomplicated childbirth, an ABC may perform low-risk cesarean deliveries and surgical management of immediate complications, postpartum sterilization on a patient who has given birth during the admission, and circumcisions.
- May administer general and local anesthesia if the personnel administering such anesthesia has statutory authority to do so. General anesthesia may be performed by an anesthesiologist or by a certified registered nurse anesthetist (CRNA) and the anesthesiologist or the CNRA must be present in the ABC until the patient is fully alert. If a CRNA is administering anesthesia, he or she must be under the direction of an onsite allopathic or osteopathic physician.[56]
- May inhibit, stimulate, or augment labor with chemical agents during the first or second stage of labor.

[56] See s. 395.0191(2)(b), F.S.

- May electively induce labor beginning at the 39th week of gestation for a patient with a documented Bishop score of 8 or greater.[57]

Section 13 amends s. 383.315, F.S., to require that ABCs maintain consultation agreements with each consultant who has agreed to provide advice and services to the ABC. An ABC must employ or maintain a consultation agreement with an obstetrician who must be present in the center at all times during which a patient is in active labor.

Section 14 amends s. 383.316, F.S., to require that each ABC make arrangements with a local ambulance service for emergency transport and enter into a written transfer agreement with a local hospital or obstetrician who has hospital privileges and who has agreed to accept the transfer of the ABC's patients. Patients are required to be transferred to a hospital should unforeseen complications arise during labor delivery or postpartum recovery.[58] An ABC must identify and have listed and immediately available neonatal-specific transportation services. Additionally, an ABC must assess and document its transportation services and transfer protocols annually.

Section 15 amends s. 383.318, F.S., to require that a mother and her infant be dismissed from an ABC within 48 hours after a vaginal delivery or within 72 hours after a delivery by cesarean section, except in unusual circumstances as defined in rule by the AHCA. If a mother or an infant is retained for longer than the timeframes established, the ABC must file a report with the AHCA within 48 hours after the scheduled discharge time, describing the circumstances and the reason for retaining the mother or infant in the ABC.

After the birth, an ABC must instill a prophylactic in the eyes of each newborn as required in s. 383.04, F.S., and must provide postpartum evaluation and follow-up care.

Section 16 amends s. 383.32, F.S., to specify what ABC clinical records must contain and to require that clinical records must be immediately available at the ABC at the time of admission, when transfer of care is necessary, and for audit by licensure personnel.

Section 17 amends s. 383.324, F.S., to require an ABC to pay an inspection fee established in rule by the AHCA.

Section 18 amends s. 383.325, F.S., to require that each ABC maintain, as public information, records of all inspection reports from any governmental agency. The most recent inspection reports must be furnished upon request to any person who has completed a written application with the intent to be admitted to the ABC, any person who is a patient of the ABC, or any relative, spouse, or guardian of any such person.

Section 19 amends s. 383.327, F.S., to require an ABC to file completed birth certificates within five days after each birth; to immediately report each maternal death, newborn death, or stillbirth

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[57] Originally created by Dr. E. Bishop in the 1960s, the Bishop score is a cost-effective, reliable method to assess cervical status. A pre-induction Bishop Score of >6 is considered favorable and is predictive of a successful vaginal delivery. See Bishop Score, *available at* https://www.calgaryfamilymedicine.ca/residency/dox/container/bishop-score-teaching.pdf (last visited on Feb. 6, 2019).

[58] This requirement also applies to birth centers.

to the medical examiner; and to annually submit a report to the AHCA with contents as prescribed by the AHCA.

Section 20 amends s. 383.33, F.S., to allow the AHCA, in addition to the requirements of Part II of ch. 408, F.S., to impose fines of up to $500 per violation, per day on ABCs for violating any provision of the act or applicable rules. The AHCA may also impose an immediate moratorium on elective admission to any ABC, or portion thereof, when the AHCA determines the ABC presents a threat to public health or safety.

Section 21 amends s. 383.332, F.S., to impose a penalty of up to $100 for a first offense and up to $500 for subsequent offenses for operating an ABC without a license. Each day of continuing violation is considered a separate offense.

Sections 26 and 27 amend ss. 465.003 and 465.019, F.S., to allow ABCs to have institutional pharmacies and modified class II institutional pharmacies.

Sections 22-25 amends ss. 408.033, 408.07, 408.802, and 408.820, F.S., respectively, to make conforming changes.

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:

Article VII, s. 19, of the State Constitution requires that a new state tax or fee, as well as an increased state tax or fee, must be approved by two-thirds of the membership of each house of the Legislature and must be contained in a separate bill that contains no other subject. Article VII, s. 19(d)(1), of the State Constitution defines “fee” to mean “any charge or payment required by law, including any fee for service, fee or cost for licenses, and charge for service.”

The bill creates a new license for ABCs. Section 4 of the bill amends s. 383.305, F.S., to require ABCs to pay a license fee, which is currently in statute but applies only to birth centers. Section 17 of the bill amends s. 383.324, F.S., to require ABCs to pay an inspection fee, which is currently in statute but applies only to birth centers. These fees are existing statutory fees that are not being increased; however, the bill imposes these fees on the new type of licensee created by the bill. As such, the State Constitution may

require that the fees be passed in a separate bill by a two-thirds vote of the membership of each house of the Legislature.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 448 may have a fiscal impact on hospitals and existing entities that become licensed ABCs if mothers choose to give birth at an ABC rather than at a hospital.

This bill may have a positive fiscal impact for expectant mothers who may see reduced costs at an ABC when compared to a hospital.

Applicants for licensure as an ABC will be subject to a non-recurring Plans and Construction project review fee of $2,000 plus $100 per hour for building plan reviews and on-site construction surveys. ABCs are subject to a biennial health care facility assessment fee of $300. In addition, biennial licensure and inspection fees will need to be established by rule and are estimated to be $1,500 for the biennial licensure fee and $500 per inspection.[59]

C. Government Sector Impact:

The state Medicaid program could experience cost savings under the bill to the extent that ABCs begin providing services to Medicaid recipients and the costs of services provided at ABCs are less than comparable services performed at hospitals.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 383.30, 383.301, 383.302, 383.305, 383.307, 383.309, 383.3105, 383.311, 383.312, 383.313, 383.315, 383.316,

[59] Agency for Health Care Administration, *Senate Bill 488 Analysis* (on file with Senate Committee on Health Policy).

383.318, 383.32, 383.324, 383.325, 383.327, 383.33, 383.332, 408.033, 408.07, 408.802, 408.820, 465.003, and 465.019.

This bill creates the following sections of the Florida Statutes: 383.3081 and 383.3131.

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.

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