HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 1099 Advanced Birth Centers
SPONSOR(S): Health Quality Subcommittee; Magar
TIED BILLS: HB 1101 **IDEN./SIM. BILLS:** SB 1564

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 1 N, As CS	Royal	McElroy
2) Health Care Appropriations Subcommittee	13 Y, 0 N, As CS	Clark	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

A birth center is any facility, institution, or place, which is not an ambulatory surgical center, a hospital or in a hospital, in which births are planned to occur away from the mother's usual residence following a normal, uncomplicated, low-risk pregnancy. 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.

A birth center may only accept those patients who are expected to have normal pregnancies and deliveries. Birth centers may not perform operative obstetrics or caesarean sections.

A mother and her infant must be discharged from a birth center within 24 hours after giving birth, except when:

- 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.

CS/HB 1099 creates a new licensure program within AHCA for advanced birth centers. An advanced birth center is a birth center that may perform trial of labor after cesarean deliveries for screened patients that qualify, planned low risk cesarean deliveries, and anticipated vaginal delivery of laboring patients at the beginning of the 37th week of gestation to the end of the 41st week of gestation.

The bill requires advanced birth centers to be operated and staffed 24 hours per day, 7 days per week. The bill requires a mother and her infant to be discharged from the advanced birth center within 48 hours after the birth of the infant for a vaginal delivery and within 72 hours when delivery is by cesarean section, except in unusual circumstances as defined by rule.

The new advanced birth center license is modeled after the current licensure program for birth centers, subjecting advanced birth centers to similar regulatory standards, inspections and rules.

The bill has an indeterminate, but likely insignificant fiscal impact on state government that can be absorbed within existing resources.

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Birth Centers

A birth center is any facility, institution, or place, which is not an ambulatory surgical center, a hospital or in a hospital, in which births are planned to occur away from the mother's usual residence following a normal, uncomplicated, low-risk pregnancy.[1] 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.[2] The governing body must develop and make available to all staff, clinicians, consultants, and licensing authorities, a manual that documents the policies, procedures, and protocols of the birth center.[3]

A birth center may only accept those patients who are expected to have normal pregnancies and deliveries; and prior to being accepted for care, the patient must sign an informed consent form.[4] A mother and her infant must be discharged from a birth center within 24 hours after giving birth, except when:[5]

- 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 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 giving birth for a reason other than those listed above.[6]

AHCA is required to adopt rules establishing minimum standards for birth centers, which ensure:[7]

- 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 that will adequately protect patient care and provide safety are established and implemented.
- Licensed facilities are established, organized, and operated consistent with established programmatic standards.

[1] 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.
[2] Section 383.307, F.S.
[3] Id.
[4] 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 (r. 59A-11.010, F.A.C.)
[5] Section 383.318(1), F.S., and Rule 59A-11.016(6), F.A.C.
[6] Section 383.318(1), F.S.
[7] Section 383.309, F.S.; The minimum standards for birth centers are contained in Chapter 59A-11, F.A.C.

A birth center is required to maintain the quality of care by:[8]

- Having at least one clinical staff[9] member for every two clients in labor;
- Having a clinical staff member or qualified personnel[10] available on site during the entire time a client is in the birth center. Services during labor and delivery must be provided by a physician, certified nurse midwife, or licensed midwife, assisted by at least one other staff member under protocols developed by clinical staff;
- Ensuring all qualified personnel and clinical staff are trained in infant and adult resuscitation and requiring qualified personnel or clinical staff who are able to perform neonatal resuscitation to be present during each birth;
- Maintaining complete and accurate medical records;
- Evaluating the quality of care by reviewing clinical records;
- Reviewing 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
- Surveillance of infection risk and cases and the promotion of preventive and corrective program designed to minimize hazards.

Birth centers must ensure that its patients have adequate prenatal care and must maintain records of prenatal care for each client and must make the records available during labor and delivery.[11]

Birth centers may perform simple laboratory tests and collect specimens for tests that are requested pursuant to its protocol.[12] Birth centers are exempt from the clinical laboratory licensure requirements under chapter 483 if the birth center employs no more than five physicians and testing is conducted exclusively in connection with the diagnosis and treatment of patients of the birth center.[13]

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.[14]

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.[15]

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.[16]

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.[17]

[8] Rule 59A-11.005(3), F.A.C.
[9] 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.
[10] 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.
[11] Section 383.312, F.S.
[12] Section 383.313, F.S.
[13] Id.
[14] Id.
[15] Id.
[16] Id.
[17] Section 383.313(3), F.S.

Birth centers must be designed to assure adequate provision for birthing rooms, bath and toilet facilities, storage areas for supplies and equipment, examination areas, and reception or family areas.[18] Birth centers must comply with provisions of the Florida Building Code and Florida Fire Prevention Code applicable to birth centers.[19] 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.[20]

Birth centers must have the equipment necessary to provide low-risk maternity care and readily available equipment to initiate emergency procedures in life-threatening events to a mother and baby.[21] A birth center must transfer the patient to a hospital if unforeseen complications arise during labor.[22] 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 facilities policy and procedures manual.[23]

Birth centers must submit an annual report to AHCA that details, among other things:[24]

- 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 reason for the transfer, whether it occurred intrapartum or postpartum, and the length of the hospital stay;
- Newborn transfers, including the reason for the transfer, birth weight, days in hospital, and APGAR score at five and ten minutes;
- 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.[25] 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.[26] Consultation may be provided onsite or by telephone.[27]

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.[28]

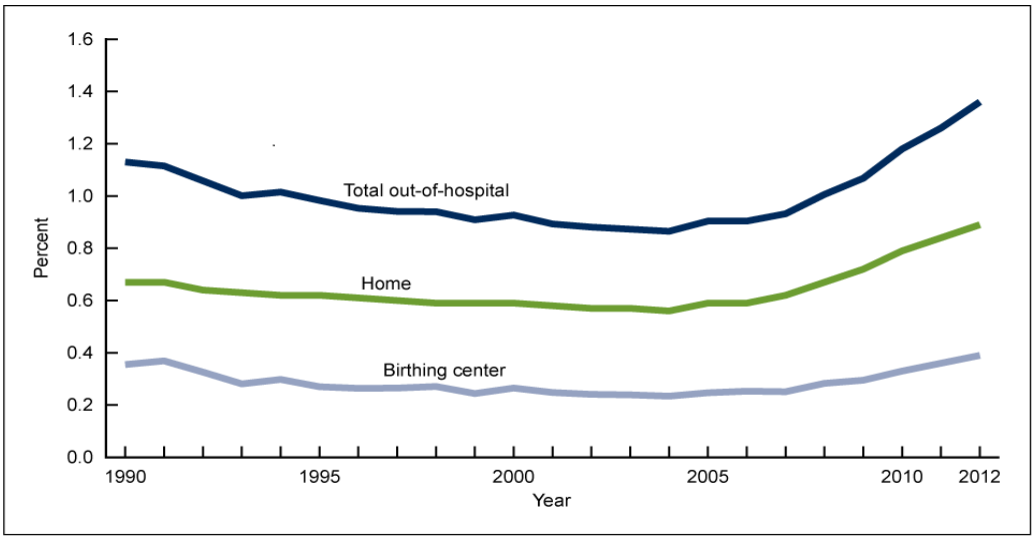
AHCA may impose an administrative fine not to exceed $500 per violation per day for the violation of any provision of the Birth Center Licensure Act, part II of chapter 408, or applicable rules.[29] AHCA may also impose an immediate moratorium on elective admissions to any birth center when it determines that any condition in the facility presents a threat to the public health or safety.[30]

[18] Section 383.308(1), F.S.
[19] Section 383.309(2), F.S.; Section 452 of the Florida Building Code provides requirements for birth centers.
[20] Id.
[21] Section 383.308(2)(a), F.S.
[22] Section 383.316, F.S.
[23] Id.
[24] Rule 59A-11.019, F.A.C., and AHCA Form 3130-3004, (Feb. 2015).
[25] Section 383.315(1), F.S.
[26] Section 383.302(4), F.S.
[27] Section 383.315(2), F.S.
[28] Section 383.3105, F.S.
[29] Section 383.33, F.S.
[30] Id.

Out-Hospital-Births at Birth Centers

Out-of-hospital births have increased from 0.87% of U.S. births in 2004 to 1.36% of U.S. births in 2012, its highest level since 1975.[31] In 2012, 66% of out-of-hospital births occurred at home and 29% occurred in a freestanding birth center.[32]

Figure 1. Percentage of births occurring out-of-hospital: United States, 1990-2012[33]



NOTE: Out-of-hospital births include those occurring in a home, birthing center, clinic or doctor's office, or other location.
SOURCE: CDC/NCHS, National Vital Statistics System, birth certificate data.

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% compared to the national cesarean section rate of 27%.[34] Out of the women who planned to give at a birth center, 4.5% were referred to a hospital before being admitted to the birth center, 11.9% transferred to the hospital during labor, 2.0% transferred after giving birth, and 2.2% had their babies transferred after birth. Fewer than 2% of the women required emergency transfer to a hospital.[35] Out of the 1,851 women who transferred to hospitals during labor, 54% ended up with a vaginal birth, 38% had a Cesarean, and 8% had a forceps or vacuum-assisted vaginal birth.[36] The study also found that 0.47 stillbirths per 1,000 women (.047%) and 0.40 newborn deaths per 1,000 women (.04%) occurred out of the births planned at the birth centers.[37]

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.[38] The Medicare facility reimbursement for an uncomplicated vaginal birth in a hospital was $3,998 compared to $1,907 in a birth center.[39]

Wesley Medical Center (Center) in Kansas is a licensed hospital that operates a freestanding, physician-led, birth center linked to the hospital through a service tunnel.[40] The birth center is equipped

[31] 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 January 12, 2017).
[32] Id.
[33] Id.
[34] Susan Rutledge Stapleton, CNM, DNP; Cara Osborne, SD, CNM; 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 January 12, 2017).
[35] Id.
[36] Id.
[37] Id.
[38] Id.
[39] Id.

equivalent to the hospital's labor and delivery unit and contains two operating rooms. A study comparing births at the Center's birth center to the hospital found that deliveries at its birth center were associated with a lower rate of cesarean sections without an increased rate of operative vaginal delivery compared to births at the hospital.[41] The study also found that maternal length of stays longer than 72 hours were less frequent in the birth center, the rate of infants requiring transfer to the high-risk were less than those born in the hospital, and adverse maternal and infant outcomes were not increased in the birth center.[42] The study also found that only 2.2% of all deliveries were transferred to the hospital, and infants of mothers that were transferred were not more likely to need transfer to the high-risk nursery.[43]

Practice of Pharmacy

The Florida Pharmacy Act (act) regulates the practice of pharmacy in Florida and contains the minimum requirements for safe practice.[44] The Board of Pharmacy (board) is tasked with adopting rules to implement the provisions of the chapter and setting standards of practice within the state.[45] 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.[46]
- 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.[47]
- 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.[48]
- 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.[49]
- Internet pharmacy – A permit is required for a location not otherwise licensed or issued a permit under this chapter, within or outside this state, which uses the Internet to communicate with or obtain information from consumers in this state to fill or refill prescriptions or to dispense, distribute, or otherwise practice pharmacy in this state.[50]
- 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.[51]
- Special sterile compounding – A separate permit is required for a pharmacy holding an active pharmacy permit that engages in sterile compounding.[52]

DOH issues three different classes of permits for institutional pharmacies[53]:

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[40] Margaret H. O'Hara, MD, Linda M. Frazier, MD, MPH, Travis W. Stembridge, MD, Robert S. McKay, MD, Sandra N. Mohr, MD, MPH, and Stuart L. Shalat, ScD, *Physician-led, hospital-linked, birth care centers can decrease Cesarean section rates without increasing rates of adverse events.* Birth Issues in Perinatal Care Vol. 40 Issue 3, September 2013. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4321785/ (Last visited January 12, 2012).
[41] Id.
[42] Id.
[43] Id.
[44] Chapter 465, F.S.
[45] Sections 465.005, 465.0155, and 465.022, F.S.
[46] Sections 465.003(11)(a)1. and 465.018, F.S.
[47] Sections 465.003(11)(a)2. and 465.019, F.S.
[48] Sections 465.003(11)(a)3. and 465.0193, F.S.
[49] Sections 465.003(11)(a)4. and 465.0196, F.S.
[50] Sections 465.003(11)(a)5. and 465.0197, F.S.
[51] Section 465.0158, F.S.
[52] 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.

- 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 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 provide the individual patient prescriptions.
- Institutional Class II: An Institutional Class II pharmacy is a pharmacy, which 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 hospital facility. A consultant pharmacist of record shall also be responsible for establishing written policy and procedure manual for the implementation of the general requirements set forth in Rule 64B16- 28.702, F.A.C.
- 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 facility that is not part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.[54] ASCs are licensed and regulated by AHCA under the same regulatory framework as hospitals.[55]

AHCA is authorized to adopt rules for minimum standards for ASCs that ensure:[56]

- A sufficient number of qualified types of personnel and 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.[57]

Effect of the Bill

CS/HB 1099 creates a new licensure program within AHCA for advanced birth centers. The advanced birth center license is modeled after the current licensure program for birth centers in Chapters 383 and 408, F.S. The bill requires advanced birth centers to meet the same licensure, inspection and administrative penalty requirements for birth centers in Chapters 383 and 408, F.S. The bill also requires advanced birth centers to provide prenatal and postpartum care and establish a governing body, an adoption protocol, a transfer agreement with an ambulance service, and consultation agreements with consultants in the same manner as birth centers.

[53] S. 465.109, F.S.
[54] S. 395.002(3), F.S.
[55] SS. 395.001-.1065, F.S., and Part II, Chapter 408, F.S.
[56] S. 395.1055, F.S.; The minimum standards for ASCs are contained in Chapter 59A-5, F.A.C.
[57] Section 395.1063, F.S.; Section 451 of the Florida Building Code provides requirements for ASCs.

The bill defines an advanced birth center as a birth center that may perform trial of labor after cesarean deliveries for screened patients that qualify, planned low risk cesarean deliveries, and anticipated vaginal delivery of laboring patients at the beginning of the 37th week of gestation to the end of the 41st week of gestation.

The bill requires advanced birth centers to be operated and staffed 24 hours per day, 7 days per week. The bill requires a mother and her infant to be discharged from the advanced birth center within 48 hours after the birth of the infant for a vaginal delivery and within 72 hours when delivery is by cesarean section, except in unusual circumstances defined by rule by AHCA. The bill requires an advanced birth center to file a report with AHCA describing the reasons and circumstances for not discharging a mother or infant within the required timeframes.

Section 383.309, F.S., F.S. directs AHCA to adopt rules establishing minimum standards for:

- 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 that will adequately protect patient care and provide safety are established and implemented.
- Licensed facilities are established, organized, and operated consistent with established programmatic standards.

The bill authorizes AHCA to adopt, by rule, appropriate standards for advanced birth centers pursuant to s. 383.309, F.S. The bill also requires AHCA to establish minimum standards for food handling and service. The bill requires the minimum standards adopted for advanced birth centers be equivalent to the minimum standards adopted for ambulatory surgical centers.

The bill requires advanced birth centers to have at least one, properly equipped, dedicated surgical suite for the performance of caesarean deliveries.

The bill requires advanced birth centers to, at a minimum, comply with the Florida Building Code and Florida Fire Prevention Code requirements for ambulatory surgical centers. The bill authorizes AHCA to enforce the special-occupancy provisions of the Florida Building Code and the Florida Fire Prevention Code that apply to advanced birth centers when conducting inspections.

The bill authorizes advanced birth centers to perform laboratory tests as permitted by AHCA rule and requires a laboratory in an advanced birth center to be licensed as a clinical laboratory pursuant to chapter 483.

The bill authorizes advanced birth centers to perform uncomplicated cesarean deliveries, surgical management of immediate complications, postpartum sterilization, and circumcisions, in addition to the surgical procedures authorized to be performed at birth centers.

The bill allows advanced birth centers to administer general, conduction, and local anesthesia if such services are provided in accordance with established protocol required by state law. The bill requires an anesthesiologist or a certified registered nurse anesthetist to administer all general anesthesia. The bill requires a physician or a certified registered nurse anesthetist to be present in the advanced birth center during the anesthesia and postanesthesia recovery period until the patient is fully alert.

The bill authorizes an advanced birth center to inhibit, stimulate, or augment labor with chemical agents during the first or second stage of labor if prescribed by personnel with statutory authority to do so. The

bill authorizes an advanced birth center to electively induce labor at 39 weeks' gestation or later for a patient with a documented Bishop score[58] of 8 or greater.

The bill requires an advanced birth center to either employ or maintain an agreement with an obstetrician who is available to attend and available to perform cesarean deliveries, when necessary.

The bill requires a patient be transferred to a hospital if unforeseen complications arise during labor, delivery, or postpartum.

The bill requires an advanced birth center with a pharmacy to obtain a Modified Class II institutional pharmacy permit from DOH.

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 383.30, F.S., relating to Birth Center Licensure Act; short title.
Section 2: Amends s. 383.301, F.S., relating to licensure and regulation of birth centers; legislative intent.
Section 3: Amends s. 383.302, F.S., relating to definitions of terms used in ss. 383.30-383.335.
Section 4: Amends s. 383.305, F.S., relating to licensure; fees.
Section 5: Amends s. 383.307, F.S., relating to administration of birth center.
Section 6: Creates s. 383.3081, F.S., relating to advanced birth center facility and equipment; requirements.
Section 7: Amends s. 383.309, F.S., relating to minimum standards for birth centers.
Section 8: Amends s. 383.3105, F.S., relating to patients consenting to adoptions; protocols.
Section 9: Amends s. 383.311, F.S., relating to education and orientation for birth center clients and their families.
Section 10: Amends s. 383.312, F.S., relating to prenatal care of birth center clients.
Section 11: Amends s. 383.313, F.S., relating to performance of laboratory and surgical services; use of anesthetic and chemical agents.
Section 12: Creates s. 383.3131, F.S., relating to advanced birth center performance of laboratory and surgical services; use of anesthetic and chemical agents.
Section 13: Amends s. 383.315, F.S., relating to agreements with consultants for advice or services; maintenance.
Section 14: Amends s. 383.316, F.S., relating to transfer and transport of clients to hospitals.
Section 15: Amends s. 383.318, F.S., relating postpartum care for birth center clients and infants.
Section 16: Amends s. 383.324, F.S., relating to inspections and investigations; inspection fees.
Section 17: Amends s. 383.327, F.S., relating to birth and death records; reports.
Section 18: Amends s. 383.33, F.S., relating to administrative penalties; moratorium on admissions.
Section 19: Amends s. 383.332, F.S., relating to establishing, managing, or operating a birth center without a license; penalty.
Section 20: Amends s. 408.033, F.S., relating to licensure fees for local and state health planning.
Section 21: Amends s. 408.07, F.S., relating to definitions.
Section 22: Amends s. 408.802, F.S., relating to licensure.
Section 23: Amends s. 408.820, F.S., relating to exemptions.
Section 24: Amends s. 465.003, F.S., relating to definitions.
Section 25: Amends s. 465.019, F.S., relating to institutional pharmacies; permits.
Section 26: Provides an effective date of July 1, 2018.

[58] Health care professionals use the Bishop score to rate the readiness of the cervix for labor. With this scoring system, a number ranging from 0–13 is given to rate the condition of the cervix. A Bishop score of less than 6 means that your cervix may not be ready for labor. The American College of Obstetricians and Gynecologists, *Frequently Asked Questions*. Available at: https://www.acog.org/Patients/FAQs/Labor-Induction#score (Last visited January 14, 2018).

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

AHCA will experience an increase in revenues from licensure fees for the new licensure program. Section 408.805, F.S., requires AHCA to set license fees that are reasonably calculated to cover the cost of regulation. Section 408.033, F.S., requires revenues collected by AHCA at each licensure renewal to be used to fund local health councils. By using the available resources, the AHCA estimates the biennial licensure fees for advanced birth centers would need to be $1,500 and $500 per inspection.[59]

Applicants for licensure as an advanced birth center will be subject to the Plans and Construction project review fee of $2,000 plus $100 per hour for building plan reviews. These are non-recurring fees.[60]

DOH may experience an increase in revenues from advanced birth centers that apply for licensure as a Modified Class II institutional pharmacy.[61] Applicants for such permits must pay a $250 application fee.[62]

2. Expenditures:

AHCA will experience costs associated with administering the new licensure program. However, due to the common requirements for birth centers and advanced birth centers, AHCA expects to absorb implementation costs using current resources and revenues from the new licensure fees.

DOH may experience an increase in costs and workload associated inspections, licensure, regulation, and enforcement of advanced birth centers that apply to be licensed as Modified Class II institutional pharmacies. It is unknown how many advanced birth centers will seek licensure; therefore, the fiscal impact is indeterminate, but likely insignificant. [63] Current DOH resources can absorb the increased workload.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Applicants for licensure as advanced birth centers will be subject to biennial licensure fees and a one-time Plans and Construction project review fee. Applicants for licensure as advanced birth centers that have a pharmacy will be subject to the Modified Class II institutional pharmacy permit fee.

D. FISCAL COMMENTS:

None.

[59] Agency for Health Care Administration, *2018 Agency Legislative Bill Analysis-HB 1099, January 11, 2018* (on file with Health Quality Subcommittee staff).
[60] Id.
[61] Department of Health, *2018 Agency Bill Analysis-HB 1099, January 12, 2018* (on file with Health Quality Subcommittee Staff).
[62] Rule 61-28.100, F.A.C.
[63] Supra, FN 51.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 16, 2018, the Health Quality Subcommittee adopted an amendment that:

- Requires minimum standards established by AHCA for the staffing, infection control, housekeeping, medical records, disaster plans, organization, and operation of advanced birth centers be equivalent to minimum standards established for ambulatory surgical centers.
- Requires minimum standards include standards for food handling and service.
- Requires at a minimum, advanced birth centers meet Florida Building Code and Florida Fire Prevention Code requirements for ambulatory surgical centers.
- Authorizes AHCA to enforce the special-occupancy provisions of the Florida Building Code and the Florida Fire Prevention Code that apply to advanced birth centers when conducting inspections.
- Authorizes advanced birth centers to collect specimens for laboratory tests and perform laboratory tests permitted by AHCA rule.
- Removes minimum staffing requirements and requires AHCA to set staffing requirements in rule.
- Removes requirement that a board-certified anesthesiologist to be on call and available at all times when a certified registered nurse anesthetist performs anesthesia services.
- Requires advanced birth centers to either employ or maintain an agreement with an obstetrician to be available to attend and available to perform cesarean section deliveries, when necessary.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.

On January 23, 2018, the Health Care Appropriations Subcommittee adopted an amendment that subjects advanced birth centers to the licensure requirements of Ch. 408, F.S., and subjects them to an assessment collected at licensure renewal that funds local health councils.

The bill was reported favorably as a committee substitute to a committee substitute. The analysis is drafted to the committee substitute to the committee substitute.