HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	CS/HB 673	**FINAL HOUSE FLOOR ACTION:**			
SUBJECT/SHORT TITLE	Reporting of Adverse Incidents in Planned Out-of-Hospital Births	114	**Y's**	0	**N's**
SPONSOR(S):	Health & Human Services Committee; Magar	**GOVERNOR'S ACTION:**		Approved	
COMPANION BILLS:	CS/CS/SB 510				

SUMMARY ANALYSIS

CS/HB 673 passed the House on March 7, 2018, as CS/CS/SB 510.

Several types of health care practitioners provide obstetric care: a physician, a certified nurse midwife (an advanced registered nurse practitioner (ARNP) with specialized training in obstetric care), or a licensed midwife. A prospective parent may choose to have labor and childbirth occur in a hospital, birthing center, or home setting.

CS/HB 673 requires a physician, certified nurse midwife, or licensed midwife attending a planned out-of-hospital birth to submit an adverse incident report to the Department of Health (DOH) within 15 days of the occurrence of the incident. The bill defines an adverse incident as an event over which the physician, certified nurse midwife, or licensed midwife could exercise control and one of the following occurs:

- A maternal death that occurs after delivery or within 42 days after delivery;
- A maternal patient is transferred to a hospital intensive care unit;
- A maternal patient experiences hemorrhagic shock or requires a transfusion of more than four units of blood or blood products;
- A fetal or newborn death, including a still birth, attributable to an obstetrical delivery;
- A newborn patient is transferred to a hospital neonatal intensive care unit (NICU) due to a traumatic birth injury;
- A newborn patient is transferred to a hospital NICU within 72 hours after birth if the newborn remains in the NICU for more than 72 hours; or
- Any other injury as determined by department rules.

The bill requires the attending health care practitioner to provide a medical summary of the events in the adverse incident report. DOH must review each adverse incident report to determine whether the incident involves conduct for which the health care practitioner may be subject to disciplinary action. The bill authorizes DOH to adopt rules to implement the provisions of the bill.

The bill will have an indeterminate, recurring negative fiscal impact on DOH, which current resources are adequate to absorb. The bill has no fiscal impact on local governments.

The bill was approved by the Governor on March 19, 2018, ch. 2018-21, L.O.F., and became effective on that date.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Present Situation

Prior to giving birth, expectant parents will make a number of decisions in planning their childbirth experiences. The parents may decide the location of the birth, as well as the type of health care practitioner they would like to provide obstetrical services.[1] The decision on the type of practitioner may dictate the place where the birth may occur, and vice versa. In Florida, the health care practitioners that may attend a childbirth include a physician,[2] certified nurse midwife (CNM), and licensed midwife. Typically, there are three settings in which childbirths occur: hospitals, birthing centers, and home.[3]

Regulation of Health Care Practitioners

The Department of Health (DOH), Division of Medical Quality Assurance (MQA), is charged with the regulation of health care practitioners in this state.[4] MQA works in conjunction with regulatory boards to adopt rules and regulate health care practitioners.[5] For all health care professions regulated by MQA or regulatory boards, ch. 456, F.S., provides the general framework for licensure and regulation; however, the individual practice acts provide greater specificity for the regulation of a health care profession.

Each practice act provides licensure requirements, the scope of practice in which the health care practitioner may engage, as well disciplinary guidelines. To be licensed in this state, an applicant must meet the minimum licensure standards as provided in the practice act and any rules adopted by the regulatory board or DOH, if there is no board.

Physicians

Both allopathic and osteopathic physicians have a broad scope of practice; they may diagnose, treat, operate, or prescribe for any human disease, pain, injury, deformity, or other physical or mental condition.[6] However, a physician may be required to meet additional standards to practice in certain settings or perform certain medical acts, such as training or continuing education.

A physician is expected to practice in a safe and competent manner.[7] A physician who fails to do so may be subject to discipline against his or her license to practice in this state.[8]

---

[1] American Pregnancy Association, *Birthing Choices: Health Care Providers and Birth Locations*, (Sept. 6, 2016), available at http://americanpregnancy.org/labor-and-birth/birthing-choices/ (last visited on December 14, 2017).

[2] A physician may delegate the performance of medical acts to a physician assistant under his or her supervision unless such delegation is expressly prohibited by law. (Sections 458.347(4), and 459.022(e), F.S.) The physician remains liable for any acts or omissions of the physician assistant acting under his or her supervision or control. *See* ss. 458.347(15), and 459.022(15), F.S.

[3] Centers for Disease Control and Prevention, *Trends in Out-of-Hospital Births in the United States, 1990-2012*, (March 4, 2014), available at https://www.cdc.gov/nchs/products/databriefs/db144.htm (last visited December 18, 2017).

[4] Pursuant to s. 456.001(4), F.S., health care practitioners are defined to include acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists, midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, counselors, and psychotherapists, among others.

[5] Section 456.001(1), F.S.

[6] Sections 458.305(3), and 459.003(3), F.S. However, an osteopathic physician's practice is based in part on education which emphasizes the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health.

[7] Sections 458.301 and 459.001, F.S.

[8] Id. See also ss. 458.331 and 459.015, F.S. Section 456.072, F.S., provides grounds for discipline that apply to all licensed health care practitioners.

Advance Registered Nurse Practitioners

An advanced registered nurse practitioner (ARNP) may perform advanced-level nursing acts approved by the Board of Nursing which, by virtue of post-basic specialized education, training, and experience are appropriately performed by an ARNP, in addition to the professional nursing acts that registered nurses are authorized to perform.[9] ARNPs are also authorized to practice certain medical acts, as opposed to nursing acts, as authorized within the framework of an established supervisory physician's protocol.[10]

To be eligible to be certified as an ARNP, the applicant must be licensed as a registered nurse, and have a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills or submit proof that the applicant holds a current national advanced practice certification from a board-approved nursing specialty board.[11] In Florida, an ARNP may be categorized as a certified nurse practitioner, certified registered nurse anesthetist (CRNA), or certified nurse midwife (CNM).[12]

A CNM may, to the extent authorized under a supervisory protocol, perform the following acts in a healthcare facility where midwifery services are performed or in the patient's home:[13]

- Superficial minor surgical procedures;
- Manage the patient's labor and delivery to include amniotomy, episiotomy, and repair;
- Order, initiate, and perform appropriate anesthetic procedures;
- Perform postpartum examinations;
- Order appropriate medications;
- Provide family-planning services and well-woman care; and
- Manage the medical care of the normal obstetrical patient and the initial care of a newborn patient.

An ARNP is expected to practice in a safe and competent manner.[14] An ARNP who fails to do so may be subject to discipline against his or her license to practice in this state.[15] For example, an ARNP may be disciplined for failing to meet the minimum standard of care for nursing practice, including engaging in acts for which he or she is not qualified by training or experience.[16]

Licensed Midwives

DOH is responsible for the licensure and regulation of the practice of midwifery in this state. The Council of Licensed Midwifery assists and advises DOH on midwifery, including the development of rules relating to regulatory requirements, including but not limited to training requirements, the licensure examination, responsibilities of midwives, emergency care plans, and reports and records to be filed by licensed midwives.[17]

To be licensed as a midwife, an applicant must graduate from an approved midwifery program, and pass the licensure examination.[18] Along with an application for licensure or licensure renewal, a licensed midwife must submit a general emergency care plan which addresses consultation with other

[9] Section 464.003(2)-(3), F.S.
[10] Id.
[11] Section 464.012(1), F.S., and Rule 64B9-4.002, F.A.C.
[12] Section 464.012(4), F.S.
[13] Section 464.012(4)(b), F.S.
[14] Section 464.002, F.S.
[15] Section 464.018, F.S., provides the grounds for which disciplinary action may be taken against the license. Section 456.072, F.S., provides grounds for discipline that apply to all licensed health care practitioners.
[16] Section 464.018(1)(n), F.S.
[17] Section 467.004, F.S.
[18] Section 467.011, F.S. Section 467.0125, F.S., provides for licensure by endorsement for applicants who hold a valid license to practice midwifery in another state.

health care providers, emergency transfer protocols, and access to neonatal intensive care units and obstetrical units or other patient care areas.[19]

A licensed midwife is responsible for ensuring the certain conditions are met, such as:[20]

- Accepting only those patients who are expected to have a normal pregnancy, labor, and delivery;
- Ensuring that each patient has signed an informed consent form developed by DOH;
- Administering medicinal drugs pursuant to a prescription issued by a practitioner licensed under ch. 458, F.S., or ch. 459, F.S.;
- Preparing a written plan of action with the family;
- Maintaining appropriate equipment and supplies and instructing the patient and family regarding the preparation of the environment, if a home birth is planned;
- Instructing the patient in the hygiene of pregnancy and nutrition as it relates to prenatal care;
- Determining the progress of labor, and when birth is imminent, be immediately available until delivery is accomplished;
- Remaining with the postpartal mother until the mother and neonate are stabilized; and
- Instilling a prophylactic into each eye of the newborn infant within one hour after birth for the prevention of neonatal ophthalmia.[21]

Licensed midwives must file an "Annual Report of Midwifery Practice," by July 31 of each year.[22] The report requires each licensed midwife to detail information regarding the number of clients seen in the previous fiscal year (July 1 to June 30), the types of births performed, maternal and newborn transfers, fetal deaths (stillbirths and neonatal), and maternal deaths.

Childbirth Settings

In 1900, almost all childbirths in the United States occurred outside of hospital; however, by 1969 that figure had fallen to one percent of all births.[23] In 2016, 1.6 percent of all births in the U.S. occurred outside of a hospital.[24] Of those, 62.2 percent occurred in a home or residence, and 31.7 percent occurred in a freestanding birthing center.[25] In Florida, 0.9 percent of births occurred at home in 2016.[26]

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 (AHCA). Every licensed hospital is required to establish and maintain an internal risk management program that is overseen by a health care risk manager.[27] As a part of its risk management program, a hospital must have an incident reporting system which places an affirmative duty on all health care providers, as well the agents and employees of the hospital, to report adverse incidents to the risk manager within 3 business days after their occurrence.[28] The hospital must annually submit a report to AHCA summarizing the incident reports filed in the facility for that year.[29]

[19] Section 467.017, F.S.
[20] Section 467.015, F.S.
[21] Section 383.04, F.S.
[22] Rule 64B24-7.014, F.A.C.
[23] *Supra* note 3.
[24] Joyce A. Martin, et. al., *Births: Final Data for 2016*, NATIONAL VITAL STATISTICS REPORTS, 66:1 (Jan. 31, 2018), available at https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_01.pdf (last visited March 8, 2018).
[25] Id
[26] Id.
[27] Section 395.0197, F.S.
[28] Section 395.0197(1)(e), F.S.
[29] Section 395.0197(6), F.S.

An adverse incident is defined as an event over which health care personnel could exercise control and which is associated with a medical intervention which results in:[30]

- Death;
- Brain or spinal damage;
- Permanent disfigurement;
- Fracture or dislocation of bones or joints;
- A resulting limitation of neurological, physical, or sensory functions which continue after discharge from the facility;
- Any condition that requires specialized medical attention or surgical intervention resulting from a nonemergency medical intervention to which the patient has not given his or her informed consent;
- Any condition that required the transfer of a 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 medical condition;
- Required surgical repair of damage resulting from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient through the informed consent process; or
- A procedure to remove unplanned foreign objects remaining from a surgical procedure.

Any of the following adverse incidents, whether occurring in the hospital or arising from health care prior to admission, must be reported to AHCA within 15 calendar days after occurrence:[31]

- 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 medical condition;
- The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient through the informed consent process; or
- The performance of a procedure to remove unplanned foreign objects remaining from a surgical procedure.

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.[32] Birth centers are licensed and regulated by 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; and prior to being accepted for care, the patient must sign an informed consent form.[33] A

[30] Section 395.0197(5), F.S.
[31] Section 395.0197(7), F.S.
[32] Section 383.302(2), F.S.
[33] 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.)

mother and her infant must be discharged from a birth center within 24 hours after giving birth, except when:[34]

- 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.

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, the birth center must file a report with AHCA within 48 hours of the birth describing the circumstances and the reasons for the decision.[35]

AHCA requires a birth center to meet minimum staffing requirements, maintain complete and accurate medical records, and evaluate its services and the quality of care it provides.[36] A birth center must be equipped with those items needed to provide low-risk maternity care and readily available equipment to initiate emergency procedures in life-threatening events to a mother and baby.[37] 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.[38]

A birth center must submit an annual report to AHCA by July 30 of each year that details, among other things:[39]

- 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
- Stillborns/Fetal deaths.

Home Births

The home delivery setting is not regulated. However, the health care practitioners who perform such services, including physicians, certified nurse midwives, and licensed midwives are regulated by their respective regulatory boards, or in the case of licensed midwives, DOH.

<u>Adverse Incident Reporting</u>

Current law requires physicians and physician assistants to report to DOH any adverse incident occurring in an office practice setting within 15 days after the occurrence of the adverse incident.[40] DOH must review each report to determine if discipline against the practitioner's license is warranted.[41]

An adverse incident in an office setting as an event over which the physician or licensee could exercise control and which is associated with a medical intervention and results in one of the following patient injuries:[42]

[34] Section 383.318(1), F.S., and Rule 59A-11.016(6), F.A.C.
[35] Section 383.318(1), F.S.
[36] Rule 59A-11.005(3), F.A.C.
[37] Section 383.308(2)(a), F.S.
[38] Section 383.316, F.S.
[39] Rule 59A-11.019, F.A.C., and AHCA Form 3130-3004, (Feb. 2015).
[40] Sections 458.351 and 459.026, F.S.
[41] Sections 458.351(5) and 459.026(5), F.S.
[42] Sections 458.351(4) and 459.026(4), F.S.

- The death of a patient;
- Brain or spinal damage to a patient;
- The performance of a surgical procedure on the wrong patient;
- If the procedure results in death; brain or spinal damage; permanent disfigurement; the fracture or dislocation of bones or joints; a limitation of neurological, physical, or sensory functions; or any condition that required the transfer of a patient, the performance of:
  - A wrong-site surgical procedure;
  - A wrong surgical procedure; or
  - A surgical repair of damage to a patient resulting 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;
- A procedure to remove unplanned 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.

There is no statutory requirement for a physician to report an adverse incident that occurs outside of an office or hospital setting. There is no statutory requirement for an ARNP or a CNM to report adverse incidents to DOH.

There is no statutory requirement for a licensed midwife to report adverse incidents to DOH. However, by rule, a licensed midwife must report maternal and fetal deaths, as well as maternal and newborn transfers, as a part of the annual report.[43]

Effect of Proposed Changes

Beginning July 1, 2018, CS/HB 673 requires a physician, CNM, or licensed midwife attending a planned out-of-hospital birth to submit an adverse incident report to DOH within 15 days of the occurrence of the incident.

The bill defines an adverse incident as an event over which the physician, certified nurse midwife, or licensed midwife could exercise control and one of the following occurs during the process of childbirth:

- A maternal death that occurs after delivery or within 42 days after delivery;
- A maternal patient is transferred to a hospital intensive care unit;
- A maternal patient experiences hemorrhagic shock or requires a transfusion of more than four units of blood or blood products;
- A fetal or newborn death, including a still birth, attributable to an obstetrical delivery;
- A newborn patient is transferred to a hospital neonatal intensive care unit (NICU) due to a traumatic birth injury;
- A newborn patient is transferred to a hospital NICU 72 hours after birth if the newborn remains in the NICU for more than 72 hours; or
- Any other injury as determined by department rules.

The attending health care practitioner must provide a medical summary of the events in the adverse incident report. DOH must review each adverse incident report to determine whether the incident involves conduct for which the health care practitioner may be subject to disciplinary action by the appropriate regulatory board or if there is no board, DOH.

The adverse incident reports required by the bill would be exempt from disclosure under public record laws pursuant to s. 456.057, F.S., which protects patient records obtained by the DOH.

---

[43] *Supra* note 22.

The bill authorizes DOH to adopt rules to develop the adverse incident form and to implement the provisions of the bill.

The bill takes effect upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH may have an indeterminate, recurring negative fiscal impact related to the increase in workload associated with the review of adverse incident reports required to be submitted under the provisions of the bill and any complaints and investigations that may be generated.[44] DOH does not have actual data available; however, there were a total of 472 hospital transfers reported in the annual reports submitted by licensed midwives for fiscal year 2016-2017.[45] DOH cautions that this may not be an accurate representation of how many adverse incidents may be reported under the provisions of the bill because some transfers are for issues not contemplated by the bill, such as slow labor; in group practices, a single transfer may be reported by each licensed midwife in the practice, and these numbers only include the reports of licensed midwives.

An expert must review each adverse incident report to determine whether the incident involves conduct which would be subject to disciplinary, as required by the bill.[46] The cost of expert review is $125 an hour and DOH estimates a review takes 1.5 hours.[47] Assuming each of the 472 hospital transfers is reviewed by an expert witness, the total cost would be $88,500 ($125 x 1.5 hours x 472). However, it is highly unlikely that this many records would require review, so a significantly lesser impact is more likely. Current resources are adequate to absorb even this unlikely impact.

DOH will incur an insignificant, nonrecurring negative fiscal impact for form development and rulemaking; however, current resources are adequate to absorb such costs.[48]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care practitioners who provide planned childbirth services outside of a hospital may incur administrative costs to comply with the adverse incident reporting required by the bill.

[44] DOH, *2018 Agency Legislative Bill Analysis for House Bill 673* (Nov. 15, 2017), on file with the Health Quality Subcommittee.
[45] E-mail correspondence with DOH, dated January 31, 2018, on file with the Health Quality Subcommittee.
[46] Id.
[47] Id.
[48] Id.

D. FISCAL COMMENTS:

None.