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:	CS/SB 1596
INTRODUCER:	Health Policy Committee and Senator Garcia
SUBJECT:	Provider Accountability
DATE:	March 29, 2023
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Fav/CS**
2.			CF	
3.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1596 amends ss. 408.809[1] and 435.04[2], F.S., to add additional crimes to the list of offenses that will disqualify a person from employment after undergoing a background screening. The bill also amends nursing home residents' rights to specify that a nursing home resident has the right to be free from sexual abuse, neglect, and exploitation. The bill amends s. 408.812, F.S., to create a new cause of action to pursue an injunction against unlicensed activity by persons or entities who are providing services for which a license is required under ch. 408, F.S.

The bill also creates registration requirements and standards of practice for physician offices registered with the Department of Health (DOH) for the performance of office surgeries.

The bill provides an effective date of July 1, 2023.

[1] Background screening specific to health care providers regulated by the Agency for Health Care Administration under ch. 408, F.S.

[2] General provisions for level 2 background screening.

II. Present Situation:

Unlicensed Activity

Section 408.812, F.S., prohibits any person or entity from offering or advertising services that require a license under Part II of ch. 408, F.S., authorizing statutes, or applicable rules to the public without obtaining a valid license from the Agency for Health Care Administration (AHCA). The section allows the AHCA, or any state attorney, to bring action for an injunction to halt the unlicensed activity or enjoin further operation or maintenance of the unlicensed provider until compliance with laws and rules has been demonstrated to the satisfaction of the AHCA. If a person or entity fails to cease operation after receiving notice from the AHCA, the person or entity is subject to penalties including a fine of up to $1,000 per each day of noncompliance, the revocation of other licenses if the unlicensed entity has an interest in other licensed providers, and the imposition of the same licensure violations that a regularly licensed provider would incur if a condition exists that poses a threat to the health, safety, or welfare of a client.

Limitations of the Current Statutory Scheme

Under the current regulatory scheme, where the unlicensed operation of a health care provider regulated by the AHCA is asserted, the AHCA may inspect the identified location to determine if the operators are providing services therein that meet the definition of a facility requiring licensure. Should the operator not provide consent for the inspection, the circuit court is empowered to issue an inspection warrant.

If the AHCA determines, during an inspection of an unlicensed provider, that the operator is in fact engaging in unlicensed activity, the AHCA's sole immediate action is to issue a notice directed to the operator indicating that the operator is engaging in unlicensed activity. Thereafter, the AHCA may conduct a subsequent inspection to determine if the unlicensed activity has ceased or continues. Should the operator be found to have continued the unlicensed activity on this second inspection, the AHCA may proceed to impose administrative fines of $1,000 per day.

Though the statutory scheme authorizes the AHCA to seek injunctive relief, the principal of exhaustion of administrative remedies prior to seeking judicial relief essentially renders this provision ineffective. The imposition of administrative fines invokes the Administrative Procedure Act in ch. 120, F.S., and its inherent time delays, which does not result in an order, administrative or otherwise, directing the operator to cease the unlicensed activity.

Thus, under the current legislative scheme, the AHCA has no statutory path to assure that unlicensed activity by an operator ceases in a timely manner to protect citizens from the health and safety risks presented by such unlicensed activity.[3]

Examples of Unlicensed Activity

In addition to other instances of unlicensed activity identified by the AHCA, individuals currently may travel to the state to receive cheaper surgical and recovery options. Lower-cost cosmetic surgeries have created a market for similarly priced post-operative care. "Recovery

[3] AHCA bill analysis for SB 1596, March 21, 2023, on file with Senate Health Policy Committee staff.

homes" charge persons to stay and receive care post-surgery. Most recovery homes offer transportation services following surgery, provide beds, and some have nurses on site that can check vital signs.

The AHCA oversees assisted living facilities (ALF), defined as any home or building where housing, meals, and nonmedical services are provided for more than 24 hours to one or more people who are not related to the homeowner or facility manager. The AHCA is typically only made aware of the existence of recovery homes if a complaint is submitted. Since January 2017, the AHCA has cited unlicensed activity a total of 289 times, including 17 times in the first six months of 2022. The AHCA does not currently have the authority to specifically regulate or license post-operative recovery homes.

Since 2017, the number of recovery care home complaints has increased yearly. The recovery home complaints slowly began to escalate in 2018, and into 2019. Various law enforcement agencies, fire department, and code enforcement personnel also began to alert the AHCA of potential unlicensed ALF/recovery home activity.

In 2019 and early 2020, prior to the COVID-19 pandemic, recovery home complaints were approximately three or fewer per month. In 2020, there were 14 unlicensed recovery home investigations with 12 being substantiated as unlicensed ALF's during the pandemic. In 2021, there were 30 unlicensed recovery home investigations with 20 being substantiated as unlicensed ALF's, and in 2022, there were 22 unlicensed recovery home investigations with 17 being substantiated.

As of March 3, 2023, four unlicensed recovery care home investigations have been conducted with three substantiated as unlicensed ALFs. Currently the AHCA has 10 ongoing and/or pending investigations.[4]

Level 2 Background Screening

Section 435.04, F.S., establishes the standards for level 2 background screenings. The section specifies that a background screening under its provisions must include fingerprinting for statewide criminal history records checks through the FDLE and a national criminal history records checks through the FBI, and may include local criminal records checks through local law enforcement agencies. Fingerprints submitted must be submitted electronically to the FDLE, and agencies may contract with one or more vendors to perform all or part of the electronic fingerprinting.

In order to pass a level 2 background screening, an individual being screened may not have been arrested for and awaiting final disposition of, have been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to, or have been adjudicated delinquent and the record has not been sealed or expunged, for any of the offenses listed in the section or similar provisions in other jurisdictions. The section provides additional disqualifying offenses applicable to participation in the Medicaid program.

[4] *Supra* n. 3

Section 408.809, F.S., requires that the following persons who are associated with a licensee under Part II of ch. 408, F.S., must pass a level 2 background screening and be rescreened every five years:

- The licensee, if an individual;
- The administrator or a similarly titled person who is responsible for the day-to-day operation of the provider;
- The financial officer or similarly titled individual who is responsible for the financial operation of the licensee or provider;
- Any person who has a controlling interest;
- Any person, as required by authorizing statutes, seeking employment with a licensee or provider who is expected to, or whose responsibilities may require him or her to, provide personal care or services directly to clients or have access to client funds, personal property, or living areas; and
- Any person, as required by authorizing statutes, contracting with a licensee or provider whose responsibilities require him or her to provide personal care or personal services directly to clients, or contracting with a licensee or provider, to work 20 hours a week or more who will have access to client funds, personal property, or living areas.

The section also provides a list of disqualifying offenses which will prevent a person from passing the background screening and which is in addition to the disqualifying offenses listed in s. 435.04, F.S.

Exemptions

Section 435.07, F.S., allows heads of agencies to grant an exemption from disqualification for an employee who would be disqualified under s. 435.04, F.S., or other background screening provisions. These exemptions may be granted for:

- Felonies for which at least three years have elapsed since the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court for the disqualifying felony;
- Misdemeanors prohibited under any of the statutes cited in this chapter or under similar statutes of other jurisdictions for which the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court;
- Offenses that were felonies when committed but that are now misdemeanors and for which the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court; or
- Findings of delinquency. For offenses that would be felonies if committed by an adult and the record has not been sealed or expunged, the exemption may not be granted until at least three years have elapsed since the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court for the disqualifying offense.

In order to be granted an exemption, the employee seeking the exemption must provide clear and convincing evidence that he or she should not be disqualified from employment. The employing, or potentially employing, agency may consider crimes committed or that he or she has been arrested for after the disqualifying offense, even if the crime is not itself a disqualifying offense.

The decision regarding whether to grant an exemption is subject to the due process provisions in ch. 120, F.S. Additionally, the section specifies that disqualification cannot be removed if the employee is seeking a child care position, if the employee is a sex offender, or if the disqualifying offense is one of a list of specified offenses.

Nursing Home Residents' Rights

Section 400.022, F.S., enumerates a number of rights for residents in a nursing home. The section requires each nursing home to adopt and make public a statement of the rights and responsibilities of residents in the facility. The facility is required to inform a resident of his or her rights and provide a copy of the statement to the resident and each staff member of the facility. The section specifies that a violation of residents' rights is grounds for AHCA licensure action and that a licensure inspection of the facility must include private informal conversations with a sample of residents to discuss their experiences with respect to residents' rights.

The section specifies that the statement of rights adopted by each facility must include the right for all residents to:

- Civil and religious liberties.
- Private and uncensored communication.
- Present grievances on behalf of themselves or others to the staff or administrator of the facility, to governmental officials, or to any other person; to recommend changes in policies and services to facility personnel; and to join with other residents or individuals within or outside the facility to work for improvements in resident care, free from restraint, interference, coercion, discrimination, or reprisal.
- Organize and participate in resident groups in the facility and the right to have their families meet in the facility with the families of other residents.
- Participate in social, religious, and community activities that do not interfere with the rights of other residents.
- Examine, upon reasonable request, the results of the most recent inspection of the facility conducted by a federal or state agency and any plan of correction in effect with respect to the facility.
- Manage their own financial affairs or to delegate such responsibility to the licensee, but only to the extent of the funds held in trust by the licensee for a resident.
- Be fully informed, in writing and orally, prior to or at the time of admission and during their stay, of services available in the facility and of related charges for such services.
- Be adequately informed of their medical condition and proposed treatment, unless they are determined to be unable to provide informed consent under Florida law, or the right to be fully informed in advance of any nonemergency changes in care or treatment that may affect their well-being.
- Participate in the planning of all medical treatment, including the right to refuse medication and treatment, unless otherwise indicated by their physician, and to know the consequences of such actions.
- Refuse medication or treatment and to be informed of the consequences of such decisions, unless determined unable to provide informed consent under state law.
- Receive adequate and appropriate health care and protective and support services, including social services; mental health services, if available; planned recreational activities; and

therapeutic and rehabilitative services consistent with their resident care plan, with established and recognized practice standards within the community, and with rules as adopted by the AHCA.
- Have privacy in treatment and in caring for personal needs; to close room doors and to have facility personnel knock before entering the room, except in the case of an emergency or unless medically contraindicated; and to security in storing and using personal possessions.
- Be treated courteously, fairly, and with the fullest measure of dignity and to receive a written statement and an oral explanation of the services provided by the licensee, including those required to be offered on an as-needed basis.
- Be free from mental and physical abuse, corporal punishment, extended involuntary seclusion, and from physical and chemical restraints, except those restraints authorized in writing by a physician for a specified and limited period of time or as are necessitated by an emergency.
- Be transferred only for specified reasons and to have no less than 30 days' notice of a transfer.
- Freedom of choice in selecting a personal physician and other related health care choices.
- Retain and use personal clothing and possessions as space permits, unless to do so would infringe upon the rights of other residents or unless medically contraindicated as documented by a physician in their medical records.
- Have copies of the rules and regulations of the facility and an explanation of the responsibility of all residents to obey all reasonable rules and regulations of the facility and to respect the personal rights and private property of the other residents.
- Receive notice before their room in the facility is changed.
- Be informed of the bed reservation policy for a hospitalization.
- Challenge a decision by the facility to discharge or transfer, for Medicaid or Medicare certified facilities.

Regulation of Office Surgeries

The Board of Medicine and the Board of Osteopathic Medicine (boards) have authority to adopt rules to regulate practice of medicine and osteopathic medicine, respectively.[5] The boards have authority to establish, by rule, standards of practice for particular settings.[6] Such standards may include education and training; medications, including anesthetics; assistance of and delegation to other personnel; sterilization; performance of complex or multiple procedures; records; informed consent; and policy and procedures manuals.[7]

The boards set forth the standards of practice that must be met for office surgeries. An office surgery is any surgery that is performed outside a facility licensed under ch. 390, F.S., or ch. 395, F.S.[8] There are several levels of office surgeries governed by rules adopted by the boards, which

[5] Chapter 458, F.S., regulates the practice of allopathic medicine, and ch. 459, F.S., regulates the practice of osteopathic medicine.
[6] Sections 458.331(v) and 459.015(z), F.S.
[7] *Id.*
[8] Rules 64B8-9.009(1)(d) and 64B15-14.007(1)(d), F.A.C. Abortion clinics are licensed under ch. 390, F.S., and facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgery centers, mobile surgical facilities, and certain intensive residential treatment programs.

set forth the scope of each level of office surgeries, the equipment and medications that must be available, and the training requirements for personnel present during the surgery.

Registration

The boards require a licensed physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, Level II procedures planned to last more than five minutes, and Level III procedures, to register the office with the DOH.[9] A physician who performs surgery in an office setting must ensure that the office is registered with DOH, regardless of whether other physicians practice in the office or the office is not owned by a physician.[10] The registration requires a physician to document compliance with transfer agreement[11] and training requirements. DOH must annually inspect registered offices or the office must be accredited by a national accreditation organization approved by the respective board. Currently, there are 719 offices registered with DOH.[12]

Standards of Practice

Prior to performing any surgery, a physician must evaluate the risk of anesthesia and of the surgical procedure to be performed.[13] A physician must maintain a complete record of each surgical procedure, including the anesthesia record, if applicable, and written informed consent.[14] The written consent must reflect the patient's knowledge of identified risks, consent to the procedure, type of anesthesia and anesthesia provider, and that a choice of anesthesia provider exists.[15]

Physicians performing office surgeries must maintain a log of all liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed and Level II and Level III surgical procedures performed, which includes:[16]

- A confidential patient identifier;
- The time the patient arrives in the operating suite;
- The name of the physician who provided medical clearance;
- The surgeon's name;
- The diagnosis;
- The CPT codes for the procedures performed;
- The patient's ASA classification;
- The type of procedure performed;
- The level of surgery;

[9] Sections 458.309(3) and 459.005(2), F.S., see also Rules 64B8-9.0091 and 64B15-14.0076, F.A.C.
[10] Rule 64B8-9.0091(1) and 64B15-14.0076(1), F.A.C.
[11] A physician or the facility where a surgical procedure is being performed must have a transfer agreement with a licensed hospital within a reasonable proximity or within 30 minutes transport time to the hospital. Rules 64B8-9.009 and 64B15-14.007, F.A.C.
[12] Department of Health, *License Verification – Office Surgery Registration, Practicing Statuses Only*, March 21, 2023, available at https://mqa-internet.doh.state.fl.us/MQASearchServices/HealthCareProviders.
[13] Rules 64B8-9.009(2) and 64B15-14.007(2), F.A.C.
[14] *Id.* A physician does not need to obtain written informed consent for minor Level I procedures limited to the skin and mucosa.
[15] *Id.* A patient may use an anesthesiologist, anesthesiologist assistant, another appropriately trained physician, certified registered nurse anesthetist, or physician assistant.
[16] Rules 64B8-9.009(2)(a) and 64B15-14.007(2)(a), F.A.C.

- The anesthesia provider;
- The type of anesthesia used;
- The duration of the procedure;
- The type of post-operative care;
- The duration of recovery;
- The disposition of the patient upon discharge;
- A list of medications used during surgery and recovery; and
- Any adverse incidents.

Such log must be maintained for at least six years from the last patient contact and must be provided to DOH investigators upon request.[17]

For elective cosmetic and plastic surgery procedures performed in a physician's office:[18]

- The maximum planned duration of all planned procedures cannot exceed eight hours.
- A physician must discharge the patient within 24 hours, and overnight stay may not exceed 23 hours and 59 minutes.
- The overnight stay is strictly limited to the physician's office.
- If the patient has not sufficiently recovered to be safely discharged within the 24-hour period, the patient must be transferred to a hospital for continued post-operative care.

Levels of Office Surgeries

Level I

Level I involves the most minor of surgeries, which require minimal sedation[19] or local or topical anesthesia, and have a remote chance of complications requiring hospitalization.[20] Level I procedures include:[21]

- Minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas and repair of lacerations, or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient;
- Liposuction involving the removal of less than 4000cc supernatant fat; and
- Incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cystoscopic procedures, and closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints).

[17] *Id.*
[18] Rules 64B8-9.009(2)(f) and 64B15-14.007(2)(f), F.A.C.
[19] Minimal sedation is a drug-induced state during which the patient responds normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilator and cardiovascular functions are not impaired. Controlled substances are limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.
[20] Rules 64B8-9.009(3) and 64B15-14.007(3), F.A.C.
[21] *Id.*

Level II

Level II office surgeries involve moderate sedation[22] and require the physician office to have a transfer agreement with a licensed hospital that is no more than 30 minutes from the office.[23] Level II office surgeries, include but are not limited to:[24]

- Hemorrhoidectomy, hernia repair, large joint dislocations, colonoscopy, and liposuction involving the removal of up to 4,000cc supernatant fat; and
- Any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation.

A physician performing a Level II office surgery must:[25]

- Have staff privileges at a licensed hospital to perform the same procedure in that hospital as the surgery being performed in the office setting;
- Demonstrate to the appropriate board that he or she has successfully completed training directly related to and include the procedure being performed, such as board certification or eligibility to become board-certified; or
- Demonstrate comparable background, training or experience.

A physician, or a facility where the procedure is being performed, must have a transfer agreement with a licensed hospital within a reasonable proximity[26] if the physician performing the procedure does not have staff privileges to perform the same procedure at a licensed hospital within a reasonable proximity.

Anesthesiology must be performed by an anesthesiologist, a certified registered nurse anesthetist (CRNA), or a qualified physician assistant (PA). An appropriately-trained physician, PA, or registered nurse with experience in post-anesthesia care, must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia.[27]

Level IIA

Level IIA office surgeries are those Level II surgeries with a maximum planned duration of five minutes or less and in which chances of complications requiring hospitalization are remote.[28] A physician, physician assistant, registered nurse, or licensed practical nurse must assist the surgeon during the procedure and monitor the patient in the recovery room until the patient is recovered from anesthesia.[29] The assisting health care practitioner must be appropriately certified

[22] Moderate sedation or conscious sedation is a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulations. No interventions are needed to manage the patient's airway and spontaneous ventilation is adequate. Cardiovascular function is maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response.
[23] Rules 64B8-9.009(4) and 64B15-14.007(4), F.A.C.
[24] *Id.*
[25] *Id.*
[26] Transport time to the hospital must be 30 minutes of less.
[27] *Id.* The assisting practitioner must be trained in advanced cardiovascular life support, or for pediatric patients, pediatric advanced life support.
[28] Rules 64B-9.009(5) and 64B15-14.007(5), F.A.C.
[29] *Id.*

in advanced cardiac life support, or in the case of pediatric patients, pediatric advanced life support.[30]

Level III

Level III office surgeries are the most complex and require deep sedation or general anesthesia.[31] A physician performing the surgery must have staff privileges to perform the same procedure in a hospital.[32] The physician must also have knowledge of the principles of general anesthesia.

Only patients classified under the American Society of Anesthesiologist's (ASA) risk classification criteria as Class I or II[33] are appropriate candidates for Level III office surgery. For all ASA Class II patients above the age of 50, the surgeon must obtain a complete workup performed prior to the performance of Level III surgery in a physician office setting.[34] If the patient has a cardiac history or is deemed to be a complicated medical patient, the patient must have a preoperative EKG and be referred to an appropriate consultant for medical optimization. The referral to a consultant may be waived after evaluation by the patient's anesthesiologist.[35] All Level III surgeries on patients classified as ASA III[36] and higher must be performed in a hospital or an ambulatory surgery center.

During the procedure, the physician must have one assistant who has current certification in advanced cardiac life support. Additionally, the physician must have emergency policies and procedures related to serious anesthesia complications, which address:

- Airway blockage (foreign body obstruction);
- Allergic reactions;
- Bradycardia;
- Bronchospasm;
- Cardiac arrest;

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[30] *Id.*

[31] Deep sedation is a drug-induced depression of consciousness during which a patient cannot be easily aroused but responds purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. A patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. General anesthesia is a drug-induced loss of consciousness during which a patient is not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. The use of spinal or epidural anesthesia is considered Level III.

[32] Rules 64B8-9.009(6) and 64B15-14.007(6), F.A.C. The physician may also document satisfactory completion of training directly related to and include the procedure being performed.

[33] An ASA Class I patient is a normal, healthy, non-smoking patient, with no or minimal alcohol use. An ASA Class II patient is a patient with mild systemic disease without substantive functional limitations. Examples include current smoker, social alcohol drinker, pregnancy, obesity, well-controlled hypertension with diabetes, or mild lung disease. *See* American Society of Anesthesiologists, *ASA Physical Status Classification System*, (Oct. 15, 2014, last amended Dec. 13, 2020), available at https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system (last visited on March 21, 2023).

[34] *Id.*

[35] *Id.*

[36] An ASA Class III patient is a patient with severe systemic disease who has substantive functional limitations and/or one or more moderate to severe diseases. This may include poorly controlled diabetes or hypertension, chronic obstructive pulmonary disease, morbid obesity, active hepatitis, alcohol dependence or abuse, implanted pacemaker, premature infant, recent history of myocardial infarction, cerebrovascular disease, transient ischemic attack, or coronary artery disease.

- Chest pain;
- Hypoglycemia;
- Hypotension;
- Hypoventilation;
- Laryngospasm;
- Local anesthetic toxicity reaction; and
- Malignant hypothermia.

Adverse Incident Reporting

A physician must report any adverse incident that occurs in an office practice setting to DOH within 15 days after the occurrence any adverse incident.[37] An adverse incident in an office setting is defined 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:[38]

- 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.

The DOH must review each adverse incident report to determine if discipline against the practitioner's license is warranted.[39]

III. Effect of Proposed Changes:

Background Screening

CS/SB 1596 amends ss. 408.809 and 435.04, F.S., to add to the lists of disqualifying offenses in those sections. The following offenses are added to s. 408.809, F.S., for violations of:

- Section 414.39, F.S., relating to fraud, if the offense was a felony.
- Section 815.04, F.S., relating to offenses against intellectual property.

[37] Sections 458.351 and 459.026, F.S.
[38] Sections 458.351(4) and 459.026(4), F.S.
[39] Sections 458.351(5) and 459.026(5), F.S.

- Section 815.06, F.S., relating to offenses against users of computers, computer systems, computer networks, and electronic devices.
- Section 831.29, F.S., relating to making or having instruments and material for counterfeiting driver licenses or identification cards.
- Section 831.311, F.S., relating to unlawful sale, manufacture, alteration, delivery, uttering, or possession of counterfeit-resistant prescription blanks for controlled substances.
- Section 836.05, F.S., relating to threats and extortion.
- Section 836.10, F.S., relating to written or electronic threats to kill or do bodily injury or conduct a mass shooting or an act of terrorism.
- Section 873.01, F.S., relating to the prohibited purchase or sale of human organs and tissue.

The following offenses are added to s. 435.04, F.S., for violations of:
- Section 39.205, F.S., relating to failure to report child abuse, abandonment, or neglect.
- Section 316.193(3)(c)3., F.S., relating to DUI manslaughter.
- Section 787.06, F.S., relating to human trafficking.
- Section 787.07, F.S., relating to human smuggling.
- Section 790.166, F.S., relating to the manufacture, possession, sale, delivery, display, use, or attempted or threatened use of weapons of mass destruction or hoax weapons of mass destruction.
- Section 838.015, F.S., relating to bribery.
- Section 859.01, F.S., relating to poisoning food or water.
- Section 873.01, F.S., relating to the prohibited purchase or sale of human organs and tissue.
- Section 876.32, F.S., relating to treason.
- Section 951.22, F.S., relating to county detention facilities and contraband articles.

Unlicensed Activity

The bill amends s. 408.812, F.S., to add a new cause of action for an ex parte injunction against continued unlicensed activity. The bill specifies that the AHCA may petition the circuit court for an ex parte injunction against continued unlicensed activity when AHCA personnel have verified, through an onsite inspection, that a person or entity is advertising, offering, or providing services for which licensure is required under this part and applicable statutes and such person or entity has previously received notification from the AHCA to discontinue such activity.

A sworn petition seeking the issuance of an ex parte injunction against continued unlicensed activity must include:
- The location of the unlicensed activity;
- The ownership and operators of the unlicensed provider;
- Identification of the service provider type for which licensure is required under the applicable statutes;
- Specific facts supporting the conclusion that the respondent engaged in unlicensed activity, specifying the date, time, and location at which the unlicensed provider was notified to discontinue such activity;
- Whether the respondent prohibited the agency from conducting a subsequent investigation to determine compliance;
- Any previous injunctive relief granted against the respondent; and

- Any previous AHCA determinations that the respondent was previously identified as engaging in unlicensed activity.

The bill prohibits a bond from being required by the court for the issuance of the injunction and also prohibits, except as provided in s. 90.204,[40] F.S., evidence being used at the hearing other than verified pleadings or affidavits by AHCA personnel or others with first-hand knowledge of the alleged unlicensed activity, unless the respondent appears at the hearing. Any denial of a petition must be by written order noting the legal grounds for denial. The bill specifies that nothing in the subsection affects the AHCA's right to promptly amend any petition or otherwise be heard in person consistent with the Florida Rules of Civil Procedure.

Should the court find that the respondent is engaged in unlicensed activity, the bill allows the court to grant an ex parte temporary injunction, pending a full hearing, and other relief the court deems appropriate such as an injunction restraining the respondent from advertising, offering, or providing services for which licensure is required under this part and applicable statutes, and requiring the respondent to provide agency personnel full access to facility personnel, records, and clients for a future inspection of the premises. An ex parte injunction must be effective for a fixed period not to exceed 30 days and must be served by the sheriff of the county in which the respondent's activities are conducted.

The AHCA is required to inspect the premises within 20 days after the injunction is issued to verify the respondent's compliance with the injunction. If the respondent is found to have complied with the temporary injunction, the AHCA must voluntarily dismiss its injunction action. If the AHCA finds that unlicensed activity has continued in apparent violation of the temporary injunction, the AHCA may file a petition for permanent injunction within 10 days after such discovery, at which time a full hearing must be set as soon as practicable. Contemporaneous with the filing of a petition for permanent injunction, the AHCA may move for an extension of the ex parte injunction until disposition of the permanent injunction proceedings.

The bill specifies that:
- Remedies provided in the bill are not exclusive but a supplement to any other administrative or criminal remedies for unlicensed activity;
- The AHCA is not required to exhaust its administrative remedies before seeking the injunctive relief provided by this subsection; and
- The AHCA may provide any records of its inspections to local law enforcement agencies or state attorney offices upon request and without redaction.

Residents' Rights in Nursing Homes

The bill amends s. 400.022, F.S., to add that a resident in a nursing home has the right to be free from sexual abuse, neglect, and exploitation.

[40] Relating to the determination of propriety of judicial notice and nature of matter noticed.

Office Surgeries

The bill amends ss. 458.328 and 459.0138, F.S., which regulate office surgeries under the Medical Practice Act and the Osteopathic Medicine Practice Act, respectively. The bill provides that:

- A physician office seeking registration must be inspected by the DOH before the office may be registered.
- If a registered office refuses any subsequent inspection required by the DOH, the office's registration must be immediately suspended and may not be reinstated before completion of an inspection by the DOH.
- Physicians performing gluteal fat grafting procedures in an office surgery setting must adhere to standards of practice provided under the bill, including:
    - An office in which a physician performs gluteal fat grafting procedures must at all times maintain a ratio of one physician to one patient during all phases of the procedure, beginning with the administration of anesthesia to the patient and concluding with the extubation of the patient.
    - A physician is not limited in the number of gluteal fat grafting procedures that he or she may safely perform in accordance with the applicable standard of care and as prescribed in the bill; however, after a physician has commenced, and while he or she is engaged in, a gluteal fat grafting procedure, the physician may not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.
    - Before a physician may delegate any duties during a gluteal fat grafting procedure, the patient must provide written, informed consent to such delegation.
    - Any duties delegated during a gluteal fat grafting procedure must be performed under the direct supervision of the physician performing the procedure.
    - Gluteal fat extractions and injections must be performed by the physician performing the procedure and may not be delegated.
    - Gluteal fat may be injected only into the subcutaneous space of the patient and may not cross the fascia overlying the gluteal muscle. Intramuscular and submuscular fat injections are prohibited.
    - When the physician performing a gluteal fat grafting procedure injects gluteal fat into the subcutaneous space of the patient, the physician must use ultrasound guidance during the placement and navigation of a cannula to ensure that the fat is placed into the subcutaneous space of the patient above the fascia overlying the gluteal muscle. Ultrasound guidance is not required for other portions of the procedure.

The bill authorizes the boards to adopt rules to prescribe additional requirements for the safe performance of gluteal fat grafting procedures, provided such rules do not conflict with the standards created under the bill.

The bill also provides standards of practice that apply to all surgeries performed in a registered office. Under the bill, surgeries performed in an office registered by the DOH may not:

- Result in blood loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin level;
- Require major or prolonged intracranial, intrathoracic, abdominal, or joint replacement procedures, except for laparoscopic procedures;

- Involve major blood vessels performed with direct visualization by open exposure of the major blood vessel, except for percutaneous endovascular intervention; or
- Be emergent or life threatening.

Effective date

The bill provides an effective date of July 1, 2023.

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:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 1596 may have a negative fiscal impact on a person who is employed, or is seeking employment, with a provider and who would fail a background screening based on one of the added disqualifying offenses if the person would not have failed such background screening otherwise.

Physician offices registered with the DOH for the performance of office surgeries may incur indeterminate costs to comply with the standards of practice created by the bill.

C. Government Sector Impact:

The AHCA's analysis of SB 1596 does not indicate that the bill will have a fiscal impact on the AHCA.[41]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 400.022, 408.809, 408.812, 435.04, 458.328, and 459.0138.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 27, 2023:
The CS adds to the bill new requirements for physician offices registered with the DOH for the performance of office surgeries and new standards of practice for surgeries performed in such settings.

B. Amendments:

None.

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

[41] *Supra* n. 3