HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 1471 Health Care Provider Accountability
SPONSOR(S): Health & Human Services Committee, Healthcare Regulation Subcommittee, Busatta Cabrera
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee	15 Y, 0 N, As CS	Poche	McElroy
2) Health Care Appropriations Subcommittee	13 Y, 0 N	Smith	Clark
3) Health & Human Services Committee	19 Y, 0 N, As CS	Poche	Calamas

SUMMARY ANALYSIS

CS/CS/HB 1471 encompasses several areas of health care provider accountability.

Section 400.022, F.S., establishes an extensive list of resident rights that a nursing home must afford to its residents. The list includes, but is not limited to, the right to civil and religious liberties, the right to participate in social and other activities that do not impact other residents' rights, and the right to refuse medication and treatment. The bill adds to the list of nursing home residents' rights the right to be free from sexual abuse, neglect, and exploitation.

The bill authorizes the Agency for Health Care Administration (AHCA) to seek an ex parte temporary injunction to prevent continuing unlicensed activity by a provider who has been warned by the agency to cease such unlicensed activity. The bill establishes the temporary injunction process, including petition requirements, subsequent inspections to determine compliance, and a permanent injunction process if the provider is not complying with the ex parte temporary injunction. This applies to any entity licensed by AHCA.

The bill establishes standards of practice for physicians performing gluteal fat grafting procedures in office settings. The bill prohibits certain procedures in an office surgery setting, sets standards for performing such grafting procedures, and includes inspection requirements to become registered to perform such office surgeries.

The bill has an indeterminate, negative fiscal impact on AHCA and the Department of Health that can be absorbed within existing resources. The bill has no fiscal impact on local government.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Nursing Home Residents' Rights

Section 400.022, F.S., establishes rights that a nursing home must afford to each of its residents. The section requires that all nursing home facilities adopt and make public a statement of the rights and responsibilities of the residents and treat such residents in accordance with the provisions of that statement. The statement must assure each resident has or receives:

- The right to civil and religious liberties.
- The right to private and uncensored communication.
- Any entity or individual that provides health, social, legal, or other services to a resident has the right to have reasonable access to the resident. The resident has the right to deny or withdraw consent to access at any time by any entity or individual. Notwithstanding the visiting policy of the facility, the section specifies that certain individuals, including immediate family members and regulatory personnel, must be permitted immediate access to the resident.
- The right to present grievances on behalf of himself or herself 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.
- The right to organize and participate in resident groups in the facility and the right to have the resident's family meet in the facility with the families of other residents.
- The right to participate in social, religious, and community activities that do not interfere with the rights of other residents.
- The right to 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.
- The right to manage his or her 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 the resident.
- The right to be fully informed, in writing and orally, prior to or at the time of admission and during his or her stay, of services available in the facility and of related charges for such services.
- The right to be adequately informed of his or her medical condition and proposed treatment, unless the resident is 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 the resident's well-being; and, except with respect to a resident adjudged incompetent, the right to participate in the planning of all medical treatment, including the right to refuse medication and treatment, unless otherwise indicated by the resident's physician; and to know the consequences of such actions.
- The right to refuse medication or treatment and to be informed of the consequences of such decisions, unless determined unable to provide informed consent under state law.
- The right to 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 the resident care plan, with established and recognized practice standards within the community, and with rules as adopted by the Agency for Health Care Administration (AHCA).
- The right to 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.

- The right to 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.
- The right to 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.
- The right to be transferred or discharged only for medical reasons or for the welfare of other residents, and the right to be given reasonable advance notice of no less than 30 days of any involuntary transfer or discharge, with certain exceptions.
- The right to freedom of choice in selecting a personal physician; to obtain pharmaceutical supplies and services from a pharmacy of the resident's choice; and to obtain information about, and to participate in, community-based activities programs, unless medically contraindicated as documented by a physician in the resident's medical record.
- The right to 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 in the resident's medical record by a physician.
- The right to have copies of the rules and regulations of the facility and an explanation of the responsibility of the resident to obey all reasonable rules and regulations of the facility and to respect the personal rights and private property of the other residents.
- The right to receive notice before the room of the resident in the facility is changed.
- The right to be informed of the bed reservation policy for a hospitalization.
- For residents of Medicaid or Medicare certified facilities, the right to challenge a decision by the facility to discharge or transfer the resident, as required under 42 C.F.R. s. 483.12.

Each nursing home must orally inform the resident of the resident's rights and provide a copy of the statement to each resident or the resident's legal representative at or before the resident's admission to a facility and to each staff member of the facility. Each licensee must prepare a written plan and provide appropriate staff training to implement the provisions of the section.

The written statement of rights must include a statement that a resident may file a complaint with the Agency for Health Care Administration (AHCA) or state or local ombudsman council. The statement must be in boldfaced type and include the telephone number and e-mail address of the State Long-Term Care Ombudsman Program and the telephone numbers of the local ombudsman council and the Elder Abuse Hotline operated by the Department of Children and Families. The section specifies that any violation of the resident's rights constitutes grounds for licensure action.

Also, in order to determine whether the licensee is adequately protecting residents' rights, the licensure inspection of the facility must include private informal conversations with a sample of residents to discuss residents' experiences within the facility with respect to rights specified in this section and general compliance with standards and consultation with the State Long-Term Care Ombudsman Program. Any person who submits or reports a complaint concerning a suspected violation of the resident's rights or concerning services or conditions in a facility or who testifies in any administrative or judicial proceeding arising from such complaint will have immunity from any criminal or civil liability for that report, unless that person acted in bad faith, with malicious purpose, or if the court finds that there was a complete absence of a justiciable issue of either law or fact raised by the losing party.

In addition to the rights listed in s. 400.022, F.S., federal law establishes rights for residents in Medicaid and Medicare certified nursing homes. Many of the rights mirror rights established in s. 400.022, F.S. In general, federal law guarantees the right to:

- Be treated with respect;
- Participate in activities;
- Be free from discrimination;
- Be free from abuse and neglect;
- Be free from restraints;
- Make complaints;

- Get proper medical care (including choosing one's own personal physician);
- Have representatives notified of certain occurrences;
- Get information on services and fees;
- Manage one's own money;
- Have proper privacy, property, and living arrangements;
- Spend time with visitors;
- Get social services;
- Leave the nursing home;
- Have protection against unfair transfers and discharges;
- Form or participate in resident groups; and
- Include family and friends.[1]

This is an extensive list of rights to which nursing home residents are guaranteed, including the right to be free from abuse and neglect. However, the list does not include express rights to be free from sexual abuse, exploitation, or neglect.

Ex Parte Temporary Injunctions

An injunction is a court order prohibiting someone from doing a specified act or commanding someone to undo some wrong or injury.[2] A temporary injunction may be granted without written or oral notice to the adverse party only if:

- it appears from the specific facts shown by affidavit or verified pleading that immediate and irreparable injury, loss, or damage will result to the movant before the adverse party can be heard in opposition; and
- the movant's attorney certifies in writing any efforts that have been made to give notice and the reasons why notice should not be required.[3]

No evidence other than the affidavit or verified pleading can be used to support the application for a temporary injunction unless the adverse party appears at the hearing or has received reasonable notice of the hearing. Every temporary injunction granted without notice shall be endorsed with the date and hour of entry and shall be filed forthwith in the clerk's office and shall define the injury, state findings by the court why the injury may be irreparable, and give the reasons why the order was granted without notice if notice was not given. The temporary injunction shall remain in effect until the further order of the court.[4]

Every injunction shall specify the reasons for entry, shall describe in reasonable detail the act or acts restrained without reference to a pleading or another document, and shall be binding on the parties to the action, their officers, agents, servants, employees, and attorneys and on those persons in active concert or participation with them who receive actual notice of the injunction.[5]

A petition for temporary injunction is immediately presented to a judge, who must review the petition. If the petition is facially sufficient, the petition and related documents become public record. If it appears to a court that an immediate and present danger exists, it may grant a temporary injunction ex parte.[6] A hearing must be set at the earliest possible time after a petition is filed and the respondent must be personally served with a copy of the petition.[7] The court may grant such relief as it deems proper.[8]

[1] 42 CFR s. 483.10; for a summary of these rights please see: Your Rights and Protections as a Nursing Home Resident, Centers for Medicare and Medicaid Services, available at https://downloads.cms.gov/medicare/your_resident_rights_and_protections_section.pdf (last viewed on April 5, 2023).
[2] Black's Law Dictionary 540 (6th ed. 1995).
[3] Fla. R. Civ. P. 1.610(a)(1)
[4] Fla. R. Civ. P. 1.610(a)(2)
[5] Fla. R. Civ. P. 1.610(c)
[6] The judge may issue a temporary injunction based solely on information provided by the petitioner.
[7] S. 741.30(4), F.S.
[8] S. 741.30(5), F.S.

Temporary injunctions cannot exceed 15 days.[9] The court may grant a continuance of the hearing for good cause, which may include obtaining service of process.[10] A temporary injunction must be extended, if necessary, during any period of continuance.[11]

Current Florida law establishes a cause of action for an ex parte temporary injunction in several criminal situations, such as domestic violence[12]; repeat violence, sexual violence, and dating violence[13]; child abuse[14]; stalking and cyberstalking[15]; and exploitation of a vulnerable adult.[16]

Current law authorizes AHCA or any state attorney to bring an action for an injunction to restrain unlicensed activity. However, such an injunction requires notice to an offending party, and follows a procedure that can take time to result in an issued injunction. In cases where unlicensed activity continues, despite notice from the agency to cease such activity, it presents an emergency situation that threatens the health, safety, and welfare of persons, and the current injunction process may allow such an emergency situation to remain in effect without any sufficient protection of the population.

Regulation of Office Surgeries

The Board of Medicine and the Board of Osteopathic Medicine (collectively, boards) have authority to adopt rules to regulate practice of medicine and osteopathic medicine, respectively.[17] The boards have authority to establish, by rule, standards of practice and standards of care for particular settings.[18] 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.[19]

The boards set forth the standards of care 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.[20] There are several levels of office surgeries governed by rules adopted by the boards, which 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 DOH.[21] 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.[22] The registration requires a physician to document compliance with transfer agreement[23] and training requirements. DOH must annually inspect registered offices or the office must be accredited by a national accreditation

[9] S. 741.30(5)(c), F.S.
[10] Id.
[11] Id.
[12] S. 741.30, F.S.
[13] S. 784.046, F.S.
[14] S. 39.504, F.S.
[15] S. 784.0485, F.S.
[16] S. 825.1035, F.S.
[17] Chapter 458, F.S., regulates the practice of allopathic medicine, and ch. 459, F.S., regulates the practice of osteopathic me dicine.
[18] Ss. 458.331(v) and 459.015(z), F.S.
[19] Id.
[20] 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 residen tial treatment programs.
[21] SS. 458.309(3) and 459.005(2), F.S., see also Rules 64B8-9.0091 and 64B15-14.0076, F.A.C.
[22] Rule 64B8-9.0091(1) and 64B15-14.0076(1), F.A.C.
[23] 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.

organization approved by the respective board.[24] Currently, there are 719 offices registered with DOH.[25]

Standards of Care

Prior to performing any surgery, a physician must evaluate the risk of anesthesia and of the surgical procedure to be performed.[26] A physician must maintain a complete record of each surgical procedure, including the anesthesia record, if applicable, and written informed consent.[27] 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.[28]

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:[29]

- 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;
- 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.[30]

For elective cosmetic and plastic surgery procedures performed in a physician's office:[31]

- 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

[24] Supra, FN 21.
[25] 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 (last visited April 5, 2023).
[26] Rules 64B8-9.009(2) and 64B15-14.007(2), F.A.C.
[27] Id. A physician does not need to obtain written informed consent for minor Level I procedures limited to the skin and mucosa.
[28] Id. A patient may use an anesthesiologist, anesthesiologist assistant, another appropriately trained physician, certified registered nurse anesthetist, or physician assistant.
[29] Rules 64B8-9.009(2)(a) and 64B15-14.007(2)(a), F.A.C.
[30] Id.
[31] Rules 64B8-9.009(2)(f) and 64B15-14.007(2)(f), F.A.C.

Level I involves the most minor of surgeries, which require minimal sedation[32] or local or topical anesthesia, and have a remote chance of complications requiring hospitalization.[33] Level I procedures include:[34]

- 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).

Level II

Level II office surgeries involve moderate sedation[35] and require the physician office to have a transfer agreement with a licensed hospital that is no more than 30 minutes from the office.[36] Level II office surgeries, include but is not limited to:[37]

- 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:[38]

- 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[39] if the physician performing the procedure does not have staff privileges to perform the same procedure at a licensed hospital within a reasonable proximity.[40]

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 RN with experience in post-anesthesia care, must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia.[41]

Level IIA

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[32] 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.

[33] Rules 64B8-9.009(3) and 64B15-14.007(3), F.A.C.

[34] Id.

[35] 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.

[36] Rules 64B8-9.009(4) and 64B15-14.007(4), F.A.C.

[37] Id.

[38] Id.

[39] Transport time to the hospital must be 30 minutes of less.

[40] Supra, FN 36.

[41] Id. The assisting practitioner must be trained in advanced cardiovascular life support, or for pediatric patients, pediatric advanced life support.

Level IIA office surgeries are those Level II surgeries with a maximum planned duration of 5 minutes or less and in which chances of complications requiring hospitalization are remote.[42] 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.[43] The assisting health care practitioner must be appropriately certified in advanced cardiac life support, or in the case of pediatric patients, pediatric advanced life support.[44]

Level III

Level III office surgeries are the most complex and require deep sedation or general anesthesia.[45] A physician performing the surgery must have staff privileges to perform the same procedure in a hospital.[46] 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[47] are appropriate candidates for Level III office surgery.[48] 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.[49] 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.[50] All Level III surgeries on patients classified as ASA III[51] and higher must be performed in a hospital or an ambulatory surgery center.[52]

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;
- Chest pain;
- Hypoglycemia;
- Hypotension;
- Hypoventilation;

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[42] Rules 64B-9.009(5) and 64B15-14.007(5), F.A.C.
[43] Id.
[44] Id.
[45] 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 imp aired. 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 ass istance 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 anesthes ia is considered Level III.
[46] 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.
[47] 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 April 5, 2023).
[48] Supra, FN 46.
[49] Id.
[50] Id.
[51] An ASA Class III patient is a patient with severe systemic disease who has substantive functional limitations and/or one or m ore moderate to severe diseases. This may include poorly controlled diabetes or hypertension, chronic obstructive pul monary disease, morbid obesity, active hepatitis, alcohol dependence or abuse, implanted pacemaker, premature infant, recent history of myoca rdial infarction, cerebrovascular disease, transient ischemic attack, or coronary artery disease.
[52] Supra, FN 46.

- 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.[53] 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:[54]

- 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.

DOH must review each adverse incident report to determine if discipline against the practitioner's license is warranted.[55]

Recent Statutory Changes

In 2019, the Legislature provided DOH and the boards additional enforcement authority for offices in which physicians perform certain liposuction procedures and office surgeries.[56]

Registration

Physicians must register offices where liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, Level II procedures lasting more than five minutes, and Level III office surgeries register with DOH. The 2019 law applies the registration requirement to the office where the surgical procedures are performed and makes all Level II office surgeries subject to the requirement and not just those surgeries lasting more than five minutes.

Each registered office must designate a physician who is responsible for complying with all laws and regulations establishing safety requirements for such offices. The designated physician must hold an active and unencumbered Florida license to practice medicine or osteopathic medicine, and must practice at the registered office. Within 10 days after termination of the designated physician, a registered office must notify DOH of the identity of a new designated physician. If a registered office does not have a designated physician, DOH may suspend its registration.

Each physician performing office surgery at a registered office must advise his or her respective board, in writing, within 10 days of beginning or ending practice at a registered office.

[53] Ss. 458.351 and 459.026, F.S.
[54] Ss. 458.351(4) and 459.026(4), F.S.
[55] Ss. 458.351(5) and 459.026(5), F.S.
[56] Ss. 458.328 and 459.0138, F.S.

DOH must inspect each registered office annually unless the office is accredited by a nationally recognized accrediting agency approved by the respective board. Such inspections may be unannounced.

Enforcement Authority

DOH may deny or revoke an office registration if any of its physicians, owners, or operators do not comply with any office surgery laws or rules. Also, DOH may deny a person applying for a facility registration if he or she was named in the registration document of an office whose registration is revoked for five years after the revocation date.

DOH may impose penalties on the designated physician if the registered office is not in compliance with safety requirements, including:[57]

- Suspension or permanent revocation of a license;
- Restriction of license;
- Imposition of an administrative fine not to exceed $10,000 for each count or separate offense. If the violation is for fraud or making a false or fraudulent representation, the board, or the department if there is no board, must impose a fine of $10,000 per count or offense.;
- Issuance of a reprimand or letter of concern.
- Placement of the licensee on probation for a period of time and subject to such conditions as the board;
- Corrective action;
- Imposition of an administrative fine in accordance with s. 381.0261 for violations regarding patient rights;
- Refund of fees billed and collected from the patient or a third party on behalf of the patient; or
- Requirement that the licensee undergo remedial education.

DOH can also issue an emergency order suspending or restricting the registration of a facility if there is probable cause that:

- The office or its physicians are not in compliance with the board rule on the standards of practice; or
- The licensee or registrant is practicing or offering to practice beyond the scope allowed by law or beyond his or her competence to perform; and
- Such noncompliance constitutes an immediate danger to the public.

The boards must adopt rules establishing the standards of practice for physicians who perform office surgery. The boards must fine physicians who perform office surgeries in an unregistered facility $5,000 per day. Lastly, performing office surgery in a facility that is not registered with DOH is grounds for disciplinary action against a physician's license.

Effect of Proposed Changes

CS/CS/HB 1471 encompasses several areas of health care provider accountability.

Nursing Home Residents' Rights

The bill adds, to the list of nursing home residents' rights, the right to be free from sexual abuse, neglect, and exploitation. By adding these rights, the bill allows licensure and Medicare certification disciplinary action against a nursing home facility for failing to protect a resident from these offenses. The enumerated nursing home residents' rights have also been used as the basis for civil litigation against nursing homes, alleging that a facility has failed to protect a resident's rights, leading to injury and damages. As a result, the rights added by the bill may also be used as the basis of future civil litigation.

Ex Parte Injunction Against Continued Unlicensed Activity

[57] S. 456.072(2), F.S.

The bill permits AHCA to petition a circuit court for an ex parte temporary injunction against continued unlicensed activity by a health care provider under chapter 408, F.S. A sworn petition seeking an ex parte temporary injunction must allege:

- The location of unlicensed activity,
- The owners and operators of the unlicensed provider,
- The type of services being provided that require a license, and
- Specific facts that support the conclusion that the unlicensed provider is engaged in unlicensed activity, including:
    - The date, time, and location at which the unlicensed provider was told to discontinue activity,
    - Whether the unlicensed provider prevented AHCA from conducting a follow up investigation to determine if the provider was engaged in unlicensed activity,
    - Any previous injunctive relief entered against the unlicensed provider, and
    - Any previous AHCA determination that the unlicensed provider was previously identified as engaging in unlicensed activity.
    - AHCA personnel have verified through an onsite inspection that the provider continues to advertise, offer, or provide services that require a license.

In a hearing for an ex parte temporary injunction, only verified pleadings or affidavits by AHCA personnel with firsthand knowledge of alleged unlicensed activity may be used, unless the respondent appears at the hearing. If the court determines that the unlicensed provider is engaged in unlicensed activity and has not abided by AHCA's notification to cease such activity, the court may grant the petition, pending a full hearing, for a period not to exceed 30 days. The court may also award relief it deems proper, including a temporary injunction to prevent the unlicensed provider from advertising, offering, or providing services that require a license, and requiring the unlicensed provider to give AHCA full access to personnel, records, and clients for future inspections. The grounds for denial of a petition for an ex parte temporary injunction must be in writing.

The bill requires AHCA to reinspect the unlicensed provider's premises within 20 days of obtaining the ex parte temporary injunction to verify the provider's compliance. If the unlicensed provider is found in compliance, AHCA must voluntarily dismiss the injunction. If the unlicensed provider is noncompliant, AHCA may file for a permanent injunction within 10 days of identifying the noncompliance, and a full hearing must be set by the court for as soon as practicable. Pending the full hearing, AHCA is authorized to apply for an extension of the ex parte temporary injunction until the hearing is held.

The bill specifically states that AHCA is not required to exhaust its' administrative remedies before seeking an ex parte temporary injunction. Lastly, the bill authorizes AHCA to provide any documents or other materials to local law enforcement or state attorney's office in the investigation of criminal violations by unlicensed activity.

Office Surgeries

The bill establishes standards of practice for physicians performing gluteal fat grafting procedures in office surgery settings. Office surgery is a surgery performed at an office that primarily serves as the doctor's office where he or she regularly performs consultations, presurgical exams, and postoperative observation and care, and where patient medical records are maintained and available.

The bill requires DOH to inspect any office where office surgeries will be done before the office is registered. If the office refuses such inspection, it will not be registered until the inspection can be completed. If an office that has already been registered with DOH refuses inspection its registration will be immediately suspended and remain suspended until the inspection is completed, and the office must close for 14 days. An ambulatory surgical center, defined in s. 395.002, F.S., a hospital, or an abortion clinic defined in s. 390.011, F.S., may not register as an office for purposes of performing office surgeries under this section.

A physician providing such fat grafting procedures must adhere to the standards of practice in statute and in rule, and the boards may not adopt rules that conflict with statutory requirements. Further, the bill requires a physician performing such procedures to be a board-eligible or board-certified plastic surgeon.

The bill requires that any duty delegated by the physician and performed during the gluteal fat grafting procedure must be completed under the direct supervision of the physician. Gluteal fat injections may not be delegated, and must be done under ultrasound guidance to ensure the fat is injected into the subcutaneous space. Gluteal fat may only be injected into the subcutaneous space and may not cross the fascia covering gluteal muscle. Intramuscular and submuscular fat injections are prohibited.

If any procedure results in hospitalization, the type of procedure and the location where the procedure was performed must be included in the hospital intake form for purposes of adverse incident reporting.

The bill prohibits office surgeries from:

- Resulting in blood loss greater than 10 percent of blood volume in a patient with normal hemoglobin;
- Requiring major or prolonged intracranial, intrathoracic, abdominal, or joint replacement procedures, excluding laparoscopy;
- Involving a major blood vessel with direct visualization by open exposure of the vessel, not including percutaneous endovascular treatment[58]; or
- Being emergent or life threatening.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 400.022, F.S., relating to residents' rights.
Section 2: Amends s. 408.812, F.S., relating to unlicensed activity.
Section 3: Amends s. 458.328, F.S., relating to office surgeries.
Section 4: Amends s. 459.0138, F.S., relating to office surgeries.
Section 5: Provides an effective date of July 1, 2023.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill will have an indeterminate, negative fiscal impact on AHCA for bringing ex parte temporary injunctions to prevent continued unlicensed activity, and prosecuting permanent injunctions, as necessary. In addition, the bill will have an indeterminate negative fiscal impact on DOH due to updating internal systems and board websites. The fiscal impact on AHCA and DOH from provisions in the bill can be absorbed within existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

[58] Such treatment addresses conditions such a peripheral artery disease and other arterial blockages.

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may have an indeterminate, negative impact on physicians who wish to perform office surgeries due to administrative compliance with inspection and registration requirements, and complying with delegation restrictions for gluteal fat grafting procedures.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not impact municipal or county governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

AHCA and DOH have sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On March 28, 2023, the Healthcare Regulation Subcommittee adopted one amendment and reported the bill favorably as a committee substitute. The amendment removed the sections of the bill that proposed additional disqualifying offenses for purposes of background screening for employment at a facility licensed under chapter 408, F.S., and for purposes of level 2 background screenings under chapter 435, F.S.

On April 17, 2023, the Health and Human Services Committee adopted one amendment and reported the bill favorable as a committee substitute. The amendment:

- Streamlined the ex parte temporary injunction process.
- Streamlined the office surgery standards of care for gluteal fat grafting procedures performed by physicians licensed under chapter 458 or chapter 459.
- Required gluteal fat grafting procedures to be done by a board-eligible or board-certified plastic surgeon.
- Required DOH to inspect an office surgery facility prior to registration.

- Authorized DOH to suspend an office surgery facility registration upon refusal to allow an inspection, which remains in effect until DOH completes the inspection.
- Required a 14-day closure for an office which refuses to allow DOH to inspect its premises.

The analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.