A bill to be entitled

An act relating to licensure of medical spas; creating s. 381.9811, F.S.; providing a short title; providing legislative findings and purpose; providing definitions; requiring medical spas to be licensed under certain circumstances; providing licensure requirements; requiring the Board of Pharmacy to maintain a public database of licensed medical spas; providing database requirements; providing that a medical spa is a dispenser; prohibiting a medical spa from acquiring or receiving certain prescription medications; providing storage requirements for prescription medications and certain devices; requiring medical spas to have certain security controls; requiring medical spas to designate a responsible person; providing requirements for a responsible person; providing that submission of an application for licensure by a medical spa constitutes permission for inspections; providing requirements for inspections; requiring medical spas to notify the board of any adverse incidents within a specified timeframe; providing notice requirements; providing that a violation of specified provisions constitutes an unfair and deceptive trade practice; authorizing the board to investigate certain violations and

provide penalties; requiring the board to adopt rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 381.9811, Florida Statutes, is created to read:

381.9811 Licensure of medical spas.—

(1) SHORT TITLE.—This section may be cited as the "Medical Spa Prescription Drug Oversight Act."

(2)(a) FINDINGS AND PURPOSE.—The Legislature finds that patients are increasingly turning to medical spas for cosmetic and medical procedures. Many of these medical spas prepare and administer prescription medications intended to be sterile, either compounded or commercially available formulations, with no regulatory oversight by the Board of Pharmacy, which raises significant patient safety concerns.

(b) The purpose of this section is to license a medical spa that prepares, handles, stores, administers, dispenses, distributes, or otherwise uses prescription medications at the medical spa or in connection with providing services.

(3) DEFINITIONS.—As used in this section, the term:

(a) "Adverse event" means any untoward medical occurrence associated with the use of a prescription medication, whether or not the event itself is considered prescription medication-

related.

(b) "Board" means the Board of Pharmacy.

(c) "Medical spa" means any facility or practice that offers medical or health care services and that holds itself out as a facility or practice focused on cosmetic or lifestyle treatments, such as weight loss, wellness, longevity, or cosmetic or aesthetic health care services, including, but not limited to, the preparation, administration, or dispensing of prescription drugs for weight loss; botulinum toxin injections; hormone therapies; or parenteral nutrient therapies. The term does not include a facility or practice that otherwise holds a health care facility license from the state.

(d) "Person" means an individual, a corporation, a government, a governmental subdivision or agency, a statutory trust, a business trust, an estate, a trust, a partnership, or an unincorporated association, or one or more of the foregoing having a joint or common interest, or any other legal or commercial entity.

(e) "Prescription medication" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined in, or described in s. 503(b) of the Federal Food, Drug, and Cosmetic Act or in s. 465.003, s. 499.003(17), s. 499.007(13), or s. 499.82(10). The term includes any biological product, except for blood and blood components intended for transfusion or biological products that are also

medical devices.

(f) "Responsible person" means a licensed healthcare provider with supervising authority at a medical spa.

(g) "Serious adverse event" means an adverse event or suspected adverse reaction that results in death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly or birth defect. The term includes events that may be considered serious when, based upon appropriate medical judgment, such events may jeopardize the patient's health and may require medical or surgical intervention to prevent one of the outcomes listed in this paragraph.

(h) "Suspected adverse reaction" means any adverse event for which there is a reasonable possibility that a prescription medication caused such event.

(4) LICENSURE.—

(a) Each medical spa location that prepares, handles, stores, administers, dispenses, distributes, or otherwise uses prescription medication at its facility or in connection with providing services must obtain and maintain a license from the board.

(b) Failure to obtain a license or comply with any requirements in this section may result in disciplinary action,

including, but not limited to, fines, suspension, or revocation of the license.

(c) The board shall maintain a public database of each medical spa licensed by this state. The database shall include, at a minimum, the name, address, and license number of each medical spa and the name and license number of the responsible person.

(5) PRESCRIPTION MEDICATIONS.—

(a) A licensed medical spa is a dispenser under s. 581(3)(A) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C., and shall comply with the requirements provided in s. 582 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 360eee-1.

(b) A licensed medical spa may only acquire or receive prescription medication from any person who holds the license, registration, permit, or other authorization required to distribute or otherwise transfer such prescription medication.

(c)1. Prescription medications, and active pharmaceutical ingredients for use in such medications, and devices shall be stored in areas that are dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Prescription medications shall be stored in accordance with specific storage requirements for controlled substances and medications, consistent with the label and instructions for use of the prescription medication.

2. Noncontrolled prescription medications and hypodermic

syringes, needles, and other objects used, intended for use, or designed for use in parenterally injecting controlled substances into the human body shall be maintained under appropriate supervision and control at all times.

(d) A licensed medical spa shall have security controls and procedures to deter and detect the theft and diversion of prescription drugs. The security and control of prescription drugs is the responsibility of both the responsible person and the medical spa.

(6) RESPONSIBLE PERSON.—

(a) Each licensed medical spa shall have a designated responsible person. The board may approve a responsible person to be the responsible person at more than one location.

(b) The responsible person shall be physically present at the medical spa location for a sufficient amount of time to perform his or her responsibilities.

(c) The responsible person must ensure the medical spa is in compliance with this section.

(7) INSPECTIONS.—Submission of an application for a license by a medical spa constitutes permission for entry and onsite inspection by the board or a third party approved by the board. Such inspection will occur in connection with initial licensure and as determined by the board. Refusal to allow the board or third-party access to conduct an inspection is a violation of this section.

(8) ADVERSE INCIDENTS.—

(a) A licensed medical spa shall notify the board within 5 business days after the occurrence of a serious adverse event.

(b) The notice shall include, to the extent such information is obtained by or reasonably available to the medical spa from any source, the date, the nature, and the location of the adverse event and medical spa records of patients directly affected by the serious adverse event.

(9) DECEPTIVE AND UNFAIR TRADE PRACTICES.—A licensed medical spa engages in deceptive and unfair trade practices, in violation of the Florida Deceptive and Unfair Trade Practices Act, when, in the course of business, the medical spa misrepresents a prescription medication as having:

(a) A particular standard, quality, or grade;

(b) Sponsorship, approval, characteristics, ingredients, uses, or benefits;

(c) A function similar to a drug approved by the federal Food and Drug Administration; or

(d) Approval from the federal Food and Drug Administration.

(10) INVESTIGATIONS AND PENALTIES.—

(a) The board shall enforce this section, including actions for which a license is required under this section when a medical spa has failed to obtain a license. If the board has or receives information that any provision of this section has

been violated, the board shall investigate and take appropriate action.

(b) Violations include, but are not limited to, all of the following:

1. Violations of the practice of pharmacy as provided under chapter 465;

2. Violations of any rule or regulation of the board;

3. Violations that pose a threat to the public health, as determined by the board;

4. Engaging or attempting to engage in the possession, sale, or distribution of controlled substances as set forth in chapter 893, for any other than legitimate purposes authorized by this section; or

5. Violations of any provision of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), 21 U.S.C. ss. 301 et seq. or 21 U.S.C. ss. 801-971.

(c) The board shall maintain a public record of disciplinary actions involving medical spas, subject to transparency and confidentiality laws.

(11) RULES.—The board shall adopt rules to implement this section within 6 months after this section takes effect.

Section 2. This act shall take effect upon becoming a law.