

STATE OF FLORIDA
AGENCY FOR HEALTH CARE ADMINISTRATION

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STATE OF FLORIDA, AGENCY FOR
HEALTH CARE ADMINISTRATION,

Petitioner,

AHCA No: 2023004166

v.

License No. 894

File No. 20

MEDICAL DEVELOPMENT CORPORATION
OF PASCO COUNTY,

Provider Type: Ambulatory Surgical Center

Respondent.

EMERGENCY SUSPENSION ORDER

THIS CAUSE came on for consideration before the Secretary of the Agency for Health Care Administration, or his duly appointed designee, who after careful review of the matter at hand and being otherwise fully advised, finds, and concludes as follows:

THE PARTIES

1. The Agency for Health Care Administration (hereinafter “the Agency”), is the licensure and regulatory authority that oversees ambulatory surgical centers in Florida and enforces the applicable state statutes and rules governing ambulatory surgical centers. Chs. 395, Part I and 408, Part II, Fla. Stat. (2022), Ch. 59A-5, Fla. Admin. Code. As part of its statutory oversight responsibilities, the Agency has the authority to impose emergency orders, including a limitation of license, a moratorium on admissions and an emergency suspension order, when circumstances dictate such action. §§ 120.60(6), 408.814, Fla. Stat. (2022).

2. The Respondent, Medical Development Corporation of Pasco County (hereinafter “the Respondent”), was issued a license (License Number 894) by the Agency to operate an ambulatory surgical center (hereinafter “the Facility”) located at 7315 Hudson Avenue, Hudson, Florida 34667, and was at all material times required to comply with the statutes and rules

governing such facilities.

3. As the holder of such a license, the Respondent is a licensee. “Licensee” means “an individual, corporation, partnership, firm, association, or governmental entity, or other entity that is issued a permit, registration, certificate, or license by the Agency.” § 408.803(9), Fla. Stat. (2022). “The licensee is legally responsible for all aspects of the provider operation.” § 408.803(9), Fla. Stat. (2022). “Provider” means “any activity, service, agency, or facility regulated by the Agency and listed in Section 408.802,” Florida Statutes (2022). § 408.803(12), Fla. Stat. (2022). Ambulatory surgical centers are regulated by the Agency under Chapter 429, Part I, Florida Statutes (2022), and listed in Section 408.802, Florida Statutes (2022). § 408.802(9), Fla. Stat. (2022). Ambulatory surgical center patients are thus clients. “Client” means “any person receiving services from a provider.” § 408.803(6), Fla. Stat. (2022).

4. The Respondent holds itself out to the public as an ambulatory surgical center that complies with the laws governing ambulatory surgical centers. These laws exist to protect the health, safety and welfare of the clients of ambulatory surgical centers. As individuals receiving services from an ambulatory surgical center, these clients are entitled to receive the benefits and protections under Chapters 120, 408, Part II, and 395, Part I, Florida Statutes (2022), and Chapter 59A-5, Florida Administrative Code.

THE AGENCY’S EMERGENCY ORDER AUTHORITY

5. The Agency may impose an immediate moratorium or emergency suspension as defined in section 120.60, Florida Statutes (2022), on any provider if the Agency determines that any condition related to the provider or licensee presents a threat to the health, safety, or welfare of a client. § 408.814(1), Fla. Stat. (2022). If the Agency finds that immediate serious danger to the public health, safety, or welfare requires emergency suspension, restriction, or limitation of a license, the Agency may take such action by any procedure that is fair under the circumstances. §

LEGAL DUTIES OF AN AMBULATORY SURGICAL CENTER

6. Florida law provides:

(3) If reasonable belief exists that conduct by a staff member or physician who delivers health care services at the licensed facility may constitute one or more grounds for discipline as provided in this subsection, a peer review panel shall investigate and determine whether grounds for discipline exist with respect to such staff member or physician. The governing board of any licensed facility, after considering the recommendations of its peer review panel, shall suspend, deny, revoke, or curtail the privileges, or reprimand, counsel, or require education, of any such staff member or physician after a final determination has been made that one or more of the following grounds exist:

- (a) Incompetence.
- (b) Being found to be a habitual user of intoxicants or drugs to the extent that he or she is deemed dangerous to himself, herself, or others.
- (c) Mental or physical impairment which may adversely affect patient care.
- (d) Being found liable by a court of competent jurisdiction for medical negligence or malpractice involving negligent conduct.
- (e) One or more settlements exceeding \$10,000 for medical negligence or malpractice involving negligent conduct by the staff member.
- (f) Medical negligence other than as specified in paragraph (d) or paragraph (e).
- (g) Failure to comply with the policies, procedures, or directives of the risk management program or any quality assurance committees of any licensed facility.

§ 395.0193(3), Fla. Stat. (2022).

(1) Surgical department. This department shall be organized under written policies and procedures relating to surgical staff privileges, anesthesia, functioning standards, staffing patterns and quality maintenance of the surgical suite.

(a) A qualified person designated by the administrator shall be responsible for the daily functioning and maintenance of the surgical suite.

(b) A surgery record shall be maintained on a current basis that contains the following information:

1. Patient's name, patient number, pre-operative diagnosis, post-operative diagnosis, surgical procedure, anesthetic, and complications, if any; and,
2. Name of each member of the surgical team, including the surgeon, first assistant, anesthesiologist, nurse anesthetist, anesthesiologist assistant, circulating nurse and operating room Technologist.

(c) Each center shall ensure, prior to any surgery being performed, that the signed informed consent for the procedure, verification of the identity of patient, operative site, and operative procedure to be performed are in the patient's

medical record.

(d) All infections of surgical cases shall be recorded and reported to the governing board or its designee and a procedure shall exist for the investigation of such cases.

(e) Emergency equipment shall be provided as needed commensurate with the services of the center, maintained in functional condition, and capable of providing and maintaining cardiorespiratory functioning.

(f) Written procedures in implementation of policies shall relate specifically to the functional activities of the surgical suite and include the following:

1. Surgical asepsis: preparation, handling, and maintenance of sterile equipment and supplies.
2. Medical asepsis: patients, staff, equipment, traffic, and equipment flow patterns.
3. Sterilization and disinfection standards and controls; equipment and supplies.
4. Housekeeping.

Fla. Admin. Code R. 59A-5.085(1).

(3) The agency shall have access to and the licensee shall provide, or if requested send, copies of all provider records required during an inspection or other review at no cost to the agency, including records requested during an offsite review.

§ 408.811(3), Fla. Stat. (2022).

(13) The agency shall have access to all licensed facility records necessary to carry out the provisions of this section. The records obtained by the agency under subsection (6), subsection (7), or subsection (9) are not available to the public under s. 119.07(1), nor shall they be discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board, nor shall records obtained pursuant to s. 456.071 be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause, except that, with respect to medical review committee records, s. 766.101 controls.

§ 395.0197(13), Fla. Stat. (2022).

(1) Each center shall have an organized medical staff organized under written bylaws approved by the governing board and responsible to the governing board of the center for the quality of all medical care provided to patients in the center and for the ethical and professional practices of its members.

(2) Committees – The structure of committee organization shall be determined by

the organized medical staff provided the following required committee functions are carried out with sufficient periodicity to assure that objectives are achieved by separate committee, combined committees, or committee of the whole:

(a) Approval of the policies, procedures, and the activities of all departments and services.

....

(c) Follow-up and appropriate disposition of all reports dealing with the various staff functions.

(d) Review of all applications for appointment and biennially review reappointment of all categories of medical staff pursuant to Sections 395.0191 and 395.0193, F.S.

(e) Medical records currently maintained describing the condition, treatment, and progress of patient in sufficient completeness to assure comprehension of transfer of patient information at any time.

(f) Clinical evaluation of the quality of medical care provided to all categories of patients on the basis of documented evidence.

Fla. Admin. Code R. 59A-5.007(1) and (2).

FACTS JUSTIFYING EMERGENCY ACTION

7. On March 9, 2023, the Agency commenced a survey visit of the Respondent Facility.

8. Based upon this survey, the Agency makes the following findings:

a. Patient number one (1):

i. On March 9, 2023, at 1:45 p.m., an Agency representative observed a portion of a surgical procedure performed on the patient.

ii. Respondent's staff member, designated by Respondent as a "Certified Surgical Technologist," applied sutures to the patient's surgical wound.

iii. The procedure the patient underwent was a spinal laminectomy.

iv. No physician was present in the surgical suite.

b. Patient number two (2):

i. On March 13, 2023 at 12:45 p.m., an Agency representative observed

- the completion of a surgical procedure performed on the patient.
- ii. Respondent's "Certified Surgical Technologist" applied a Jackson-Pratt surgical drain to the patient's surgical wound.
 - iii. The procedure the patient underwent was a spinal laminectomy.
 - iv. No physician was present in the surgical suite.
- c. Respondent's "Certified Surgical Technologist" does not hold licensure, certification, or other statutorily authorized authority in any profession regulated and licensed by Florida's Department of Health.
- d. Respondent's risk manager indicated:
- i. Respondent's "Certified Surgical Technologist" performed an entire spinal surgery on a patient in the recent past.
 - ii. The risk manager directly addressed Respondent's "Certified Surgical Technologist" and told him that he is not a licensed physician and cannot perform surgical procedures.
 - iii. Respondent's "Certified Surgical Technologist" indicated in response to this directive that he was performing procedures "... under the surgeon's license."
 - iv. Respondent's "Certified Surgical Technologist" has been performing surgical procedures for several years, and the risk manager had directed the "Certified Surgical Technologist" not to do so on multiple occasions.
 - v. On at least one (1) occasion, the Respondent's "Certified Surgical Technologist" replied that the surgeon is no longer capable to perform these procedures due to the physician's age and health status, and after

- being informed by the risk manager that the practice of medicine without licensure is in violation of law, shrugged his shoulders and left.
- vi. The risk manager has addressed this issue to Respondent's surgeon who dismissed the risk manager's concerns and has refused to take any action to cease the unlicensed activities of Respondent's "Certified Surgical Technologist."
 - vii. The risk manager has informed Respondent's medical director of this ongoing unlicensed activity on at least eight (8) occasions, however Respondent's medical director and governing body have taken no action to address this ongoing issue.
 - viii. The risk manager addressed a letter to Respondent's governing body on May 3, 2022, specifically addressing the scope of practice for a certified surgical Technologist and a certified surgical first assistant. No action from the governing body was evidenced.
 - ix. The risk manager also addressed this issue with Respondent's legal counsel on several occasions in 2022, who allegedly shared the risk manager's concerns, however no action was taken to address the ongoing issue.
- e. One (1) of Respondent's registered nurses, who previously served as Respondent's operating room director, indicated:
- i. Respondent's "Certified Surgical Technologist" performed an entire surgical procedure on a patient.
 - ii. The nurse directly addressed Respondent's "Certified Surgical

Technologist” and told him that he is not a licensed physician and cannot perform surgical procedures and the “Certified Surgical Technologist” indicated in response that he was performing procedures “... under the surgeon’s license.”

- iii. The nurse has informed the “Certified Surgical Technologist” on several occasions while the nurse was the operating room director that the Technologist is not a licensed physician and cannot perform surgical procedures.
 - iv. The nurse has informed the surgeon of this ongoing activity, however the surgeon has refused to take any action to address the issue.
- f. Respondent’s “Certified Surgical Technologist” holds such certification from The National Board of Technology and Surgical Assisting situated in Littleton Colorado. Nothing in the entity’s Candidate Handbook would indicate that any such certification would qualify a certificate holder to conduct spinal surgery procedures, even were such a professional category be licensed by Florida’s Department of Health.
- g. Respondent has failed or refused to provide the medical records of patients identified during the survey, despite the regulatory requirement that such records be provided to the Agency upon request. As such, no conclusions may be reached as to the surgical outcomes of the identified procedures completed by Respondent’s “Certified Surgical Technologist.”
- h. Two (2) other staff members, the current compliance officer, and the previous operating room director, also expressed their concerns about the surgical activities being performed by Respondent’s “Certified Surgical Technologist”

to the Technologist, the surgeon, and Respondent's risk manager. When no action was taken to cease the ongoing unlicensed surgical activities of the "Certified Surgical Technologist," these individuals resigned their positions at the Respondent center.

NECESSITY FOR EMERGENCY ACTION

9. The Agency is charged with the responsibility of enforcing the laws enacted to protect the health, safety and welfare of clients of Florida's ambulatory surgical centers. Ch. 395, Fla. Stat. (2022), Ch. 408, Part II, Fla. Stat. (2022); Ch. 59A-5, Fla. Admin. Code. In those instances, where the health, safety or welfare of potential patients of ambulatory surgical centers are at risk, the Agency will take prompt and appropriate action.

10. Persons receiving surgical care must receive the level of care and services mandated by law. These specific requirements include, but are not limited to a requirement that policies and procedures relating to surgical staff privileges, anesthesia, functioning standards, staffing patterns and quality maintenance of the surgical suite. Rule 59A-5.0085(1), Florida Administrative Code.

11. As the facts reflect, Respondent has failed to meet these minimum licensure standards and these failures are not isolated events, but operational and management system deficiencies endangering the health, safety, and welfare of Respondent's patients.

12. Respondent has willfully and knowingly permitted a non-licensed individual to conduct surgical procedures and or provide on hand patient surgical related care to its patients. No patient should be subject to a surgical procedure conducted in an ambulatory surgical center by a person who does not possess the minimum requirements to perform such procedures by education, licensure, the granting of privileges, and competency determination. No patient should be subject to a surgical procedure where a licensed professional does not perform such

services.

13. Respondent has not fulfilled its requirement to promulgate and implement policy and procedure related to surgical staff privileges, anesthesia, functioning standards, staffing patterns and quality maintenance of the surgical suite. No policy or procedure was provided, nor is it likely that a policy and procedure would be promulgated, that would endorse an unlicensed individual to conduct surgical spinal procedures on any patient. Such would be the case whether or not a licensed physician was in the surgical suite or whether this unlicensed individual was of the opinion such services were under the aegis of the licensed professional's licensure.

14. Respondent's risk management and quality control processes, if functional at all, have not been effective or implemented by Respondent. The identified unlicensed surgical activities of Respondent's "Certified Surgical Technologist" have been challenged by Respondent's staff on a multitude of occasions. Complaints have been addressed to the technologist, the surgeon, the risk manager, Respondent's governing body, and even corporate counsel, yet Respondent could demonstrate no response to these frequent and repeated concerns related to the unlicensed practice by Respondent's "Certified Surgical Technologist."

15. These failures to respond, and the activities of the "Certified Surgical Technologist" upon which complaints were registered, are not isolated but span perhaps years of this ongoing activity. Respondent knew or should have known of alleged unlicensed surgical practice within its ambulatory surgical center but has demonstrated no action to even investigate the repeated allegations of unlicensed activity, much less address the issue.

16. Patients of Respondent have been placed at great risk by Respondent's failure to identify and end such activities. Future patients would also be subject to these intolerable risks.

17. In addition, Respondent has refused to provide the Agency with patient records requested as required by Florida's regulatory scheme, *See*, §§ 395.0197(13) and 408.811(3), Fla.

Stat. (2022). This decision inhibits the Agency's capability to fully determine Respondent's compliance with regulatory minimum requirements. Where a provider cannot produce records to demonstrate compliance, compliance may not be fully determined by the Agency. Without patient records, the Agency cannot review documentation memorializing surgical procedures, cannot review documentation memorializing post operative status, and cannot review ultimate surgical outcomes. This inability does not permit the Agency to complete the survey process and determine compliance or non-compliance with the regulatory scheme.

18. Individually and collectively, the deficient practice demonstrated by the facts place the health, safety, and welfare of future patients of Respondent at immediate risk. A patient seeking services is entitled to receive, and the regulatory scheme mandates, the care and service protections enumerated in law to facilitate a safe procedure, and to assure that monitoring and services, both on-site and after discharge, are effectively and consistently provided.

19. Respondent's conduct demonstrates a pattern of non-compliance that places patient health, safety, and welfare at immediate risk.

20. Respondent knew or should have known that it was woefully insufficient in regulatory compliance. The repeated and knowing use of unlicensed personnel to perform surgical functions requiring licensure demonstrates a willful disregard for patient safety and the licensing schemes under which an ambulatory surgical center and its professionals operate. Respondent has demonstrated either an unwillingness or inability to assure these protections of law and professional standards for patient safety are implemented. As a result, patients have been placed at immediate risk to their health and wellbeing.

21. Respondent's deficient practices exist presently, have existed in the past, and will continue to exist if the Agency does not act promptly by taking this emergency action. Respondent knew, or should have known, of its deficient practice, but has not acted to

independently address these issues.

CONCLUSIONS OF LAW

22. The Agency has jurisdiction over the Respondent pursuant to Chapters 408, Part II, and 395, Part I, Florida Statutes, and Chapter 59A-5, Florida Administrative Code.

23. Based upon the above stated provisions of law and findings of fact, the Agency concludes that: (1) an immediate serious danger to the public health, safety, or welfare presently exists at the Respondent's Facility which justifies an emergency suspension of Respondent's licensure to operate an ambulatory surgical center in the State of Florida; and (2) the present conditions related to the Respondent and its Facility present a threat and immediate serious danger to the health, safety, or welfare of patients or clients, which requires an emergency suspension of Respondent's license to operate an ambulatory surgical center in the State of Florida.

24. Based upon the above-stated provisions of law and findings of fact, the Agency concludes that an Emergency Suspension Order is necessary in order to protect prospective patients or clients from (1) the unsafe conditions and deficient practices that currently exist, (2) being placed at risk of undergoing a procedure where the provider is ill-equipped to provide for patient health, safety and welfare, and (3) being placed in an environment where the regulatory mechanisms enacted for patient protection have been repeatedly overlooked.

25. The Respondent's deficient practices exist presently, have existed in the past without corrective action, and will continue to exist if the Agency does not act promptly. If the Agency does not act, it is likely that the Respondent's conduct will continue. Such deficient practices and conditions justify the imposition of an Emergency Suspension Order. Less restrictive actions, such as the assessment of administrative fines or the implementation of a moratorium, will not ensure that current patients or future patients receive the appropriate care,

services, and monitoring dictated by Florida law.

26. The emergency action taken by the Agency in this particular instance is fair under the circumstances and the least restrictive action that the Agency could take given the facts and circumstances. This remedy is narrowly tailored to address the specific harm in this instance.

IT IS THEREFORE ORDERED THAT:

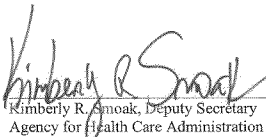
27. The Respondent's license to operate this ambulatory surgical center is hereby SUSPENDED effective March 15, 2023, at 5:00 p.m.

28. Upon receipt of this order, the Respondent shall post this Order on its premises in a place that is conspicuous and visible to the public.

29. As of the effective date and time of this Emergency Suspension Order, Respondent shall not operate as an ambulatory surgical center.

30. The Agency shall promptly file an administrative action against the Respondent based upon the facts set out in this Emergency Suspension Order and provide notice to the Respondent of the right to a hearing under Section 120.57, Florida Statutes (2022), at the time that such action is taken.

ORDERED in Tallahassee, Florida, this 15th day of March, 2023.



Kimberly R. Amoak, Deputy Secretary
Agency for Health Care Administration

NOTICE OF RIGHT TO JUDICIAL REVIEW

This emergency order is a non-final order subject to facial review for legal sufficiency. See Broyles v. State, 776 So.2d 340 (Fla. 1st DCA 2001). Such review is commenced by filing a petition for review in accordance with Florida Rules of Appellate Procedure 9.100(b) and (c). See Fla. R. App. P. 9.190(b)(2). In order to be timely, the petition for review must be filed within thirty (30) days of the rendition of this non-final emergency order.