



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV460 - Office Surgery Center**



File #
Insp #

NAME	PERMIT NUMBER	DATE OF INSPECTION	
DOING BUSINESS AS			
STREET ADDRESS		TELEPHONE #	EXT
CITY	COUNTY	STATE/ZIP	

License Relations

Office Surgery Registration

	License #
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Requirement for Physician Office Registration

The Office Surgery Center is registered with the department and the department has been notified of the designated physician. [458.328, F.S.] [459.0138, F.S.]	
The designated physician practices at the office surgery center location. [458.328, F.S.] [459.0138, F.S.]	
Office surgery center meets and maintains financial responsibility requirements under 458.320 or 459.0085 as applicable. [458.328, F.S.] [459.0138, F.S.]	
Physician(s) practicing at the office surgery center meets the financial responsibility requirements under 458.320 or 459.0085 as applicable. [458.328, F.S.] [459.0138, F.S.]	
The physician(s) is registered to perform office-based surgery with the Board of Medicine [64B8-9.0091(1), FAC]	
The physician(s) office is not accredited with a national accrediting organization or Board approved organization	
The physician(s) performs surgery as defined in the Board Rule [64B8-9.009(1)(a), FAC]	
The surgeon(s) is an active licensed physician(s) in the State of Florida [64B8- 9.009(1)(b), FAC]	
The physician(s) notified the Department, in writing of any changes to the registration information. [64B8- 9.0091(1)(c), FAC]	
The registration is posted in the office [64B8- 9.0091(1)(d), FAC]	
The equipment meets the current performance standards[64B8-9.009(1)(c), FAC]	
The surgery is being performed outside a hospital, ambulatory surgical center, abortion clinic or other medical facility licensed by the Department of Health or the Agency for Health Care Administration[64B8-9.009(1)(d), FAC]	
The surgery is being performed pursuant to definition of office surgery as described in 64b8-9.009(1)(d), FAC.	

General Requirements for Office Surgery

Compliance with pre-operative Evaluation[64B8-9.009(2)(a) FAC]	
The surgeon(s) examined the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed	
The surgeon(s) delegated the preoperative heart lung evaluation to a qualified anesthesia provider within the scope of the provider's practice and, if applicable, protocol.	
Compliance with Patient/Procedures Records[64B8-9.009(2)(a) FAC]	
Compliance with Informed Consent[64B8-9.009(2)(a), FAC]	
Surgical Logs contain confidential patient identifier, time of arrival in the operating suite, documentation of completion of the medical clearance as performed by the anesthesiologist or the operating physician, the surgeon's name, diagnosis, CPT Codes, patient ASA classification, the type of procedure, the level of surgery, the anesthesia provider, the type of anesthesia used, the duration of the procedure, and any adverse incidents [64B8-9.009(2)(c), FAC]	
The surgeon(s) completed Level II, Level III or Liposuction over 1,000cc procedures	
Surgical Logs are maintained for six years after last patient contact	
Compliance with liposuction procedures[64B8-9.009(2)(d), FAC]	
The surgeon(s) removed no more than 4,000 cc of fat	
The surgeon(s) injected no more than 50mg/kg of Lidocaine for tumescent liposuction	
Compliance with Elective Cosmetic and Plastic Surgery Procedures [64B8- 9.009(2)(f), FAC]	
Surgery was completed in under 8 hrs.	
Patients were discharged within 24 hrs.	

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If Patients time in office exceed 23 hrs. 59 minutes patient was transferred to a hospital.	
Compliance with overnight stays except for elective cosmetic and plastic surgery[64B8-9.009(2)(f), FAC]	
Only elective cosmetic and plastic surgery patients stayed past midnight	
Overnight stays were limited to the physician' office	
Compliance with overnight stays in relation to any surgical procedure[64B8-9.009(2)(h), FAC]	
Two monitors were present (one monitor was ACLS certified)	
Monitor to patient ratio was kept at 1 monitor to 2 patients	
Once physician signed a timed and dated discharge order, single monitoring began by a ACLS certified monitor	
The surgeon(s) was reachable by telephone and available to return to the office within 15 minutes	
Compliance with post-operative care[64B8-9.009(2)(h), FAC]	
Compliance with risk management program[64B8-9.009(2)(j), FAC]	
Risk Management program includes the identification, investigation, and analysis of the frequency and causes of adverse incidents to patients	
Risk Management program includes the identification of trends or patterns of incidents	
Risk Management program includes the development of appropriate measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients	
Risk Management program includes the documentation of these functions and periodic review no less than quarterly of such information by the surgeon	
Compliance with adverse incident reporting[64B8-9.009(2)(k), FAC] [64B8-9.001, FAC] [458.351 (4), FS]	

Requirements for Level I (Liposuction) Office Surgery

Compliance with Training Requirements[64B8-9.009(3)(b)1, FAC]	
Compliance with Equipment and Supplies Required[64B8-9.009(3)(b)2, FAC]	
Office has Intravenous access supplies, oxygen, oral airways, and a positive pressure ventilation device	
Office stores the following medications at manufacturer's recommendation: Atropine 3 mg; Diphenhydramine 50 mg; Epinephrine 1 mg in 10 ml; Epinephrine 1 mg in 1 ml vial, 3 vials total; and Hydrocortisone 100 mg	

Requirements for Level II Office Surgery

The surgeon(s) have Transfer Agreements or Hospital Staff Privileges for a licensed hospital within reasonable proximity (30 mins.) [64B8-9.009(4)(b)1, FAC]	
Compliance with Training Requirements[64B8-9.009(4)(b)2, FAC]	
At least one assistant is certified with Basic Life Support Certification[64B8-9.009(4)(b)2, FAC]	
The surgeon(s) are currently certified with Advanced Cardiac Life Support Certification[64B8-9.009(4)(b)2, FAC]	
The office has the following equipment/supplies: a Benzodiazepine must be present in the office.; Positive pressure ventilation device (e.g. Ambu) plus oxygen supply; End tidal CO2 detection device; Monitors for blood pressure/EKG/Oxygen saturation; Emergency intubation equipment, which shall at a minimum include suction devices, endotracheal tubes, laryngoscopes, oropharyngeal airways, nasopharyngeal airways and bag valve mask apparatus that are patient-size specific; Defibrillator with defibrillator pads or defibrillator gel, or an Automated External Defibrillator unit (AED); Sufficient back up power is required to allow the physician to safely terminate the procedure and to allow the patient to emerge from the anesthetic, all without compromising the sterility of the procedure or the environment of care; Sterilization equipment and IV solution and IV equipment. [64B8-9.009(4)(b)3, FAC]	
Crash cart contains: Adenosine 18 mg; Albuterol 2.5 mg with small volume nebulizer; Amiodarone 300 mg; Atropine 3 mg; Calcium chloride 1 gram; Dextrose 50%; 50 ml; Diphenhydramine 50 mg; Dopamine 200 mg minimum; Epinephrine 1 mg in 10 ml; Epinephrine 1 mg in 1 ml vial, 3 vials total; Flumazenil 1 mg; Furosemide 40 mg; Hydrocortisone 100 mg; Lidocaine appropriate for cardiac administration 100 mg; Magnesium sulfate 2 grams; Naloxone 1.2 mg; A beta blocker class drug; Sodium bicarbonate 50 mg/50 ml; Paralytic agent that is appropriate for use in rapid sequence intubation; A calcium channel blocker class drug; and, Intralipid 20% 500 ml solution (only if non-neuraxial regional blocks are performed). [64B8- 9.009(4)(b)3a, FAC]	
Compliance with Anesthesia Provider[64B8-9.009(4)(b)4, FAC]	
Compliance with Additional Assistance[64B8-9.009(4)(b)4, FAC]	

Requirements for Level III (Include the requirement for level II Office surgery as well as the requirements outlined)

Compliance with the American Society of Anesthesiologist's Classifications for appropriate candidates for level III office surgery[64B8-9.009(6)(a)2, FAC]	
Complies with Additional Training Requirements[64B8-9.009(6)(b)1, FAC]	
Emergency policies and procedures are periodically reviewed, updated, and posted in a conspicuous location. [64B8-9.009(6)(b)2, FAC]	
Emergency policies and procedures cover the following: a. Airway Blockage (foreign body obstruction); b. Allergic Reactions; c. Bradycardia; d. Bronchospasm; e. Cardiac Arrest; f. Chest Pain; g. Hypoglycemia; h. Hypotension; i. Hypoventilation; j. Laryngospasm; k. Local Anesthetic Toxicity Reaction; and, l. Malignant Hyperthermia.	
Office has the following equipment/supplies: at least 720 mg of dantrolene on site (if halogenated anesthetics or succinylcholine are utilized); must be comparable to a free standing ambulatory surgical center, including, but not limited to, recovery capability, and must have provisions for proper recordkeeping; Blood pressure monitoring equipment; EKG; end tidal CO2 monitor; pulse oximeter, emergency intubation equipment and a temperature monitoring device; and Table capable of trendelenburg and other positions necessary to facilitate the surgical procedure [64B8-9.009(6)(b)3, FAC]	

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Complies with Anesthesia Provider[64B8-9.009(6)(b)4, FAC]	
Complies with Additional Assistance of Other Personnel Required[64B8-9.009(6)(b)4, FAC]	

Corrective Action Plan

Pursuant to 64B8-9.0091(2)(e), a corrective action plan is required to be submitted within 30 days for the noncompliant items listed above.	
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Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

Representative:

Date:

Date: