



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



File #  
Insp #

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

**License Relations**

**OSR - Additional Surgical Staff**

	License #
	License #
	License #
	License #
	License #
	License #
	License #
	License #

**OSR - Agent**

	License #
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**OSR - Anesthesia Provider**

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	License #

**OSR - Designated Physician**

	License #
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**OSR - Managing Employee**

	License #
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**OSR - Office Manager**

	License #
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**OSR - Officer**

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	License #
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**OSR - Owner**

	License #
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**OSR - Physician**

	License #
	License #
	License #

**OSR - Principal**

	License #
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**OSR - Recovery**

	License #
	License #

**Office Surgery Registration**

	License #
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### INV460 - Office Surgery Center

#### Requirement for Physician Office Registration

The Office Surgery registration is registered with the department and the department has been notified of the designated physician. [458.328, F.S] [459.0138, F.S.] [64B8-9.0091(1)(a)] [64B15-14.0076, (1)(b) F.A.C.]	
The designated physician has a full, active, and unencumbered license and practices at the office for which he or she is responsible. [458.32 (1)(b), F.S.] [459.0138, F.S.] [64B8-9.0091(1)(b)(c), F.A.C.] [64B15-14.0076, (1)(b) F.A.C.]	
Office surgery registration meets and maintains financial responsibility requirements under 458.320 or 459.0085 as applicable. [458.320, F.S.] [459.0085, F.S.]	
Physician(s) practicing at the office surgery registration meets the financial responsibility requirements under 458.320 or 459.0085 as applicable. [458.320, F.S.] [459.0085, F.S.] [64B8-9.0091(1)(c), F.A.C.]	
The physician(s) is registered to perform office-based surgery with the Board of Medicine or Board of Osteopathic Medicine. [64B8-9.0091(1)(c), F.A.C.] [64B15-14.0076, (1)(c)1, F.A.C.]	
The physician(s) office is not accredited with a national accrediting organization or Board approved organization. [64B8-9.0091 (2) (a)] [64B15-14.0076(2)(a), F.A.C.]	
The physician(s) performs surgery as defined in the Board Rule [64B8-9.009(1)(a), F.A.C.] [64B15-14.0076, (1)(a), F.A.C.]	
The surgeon(s) is an active licensed physician(s) in the State of Florida [64B8- 9.009(1)(b), F.A.C.] [64B15-14.0076, (1)(b), F.A.C.]	
The physician(s) notified the Department, in writing of any changes to the registration information. [64B8- 9.0091(1)(c), F.A.C.] [64B15-14.0076, (1)(c), F.A.C.]	
The registration is posted in the office. [64B8- 9.0091,(4)(e) F.A.C.] [64B15-14.0076, (1)(e), F.A.C.]	
A sign must be prominently posted in the office which states that the office is a doctor's office regulated pursuant to the rules of the Board of Medicine as set forth in rule Division 64B8, F.A.C or the Board of Osteopathic Medicine as set forth in rule Division 64B15, F.A.C. This notice must also appear prominently within the required patient informed consent. [64B8-9.009(2)(n), F.A.C.] [64B15-14.007 (2)(m)]	
The equipment meets the current performance standards [64B8-9.009(1)(c), F.A.C.] [64B15-14.007, (1)(c), F.A.C.]	
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), F.A.C.] [64B15-14.007, (1)(d), F.A.C.]	
The surgery is being performed pursuant to definition of office surgery as described in 64B8-9.009(1)(d), F.A.C) and/or 64B15-14.007, (1)(d), F.A.C.	
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.]	

#### General Requirements for Office Surgery

Compliance with pre-operative evaluation [64B8-9.009(2)(a), F.A.C] [64B15-14.007, (2)(a), F.A.C.]	
The surgeon(s) or qualified anesthesia provider examined the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed. [64B8-9.009(2)(a), F.A.C.] [64B15-14.007 (2)(a), F.A.C.]	
Compliance with patient/procedures records. [64B8-9.009(2)(a), F.A.C.] [64B15-14.007, (2)(a), F.A.C.]	
Compliance with informed consent. [64B8-9.009(2)(a), F.A.C.] [64B15-14.007, (2)(a), F.A.C.]	
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), F.A.C.] [64B15-14.007, (2)(c), F.A.C.]	
Surgical Logs are maintained for six years after last patient contact. [64B8-9.009(2)(c), F.A.C.]	
Compliance with post-operative care. [64B8-9.009(2)(i), F.A.C.]	

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A policy and procedure manual must be maintained in the office, updated annually, and implemented. The policy and procedure manual must contain the following: duties and responsibilities of all personnel, quality assessment and improvement systems comparable to those required by Rule 59A-5.019, F.A.C.; cleaning, sterilization and infection control, and emergency procedures. This applies only to physician offices at which Level II and Level III procedures are performed. [64B8-9.009(2)(k), F.A.C.] [64B15-14.007 (2)(j) F.A.C.]	
Compliance with risk management program. [64B8-9.009(2)(l), F.A.C.] [64B15-14.007 (2)(k) F.A.C.]	
Risk Management program includes the documentation of these functions and periodic review no less than quarterly of such information by the surgeon. [64B8-9.009(2)(l) 4, F.A.C.] [64B15-14.007 (2)(k) F.A.C.]	
Compliance with adverse incident reporting. [64B8-9.009(2)(k), F.A.C.] [64B8-9.001, F.A.C.] [458.351 (4), FS] [64B15-14.0075, F.A.C.] [64B15-14.007 (2)(l) F.A.C.]	

### Liposuction Procedures

Compliance with liposuction procedures. [64B8-9.009(2)(d), F.A.C.] [64B15-14.007, (2)(d) (e), F.A.C.]	
The surgeon(s) removed no more than 4,000 cc of fat. [64B8-9.009(2)(d), F.A.C.] [64B15-14.007, (2)(d), F.A.C.]	
The surgeon(s) removed no more than 1,000 cc of fat when combined with another procedure. [64B8-9.009(2)(e) F.A.C.] [64B15-14.007, (2)(d), F.A.C.]	
The surgeon(s) injected no more than 50mg/kg of Lidocaine for tumescent liposuction. [64B8-9.009(2)(d) F.A.C.] [64B15-14.007 (2)(d), F.A.C.]	
Compliance with Elective Cosmetic and Plastic Surgery Procedures. [64B8-9.009(2)(f), F.A.C.] [64B15-14.007 (2)(f), F.A.C.]	
Surgery was completed in under 8 hrs. [64B8-9.009(2)(g) F.A.C.] [64B15-14.007 (2)(g), F.A.C.]	
Patients were discharged within 24 hrs. [64B8-9.009(2)(g) F.A.C.] [64B15-14.007 (2)(g), F.A.C.]	
If patients time in office exceed 23 hrs. 59 minutes patient was transferred to a hospital. [64B8-9.009(2)(g) F.A.C.] [64B15-14.007 (2)(g), F.A.C.]	
Compliance with overnight stays except for elective cosmetic and plastic surgery. [64B8-9.009(2)(g) F.A.C.] [64B15-14.007 (2)(g), F.A.C.]	
Only elective cosmetic and plastic surgery patients stayed past midnight. [64B8-9.009(2)(g) F.A.C.] [64B15-14.007 (2)(g), F.A.C.]	
Overnight stays were limited to the physician's office. [64B8-9.009(2)(g) F.A.C.] [64B15-14.007 (2)(g), F.A.C.]	
Compliance with overnight stays in relation to any surgical procedure. [64B8-9.009(2) (g), F.A.C.] [64B15-14.007 (2)(g), F.A.C.]	
Two monitors were present (one monitor was ACLS certified) [64B8-9.009(2)(j)1 F.A.C.] [64B15-14.007 (2)(i) 1, F.A.C.]	
Monitor to patient ratio was kept at 1 monitor to 2 patients. [64B8-9.009(2)(j)1 F.A.C.] [64B15-14.007 (2)(i) 1, F.A.C.]	
Once physician signed a timed and dated discharge order, single monitoring began by a ACLS certified monitor. [64B8-9.009(2)(j)1 F.A.C.] [64B15-14.007 (2)(i) 1, F.A.C.]	
The surgeon(s) was reachable by telephone and available to return to the office within 15 minutes. [64B8-9.009(2)(j) 2 F.A.C.] [64B15-14.007 (2)(i) 2, F.A.C.]	

### Requirements for Level I (Liposuction) Office Surgery

Compliance with training requirements. [64B8-9.009(3)(b)1, F.A.C.] [64B15-14.007, (3)(b)1, F.A.C.]	
Compliance with equipment and supplies required. [64B8-9.009(3)(b)2, F.A.C.] [64B15-14.007, (3)(b)2, F.A.C.]	
Office has Intravenous access supplies, oxygen, oral airways, and a positive pressure ventilation device. [64B8-9.009(3)(b)2, F.A.C.] [64B15-14.007, (3)(b)2, F.A.C.]	
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. If a benzodiazepine is administered, Flumazenil 0.5 mg in 5 ml vial, 2 vials total. If an opiate is administered, Naloxone 0.4 mg in 1 ml vial, 2 vials total. [64B8-9.009(3)(b)2, F.A.C.] [64B15-14.007, (3)(b)2, F.A.C.]	
The surgeon(s) are currently certified with Advanced Cardiac Life Support Certification. [64B8-9.009(4)(b)2, F.A.C.] [64B15-14.007, (4)(b)2, F.A.C.]	
At least one assistant is certified with Basic Life Support Certification. [64B8-9.009(4)(b)2, F.A.C.] [64B15-14.007, (4)(b)2, F.A.C.]	

### 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, F.A.C.]	
Compliance with training requirements [64B8-9.009(4)(b)2, F.A.C.]	
At least one assistant is certified with Basic Life Support Certification [64B8-9.009(4)(b)2, F.A.C.]	
The surgeon(s) are currently certified with Advanced Cardiac Life Support Certification [64B8-9.009(4)(b)2, F.A.C.]	
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, F.A.C.]	
Compliance with anesthesia provider [64B8-9.009(4)(b)4, F.A.C.]	
Compliance with additional assistance [64B8-9.009(4)(b)4, F.A.C.]	

### Crash Cart Contains the Following

Adenosine 18 mg [64B8-9.009(4)(b)3. a.(I), F.A.C.] [64B15-14.007(4)(b)3. a.(I), F.A.C.]	
Albuterol 2.5 mg with small volume nebulizer [64B8-9.009(4)(b)3. a. (II), F.A.C.] [64B15-14.007(4)(b)3. a. (II), F.A.C.]	
Amiodarone 300 mg [64B8-9.009(4)(b)3. a. (III), F.A.C.] [64B15-14.007(4)(b)3. a. (III), F.A.C.]	
Atropine 3 mg [64B8-9.009(4)(b)3. a. (IV), F.A.C.] [64B15-14.007(4)(b)3. a. (IV), F.A.C.]	
Calcium chloride 1 gram [64B8-9.009(4)(b)3. a.(V), F.A.C.] [64B15-14.007(4)(b)3. a.(V), F.A.C.]	

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Dextrose 50%; 50 ml [64B8-9.009(4)(b)3. a. (VI), F.A.C.] [64B15-14.007(4)(b)3. a. (VI), F.A.C.]	
Diphenhydramine 50 mg [64B8-9.009(4)(b)3. a. (VII), F.A.C.] [64B15-14.007(4)(b)3. a. (VII), F.A.C.]	
Dopamine 200 mg minimum [64B8-9.009(4)(b)3. a. (VIII), F.A.C.] [64B15-14.007(4)(b)3. a. (VII), F.A.C.]	
Epinephrine 1 mg in 10 ml [64B8-9.009(4)(b)3. a. (IX), F.A.C.] [64B15-14.007(4)(b)3. a. (IX), F.A.C.]	
Epinephrine 1 mg in 1 ml vial, 3 vials total [64B8-9.009(4)(b)3. a.(X), F.A.C.] [64B15-14.007(4)(b)3. a.(X), F.A.C.]	
Flumazenil 1 mg [64B8-9.009(4)(b)3. a. (XI), F.A.C.] [64B15-14.007(4)(b)3. a. (XI), F.A.C.]	
Furosemide 40 mg [64B8-9.009(4)(b)3. a. (XII), F.A.C.] [64B15-14.007(4)(b)3. a. (XII), F.A.C.]	
Hydrocortisone 100 mg [64B8-9.009(4)(b)3. a. (XIII), F.A.C.] [64B15-14.007(4)(b)3. a. (XIII), F.A.C.]	
Lidocaine appropriate for cardiac administration 100 mg [64B8-9.009(4)(b)3. a. (XIV), F.A.C.] [64B15-14.007(4)(b)3. a. (XIV), F.A.C.]	
Magnesium sulfate 2 grams [64B8-9.009(4)(b)3. a. (XV), F.A.C.] [64B15-14.007(4)(b)3. a. (XV), F.A.C.]	
Naloxone 1.2 mg [64B8-9.009(4)(b)3. a. (XVI), F.A.C.] [64B15-14.007(4)(b)3. a. (XVI), F.A.C.]	
A beta blocker class drug [64B8-9.009(4)(b)3. a. (XVII), F.A.C.] [64B15-14.007(4)(b)3.a.(XVII), F.A.C.]	
Sodium bicarbonate 50 mEq/50 ml [64B8-9.009(4)(b)3. a. (XVIII), F.A.C.] [64B15-14.007(4)(b)3. a. (XVII), F.A.C.]	
Paralytic agent that is appropriate for use in rapid sequence intubation [64B8-9.009(4)(b)3. a. (XIX), F.A.C.] [64B15-14.007(4)(b)3. a. (XIX), F.A.C.]	
A calcium channel blocker class drug [64B8-9.009(4)(b)3. a. (XX), F.A.C.] [64B15-14.007(4)(b)3. a. (XX), F.A.C.], and	
Intralipid 20% 500 ml solution (only if non-neuraxial regional blocks are performed) [64B8-9.009(4)(b)3. a. (XXI), F.A.C.] [64B15-14.007(4)(b)3. a. (XXI), F.A.C.]	

### Gluteal Fat Grafting

Physician performing a gluteal fat grafting procedure conducted an in-person examination of the patient, while physically present in the same room as the patient, no later than the day before the procedure. [458.328, (2)(c) 1 F.S.] [459.0138, (2)(c) 1 F.S.]	
Physician performing a gluteal fat grafting procedure uses ultrasound guidance during the placement and navigation of the cannula to ensure that fat is injected into the subcutaneous space of the patient above the fascia overlying the gluteal muscle. [458.328, (2)(c) 4 F.S.] [459.0138, (2)(c) 4 F.S.]	
Informed consent for delegation of duties during a gluteal fat grafting procedure. [458. 328 (2)(c) 2, F.S.] [459.0138, (2)(c) 2 F.S.]	
Physician provided direct supervision for any delegated duties. [458. 328 (2)(c) 2, F.S.] [459.0138, (2)(c) 2 F.S.]	
Office surgery registrant performing gluteal fat grafting procedures meets the financial responsibility requirements under 458.320 (2) (b) or (c) or 459.0085 (2) (b) or (c) as applicable. Professional liability coverage in an amount not less than \$250,000 per claim, with a minimum annual aggregate of not less than \$750,000 from an authorized insurer or an unexpired irrevocable letter of credit in an amount not less than \$250,000 per claim, with a minimum aggregate availability of credit of not less than \$750,000. [458.328, F.S.] [459.0138, F.S.] [64B8-9.0091(1)(c), F.A.C.]	
Physician performing gluteal fat grafting procedures maintains 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. [458.328, F.S.] [459.0138, F.S.]	
After a physician has commenced, and while engaged in, a gluteal fat grafting procedure, the physician did not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time. [458.328, F.S.] [459.0138, F.S.]	

### Requirements for Level III Office Surgery (include the requirements 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., F.A.C.] [64B15-14.007 (6)(a)2., F.A.C.]	
Complies with training requirements. [64B8-9.009(6)(b)1., F.A.C.] [64B15-14.007 (6)(b)1., F.A.C.]	
Emergency policies and procedures are periodically reviewed, updated, and posted in a conspicuous location. [64B8-9.009(6)(b)2., F.A.C.] [64B15-14.007 (6)(b)2., F.A.C.]	
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.; [64B8-9.009(6)(b)2., F.A.C.] [64B15-14.007 (6)(b)2., F.A.C.]	
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., F.A.C.] [64B15-14.007 (6)(b)3., F.A.C.]	
Complies with anesthesia provider. [64B8-9.009(6)(b)4., F.A.C.] [64B15-14.007 (6)(b)4., F.A.C.]	
Complies with additional assistance of other personnel required. [64B8-9.009(6)(b)4., F.A.C.] [64B15-14.007 (6)(b)4., F.A.C.]	

### Corrective Action Plan

Pursuant to 64B8-9.0091(2)(e) or 64B15-14.0076(2)(d), a corrective action plan is required to be submitted within 30 days for the noncompliant items listed above.	
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### Remarks:

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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.

Inspector Signature

Representative:

Date:

Date: