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Dear Officers and Members of the Brevard County Medical Society,

I write to you and the membership at large, regarding the importance of accreditation/inspection of office surgery facilities and the responsibility of physicians at those facilities. As more and more practices turn to performing procedures in their office locations, it is important that physicians understand the rules and liabilities for performing such procedures in the office setting. I have learned after failing to comply with all the rules how different they are when compared to rules that regulate operating in an approved surgical facility. I assure you the Board of Medicine takes these regulations very seriously indeed, and I doubt they are widely known by surgeons.

The Florida Department of Health (the "Department") and the Florida Board of Medicine (the "Florida Board") retain the authority to regulate physician office surgery. Standards of care and practice in these settings are established by the Florida Board, while the Department is responsible for the registration and inspection of certain office surgery facilities.

Regulation of Office Surgery

The Florida Board specifically defines office surgery and office surgery levels, and establishes the general requirements for office surgery. Physicians performing office surgery must be qualified by education, training and experience to perform any procedure the physician performs in the office surgery setting. Physicians are urged the familiarize themselves with all rules and regulations governing the practice of medicine, but especially Rule 64B8-9.009, F.A.C., which specifically delineates the Standard of Care for Office Surgery, including general requirements for office surgery. Briefly, this rule concerns pre-anesthesia evaluation, informed consent, scope of care, maintenance of complete records, surgical logs, medical clearance, postoperative care and patient disposition and time frames for which surgical logs must be maintained. Additionally, this rule discusses parameters for liposuction in office surgery, maximum time length for elective cosmetic and plastic surgery cases, anesthesia monitoring standards, ventilation and circulation, and body temperature guidelines. Importantly, it also sets forth requirements and standards for a policy and procedure manual, necessary components for risk management programs, emergency policies and procedures, incident reporting requirements, necessary signage, necessary crash cart items, equipment, supplies and medications. Furthermore, the Board defines the scope of office surgery into Level I, II, IIA, and III office surgery.

Registration

Every Florida licensed physician who holds an active Florida license and performs Level II surgical procedures in Florida with a maximum planned duration of five (5) minutes or longer or any Level III office surgery, as fully defined in 64B8-9.009, shall notify the Department. It is the physician's responsibility to ensure that every office in which he or she performs Levels II or III surgical procedures as described above is registered, regardless of whether other physicians are practicing in the same office or whether the office is non-physician owned. The Department must immediately be notified in writing, via the Office Surgery Registration form and all required documentations, of all changes to the registration information. The Registration form is accessible at http://www.floridahealth.gov/licensing-and-regulation/office-surgery-registration/applications-forms/_documents/apf-os-regis.pdf

Inspection

Pursuant to Rule 64B-9.0091, F.A.C., each and every office surgery facility must submit to an annual inspection by the Department of Health, unless that office facility hold current accreditation by the American Association for

Accreditation of Ambulatory Surgery Facilities (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC), or the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Additionally, each office, as defined in Sections 458.309(3) and 459.005(2), F.S., must register and maintain a valid registration with the Department, and pay a registration fee of \$150 (Rule 64B-4.003, F.A.C.).

Frankly, it is critical that these regulations exist, and particularly essential that regular inspections occur to ensure optimal patient safety and care, as well as professional compliance with existing laws and rules. Physicians must remain ever mindful that should deficiencies or non-compliance be identified during an inspection by the Department, such may be reported to the Department's investigatory unit, at which time an investigation will be initiated against the medical license of the physician. This can result in a costly legal headache, including potential disciplinary action against the physician's license, to include requirement payment of fines, costs, CMEs and related penalties.

To ensure compliance with office surgery rules, physicians are encouraged to view the Department's inspection form at http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-program/_documents/office-surgery-center-insp-form.pdf and to then review their own practices/offices to ensure that they fully comply with all governing rules and regulations. While risk management review of a practice can be expensive and time consuming, such is essential to ensure complete compliance and should occur on an ongoing basis.

I respectfully request that my letter be shared by the Brevard County Medical Society with its members via either publication in its newsletter, on its website, or by some other means as I hope to help my colleagues avoid the trap I found myself in. Anyone interested in contacting me personally to discuss this matter further is invited to do so.

Sincerely,

John Hermansdorfer, M.D.