

NYS Department of Health

OFFICE-BASED SURGERY OVERSIGHT

Office of Health Systems Management

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January 15, 2008

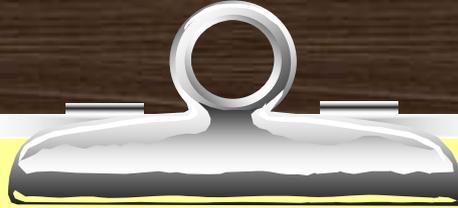
New York, New York



CHAPTER 365 OF THE LAWS OF 2007

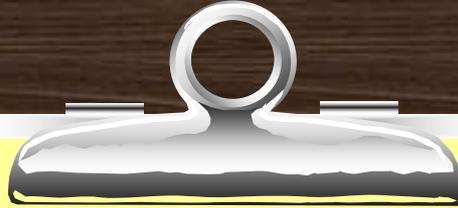
Legislation introduced at the request of the Department of Health
A.7948-A (Gottfried)/ S.6052-A (Hannon)

- **New Law signed by the Governor on July 18, 2007**
- **Provides oversight of certain, specific office-based surgery practices (OBS)**
- **Two main components:**
 - **Adverse event reporting (effective January 2008)**
 - **Accreditation requirement (effective July 2009)**



BACKGROUND

- **Ten year history on this issue**
- **December 1997 - Committee on Quality Assurance in Office Based Surgery was established and chaired by Dr. Bernard Rosof**
- **Committee membership included physicians and consumers**
- **In 2001, clinical guidelines for OBS were produced and distributed.**
 - **They were the subject of a legal challenge.**
 - **The higher court decided in the state's favor.**



BACKGROUND (CONTINUED)

- **Committee reconvened in Fall 2005**
 - **concerns regarding several egregious cases involving OBS**
- **Original committee was reestablished with additional representation**
 - **consumers**
 - **nursing**
 - **medical specialties**
- **Committee's goal - improve quality of care and safety in OBS**
- **Committee held four full day meetings**



(BACKGROUND CONTIUNED)
Committee on Quality Assurance

Bernard Rosof, MD, MACP (Chair) - Gastroenterologist

Elizabeth Almeyda, MD - Plastic Surgeon

David Bank, MD - Dermatologist

Joseph E. Bernat, DDS - Dentist

Russell W. Bessette, MD, DDS - Oral Surgeon

William A. Dolan, MD - Orthopedic Surgeon

Thea Graves Pellman - Consumer Advocate

Deborah Gray - Hospital Administrator

Stanley Grossman, MD - General Surgeon

Scott Groudine, MD - Anesthesiologist



(BACKGROUND CONTINUED)
Committee on Quality Assurance

Robert Kennedy, MD, FACS - Ophthalmologist

Andrew Kleinman, MD - Plastic Surgeon

Arthur Aaron Levin, MPH - Consumer Advocate

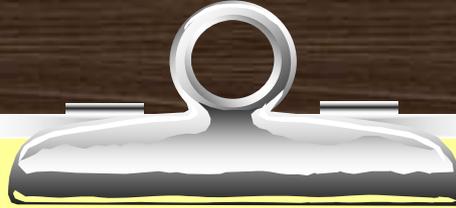
William B. Rosenblatt, MD - Plastic Surgeon

**Deborah G. Spratt, RN, MPA, CNAA, CNOR -
Operating Nurse Clinician**

Susan Sullivan, RN, CNOR - Operating Nurse Clinician

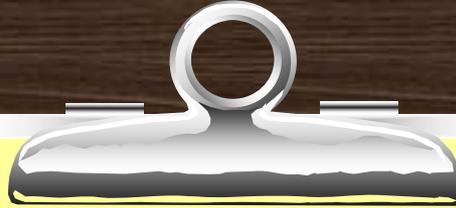
James G. Tifft, MD - Gastroenterologist

Rebecca Twersky, MD, MPH - Anesthesiologist



BACKGROUND (CONTINUED)

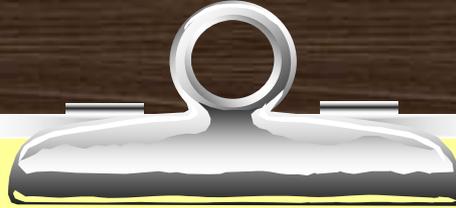
- **Four subcommittees formed:**
 - **Statute/Regulation, William Rosenblatt, MD - Chair**
 - **Adverse Events, James Tift, MD - Chair**
 - **Guidelines, Russell Bessette, MD - Chair**
 - **Accreditation, Rebecca Twersky, MD - Chair**



BACKGROUND (CONTINUED)

Committee heard testimony from:

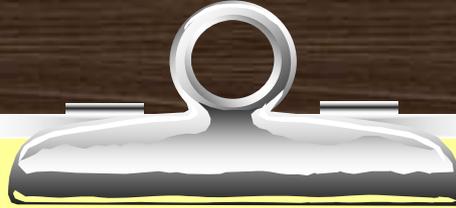
- **DOH representatives from the Florida & California**
- **Organizations that accredit OBS (AAAASF, AAAHC, The Joint Commission)**
- **Associations – GNYHA, HANYS, NYAASC**
- **Provider organizations, e.g., MSSNY, NYSANA, NY Chap. ACS, NYSAFP**



FINDINGS

Health care continues to evolve:

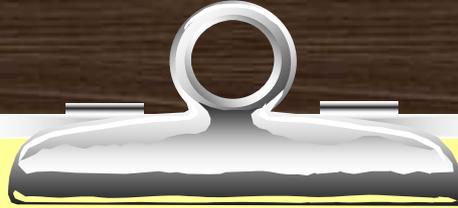
- **Increasingly complex procedures being done in the office**
- **Safer forms of anesthesia**
- **Efforts to improve efficiency and reduce cost**
- **Improving access/patient convenience**



FINDINGS

Guiding Principle - Balance

- **the need for Patient Safety (1⁰ goal)**
- **the need to advance care and efficiency**



RECOMMENDATIONS OF THE COMMITTEE ON QUALITY ASSURANCE IN OFFICE BASED SURGERY

- **DOH should seek legislative authority to provide oversight of the quality of care in OBS**
- **Report includes a model legislative proposal which provides:**
 - **Offices be accredited by a national accrediting body**
 - **Adverse events be reported to DOH - OPMC**

Report of the Committee on Quality Assurance in Office-Based Surgery

Bernard Rosof, M.D., MACP, Chair

January 2007

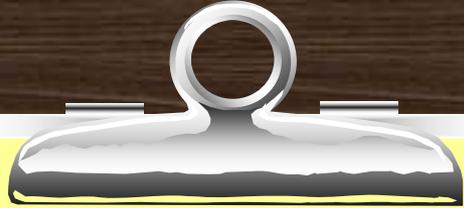
New York State Public Health Council

New York State Department of Health



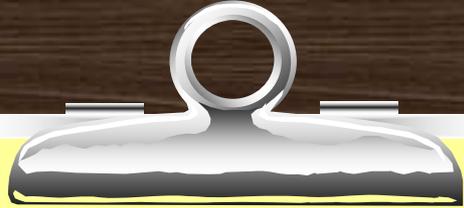
BILL HISTORY

- **DOH, with Governor Spitzer's support, submitted proposal to Legislature for introduction in February 2007**
- **Bill is introduced in the Assembly in May and the Senate in June.**
- **Intense negotiations in June.**
- **Amended bill passed both houses in June.**
- **Bill signed by Governor Spitzer on July 18, 2007**



MAJOR CHANGES TO THE PROPOSED LEGISLATION

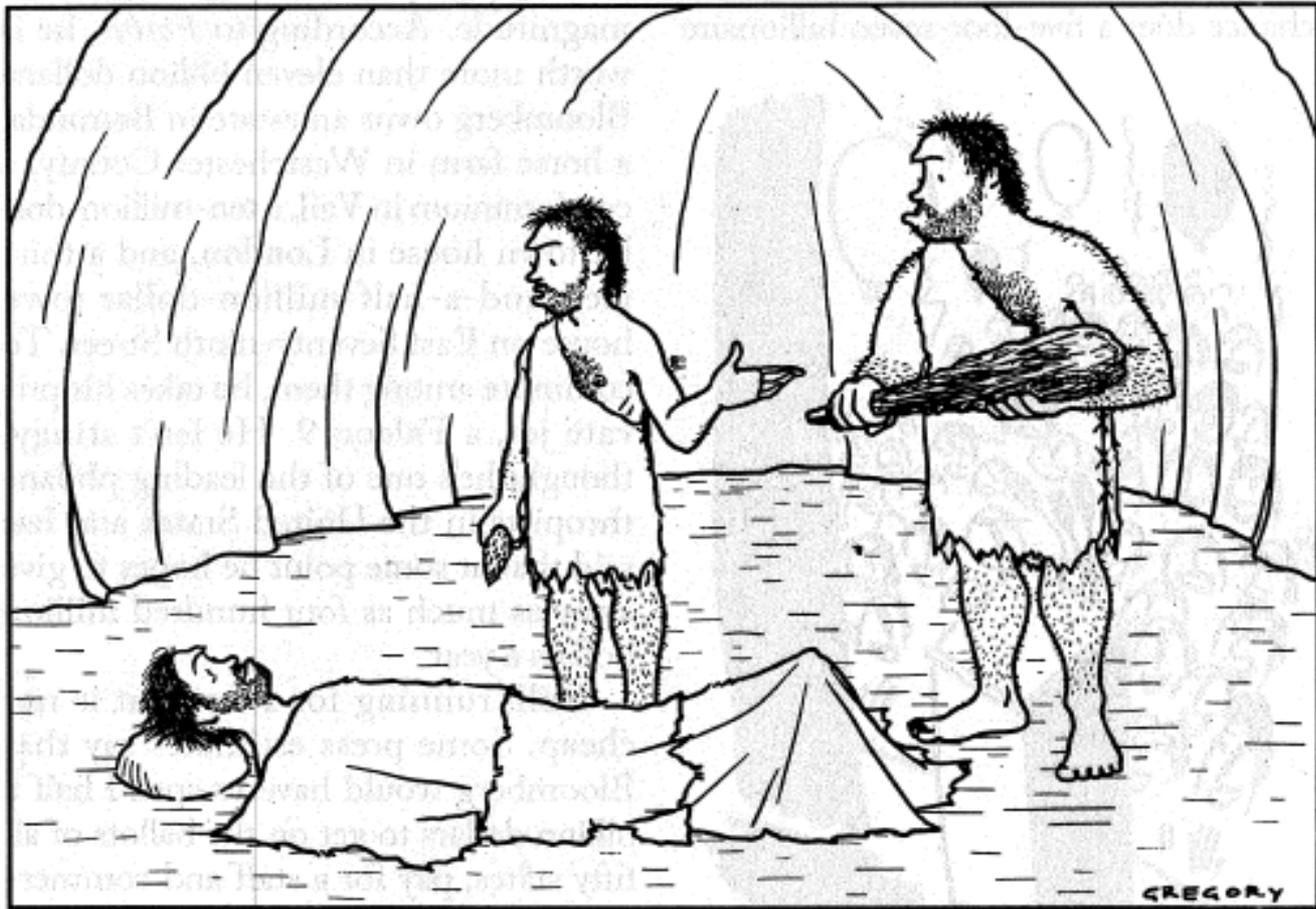
- **Adverse event reports will go to DOH Patient Safety Center rather than DOH - OPMC**
- **Specific reference to State Education Department (SED) in the regulatory process -- if any regulations affect scope of practice then concurrence of SED is required**
(scope of practice changes are not anticipated)



KEY DEFINITIONS

OBS includes -

- any surgical or invasive procedure **requiring moderate or deep sedation or general anesthesia.**
- **“Invasive Procedure” includes (but is not limited to):**
 - Endoscopy
 - Needle biopsy
 - Contrasted (intravascular injection) imaging.
- liposuction of greater than 500 cc of fat.

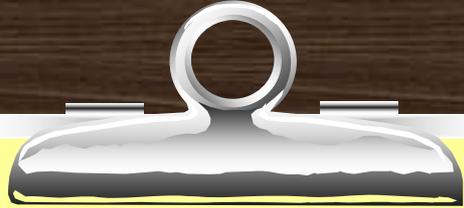


"I'll be performing the operation, and this is the anesthesiologist."



KEY DEFINITIONS

Moderate Sedation - a drug-induced depression of consciousness during which (i) the patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation; (ii) no interventions are required to maintain a patent airway; (iii) spontaneous ventilation is adequate; and (iv) *the patient's cardiovascular function is usually maintained without assistance.*



KEY DEFINITIONS

Excludes - “minor procedures” defined as:

- local anesthesia
- liposuction of less than 500 cc fat with unsupplemented local

Excludes - “minimal sedation”

- defined as a drug induced state in which patients respond normally to verbal commands and although cognitive function and coordination may be impaired, *ventilatory and cardiovascular functions are unaffected*

<http://www.asahq.org/>

Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists

An Updated Report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists

ANESTHESIOLOGISTS possess specific expertise in the pharmacology, physiology, and clinical management of patients receiving sedation and analgesia. For this reason, they are frequently called on to participate in the development of institutional policies and procedures for sedation and analgesia for diagnostic and therapeutic procedures. To assist in this process, the American Society of Anesthesiologists (ASA) has developed these "Guidelines for Sedation and Analgesia by Non-Anesthesiologists."

Practice guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints. Practice guidelines are not intended as standards or absolute requirements. The use of practice guidelines cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. The guidelines provide basic recommendations that are supported by analysis of the current literature and by a synthesis of expert opinion,

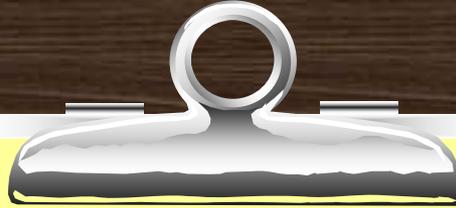
data and recommendations for a wider range of sedation levels than was previously addressed.

Definitions

"Sedation and analgesia" comprise a continuum of states ranging from minimal sedation (anxiolysis) through general anesthesia. Definitions of levels of sedation-analgesia, as developed and adopted by the ASA, are given in table 1. These Guidelines specifically apply to levels of sedation corresponding to moderate sedation (frequently called conscious sedation) and deep sedation, as defined in table 1.

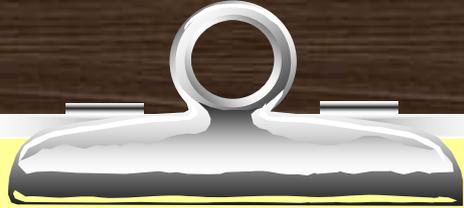
Focus

These Guidelines are designed to be applicable to procedures performed in a variety of settings (e.g., hospitals, freestanding clinics, physician, dental, and other offices) by practitioners who are not specialists in anesthesiology. Because minimal sedation (anxiolysis) entails



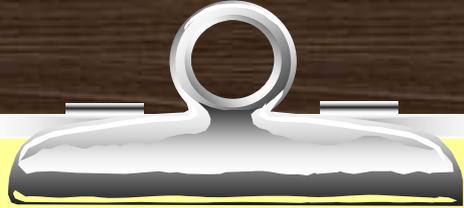
BASIC REQUIREMENTS -- OBS

- **Physicians, physician assistants (PAs), and specialist assistants (SAs) can only perform OBS in a setting that has received accreditation**
- **Physicians, physician assistants, and specialist assistants must report certain defined adverse events**
- **Failure to do either of the above constitutes professional misconduct** <http://www.op.nysed.gov/article131-a.htm>



ACCREDITATION

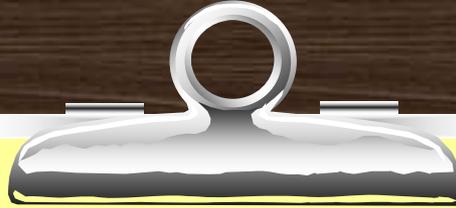
- **Practice must be accredited**
 - **if there are multiple locations each site must be accredited**
- **The new law applies to physicians, PAs, and SAs performing OBS as defined in the bill.**
 - **This legislation does not apply to dentistry/podiatry or other licensed healthcare professionals**



ACCREDITATION

Requirement for accreditation depends on level of sedation the patient experiences

- **NOT determined by the drugs used but by the affect on the patient.**
- **NOT determined by the procedure - 1 exception (>500cc's liposuction).**
- **Some examples of practices that are anticipated to be covered by this law include those performing:**
 - **GI endoscopy – colonoscopy, EGD**
 - **Rhinoplasty**
 - **Mammoplasty (reduction or augmentation)**

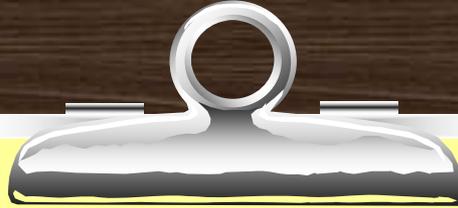


PLEASE NOTE:
“Urgent Care Center”

An “urgent care center” at which surgical or invasive procedures using moderate (or deeper) sedation is being used is either:

- an Article 28 facility or
- subject to OBS Law

must be 1 or the other.



PLEASE NOTE:

Faculty Practice Plan

A “Faculty Practice Plan” at which surgical or invasive procedures using moderate (or deeper) sedation is being used **is either:**

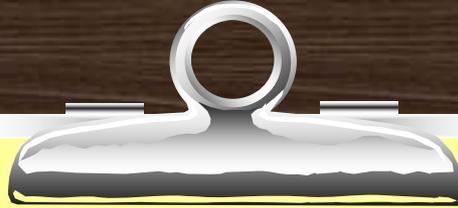
- an Article 28 facility or
- subject to OBS Law

must be 1 or the other.



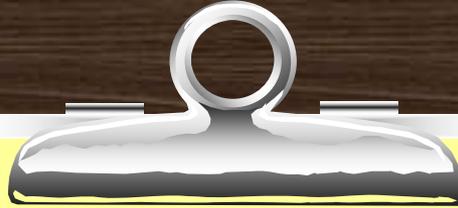
ADVERSE EVENT REPORTING

- **Physicians, PAs and SAs must report the following adverse events within one business day of learning of the event:**
 - **Patient death within 30 days**
 - **Unplanned transfer to a hospital (Emergency Department)**
 - **Unscheduled hospital admission within 72 hours of the office-based surgery for longer than 24 hours**
 - **Any other serious or life-threatening event**
- **Confidentiality protections are provided for the adverse event reporting.**
- **The Patient Safety Center is required to refer cases when appropriate to OPMC or any other office within the DOH.**

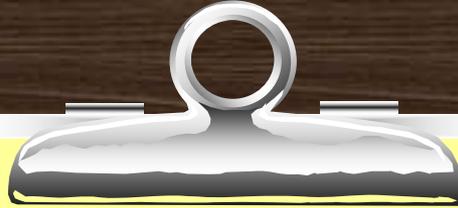


COMMISSIONER DESIGNATED ACCREDITATION AGENCIES

- **Accreditation Association for Ambulatory Health Care (AAAHC)**
- **American Association for Accreditation of Ambulatory Surgical Facilities, Inc. (AAAASF)**
- **The Joint Commission**



BUSINESS ISSUES



PROHIBITION ON THE CORPORATE PRACTICE OF MEDICINE

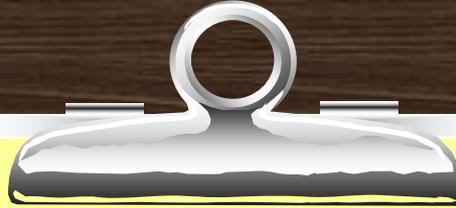
- New York Law does not permit a **business entity** to provide medical services unless the entity is an established Article 28 facility
- **NO** business or not-for-profit corporations or limited liability company may practice medicine
- Reference to the Law can be found at Education Law § 6512



PERMISSIBLE PHYSICIAN PRACTICE MODELS

- **Professional Partnerships**
- **Professional Corporations**
- **Professional Limited Liability Companies**

ALL partners, shareholders, officers, directors, members and managers must be NYS licensed physicians



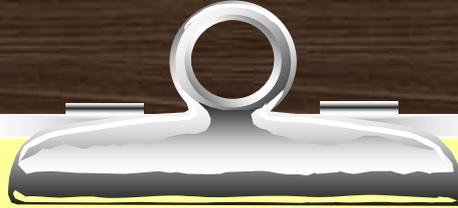
PUBLIC HEALTH REGULATIONS

- **“It shall be prima facie evidence that a diagnostic or treatment center is being operated when any provider of medical or health services describes itself to the public as a ‘center,’ ‘clinic’ or by any name other than the name of one or more of the practitioners providing these services”.**

10 NYCRR § 600.8

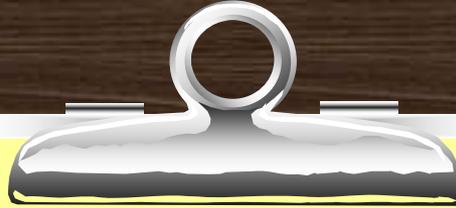


- It may be fraud for a physician practice to use a name which implies it is a facility in order to collect a facility fee
- We have had inquiries from Insurers and from the State Insurance Department regarding whether or not an entity is licensed.



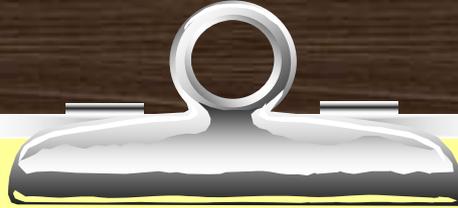
NO FACILITY RATE

- **Neither Medicare nor Medicaid reimburse physician practices (Non-Article 28) a facility fee**



IMPLEMENTATION

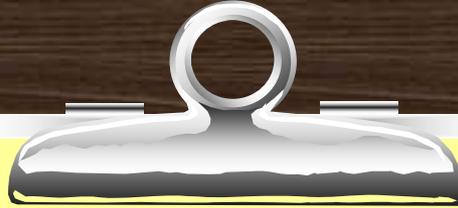
- **Letter to all MDs, PAs and SAs**
- **Frequently Asked Questions**



EDUCATION SESSIONS

- **January 15th – 5:00 pm to 6:30 pm**
90 Church Street, New York, NY

- **February 12th – 3:00 – 5:00 p.m.**
HANYS, Albany, NY



Contact Information

- **For website information go to:**
www.nyhealth.gov/professionals/office-based_surgery
- **Email address is:** obs@health.state.ny.us
- **Phone Contacts:**

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