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

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New York State Public Health Council

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New York State Public Health Council
Committee on Quality Assurance in Office Based Surgery

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Committee on Quality Assurance in Office-Based Surgery

Background

The New York State Department of Health reconvened the Committee on Quality Assurance in Office-Based Surgery (the Committee) in the fall of 2005. The Committee was reconvened, with additional members, because office-based surgical (OBS) procedures have increased to approximately 10 million annually in the United States; the New York State Department of Health's experience with several high profile cases of medical misconduct in the office-based surgical setting; and the Department's concern for public safety.

The Committee was originally established in late 1997 under the auspices of the New York State Public Health Council. The Committee was comprised of individuals representing various specialties including anesthesiology, internal medicine, gastroenterology, ophthalmology, general surgery, orthopedics, dentistry, professional organizations and consumers. The Committee developed clinical guidelines that physicians, dentists and podiatrists could use in establishing and operating office-based surgical practices. The guidelines were finalized in December 2000 and outlined recommendations for the environment of care and the safe provision of anesthesia services by trained and qualified personnel. They also included recommendations for the hiring and privileging of staff, office procedures, medical record keeping, infection control techniques, informed consent and the maintenance of equipment and operating rooms.

Distribution of the guidelines was suspended in 2001 due to a legal challenge by the New York State Association of Nurse Anesthetists (NYSANA). During this time the Department was enjoined from publishing and distributing the guidelines. In March

2004, the New York Court of Appeals ruled in favor of the New York State Department of Health and the Department reissued the guidelines.

Charge and Organization

The reconvened Committee, chaired by Bernard Rosof, MD, included the majority of the members who participated in the original committee, as well as consumer, registered professional nursing and additional medical specialty representation.

At the first meeting of the reconstituted Committee on October 11, 2005, the Department outlined several areas for which it requested recommendations:

a) Identify and track adverse events in the office-based setting;

b) Review what additional data is required in order to discover, evaluate and prevent adverse events, such as transfer to the emergency department of patients following office-based surgical care;

c) Study the potential risks and complications associated with multiple surgical procedures being performed on a single patient during the same day;

d) Make any additional recommendations the Committee deems necessary to improve the quality of care in office-based surgical practices, including recommendations to increase consumer awareness in this area.

The Committee held four full day meetings in late 2005 and early 2006. The initial October 11, 2005 meeting focused on the Department's charge to the committee; history of the original Committee and the subsequent litigation; and clarification of the limit of Department of Health's authority to regulate the office setting under current law. This and subsequent meetings included reviews of materials on other states' OBS requirements, and public comment from a variety of organizations: the American Association of Accreditation of Ambulatory Surgery Facilities, (AAAASF), the Accreditation Association for Ambulatory Health Care, (AAAHC) Validare Inc., Somnia

Inc., the Greater New York Hospital Association, the NYS Association of Nurse Anesthetists, the NYS Academy of Family Medicine, the American College of Surgeons and the NYS Ambulatory Surgical Association regarding their perspective on office-based surgery.

In considering the scope of their work, the Committee very strongly supported the concept that consumers should be assured there are consistent, equal regulatory standards in place regardless of the outpatient surgical setting. For example, the same standard should apply in an ambulatory surgical care center, as in a physician office-based surgical practice, or in a dentist or podiatrist's office. The Committee recognized that the New York State Department of Health does not have regulatory oversight over the practice of podiatry, dentistry or nursing. This oversight rests with the New York State Education Department. Representatives of the New York State Education Department participated in all the Committee meetings. While the Committee understood and appreciated this separation of regulatory authority, it supported the position that recommendations apply to all OBS settings, including podiatry and dentistry, so that consumers can be assured there is a single standard of care.

Work of the Subcommittees

In order to accomplish its work, Dr. Rosof assigned four subcommittees:

The Statutory/Regulation Subcommittee was chaired by Dr. William Rosenblatt, the Accreditation Subcommittee was chaired by Dr. Rebecca Twersky, the Adverse Event Reporting Subcommittee was chaired by Dr. James Tifft and the Guidelines Subcommittee was chaired by Dr. Russell Bessette**.**

Each subcommittee developed a mission statement. The following is the membership and mission statement for each subcommittee.

Statutory/Regulation Subcommittee

William Rosenblatt, MD Chair; Robert Kennedy, MD; Arthur Levin, MPH; Deborah Gray

"To provide a safe environment for procedures done in the office-based setting."

Accreditation Subcommittee

Rebecca Twersky, MD, Chair; Andrew Kleinman, MD; Susan Sullivan, RN; Joseph Bernatt, DDS

"To review existing/current national data on accreditation for office-based surgery and make recommendations to improve the quality of care."

Adverse Event Subcommittee

James Tifft, MD, Chair; Deborah Spratt, RN, MPA; William Dolan, MD; Elizabeth Almeyda, MD

"To provide assurance that adverse events occurring in any private office setting specifically related to the procedure are reported and reviewed for quality and appropriateness of care. Poor quality, as defined by generally accepted medical standards and/or practice, will be reported to an appropriate sanctioning body for action."

Guidelines Subcommittee

Russell Bessette MD, Chair; Thea Graves Pellman; Stanley Grossman, MD; David Bank, MD; Scott Groudine, MD

1) "To study the potential risks and complications associated with multi-specialty, multi-procedures performed on a single patient in a single day in an office-based setting;
2) To make additional recommendations to the existing guidelines, as necessary;
3) To publicize the guidelines to practitioners who perform procedures and surgery in an office-based setting and their patients;

4) To understand the value of the current guidelines from both a practitioner and patient perspective."

At the November 29, 2005 meeting of the Committee, the subcommittees also met and deliberated the pros and cons of requiring office-based surgical practices to be accredited and considered the definition of adverse events, which would require a process for reporting. The subcommittees received input from the three existing national office-based accrediting organizations: AAAASF, Joint Commission on Accreditation of Health Care Organizations (JCAHO), & AAAHC on how accreditation is done in their organization, including adverse event reporting. Discussions also centered on a new requirement for the Statewide Planning and Research Cooperative System (SPARCS) to report patients transferred, admitted or treated at a hospital subsequent to a medical, surgical, or diagnostic procedure.

Subcommittee Recommendations

The January 18, 2006 meeting of the Committee included presentations on the Florida and California requirements for office-based surgical practices, as well as a presentation by the American Association of Accreditation of Ambulatory Surgery Facilities (AAAASF) of their aggregated data, and a discussion by Dr. Stanley Grossman regarding Medical Liability Mutual Insurance Company (MLMIC) closed claims related to office-based surgical practices. At the March 31, 2006 committee meeting each subcommittee gave its final recommendations.

The Accreditation Subcommittee submitted its recommendation that New York State require accreditation of office-based surgical practices by nationally recognized accrediting agencies, as determined by the Commissioner of Health.

Prior to reaching this final recommendation, the Accreditation Subcommittee invited representatives of the following accrediting organizations to provide information to the Subcommittee:

- American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF).
- Accreditation Association for Ambulatory Health Care, Inc. (AAAHC)
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Each accrediting body submitted its specific accreditation criteria and developed a crosswalk between the current New York State OBS guidelines and the accreditation criteria for the subcommittee's review. A series of questions was also developed and posed to the accrediting bodies to determine if there are areas not covered by their accreditation process that are substantive to the New York State OBS guidelines and patient safety.

The subcommittee noted variability among accreditation agencies in the areas of adverse event reporting, peer review process, and credentialing/privileging of practitioners without hospital privileges and enforcement, which will require development of a New York State specific template.

The Adverse Event Subcommittee discussed the current reporting requirements for hospitals, diagnostic and treatment centers and ambulatory surgery centers. The Subcommittee also considered the draft consensus document developed by AAAASF, AAAHC and JCAHO for reportable adverse events in office-based surgery. The Subcommittee considered the following definitions of reportable adverse events:

- Patient deaths related to the procedure for surgery that takes place in the office setting or within 30 days of discharge from the office;

- Transfer to a hospital or emergency center for a period exceeding 24 hours;
- Unscheduled hospital admission for longer than 24 hours, within 72 hours of an office procedure and which is related to the procedure;
- Other serious events: a serious or life threatening event/ occurrence or situation in the office setting, involving the clinical care of a patient that comprises patient safety and results in unanticipated injury requiring the delivery of additional health care services to the patient.

After deliberation the subcommittee recommended that adverse events as defined be reported to the Department of Health. Confidentiality provisions should protect reported information consistent with the confidentiality provisions set forth in Section 230 of the Public Health Law (Office of Professional Medical Conduct).

The subcommittee also supported that the State Department of Health have regulatory oversight over office-based surgical practices. The subcommittee recommended that a new statute should include the following definition of adverse events: (i) patient death within 30 days (ii) unplanned transfer to a hospital (iii) unscheduled hospital admission within 72 hours of the office-based surgery for longer than 24 hours; or (iv) any other serious or life threatening event. Events must be reported within one business day from the date of awareness that a reportable event occurred.

The Guidelines Subcommittee discussed strategies to assure that staff are qualified to perform procedures in the office setting, mechanisms to assure safety when multiple procedures are done in one day and public education regarding OBS.

The Guidelines Subcommittee recommended that:

1 a) Any physician, performing surgery in an office setting should have hospital privileges in the specialty that is to be practiced in the office-based surgery setting.

The procedures that a physician is performing should be one(s) that are generally recognized by the American Board of Medical Specialties (ABMS) or its American Osteopathic Association (AOA) counterpart specific specialty as falling within the scope of practice of the physician providing the care;

OR

1 (b) The physician should be board certified by one of the American Board of Medical Specialties (ABMS) or its American Osteopathic Association (AOA) counterpart within three years of completion of residency (or as recommended by the ABMS/AOA specific specialty), and must have a transfer agreement with another physician who has admitting privileges at a nearby hospital. The procedures that a physician is performing should be ones that are generally recognized by that certifying board as falling within the scope of practice of the physician providing the care.

AND

2. The office must be accredited by a Department of Health approved accrediting agency.

3. A physician in an office-based surgery setting must document that all non-physician, licensed personnel practice in accordance with education, training, experience and scope of service for their assigned function.

4. When multiple procedures are performed in an office-based surgery setting, the physician should follow the guidelines and/or recommendations of the appropriate specialty society. The accrediting bodies will provide assurances to the New York State Department of Health, that the physicians are following the guidelines and recommendations of the appropriate specialty/subspecialty with regard to multiple procedures in an office-based setting.

5. All offices must be accredited by a New York State Department of Health deemed accrediting agency and should have a plaque, prominently displayed in the office, naming the accrediting body of which the physician is a member, and giving contact information for that accrediting body. The Department of Health and/or in conjunction with other New York State agencies should make information available to consumers regarding what steps should be taken prior to having an office-based surgical procedure, and in particular, what questions might be helpful to ask.

The Statutory/Regulation Subcommittee discussed the pros and cons of regulation versus guidelines regarding OBS. The subcommittee concluded that since guidelines do not carry the weight of regulation and are not enforceable, legislation was necessary, and submitted its recommendation, a draft legislative proposal, as follows:

Section 1. While the overwhelming majority of medical practitioners in private offices are providing outstanding care to their patients, the department of health has seen instances of improper care provided to surgery patients in the office-based setting. The problems that occur range from failure to adequately monitor patients to permanent injuries or death. Although New York State is recognized as a national leader in quality improvement and patient safety, the committee believes that in the area of office-based surgery, more needs to be done to ensure that patients receive the highest quality of care that is safe, effective, patient centered, timely, efficient and equitable.

§2. A new subdivision 48 is hereby added to section sixty five hundred thirty of the Education Law:

48. A violation of section two hundred thirty-d of the public health law or the regulations of the commissioner of health enacted thereunder.

§3 A new section two hundred thirty-d is hereby added to the Public Health Law:

230-d. Office-Based Surgery

1. Definitions: The following words or phrases, as used in this section shall have the following meanings:

(a) "Accredited status" means full accreditation by a nationally-recognized accrediting agency, as determined by the commissioner.

(b) "Adverse event" means (i) patient death within 30 days; (ii) unplanned transfer to a hospital; (iii) unscheduled hospital admission, within 72 hours of the office-based surgery, for longer than 24 hours; or (iv) any other serious or life-threatening event.

(c) "Deep sedation" means a drug-induced depression of consciousness during which (i) the patient cannot be easily aroused but responds purposefully following repeated painful stimulation; (ii) the patient's ability to maintain independent ventilatory function may be impaired; (iii) the patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate; and (iv) the patient's cardiovascular function is usually maintained without assistance.

(d) "General anesthesia" means a drug-induced depression of consciousness during which (i) the patient is not arousable, even by painful stimulation; (ii) the patient's ability to maintain independent ventilatory function is often impaired; (iii) the patient often requires assistance in maintaining a patent airway and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function; and (iv) the patient's cardiovascular function may be impaired.

(e)"Moderate sedation" means a drug-induced depression of consciousness during (i) which 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.

(f) "Minimal sedation" means a drug induced state during (i) which patients respond normally to verbal commands; (ii) cognitive function and coordination may be impaired; and (iii) ventilatory and cardiovascular functions are unaffected.

(g) "Minor procedures" means procedures that can be performed safely with a minimum of discomfort where the likelihood of complications requiring hospitalization is minimal; (i) procedures performed with local or topical anesthesia; ii) liposuction with removal of less than 500 cc of fat under unsupplemented local anesthesia.

(h) "Office-based surgery" means any surgical or other invasive procedure, excluding minor procedures and procedures requiring minimal sedation as previously defined, requiring general anesthesia, moderate sedation, or deep sedation, and liposuction, which is performed by a licensee in a location other than a hospital, as such term is defined in Article 28 hereof.

2. Licensee practices in which office-based surgery is performed shall obtain and maintain full accredited status.

3. Licensees may only practice in an office-based surgery practice that has obtained and maintained full accredited status.

4. Licensees must report within one business day, thereof, adverse events to the department's office of professional medical conduct, which data shall be subject to all confidentiality provisions provided by sections two hundred thirty and two hundred thirty-a of this title.

5. The commissioner of health shall make, adopt, promulgate and enforce such rules and regulations, as he or she may deem appropriate, to effectuate the purposes of this section.

6. The commissioner shall enter into agreements with accrediting agencies pursuant to which the accrediting agencies shall report, at a minimum, aggregate data on adverse

events for all office-based surgical practices accredited by the accrediting agencies to the department. The department may disclose reports of aggregate data to the public.

7. The information required to be collected, maintained and reported directly to the department regarding adverse events pursuant to this section shall be kept confidential and shall not be released, except to the department and except as required or permitted under sections two hundred thirty-a (9)(a) and two hundred thirty-a (10)(a)(v) of the public health law. Notwithstanding any other provision of law, none of such information shall be subject to disclosure under article six of the public officers law or article thirty-one of the civil practice law and rules.

8. This act shall take effect immediately, provided, however, that subdivisions two and three of section two hundred thirty - d of the public health law shall take effect two years after the effective date thereof.

Committee Recommendations

The full committee met on March 30, 2006 and after a public comment period considered all the subcommittees recommendations. The full committee endorsed all the recommendations of the subcommittees. The committee concluded that the New York State Department of Health should seek the legislative authority to require accreditation of office-based surgical practices, including adverse event reporting as outlined in this report. This legislative proposal only applies to physicians, since that is the only OBS practitioner regulated by the New York State Department of Health. However, the committee strongly recommended that this be a template for the New York State Education Department and that the New York State Education Department adopt the same recommendations for the professions it regulates that perform OBS so that consumers are assured that there is one standard of care across all office based practices. The committee was hopeful that if these recommendations are adopted and followed by practitioners, quality in office-based surgical practices will be optimized.

APPENDIX

1) Meeting summary of October 11, 2005 full committee meeting.

2) Meeting summary of November 29, 2005 full committee meeting.

3) Meeting summary of January 18, 2006 full committee meeting.

4) Meeting summary of March 30, 2006 full committee meeting.

Committee on Quality Assurance in Office Based Surgery
New York State Public Health Council
October 11, 2005
Meeting Summary

Agenda Item	Discussion
Welcome and Introductions	Introductions were made by Committee Members, Department of Health representatives and the public
Charge to the Committee	The Department presented the charge to the Committee. Since the Committee first issued the guidelines in late 2000, the number of surgical procedures performed in the office setting has continued to increase and has more than doubled in the last decade – with approximately 10 million procedures performed annually. The Department requested that the Committee make recommendations focused in four areas: • Better identify and track adverse events involving OBS patients; • Look at data on the use of emergency care administered to patients following OBS and determine what additional data should be reported to prevent adverse events; • Study the potential risks and complications associated with multiple surgical procedures being performed on a single patient on the same day and make additional recommendations to the guidelines; Make any other additional recommendations it deems necessary to improve the quality of care in OBS including recommendations on empowering the consumer to increase safety in OBS.
History of the Original Committee	Dr. Rosof and Lisa McMurdo provided the history, background and charge to the original committee, many of whom are on the current committee. The group was convened in December 1997 and issued its report in December 2001. The Executive Summary of the report was reviewed by the group. This included the following recommendations: • Department of Health develop a mechanism to monitor outcomes in OBS; • Department of Health should seek statutory authority if the guidelines are found to be ineffective; • OBS practices should seek accreditation from outside agencies;

	• OBS practices should establish performance improvement programs and Department of Health should seek legislation to protect information from discovery and disclosure; • Department of Health should explore whether NYPORTS can be adapted to collect information on OBS adverse events; • Department of Health should consider the feasibility of a voluntary reporting system. There were three workgroups established in the original committee to work on credentialing, standards and guidelines. The group held three public hearings where it heard testimony from health care professionals, consumers and accrediting bodies. A survey of office based physician practices was conducted with the MSSNY. The guidelines covered all settings of care including podiatry, dental as well as medical practices. An RFP was developed and issued to assess the impact of the guidelines. However, it was never awarded due to a lawsuit brought against Department of Health by CRNAs. Also, any evaluation of the impact of the guidelines was impossible as the guidelines were not able to be distributed after the lawsuit was filed in 2001.
Legal issues	Don Berens summarized the legal action and disposition of the lawsuit against Department of Health. (see handout) The lower court interpreted the guidelines as enforceable standards, which was never Department of Health's intent. The State Appellate Court agreed with the decision of the lower court. The highest court, the State Court of Appeals dismissed the suit on the grounds that CRNAs did not have standing to bring a lawsuit. The Court of Appeals did not rule on the decision made by the lower courts regarding the interpretation of the guidelines as enforceable standards. Department of Health cannot issue regulations per State Education Law 6532. Department of Health reissued the guidelines in the spring of 2004. There was discussion about how current the guidelines are and recommendations by national organizations that guidelines should be reviewed every two years. There was also discussion on whether the guidelines would have changed the outcome of the highlighted OPMC cases, the speaker indicating that outliers don't follow the rules that most OBS practices adhere to. Legislation was recently passed that established a new code in

	SPARCS that indicates whether a patient came to the hospital or ED as a result of an OBS procedure, which becomes effective in January 2006. It was noted that additional legislation is needed to protect the confidentiality of OBS information as many practitioners collect this data already, as it is required by the various accrediting bodies. Further discussion ensued about how the SED law would have to be changed to allow Department of Health to regulate physician practice and the current limits of Department of Health regulatory authority on OBS. The distinction was made between physician practices and "hospitals" and how there are different standards for different settings. Lisa will provide the outmigration document and applicable regulations by email after the meeting.
Other states requirements for OBS practices	Cynthia Weber Glynn and Dr. Renee Samelson reviewed models from other states regarding OBS, focusing on Florida, California and New Jersey. (see handouts). OPMC is a member of the Federation of State Medical Boards. That group generated model guidelines and looked at NY's guidelines during the development process. In their recommendations, they outlined three pathways states could take regarding OBS practices: • Adopt federation "model" guidelines • Require accreditation • Develop regulations or their own guidelines 20 states have gone through the process of developing guidelines/regs/statute around OBS. Of those states that developed guidelines, 3 states are looking to move to regulation. There was further discussion about data collection. NY has no data and therefore does not know the prevalence of adverse events in the OBS setting. One can't compare to the hospital setting or ASC's because they are regulated and are required to report certain types of events. There are other sources of data to use – AAAASF has data on over 900,000 surgeries. There was discussion of why there is a trend towards OBS vs. more traditional settings for procedures: • Patient satisfaction • Physician efficiency

	• Regulatory burden in hospital setting • Cost
Public Comment Period	There were several audience members who spoke during the public comment period. Representatives from accrediting organizations, a healthcare consulting group, an anesthesiology group providing anesthesia services in several states including NY and an operator of 2 ASCs in central NY and surveyor for AAAHC. Many submitted written comments. JCAHO submitted a letter after the meeting which has been distributed to the committee. The speakers were: 1- Jeff Pearcy - AAAASF 2- Karen Lokurtz - AAAHC 3- Linda Rudolph, RN - Validare 4- Marc Koch MD, Somnia, Inc. 5 - Syed Ishaq-surveyor, AAAHC 6 - Margaret Alteri, NYS Amb Surgery Assoc.
Committee Workplan	Dr. Rosof proposed the formation of workgroups, similar to what was done previously, to study the pros/cons/barriers in 4 different areas and recommended committee chairs for each group: • Regulations - Dr. Rosenblatt Chair • Accreditation - Dr. Twersky Chair • Reporting - Dr. Tifft Chair • Guidelines - Dr. Bessette Chair
Next Steps	• Department of Health staff will be assigned to each workgroup • Committee members should email Lisa with preferences for appointment to a workgroup. • Contact State Education Department since original guidelines addressed a broader range of practitioners (i.e. podiatrists, dentists) • Workgroups will meet in the morning with the larger group convening in the afternoon • Next meeting scheduled for November 29, 2005 at 90 Church Street in New York City • A conference call will be scheduled prior to the next meeting • Anticipate 1 - 2 subsequent meetings after November with issuance of recommendations in the Spring 2006.

Committee on Quality Assurance in Office Based Surgery
New York State Public Health Council
NYS Department of Health
November 29, 2005
Meeting Summary

Agenda Item	Discussion
Welcome and Introductions	Introductions were made by Committee members, Department of Health representatives, State Education Department representatives and the public.
Subcommittee Reports	Reports were presented by the Subcommittee Chairs and discussion followed (see attached subcommittee meeting summaries) o Regulations - Dr. Rosenblatt o Accreditation - Dr. Twersky o Adverse Events Reporting - Dr. Tifft o Guidelines - Dr. Bessette
Committee Deliberations	The subcommittees have additional work to complete before final recommendations can be made. The following issues still need to be addressed: o If accreditation is endorsed, what will be the impact from a fiscal, geographic and access to health care perspective; o If the committee recommends accreditation, should a NYS template be developed; o Look at lessons learned from experience of other states that have required accreditation - pros/cons; o Statute (draft) needs to be considered by the full committee; o Adverse events - consider current models, self reporting and the SPARCS legislative amendment; o Guidelines - look toward a single statewide standard related to quality and safety by State Education Department and Department of Health; o If the committee moves from guidelines to statute, need to look at the most current definitions (may need to be updated from the original guidelines that were issued); how will that guide the Department; should they be more specific or less specific? o Discordance among accreditation groups on their

	requirements; o How will reporting help meet the goals of this committee related to improving quality and safety.
Next Steps	o AAAASF will present a report to the committee on aggregate data and NY trends as compared to other states at the next meeting; o JCAHO & AAAHC will be contacted to see what data they may have o Reports will be presented regarding the barriers to implementation, successes and lessons learned in other states that currently require accreditation for office based surgical practices; o Data from the 3 accrediting organizations will be shared prior to the next meeting; o Dr. Grossman will present a report on findings from MLMC data (claims data); o Draft subcommittee recommendations will be presented to the full committee; o Next meeting will be held on January 18, 2006 at 90 Church Street, New York City

Committee on Quality Assurance in Office Based Surgery
New York State Public Health Council
NYS Department of Health
January 18, 2006
Meeting Summary

Agenda Item	Discussion
Opening Remarks by Dr. Rosof	Dr. Rosof presented a meeting overview beginning with the information the committee would be hearing from Florida and California keeping in mind the following: ▪ Adverse event reporting requirements ▪ What would states do differently - lessons learned ▪ Public comments Data will be presented from MLMIC and from AAAASF After the presentations, the full committee can start the discussion on a consensus document or final draft recommendations. Other issues: ▪ Specific questions to the accreditation agencies ▪ Education - Physicians, public - how to accomplish? ▪ Department of Health communication with specialty societies - prior to completion of committees task ▪ AMA Core Principles regarding OBS: o Guidelines/regulations developed by states according to levels of anesthesia o Criteria for patient selection based on ASA class o Accredited by state recognized entity o Admitting privileges to a hospital or transfer agreement o FSMB guidelines followed o Adverse events defined - FSMB o Board certification within 5 years of completing residency o Core privileges at a hospital or ASC o ACLS on premises o Moderate, deep sedation or general anesthesia requires appropriate education or training
Welcome and Introductions	Introductions were made by Committee Members, Department of Health representatives, State Education Department representatives, invited guests and the public.

Report by Florida Board of Medicine	A powerpoint presentation was given by Larry McPherson via teleconference (see handout). Highlights included: ▪ Regulatory framework in FL includes the Agency for Healthcare Administration and the Florida Department of Health ▪ Three statutes that allow Florida to regulate OBS ▪ The Board may approve accrediting agencies other than the nationally known organizations ▪ Reporting requirements are public. No confidentiality protections. Patient identifiers are redacted. ▪ Patient safety has improved with the passage of legislation ▪ If an OBS practice is not accredited by a national organization, the state performs annual inspections for a flat fee ▪ Level III requirements include staff privileges at a hospital or a transfer agreement or demonstration to the Board the training and knowledge to perform such procedures ▪ The Board of Medicine has 10 committees. Committee members are all Board members. The Committees do research, hold meetings and present recommendations to the full Board. ▪ OBS practices performing Level II and III procedures must be registered but are not licensed (such as hospitals and ASCs) ▪ Reporting publicly has not been an issue in terms of causing "harm" to physicians. There has been no attempt to "paint" physician practices in a bad light ▪ There have been consumer educational efforts regarding OBS and the accreditation process. They have made enhancements to their website and there is a brochure for consumers on OBS ▪ Advice for NYS o Stay on target - focus should be on patient safety o FLA physicians have been supportive - they have been kept involved in the process o Continuous process addressing issues, making changes and improvements.

California Medical Board Requirements	There was no one from California available to make a presentation. Cynthia Weber Glynn summarized the California requirements outlined in a handout. There was discussion about Florida's experience as compared to California. Even though California has had regulations in place for about ten years, there appeared to be little hard data from the system.
MLMIC Presentation	Dr. Stanley Grossman reported on the findings from claims data related to medical malpractice closed cases from 1993 - 2003. Cases were reviewed by specialty and location: ▪ Gastroenterology - payouts for procedures performed in offices were higher than in the hospital ▪ Plastic Surgery - payouts from OBS twice as high as those in the hospital setting ▪ Anesthesia - only 8 cases - average payout was $235,000 - most frequent procedure was pain management Other issues: ▪ Physicians trained in one field, but because of new technology are using that technology in the office based setting ▪ Difficult to gather hard data on outcomes in the hospital and outpatient setting ▪ Translating anecdotal stories to hard data is a challenge ▪ Other countries such as Australia and Canada have hard data, but their systems are different than the US (socialized medicine) ▪ Difficult to determine denominators ▪ Liability carriers have some responsibility with coverage of procedures and the criteria used ▪ 2 of 3 accreditation agencies do not require a medical staff appointment. Hospitals will not grant physician privileges without medical malpractice insurance ▪ Need qualified OR and recovery room nurses in the OBS setting
AAAASF Presentation	Dr. Geoffrey Keyes presented a powerpoint presentation of morbidity and mortality findings from 900,000 OBS procedures. Overview of the AAAASF System and key principles:

	▪ Internet based relational database ▪ Decreasing variability improves outcomes ▪ Unanticipated sequelae occur regardless of the setting ▪ Look at outcomes during pre/intra/post operative state ▪ Deaths are reported within 5 days of occurrence ▪ An online web system is being rolled out ▪ Information is collected on random procedures and adverse events ▪ A summary of findings from their published paper were presented (yellow handout) o 1/299 procedures or .34% result in significant sequelae o A second study from 2001- 2004 showed 1/243 procedures or .41% resulted in significant sequelae o Most common complication is a hematoma o No deaths occurred from bleeding o 16 deaths occurred during the 4 year period (2001 - 2004) or .0018% o 10/16 deaths were attributable to a PE o 1 intraoperative death was related to anesthesia o Further study completed of PE deaths: • Looked at thromboprophylaxis management of patients at risk • 9/10 PE deaths were the result of abdominoplasty procedures • Looked at BMI and hypertension in PE deaths ▪ Physicians should have the same level of training for OBS procedures as in the hospital setting ▪ 116 approved AAAASF facilities in NYS ▪ Assurance of complete reporting - 3 cycle inspection - random cycle reviews - log books - no 100% guarantee but believe they would be able to recognize a problem if a facility wasn't reporting ▪ Of 1000 facilities that are accredited nationally, about 80% are plastic surgery practices ▪ Willing to share system with other accrediting agencies ▪ Don't have ASA breakdown for patients, but average age is 43, so assumption is that most patients are ASA Class I or II ▪ Will present NY data at a later date

Next Steps	▪ The full committee will meet from now on to discuss all issues and achieve consensus ▪ A single document will be produced that puts forth all of the recommendations of the subcommittees, including any inconsistencies (but noting them) in the document ▪ Need to discuss issues related to dentists and podiatrists at the next meeting ▪ A proposed statute will take time to negotiate, enact and implement. The committee needs to discuss interim steps, such as updating the guidelines ▪ Publicize educational effort while awaiting the legislation ▪ Need to reach out to medical societies, physician groups and specialty societies and invite them to the next meeting for public comment ▪ Next meeting is March 30, 2006 at 90 Church Street in New York City

Committee on Quality Assurance in Office Based Surgery
New York State Public Health Council
NYS Department of Health
March 30, 2006
Meeting Summary

Agenda Item	Discussion
Opening Remarks by Dr. Rosof	Dr. Rosof gave a meeting overview which involved a discussion of three letters that were sent to the Department of Health. He noted they will be part of the official record. They are from: ▪ NYS State Education Department ▪ NYS Podiatric Medical Association ▪ NYS Nurse's Association Dr. Rosof also reminded everyone of the Department's charge reflected on page 5 of the draft report and that the focus of the committee should be on public interest and safety. He wanted to reiterate the responsibilities of Department of Health and State Education Department in these areas and his goal to complete the work of the committee today. Dr. Rosof announced that there would be an executive session held after the public comment period. The Guidelines Subcommittee was requested to develop a statement, to be inserted in the draft report, recommending a single standard of care for all licensed healthcare professions performing office based surgical and diagnostic procedures. Additional Guidelines subcommittee recommendations will also be added to the report.
Public Comment	The following individuals provided remarks during the public comment period: ▪ Dr. John Sherman - NY Chapter of the American College of Surgeons, offered these considerations and concerns: o Reporting of adverse events to NYS OPMC is a concern o Board certification - the director needs to be certified, but anyone practicing at the facility should also be board certified or board eligible and that should be part of the bylaws

- All physicians practicing OBS should have admitting privileges to a hospital, the practice should have a transfer agreement in place and the physician should be credentialed for the procedure they are performing in the office (same scope of practice in the office as in the hospital)
- he recommends more active dissemination of all OPMC final actions

- Dr. LaBarbera - NYS Academy of Family Physicians, offered these comments:
  - No inherent greater risk of procedures in the office setting vs. other settings (quoted MILMC data on payouts in ambulatory settings being less than hospital settings)
  - Standard of care for colposcopy and endoscopy involve higher levels of sedation
  - Concerns with reporting of adverse events to OPMC with no prior peer review, this is overburdensome and there are issues of confidentiality
  - Most office-based procedures in FP practices are done under local anesthesia, but she had concerns about expansion

In response to Dr. LaBarbera's concerns, the issue of failure to rescue events was raised and how studies show that there is a difference in outcomes in an office based setting vs. an ASC or a hospital. Dr Grossman (who originally gave the MILMC report) indicated that no inference regarding the quality of the procedures based on where they were performed could be drawn from the statistics he gave. OPMC would handle the reporting of adverse events under their complaint program where the investigation and disposition is confidential, unless there is a final disciplinary action taken. Currently, OPMC receives approximately 7000 complaints annually, of which about 400 lead to some form of disciplinary action which also includes administrative warnings.

- Margaret Altieri - NYS Association of Ambulatory Surgery Centers, offered these remarks:
  - Concerns about length of time under sedation in report (Guidelines Subcommittee removed reference to 6 hours)
  - Section 230 of the PHL offers confidentiality protections to the licensee, regardless of the setting

	○ Supportive of draft thus far ▪ Margy Brown - NY Association of Nurse Anesthetists, offered these comments: ○ Supportive of safety in OBS ○ Choice of which accreditation organization to use should be at the discretion of the physician's office ○ Both CRNAs and anesthesiologists should have a seat on this committee ▪ Doris Varlese - Greater New York Hospital Association, had these comments: ○ Supportive of legislation proposed by the committee and agree that there should be a single standard of care regardless of setting ○ Supportive of the reporting of adverse events, but should also look at volume data In response to Ms. Varlese's remarks, it was noted that one problem with generating volume data is logistics, since physicians are not currently required to submit discharge data to SPARCS, as hospitals and Ambulatory Surgery Centers do. However AAAASF does collect volume data and is willing to provide NYS aggregate data to Department of Health. ▪ Jeff Pearcy - AAAASF voiced his support and indicated that as this moves toward the legislative end of the spectrum, they will continue to provide information as needed.
Executive Session	Committee Members and Department of Health staff met for approximately one hour.
Committee deliberations and development of final recommendations	The OBS draft report was reviewed page by page and changes will be reflected in the new draft document. Dr. Rosof suggested that a conference call be scheduled with him and the chairs of each subcommittee to discuss the final changes/recommendations to the report before it is presented to the Public Health Council (July) and the State Hospital Review and Planning Council (5/25/06).