

North Carolina Medical Board
Policy Committee Meeting
Wednesday, May 18, 2011

Committee Members: Dr. Loomis, Chairman; Dr. Camnitz and Dr. Greene

1. Old Business:

a. Position Statement Review

Issue: In November 2009, the Board approved the Policy Committee's recommendation to review Position Statements at least once every four years. A review schedule has been formulated for the Committee's consideration.

Position Statements for continued review:

- i. Office-Based Procedures
- ii. Self-Treatment and Treatment of Family Members and Others with Whom Significant Emotional Relationships Exist

2. New Business:

a. Position Statement Review

Issue: In November 2009, the Board approved the Policy Committee's recommendation to review Position Statements at least once every four years. A review schedule has been formulated for the Committee's consideration.

Position Statements for review:

- i. Prescribing Legend or Controlled Substances for Other Than Valid Medical or Therapeutic Purposes, with Particular Reference to Substances or Preparations with Anabolic Properties
- ii. Sale of Goods from Physician Offices

b. Writing of Prescriptions

Issue: Does our position statement require changing in light of DEA's decision to permit e-prescribing of controlled substances?

1. Old Business

a. Position Statement Review

i. – Office Based Procedures

Issue: In November 2009, the Board approved the Policy Committee's recommendation to review Position Statements at least once every four years. A review schedule has been formulated for the Committee's consideration.

9/2010 Committee Recommendation: Table this issue to allow comments from the full Board to be received. All comments will be considered at the November Committee meeting.

9/2010 Board Action: Adopt the Committee recommendation

11/2010 Committee Recommendation: Table this issue. Request input from standard distribution list, as well as, plastic surgeon speciality, dermatology speciality, OBGYN speciality, GI speciality, and insurance companies.

11/2010 Board Action: Adopt Committee recommendation.

1/2011 Committee Discussion: The Committee discussed comments received from various parties. The Committee agreed that the position statement is lengthy, but included important and useful information. The Committee instructed the staff to inquire about the inclusion of language addressing "expenses of accreditation." The Committee also suggested that language may be added to better explain what the Board views as "reasonable proximity."

1/2011 Committee Recommendation: Table issue until the March 2011 meeting. Legal will wordsmith the position statement to incorporate suggested changes and attempt to reorganize the position statement to make it more accessible.

1/2011 Board Action: Adopt Committee recommendation.

3/2011 Committee Discussion: The Committee reviewed the current position statement with new formatting that the staff felt would make it easier to negotiate its content. The staff reported that the language addressing "expenses of accreditation" was considered fundamental at the time of the position statement's creation. The Committee made suggestions regarding the formatting of the preface section. It was suggested that "reasonable proximity" might be 30 minutes. The staff recommended adding "reasonable proximity" to the definition section. Additionally, it was suggested that the definition section be renamed Definitions and Acronyms.

3/2011 Committee Recommendation: Remain tabled until a draft encompassing the suggested changes could be prepared. The proposed position statement will be submitted to the Policy Committee prior to the May Board meeting.

3/2011 Board Action: Adopt Committee recommendation.

OFFICE-BASED PROCEDURES

Preface

This Position Statement on Office-Based Procedures is an interpretive statement that attempts to identify and explain the standards of practice for Office-Based Procedures in North Carolina. The Board's intention is to articulate existing professional standards and not to promulgate a new standard.

This Position Statement is in the form of guidelines designed to assure patient safety and identify the criteria by which the Board will assess the conduct of its licensees in considering disciplinary action arising out of the performance of office-based procedures. Thus, it is expected that the licensee who follows the guidelines set forth below will avoid disciplinary action by the Board. However, this Position Statement is not intended to be comprehensive or to set out exhaustively every standard that might apply in every circumstance. The silence of the Position Statement on any particular matter should not be construed as the lack of an enforceable standard.

General Guidelines

The Physician's Professional and Legal Obligation:

The North Carolina Medical Board has adopted the guidelines contained in this Position Statement in order to assure patients have access to safe, high quality office-based surgical and special procedures. The guidelines further assure that a licensed physician with appropriate qualifications takes responsibility for the supervision of all aspects of the perioperative surgical, procedural and anesthesia care delivered in the office setting, including compliance with all aspects of these guidelines.

These obligations are to be understood (as explained in the Preface) as existing standards identified by the Board in an effort to assure patient safety and provide licensees guidance to avoid practicing below the standards of practice in such a manner that the licensee would be exposed to possible disciplinary action for unprofessional conduct as contemplated in N.C. Gen. Stat. § 90-14(a)(6).

Exemptions:

These guidelines do not apply to Level I procedures.

Written Policies and Procedures:

Written policies and procedures should be maintained to assist office-based practices in providing safe and quality surgical or special procedure care, assure consistent personnel performance, and promote an awareness and understanding of the inherent rights of patients.

Emergency Procedure and Transfer Protocol:

The physician who performs the surgical or special procedure should assure that a transfer protocol is in place, preferably with a hospital that is licensed in the jurisdiction in which it is located and that is within reasonable proximity of the office where the procedure is performed.

All office personnel should be familiar with and capable of carrying out written emergency instructions. The instructions should be followed in the event of an emergency, any untoward anesthetic, medical or surgical complications, or other conditions making hospitalization of a

patient necessary. The instructions should include arrangements for immediate contact of emergency medical services when indicated and when advanced cardiac life support is needed. When emergency medical services are not indicated, the instructions should include procedures for timely escort of the patient to the hospital or to an appropriate practitioner.

Infection Control:

The practice should comply with state and federal regulations regarding infection control. For all surgical and special procedures, the level of sterilization should meet applicable industry and occupational safety requirements. There should be a procedure and schedule for cleaning, disinfecting and sterilizing equipment and patient care items. Personnel should be trained in infection control practices, implementation of universal precautions, and disposal of hazardous waste products. Protective clothing and equipment should be readily available.

Performance Improvement:

A performance improvement program should be implemented to provide a mechanism to review yearly the current practice activities and quality of care provided to patients.

Performance improvement activities should include, but are not limited to, review of mortalities; the appropriateness and necessity of procedures performed; emergency transfers; reportable complications, and resultant outcomes (including all postoperative infections); analysis of patient satisfaction surveys and complaints; and identification of undesirable trends (such as diagnostic errors, unacceptable results, follow-up of abnormal test results, medication errors, and system problems). Findings of the performance improvement program should be incorporated into the practice's educational activity.

Medical Records and Informed Consent:

The practice should have a procedure for initiating and maintaining a health record for every patient evaluated or treated. The record should include a procedure code or suitable narrative description of the procedure and should have sufficient information to identify the patient, support the diagnosis, justify the treatment, and document the outcome and required follow-up care.

Medical history, physical examination, lab studies obtained within 30 days of the scheduled procedure, and pre-anesthesia examination and evaluation information and data should be adequately documented in the medical record.

The medical records also should contain documentation of the intraoperative and postoperative monitoring required by these guidelines.

Written documentation of informed consent should be included in the medical record.

Credentialing of Physicians:

A physician who performs surgical or special procedures in an office requiring the administration of anesthesia services should be credentialed to perform that surgical or special procedure by a hospital, an ambulatory surgical facility, or substantially comply with criteria established by the Board.

Criteria to be considered by the Board in assessing a physician's competence to perform a surgical or special procedure include, without limitation:

1. state licensure;

2. procedure specific education, training, experience and successful evaluation appropriate for the patient population being treated (*i.e.*, pediatrics);
3. for physicians, board certification, board eligibility or completion of a training program in a field of specialization recognized by the ACGME or by a national medical specialty board that is recognized by the ABMS for expertise and proficiency in that field. For purposes of this requirement, board eligibility or certification is relevant only if the board in question is recognized by the ABMS, AOA, or equivalent board certification as determined by the Board;
4. professional misconduct and malpractice history;
5. participation in peer and quality review;
6. participation in continuing education consistent with the statutory requirements and requirements of the physician's professional organization;
7. to the extent such coverage is reasonably available in North Carolina, malpractice insurance coverage for the surgical or special procedures being performed in the office;
8. procedure-specific competence (and competence in the use of new procedures and technology), which should encompass education, training, experience and evaluation, and which may include the following:
 - a. adherence to professional society standards;
 - b. credentials approved by a nationally recognized accrediting or credentialing entity; or
 - c. didactic course complemented by hands-on, observed experience; training is to be followed by a specified number of cases supervised by a practitioner already competent in the respective procedure, in accordance with professional society standards.

If the physician administers the anesthetic as part of a surgical or special procedure (Level II only), he or she also should have documented competence to deliver the level of anesthesia administered.

Accreditation:

After one year of operation following the adoption of these guidelines, any physician who performs Level II or Level III procedures in an office should be able to demonstrate, upon request by the Board, substantial compliance with these guidelines, or should obtain accreditation of the office setting by an approved accreditation agency or organization. The approved accreditation agency or organization should submit, upon request by the Board, a summary report for the office accredited by that agency.

All expenses related to accreditation or compliance with these guidelines shall be paid by the physician who performs the surgical or special procedures.

Patient Selection:

The physician who performs the surgical or special procedure should evaluate the condition of the patient and the potential risks associated with the proposed treatment plan. The physician also is responsible for determining that the patient has an adequate support system to provide for necessary follow-up care. Patients with pre-existing medical problems or other conditions, who are at undue risk for complications, should be referred to an appropriate specialist for preoperative consultation.

ASA Physical Status Classifications:

Patients that are considered high risk or are ASA physical status classification III, IV, or V and require a general anesthetic for the surgical procedure, should not have the surgical or special procedure performed in a physician office setting.

Candidates for Level II Procedures:

Patients with an ASA physical status classification I, II, or III may be acceptable candidates for office-based surgical or special procedures requiring conscious sedation/ analgesia. ASA physical status classification III patients should be specifically addressed in the operating manual for the office. They may be acceptable candidates if deemed so by a physician qualified to assess the specific disability and its impact on anesthesia and surgical or procedural risks.

Candidates for Level III Procedures:

Only patients with an ASA physical status classification I or II, who have no airway abnormality, and possess an unremarkable anesthetic history are acceptable candidates for Level III procedures.

Surgical or Special Procedure Guidelines

Patient Preparation:

A medical history and physical examination to evaluate the risk of anesthesia and of the proposed surgical or special procedure should be performed by a physician qualified to assess the impact of co-existing disease processes on surgery and anesthesia. Appropriate laboratory studies should be obtained within 30 days of the planned surgical procedure.

A pre-procedure examination and evaluation should be conducted prior to the surgical or special procedure by the physician. The information and data obtained during the course of this evaluation should be documented in the medical record

The physician performing the surgical or special procedure also should:

1. ensure that an appropriate pre-anesthetic examination and evaluation is performed proximate to the procedure;
2. prescribe the anesthetic, unless the anesthesia is administered by an anesthesiologist in which case the anesthesiologist may prescribe the anesthetic;
3. ensure that qualified health care professionals participate;
4. remain physically present during the intraoperative period and be immediately available for diagnosis, treatment, and management of anesthesia-related complications or emergencies; and
5. ensure the provision of indicated post-anesthesia care.

Discharge Criteria:

Criteria for discharge for all patients who have received anesthesia should include the following:

1. confirmation of stable vital signs;
2. stable oxygen saturation levels;
3. return to pre-procedure mental status;
4. adequate pain control;
5. minimal bleeding, nausea and vomiting;
6. resolving neural blockade, resolution of the neuraxial blockade; and
7. eligible to be discharged in the company of a competent adult.

Information to the Patient:

The patient should receive verbal instruction understandable to the patient or guardian, confirmed by written post-operative instructions and emergency contact numbers. The instructions should include:

1. the procedure performed;
2. information about potential complications;
3. telephone numbers to be used by the patient to discuss complications or should questions arise;
4. instructions for medications prescribed and pain management;
5. information regarding the follow-up visit date, time and location; and
6. designated treatment hospital in the event of emergency.

Reportable Complications:

Physicians performing surgical or special procedures in the office should maintain timely records, which should be provided to the Board within three business days of receipt of a Board inquiry. Records of reportable complications should be in writing and should include:

1. physician's name and license number;
2. date and time of the occurrence;
3. office where the occurrence took place;
4. name and address of the patient;
5. surgical or special procedure involved;
6. type and dosage of sedation or anesthesia utilized in the procedure; and
7. circumstances involved in the occurrence.

Equipment Maintenance:

All anesthesia-related equipment and monitors should be maintained to current operating room standards. All devices should have regular service/maintenance checks at least annually or per manufacturer recommendations. Service/maintenance checks should be performed by appropriately qualified biomedical personnel. Prior to the administration of anesthesia, all equipment/monitors should be checked using the current FDA recommendations as a guideline. Records of equipment checks should be maintained in a separate, dedicated log which must be made available to the Board upon request. Documentation of any criteria deemed to be substandard should include a clear description of the problem and the intervention. If equipment is utilized despite the problem, documentation should clearly indicate that patient safety is not in jeopardy.

The emergency supplies should be maintained and inspected by qualified personnel for presence and function of all appropriate equipment and drugs at intervals established by protocol to ensure that equipment is functional and present, drugs are not expired, and office personnel are familiar with equipment and supplies. Records of emergency supply checks should be maintained in a separate, dedicated log and made available to the Board upon request.

A physician should not permit anyone to tamper with a safety system or any monitoring device or disconnect an alarm system.

Compliance with Relevant Health Laws:

Federal and state laws and regulations that affect the practice should be identified and procedures developed to comply with those requirements.

Nothing in this position statement affects the scope of activities subject to or exempted from the North Carolina health care facility licensure laws.¹

Patient Rights:

Office personnel should be informed about the basic rights of patients and understand the importance of maintaining patients' rights. A patients' rights document should be readily available upon request.

Enforcement:

In that the Board believes that these guidelines constitute the accepted and prevailing standards of practice for office-based procedures in North Carolina, failure to substantially comply with these guidelines creates the risk of disciplinary action by the Board.

Level II Guidelines

Personnel:

The physician who performs the surgical or special procedure or a health care professional who is present during the intraoperative and postoperative periods should be ACLS certified, and at least one other health care professional should be BCLS certified. In an office where anesthesia services are provided to infants and children, personnel should be appropriately trained to handle pediatric emergencies (*i.e.*, APLS or PALS certified).

Recovery should be monitored by a registered nurse or other health care professional practicing within the scope of his or her license or certification who is BCLS certified and has the capability of administering medications as required for analgesia, nausea/vomiting, or other indications.

Surgical or Special Procedure Guidelines

Intraoperative Care and Monitoring:

The physician who performs Level II procedures that require conscious sedation in an office should ensure that monitoring is provided by a separate health care professional not otherwise involved in the surgical or special procedure. Monitoring should include, when clinically indicated for the patient:

- direct observation of the patient and, to the extent practicable, observation of the patient's responses to verbal commands;
- pulse oximetry should be performed continuously (an alternative method of measuring oxygen saturation may be substituted for pulse oximetry if the method has been demonstrated to have at least equivalent clinical effectiveness);
- an electrocardiogram monitor should be used continuously on the patient;
- the patient's blood pressure, pulse rate, and respirations should be measured and recorded at least every five minutes; and

¹ See N.C. Gen. Stat. § 131E-145 et seq.

- the body temperature of a pediatric patient should be measured continuously.

Clinically relevant findings during intraoperative monitoring should be documented in the patient's medical record.

Postoperative Care and Monitoring:

The physician who performs the surgical or special procedure should evaluate the patient immediately upon completion of the surgery or special procedure and the anesthesia.

Care of the patient may then be transferred to the care of a qualified health care professional in the recovery area. A registered nurse or other health care professional practicing within the scope of his or her license or certification and who is BCLS certified and has the capability of administering medications as required for analgesia, nausea/vomiting, or other indications should monitor the patient postoperatively.

At least one health care professional who is ACLS certified should be immediately available until all patients have met discharge criteria. Prior to leaving the operating room or recovery area, each patient should meet discharge criteria.

Monitoring in the recovery area should include pulse oximetry and non-invasive blood pressure measurement. The patient should be assessed periodically for level of consciousness, pain relief, or any untoward complication. Clinically relevant findings during post-operative monitoring should be documented in the patient's medical record.

Equipment and Supplies:

Unless another availability standard is clearly stated, the following equipment and supplies should be present in all offices where Level II procedures are performed:

1. Full and current crash cart at the location where the anesthetizing is being carried out. (the crash cart inventory should include appropriate resuscitative equipment and medications for surgical, procedural or anesthetic complications);
2. age-appropriate sized monitors, resuscitative equipment, supplies, and medication in accordance with the scope of the surgical or special procedures and the anesthesia services provided;
3. emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours;
4. electrocardiographic monitor;
5. noninvasive blood pressure monitor;
6. pulse oximeter;
7. continuous suction device;
8. endotracheal tubes, laryngoscopes;
9. positive pressure ventilation device (e.g., Ambu);
10. reliable source of oxygen;
11. emergency intubation equipment;
12. adequate operating room lighting;
13. appropriate sterilization equipment; and
14. IV solution and IV equipment.

Level III Guidelines

Personnel:

Anesthesia should be administered by an anesthesiologist or a CRNA supervised by a physician. The physician who performs the surgical or special procedure should not administer the anesthesia. The anesthesia provider should not be otherwise involved in the surgical or special procedure.

The physician or the anesthesia provider should be ACLS certified, and at least one other health care professional should be BCLS certified. In an office where anesthesia services are provided to infants and children, personnel should be appropriately trained to handle pediatric emergencies (*i.e.*, APLS or PALS certified).

Surgical or Special Procedure Guidelines

Intraoperative Monitoring:

The physician who performs procedures in an office that require major conduction blockade, deep sedation/analgesia, or general anesthesia should ensure that monitoring is provided as follows when clinically indicated for the patient:

- direct observation of the patient and, to the extent practicable, observation of the patient's responses to verbal commands;
- pulse oximetry should be performed continuously. Any alternative method of measuring oxygen saturation may be substituted for pulse oximetry if the method has been demonstrated to have at least equivalent clinical effectiveness;
- an electrocardiogram monitor should be used continuously on the patient;
- the patient's blood pressure, pulse rate, and respirations should be measured and recorded at least every five minutes;
- monitoring should be provided by a separate health care professional not otherwise involved in the surgical or special procedure;
- end-tidal carbon dioxide monitoring should be performed on the patient continuously during endotracheal anesthesia;
- an in-circuit oxygen analyzer should be used to monitor the oxygen concentration within the breathing circuit, displaying the oxygen percent of the total inspiratory mixture;
- a respirometer (volumeter) should be used to measure exhaled tidal volume whenever the breathing circuit of a patient allows;
- the body temperature of each patient should be measured continuously; and
- an esophageal or precordial stethoscope should be utilized on the patient.

Clinically relevant findings during intraoperative monitoring should be documented in the patient's medical record.

Postoperative Care and Monitoring:

The physician who performs the surgical or special procedure should evaluate the patient immediately upon completion of the surgery or special procedure and the anesthesia.

Care of the patient may then be transferred to the care of a qualified health care professional in the recovery area. Qualified health care professionals capable of administering medications as

required for analgesia, nausea/vomiting, or other indications should monitor the patient postoperatively.

Recovery from a Level III procedure should be monitored by an ACLS certified (PALS or APLS certified when appropriate) health care professional using appropriate criteria for the level of anesthesia. At least one health care professional who is ACLS certified should be immediately available during postoperative monitoring and until the patient meets discharge criteria. Each patient should meet discharge criteria prior to leaving the operating or recovery area.

Monitoring in the recovery area should include pulse oximetry and non-invasive blood pressure measurement. The patient should be assessed periodically for level of consciousness, pain relief, or any untoward complication. Clinically relevant findings during postoperative monitoring should be documented in the patient's medical record.

Equipment and Supplies:

Unless another availability standard is clearly stated, the following equipment and supplies should be present in all offices where Level III procedures are performed:

1. full and current crash cart at the location where the anesthetizing is being carried out (the crash cart inventory should include appropriate resuscitative equipment and medications for surgical, procedural or anesthetic complications);
2. age-appropriate sized monitors, resuscitative equipment, supplies, and medication in accordance with the scope of the surgical or special procedures and the anesthesia services provided;
3. emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours;
4. electrocardiographic monitor;
5. noninvasive blood pressure monitor;
6. pulse oximeter;
7. continuous suction device;
8. endotracheal tubes, and laryngoscopes;
9. positive pressure ventilation device (e.g., Ambu);
10. reliable source of oxygen;
11. emergency intubation equipment;
12. adequate operating room lighting;
13. appropriate sterilization equipment;
14. IV solution and IV equipment;
15. sufficient ampules of dantrolene sodium should be emergently available;
16. esophageal or precordial stethoscope;
17. emergency resuscitation equipment;
18. temperature monitoring device;
19. end tidal CO₂ monitor (for endotracheal anesthesia); and
20. appropriate operating or procedure table.

Definitions and Acronyms

AAAASF – the American Association for the Accreditation of Ambulatory Surgery Facilities.

AAHC – the Accreditation Association for Ambulatory Health Care

ABMS – the American Board of Medical Specialties

ACGME – the Accreditation Council for Graduate Medical Education

ACLS certified – a person who holds a current “ACLS Provider” credential certifying that they have successfully completed the national cognitive and skills evaluations in accordance with the curriculum of the American Heart Association for the Advanced Cardiovascular Life Support Program.

Advanced cardiac life support certified – a licensee that has successfully completed and recertified periodically an advanced cardiac life support course offered by a recognized accrediting organization appropriate to the licensee’s field of practice. For example, for those licensees treating adult patients, training in ACLS is appropriate; for those treating children, training in PALS or APLS is appropriate.

Ambulatory surgical facility – a facility licensed under Article 6, Part D of Chapter 131E of the North Carolina General Statutes or if the facility is located outside North Carolina, under that jurisdiction’s relevant facility licensure laws.

Anesthesia provider – an anesthesiologist or CRNA.

Anesthesiologist – a physician who has successfully completed a residency program in anesthesiology approved by the ACGME or AOA, or who is currently a diplomate of either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982.

AOA – the American Osteopathic Association

APLS certified – a person who holds a current certification in advanced pediatric life support from a program approved by the American Heart Association.

Approved accrediting agency or organization – a nationally recognized accrediting agency (e.g., AAAASF; AAAHC, JCAHO, and HFAP) including any agency approved by the Board.

ASA – the American Society of Anesthesiologists

BCLS certified – a person who holds a current certification in basic cardiac life support from a program approved by the American Heart Association.

Board – the North Carolina Medical Board.

Conscious sedation – the administration of a drug or drugs in order to induce that state of consciousness in a patient which allows the patient to tolerate unpleasant medical procedures without losing defensive reflexes, adequate cardio-respiratory function and the ability to respond purposefully to verbal command or to tactile stimulation if verbal response is not possible as, for example, in the case of a small child or deaf person. Conscious sedation does not include an oral dose of pain medication or minimal pre-procedure tranquilization such as the administration of a pre-procedure oral dose of a benzodiazepine designed to calm the patient. “Conscious sedation” should be synonymous with the term “sedation/analgesia” as used by the American Society of Anesthesiologists.

Credentialed – a physician that has been granted, and continues to maintain, the privilege by a hospital or ambulatory surgical facility licensed in the jurisdiction in which it is located to provide specified services, such as surgical or special procedures or the administration of one or more types of anesthetic agents or procedures, or can show documentation of adequate training and experience.

CRNA – a registered nurse who is authorized by the North Carolina Board of Nursing to perform nurse anesthesia activities.

Deep sedation/analgesia – the administration of a drug or drugs which produces depression of consciousness during which patients cannot be easily aroused but can respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

FDA – the Food and Drug Administration.

General anesthesia – a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require 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. Cardiovascular function may be impaired.

Health care professional – any office staff member who is licensed or certified by a recognized professional or health care organization.

HFAP – the Health Facilities Accreditation Program, a division of the AOA.

Hospital – a facility licensed under Article 5, Part A of Chapter 131E of the North Carolina General Statutes or if the facility is located outside North Carolina, under that jurisdiction's relevant facility licensure laws.

Immediately available – within the office.

JCAHO – the Joint Commission for the Accreditation of Health Organizations

Level I procedures – any surgical or special procedures:

- a. that do not involve drug-induced alteration of consciousness;
- b. where preoperative medications are not required or used other than minimal preoperative tranquilization of the patient (anxiolysis of the patient) ;
- c. where the anesthesia required or used is local, topical, digital block, or none; and
- d. where the probability of complications requiring hospitalization is remote.

Level II procedures – any surgical or special procedures:

- a. that require the administration of local or peripheral nerve block, minor conduction blockade, Bier block, minimal sedation, or conscious sedation; and
- b. where there is only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely.

Level III procedures – any surgical or special procedures:

- a. that require, or reasonably should require, the use of major conduction blockade, deep sedation/analgesia, or general anesthesia; and
- b. where there is only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely.

Local anesthesia – the administration of an agent which produces a transient and reversible loss of sensation in a circumscribed portion of the body.

Major conduction blockade – the injection of local anesthesia to stop or prevent a painful sensation in a region of the body. Major conduction blocks include, but are not limited to, axillary, interscalene, and supraclavicular block of the brachial plexus; spinal (subarachnoid), epidural and caudal blocks.

Minimal sedation (anxiolysis) – the administration of a drug or drugs which produces a state of consciousness that allows the patient to tolerate unpleasant medical procedures while responding normally to verbal commands. Cardiovascular or respiratory function should remain unaffected and defensive airway reflexes should remain intact.

Minor conduction blockade – the injection of local anesthesia to stop or prevent a painful sensation in a circumscribed area of the body (*i.e.*, infiltration or local nerve block), or the block of a nerve by direct pressure and refrigeration. Minor conduction blocks include, but are not limited to, intercostal, retrobulbar, paravertebral, peribulbar, pudendal, sciatic nerve, and ankle blocks.

Monitoring – continuous, visual observation of a patient and regular observation of the patient as deemed appropriate by the level of sedation or recovery using instruments to measure, display, and record physiologic values such as heart rate, blood pressure, respiration and oxygen saturation.

Office – a location at which incidental, limited ambulatory surgical procedures are performed and which is not a licensed ambulatory surgical facility pursuant to Article 6, Part D of Chapter 131E of the North Carolina General Statutes.

Operating room – that location in the office dedicated to the performance of surgery or special procedures.

OSHA – the Occupational Safety and Health Administration.

PALS certified – a person who holds a current certification in pediatric advanced life support from a program approved by the American Heart Association.

Physical status classification – a description of a patient used in determining if an office surgery or procedure is appropriate. For purposes of these guidelines, ASA classifications will be used. The ASA enumerates classification: I-normal, healthy patient; II-a patient with mild systemic disease; III a patient with severe systemic disease limiting activity but not incapacitating; IV-a patient with incapacitating systemic disease that is a constant threat to life; and V-moribund, patients not expected to live 24 hours with or without operation.

Physician – an individual holding an MD or DO degree licensed pursuant to the NC Medical Practice Act and who performs surgical or special procedures covered by these guidelines.

Reasonable Proximity – The Board recognizes that reasonable proximity is a somewhat ambiguous standard. The Board believes that the standard often used by hospitals of thirty (30) minutes travel time is a useful benchmark.

Recovery area – a room or limited access area of an office dedicated to providing medical services to patients recovering from surgical or special procedures or anesthesia.

Reportable complications – untoward events occurring at any time within forty-eight (48) hours of any surgical or special procedure or the administration of anesthesia in an office setting including, but not limited to, any of the following: paralysis, nerve injury, malignant hyperthermia, seizures, myocardial infarction, pulmonary embolism, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, unintended hospitalization for more than twenty-four (24) hours, or death.

Special procedure – patient care that requires entering the body with instruments in a potentially painful manner, or that requires the patient to be immobile, for a diagnostic or therapeutic procedure requiring anesthesia services; for example, diagnostic or therapeutic endoscopy; invasive radiologic procedures, pediatric magnetic resonance imaging; manipulation under anesthesia or endoscopic examination with the use of general anesthesia.

Surgical procedure – the revision, destruction, incision, or structural alteration of human tissue performed using a variety of methods and instruments and includes the operative and non-operative care of individuals in need of such intervention, and demands pre-operative assessment, judgment, technical skill, post-operative management, and follow-up.

Topical anesthesia – an anesthetic agent applied directly or by spray to the skin or mucous membranes, intended to produce a transient and reversible loss of sensation to a circumscribed area.

[A Position Statement on Office-Based Surgery was adopted by the Board on September 2000. The statement above (Adopted January 2003) replaces that statement.]

1. Old Business

a. Position Statement Review continued

ii. Self- Treatment and Treatment of Family Members and Others with Whom Significant Emotional Relationships Exist

Issue: In November 2009, the Board approved the Policy Committee's recommendation to review Position Statements at least once every four years. A review schedule has been formulated for the Committee's consideration.

3/2011 Committee Discussion: Mr. Brosius suggested that the Board may need to establish some bright lines, because the current position statement leaves room for some treatments that the Board may deem unethical depending on physician interpretation. Dr. Loomis suggested that he preferred a hardline approach and would recommend eliminating minor treatment of illness. He indicated that the Board's interest is for the patients to receive the best care. Dr. Greene agreed that eliminating treatment of minor illness would remove any room for confusion, but also felt we should leave the ability to treat during an emergency in the position statement. Dr. Camnitz indicated that he did not like the vagueness of the position statement and would prefer it be more specific regarding over-the-counter medications and prescription medications, possibly indicating specific schedules that would be restricted. The Committee further discussed chronic versus acute. It was also recommended that "physician" should be replaced with "licensee" to be consistent with edits made in previous position statement reviews.

3/2011 Committee Recommendation: Table issue for the Legal Department to incorporate the recommendations from the Committee discussion.

3/2011 Board Action: No Action necessary.

This Position Statement has now been assigned to a Task Force specifically analyzing the issue and headed by Dr. Loomis.

Self-treatment and treatment of family members and others with whom significant emotional relationships exist*

It is the position of the North Carolina Medical Board that, except for minor illnesses and emergencies, physicians should not treat, medically or surgically, or prescribe for themselves, their family members, or others with whom they have significant emotional relationships. The Board strongly believes that such treatment and prescribing practices are inappropriate and may result in less than optimal care being provided. A variety of factors, including personal feelings and attitudes that will inevitably affect judgment, will compromise the objectivity of the physician and make the delivery of sound medical care problematic in such situations, while real patient autonomy and informed consent may be sacrificed.

When a minor illness or emergency requires self-treatment or treatment of a family member or other person with whom the physician has a significant emotional relationship, the physician must prepare and keep a proper written record of that treatment, including but not limited to prescriptions written and the medical indications for them. Record keeping is too frequently neglected when physicians manage such cases.

The Board expects physicians to delegate the medical and surgical care of themselves, their families, and those with whom they have significant emotional relationships to one or more of their colleagues in order to ensure appropriate and objective care is provided and to avoid misunderstandings related to their prescribing practices.

*This position statement was formerly titled, "Treatment of and Prescribing for Family Members."

(Adopted May 1991) (Amended May 1996; May 2000; March 2002; September 2005)

2. New Business:

a. Position Statement Review

1/2010 Committee Recommendation: (Loomis/Camnitz) Adopt a 4 year review schedule as presented. All reviews will be offered to the full Board for input. Additionally all reviews will be documented and will be reported to the full Board, even if no changes are made.

1/2010 Board Action: Adopt the recommendation of the Policy Committee.

POSITION STATEMENT	ADOPTED	SCHEDULED FOR REVIEW	LAST REVISED/ REVIEWED/ ADOPTED	REVISED/ REVIEWED	REVISED/ REVIEWED	REVISED/ REVIEWED	REVISED/ REVIEWED
Office-Based Procedures	Sep-00	May-11	Jan-03				
Self- Treatment and Treatment of Family Members and Others With Whom Significant Emotional Relationships Exist	May-91	May-11	Sep-05	Mar-02	May-00	May-96	
Prescribing Legend or Controlled Substances for Other Than Valid Medical or Therapeutic Purposes, with Particular Reference to Substances or Preparations with Anabolic Properties	May-98	May-11	Nov-05	Jan-01	Jul-98		
Sale of Goods From Physician Offices	Mar-01	May-11	Mar-06				
Competence and Reentry to the Active Practice of Medicine	Jul-06		Jul-06				
Availability of Physicians to Their Patients	Jul-93		Jul-06	Oct-03	Jan-01	May-96	
Referral Fees and Fee Splitting	Nov-93		Jul-06	May-96			
Sexual Exploitation of Patients	May-91		Sep-06	Jan-01	Apr-96		
Care of the Patient Undergoing Surgery or Other Invasive Procedure	Sep-91		Sep-06	Mar-01			
The Physician-Patient Relationship	Jul-95		Sep-06	Aug-03	Mar-02	Jan-00	Jul-98
The Retired Physician	Jan-97		Sep-06				
Physician Supervision of Other Licensed Health Care Practitioners	Jul-07		Jul-07				
Medical Testimony	Mar-08		Mar-08				
Advance Directives and Patient Autonomy	Jul-93		Mar-08	May-96			
End-of-Life Responsibilities and Palliative Care	Oct-99		Mar-08	May-07			

Drug Overdose Prevention	Sep-08		Sep-08				
Policy for the Use of Controlled Substances for the Treatment of Pain	Sep-96		Sep-08	Jul-05			
Medical Record Documentation	May-94		May-09	May-96			
Retention of Medical Records	May-98		May-09				
Capital Punishment	Jan-07		Jul-09				
Departures from or Closings of Medical	Jan-00		Jul-09	Aug-03			
Professional Obligations pertaining to incompetence, impairment, and unethical conduct of healthcare providers	Nov-98		Mar-10	Nov-98			
Unethical Agreements in Complaint Settlements	Nov-93		Mar-10	May-96			
What Are the Position Statements of the Board and To Whom Do They Apply?	Nov-99		May-10	Nov-99			
Telemedicine	May-10		May-10				
Contact With Patients Before Prescribing	Nov-99		Jul-10	Feb-01			
Guidelines for Avoiding Misunderstandings During Physical Examinations	May-91		Jul-10	Oct-02	Feb-01	Jan-01	May-96
Access to Physician Records	Nov-93		Sep-10	Aug-03	Mar-02	Sep-97	May-96
Medical Supervisor-Trainee Relationship	Apr-04		Nov-10	Apr-04			
The Treatment of Obesity	Oct-87		Nov-10	Jan-05	Mar-96		
Advertising and Publicity	Nov-99		Nov-10	Sep-05	Mar-01		
Medical, Nursing, Pharmacy Boards: Joint Statement on Pain Management in End-of-Life Care	Oct-99		Jan-11	Oct-99			
HIV/HBV Infected Health Care Workers	Nov-92		Jan-11	Jan-05	May-96		
Writing of Prescriptions	May-91		Mar-11	Mar-05	Jul-02	Mar-02	May-96
Laser Surgery	Jul-99		Mar-11	Jul-05	Aug-02	Mar-02	Jan-00

2. New Business:
 - a. Position Statement Review
 - i. Prescribing Legend or Controlled Substances for Other Than Valid Medical or Therapeutic Purposes, with Particular Reference to Substances or Preparations with Anabolic Properties

Prescribing legend or controlled substances for other than validated medical or therapeutic purposes, with particular reference to substance or preparations with anabolic properties

General

It is the position of the North Carolina Medical Board that prescribing any controlled or legend substance for other than a validated medical or therapeutic purpose is unprofessional conduct.

The physician shall complete and maintain a medical record that establishes the diagnosis, the basis for that diagnosis, the purpose and expected response to therapeutic medications, and the plan for the use of medications in treatment of the diagnosis.

The Board is not opposed to the use of innovative, creative therapeutics; however, treatments not having a scientifically validated basis for use should be studied under investigational protocols so as to assist in the establishment of evidence-based, scientific validity for such treatments.

Substances/Preparations with Anabolic Properties

The use of anabolic steroids, testosterone and its analogs, human growth hormone, human chorionic gonadotrophin, other preparations with anabolic properties, or autotransfusion in any form, to enhance athletic performance or muscle development for cosmetic, nontherapeutic reasons, in the absence of an established disease or deficiency state, is not a medically valid use of these medications.

The use of these medications under these conditions will subject the person licensed by the Board to investigation and potential sanctions.

The Board recognizes that most anabolic steroid abuse occurs outside the medical system. It wishes to emphasize the physician's role as educator in providing information to individual patients and the community, and specifically to high school and college athletes, as to the dangers inherent in the use of these medications.

(Adopted May 1998) (Amended July 1998, January 2001) (Reviewed November 2005)

2. New Business:
 - a. Position Statement Review
 - ii. Sale of Goods from Physician Offices

Sale of goods from physician offices

Inherent in the in-office sale of products is a perceived conflict of interest. On this issue, it is the position of the North Carolina Medical Board that the following instructions should guide the conduct of physicians or licensees.

Sale of practice-related items such as ointments, creams and lotions by Dermatologists, splints and appliances by Orthopedists, spectacles by Ophthalmologists, etc., may be acceptable only after the patient has been told those or similar items can be obtained locally from other sources. Any charge made should be reasonable.

Due to the potential for patient exploitation, the Medical Board opposes licensees participating in exclusive distributorships and/or personal branding, or persuading patients to become dealers or distributors of profit making goods or services.

Licensees should not sell any non health-related goods from their offices or other treatment settings. (This does not preclude selling of such low cost items on an occasional basis for the benefit of charitable or community organizations, provided the licensee receives no share of the proceeds, and patients are not pressured to purchase.)

All decisions regarding sales of items by the physician or his/her staff from the physician's office or other place where health care services are provided, must always be guided by what is in the patient's best interest.

(Adopted March 2001) (Amended March 2006)

2. New Business:
 - b. Writing of Prescriptions

Issue: See inquiry below.

David,

I've received a question from a practice manager lately about the Medical Board's Position on e-prescribing of controlled substances. I believe that in the past the NCMB has not favored this practice. Can you tell me if I'm correct and if there is any plan to revisit this policy in the near future? Thanks so much!

Amy Whited

3/2011 Committee Recommendation: (PC/EG) The Committee recommends omitting from the current position statement: "Quantities should be indicated in both numbers AND words, e.g., 30 (thirty)."

3/2011 Board Action: Amend position statement to reflect that only hand written controlled substance prescriptions are required to indicate the quantity in both numbers and words.

Writing of prescriptions

It is the position of the North Carolina Medical Board that prescriptions should be written in ink or indelible pencil or typewritten or electronically printed and should be signed by the practitioner at the time of issuance. Prescription that are handwritten should indicate the quantity ~~Quantities should be indicated~~ in both numbers AND words, e.g., 30 (thirty). Such prescriptions must not be written on pre-signed prescription blanks.

Each prescription for a DEA controlled substance (2, 2N, 3, 3N, 4, and 5) should be written on a separate prescription blank. Multiple medications may appear on a single prescription blank only when none are DEA-controlled.

No prescriptions should be issued for a patient in the absence of a documented physician-patient relationship.

No prescription should be issued by a practitioner for his or her personal use. (See Position Statement entitled "Self-Treatment and Treatment of Family Members and Others with Whom Significant Emotional Relationships Exist.")

The practice of pre-signing prescriptions is unacceptable to the Board.

It is the responsibility of those who prescribe controlled substances to fully comply with applicable federal and state laws and regulations. Links to these laws and regulations may be found on the Board's Web site (www.ncmedboard.org).

(Adopted May 1991, September 1992) (Amended May 1996; March 2002; July 2002)
(Reviewed March 2005)