

North Carolina Medical Board
Policy Committee Meeting
Wednesday, March 16, 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. Writing of Prescriptions

b. Practice Drift Committee

Issue: A proposed Position Statement is to be presented from the Special Committee on Practice Drift.

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. Laser Surgery
- ii. Self- Treatment and Treatment of Family Members and Others With Whom Significant Emotional Relationships Exist

b. Reporting Primary and Subspecialty

Issue: Should the Board change the board certification headline on the licensee information page to accurately reflect the Board's new position statement?

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.

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
- 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.

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

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

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

AAAHHC – 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.

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. Writing of Prescriptions

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.

1/2011 Committee Discussion: The Committee discussed the current position statement. It was pointed out that many practitioners currently do not spell out the quantity but simply write the numerical amount on prescriptions. Additionally, many practices and hospitals have computer systems that only use the numerical amount. The Committee considered whether the sentence in question was useful, and decided to bring it to the full Board for discussion.

1/2011 Committee Recommendation: Present for full Board discussion for consideration regarding changing: "Quantities should be indicated in both numbers AND words, e.g., 30 (thirty)."

1/2011 Board Action: Table issue for Committee to do further research.

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. 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)

1. Old Business:
b. Practice Drift Committee

1/2011 Committee Discussion: Nancy Hemphill reviewed the executive summary of the Special Committee on Practice Drift with the Policy Committee. The Committee discussed the struggle of holding licensees accountable and also allowing for professional growth. The Committee also discussed the need for access to care. The Committee agreed that licensees should be held to the prevailing standards of practice relevant to the area of specialty or modality in which they are practicing regardless of the area in which they received their formal training.

1/2011 Committee Recommendation: Adopt proposed Position Statement.

1/2011 Board Action: Table issue until it can be determined if the final version of the proposed Position Statement was reviewed by the Special Committee prior to being presented to the Board. The Board would like the Policy Committee to consider editing the last sentence of the third paragraph of the proposed position statement.

North Carolina Medical Board
Special Committee on Practice Drift
Public Meeting Wednesday, October 13, 2010
Executive Summary

Attendees: Committee members: Thomas Hill, MD, Chair; Karen Gerancher, MD; Thelma Lennon. Other Board members: Donald Jablonski, DO; Janice Huff, MD. Staff: Scott Kirby, MD; Christina Apperson; Nancy Hemphill; Maureen Bedell. Guests: Keith Neff and Julie Brightwell (The Doctors Company); Charles Bregier, Jr., MD (ER physician); Gerald Aronoff, MD (pain physician); Steve Herring, MD (cosmetic surgeon); Steve Keene and Amy Whited (NCMS); Sheila Elliot and Karen Still (MAG Mutual Insurance Company); Gregory Griggs (ED of the NCAFP); Brian Forrest, MD (family practice); Beverly Goode Kanawati, DO and Bill Kanawati (family practice); Sharon Mussellman (Medical Mutual Insurance Company); Rob Clark, MD (dermatology); Alan Skipper (NCMS specialty boards); John Fagg, MD (cosmetic surgery); John Foreman, MD (pediatric nephrology); Charles Willson, MD (pediatrics/EUCO GME).

Practice drift (which differs from practice evolution) occurs primarily for economic reasons, as physicians seek new revenue sources while underestimating the inherent risks and additional training needed to successfully perform procedures for which they did not receive formal education. Industry also drives physicians into new lucrative areas. Other factors: necessity because of patients' limited access to specialists, whether geographic or monetary.

Practice drift occurs primarily outside of hospital settings or other peer review facilities, since hospitals have credentialing procedures which vet physicians' qualifications to perform certain procedures. Drift also occurs after a physician has been covered by professional liability insurance, because the liability carriers' underwriters also serve as a check on a physician's scope of practice. A related problem is inadequate supervision of allied health providers performing procedures into which the supervising physician may not be adequately trained. Sometimes drift can be positive: i.e., bringing retinal scans to the primary care setting so diabetic patients' eye care needs can be met.

Areas in which drift is prevalent:

Cosmetic procedures (Botox, liposuction, laser hair removal)
Pain management
Moh's surgery
Mental health (both for adults, and children being treated with off-label adult meds)
Hair restoration
Weight loss
Sleep issues
Urgent care
Hormone replacement therapy
Complex patients who are seen initially in tertiary centers and then must be followed by generalists in home community
Special situations where a patient or patient's family has developed a strong connection to a particular physician, such as pediatrician continuing to treat a mentally handicapped adult

Patient safety issues: inadequate knowledge of treating physician. Missed diagnoses; over testing or overexposure to X rays for follow up care; insurance companies may refuse to pay for duplicative testing.

Whose responsibility: mostly on the individual physician to consider whether practice is in the best interest of the patient, and whether the procedure can be done safely. Health and professional liability insurers also have a role to play.

Resource: Use of telemedicine to provide expertise to physicians in rural areas.

Board's role: create Position Statement that provides guidance to physicians. Allow practice evolution. Allow some leeway (look to Position Statement on Supervision of Other License Health Care Practitioners). Consider relying on objective sources which evaluate the validity and rigor of training (ACGME, AAAHC, etc.) if/when Board investigates a physician and reviews his/her CME resume.

PHYSICIAN SCOPE OF PRACTICE

This Position Statement is intended to guide physicians who undertake to perform new procedures, use new technologies, or migrate into areas of practice for which they have not received formal graduate medical education. The Board recognizes that medicine is a dynamic field that, along with individual practices, continues to evolve. Economic pressures, business opportunities, lifestyle considerations, and access to care are all reasons that physicians move into new areas of practice. However, patient harm can occur when physicians practicing outside areas in which they were trained are unable to meet accepted and prevailing standards of care in the new practice area.

The informed, prudent care of patients begins with adequate training and the selection of appropriate patients. Follow up care and the ability to address complications is paramount. Physicians intending to expand their practice to an area outside of their graduate medical education should ensure that they have acquired the appropriate level of education and training.

It is the Board's position that all physicians, irrespective of their training, will be held to the standard of acceptable and prevailing medical practice as set forth in N.C. Gen. Stat. § 90-14(a)(6).^{*} It also may be prudent for physicians to confirm that their liability insurance provides coverage for the procedures they intend to perform.

^{*} In some instances, the Board may have provided relevant guidance to particular practice areas. See for example the Board's position statements on Laser Surgery, Office-Based Procedures, Care of the Patient Undergoing Surgery or Other Invasive Procedure, and Advertising and Publicity

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	Mar-11	Jan-03				
Writing of Prescriptions	May-91	Mar-11	Mar-05	Jul-02	Mar-02	May-96	Sep-92
Laser Surgery	Jul-99	Mar-11	Jul-05	Aug-02	Mar-02	Jan-00	
Self- Treatment and Treatment of Family Members and Others With Whom Significant Emotional Relationships Exist	May-91	Mar-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		Nov-05	Jan-01	Jul-98		
Sale of Goods From Physician Offices	Mar-01		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		
HIV/HBV Infected Health Care Workers	Nov-92		Jan-11	Jan-05	May-96		
Medical, Nursing, Pharmacy Boards: Joint Statement on Pain Management in End-of-Life Care	Oct-99		Jan-11	Oct-99			

2. New Business:
 - a. Position Statement Review
 - i. Laser Surgery

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.

Laser Surgery

It is the position of the North Carolina Medical Board that the revision, destruction, incision, or other structural alteration of human tissue using laser technology is surgery.* Laser surgery should be performed only by a physician or by a licensed health care practitioner working within his or her professional scope of practice and with appropriate medical training functioning under the supervision, preferably on-site, of a physician or by those categories of practitioners currently licensed by this state to perform surgical services.

Licensees should use only devices approved by the U.S. Food and Drug Administration unless functioning under protocols approved by institutional review boards. As with all new procedures, it is the licensee's responsibility to obtain adequate training and to make documentation of this training available to the North Carolina Medical Board on request.

Laser Hair Removal

Lasers are employed in certain hair-removal procedures, as are various devices that (1) manipulate and/or pulse light causing it to penetrate human tissue and (2) are classified as "prescription" by the U.S. Food and Drug Administration. Hair-removal procedures using such technologies should be performed only by a physician or by an individual designated as having adequate training and experience by a physician who bears full responsibility for the procedure. The physician who provides medical supervision is expected to provide adequate oversight of licensed and non-licensed personnel both before and after the procedure is performed. The Board believes that the guidelines set forth in this Position Statement are applicable to every licensee of the Board involved in laser hair removal, whether as an owner, medical director, consultant or otherwise.

It is the position of the Board that good medical practice requires that each patient be examined by a physician, physician assistant or nurse practitioner licensed or approved by this Board prior to receiving the first laser hair removal treatment and at other times as medically indicated. The examination should include a history and a focused physical examination. Where prescription medication such as topical anesthetics are used, the Board expects physicians to follow the guidelines set forth in the Board's Position Statement titled "Contact with Patients Before Prescribing." When medication is prescribed or dispensed in connection with laser hair removal, the supervising physician shall assure the patient receives thorough instructions on the safe use or application of said medication.

The responsible supervising physician should be on site or readily available to the person actually performing the procedure. What constitutes "readily available" will depend on a variety of factors. Those factors include the specific types of procedures and equipment used; the level of training of the persons performing the procedure; the level and type of licensure, if any, of the

persons performing the procedure; the use of topical anesthetics; the quality of written protocols for the performance of the procedure; the frequency, quality and type of ongoing education of those performing the procedures; and any other quality assurance measures in place. In all cases, the Board expects the physician to be able to respond quickly to patient emergencies and questions by those performing the procedures.

*Definition of surgery as adopted by the NCMB, November 1998:

Surgery, which involves the revision, destruction, incision, or structural alteration of human tissue performed using a variety of methods and instruments, is a discipline that includes the operative and non-operative care of individuals in need of such intervention, and demands pre-operative assessment, judgment, technical skills, post-operative management, and follow up.

(Adopted July 1999) (Amended January 2000; March 2002; August 2002; July 2005)

2. New Business:

a. Position Statement Review

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.

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:

b. Reporting Primary and Subspecialty

Issue: Should the Board change the board certification headline on the licensee information page to accurately reflect the Board's new position statement?

[REDACTED]

LICENSE#: [REDACTED]
ISSUE DATE: [REDACTED]

LICENSE STATUS: Active
RENEWAL DATE: [REDACTED]

NCMB PUBLIC ACTION: No

Licensee General Information	Practice Information	Education, Certifications & Area of Practice	Memberships, Honors, Awards, & Public Service
Academic Appointments & Publications	Actions - Regulatory Board, Agency, & Health Care Institution	Malpractice	Convictions

Education, Certifications & Area of Practice

Medical School

[REDACTED] Year of Graduation: [REDACTED]

Post Graduate Training

Institution	Specialty	State Country	Training Program	Year Completed
[REDACTED]				

Current ABMS or AOA Board Certification and Year of Certification/Recertification

Primary/Subspecialty	Year
Facial Plastic Surgery	2008
Otolaryngology/Facial Plastic Surgery	2005

Area of Practice

Area Of Practice	Primary Area of Practice
Facial Plastic Surgery	Yes
Otolaryngology/Facial Plastic Surgery	
Plastic Surgery Within the Head and Neck	

Years of active clinical practice: 7

February 3, 2011

PERSONAL AND CONFIDENTIAL



Re: Complaint follow-up

Dear Dr. 

The Board has completed its review of the complaint from 
 Your response to the inquiry in this matter assisted the Board in fulfilling its responsibilities.

Based on the current review no further action will be taken in this matter. However, the Board advises that you should take care to ensure accurate and appropriate representations are made regarding your training and credentials in all aspects of your practice. During review of this complaint it was noticed you have indicated ABMS board certification in facial plastic surgery on your licensee information page. If you are unable to provide verification of ABMS board certification in this area of practice the Board requests you update and correct this information.

For your information, under current law the complaint in question is not subject to public disclosure and will not be reported to the media or any data bank.

The Board appreciates your cooperation in this matter. If you have any questions regarding this letter, please contact me at 919-326-1109, ext 247.

Sincerely,

