North Carolina Medical Board
Policy Committee Meeting
Wednesday, January 19, 2010

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. Medical, Nursing, Pharmacy Boards: Joint Statement on Pain Management in End-of-Life Care

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. HIV/HBV Infected Health Care Workers

      ii. Writing of Prescriptions

   b. Practice Drift Committee

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

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.

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.

C**andidates 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.

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[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.

AAAHC – 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. Medical, Nursing, Pharmacy Boards: Joint Statement on Pain Management in End-of-Life Care

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.

5/2010 Committee Discussion: The Committee discussed whether changes should be made to specify that the position statement applies to other licensees as well. It was suggested that, since the position statement was initially propounded as a joint statement, it might be helpful to discuss this matter with the other licensing boards.

5/2010 Committee Recommendation: Mr. Brosius to contact the Pharmacy Board and the Nursing Board to determine if they object to the proposed changes and if they will join in those changes.

5/2010 Board Action: Adopt the Committee recommendation.

7/2010 Committee Recommendation: Mr. Brosius to contact the Pharmacy Board and the Nursing Board to determine if they object to the proposed changes and if they will join in those changes.

7/2010 Board Action: Adopt Committee recommendation.

9/2010 Committee Discussion: The Committee will wait for a response from the Pharmacy Board and Nursing Board.

9/2010 Committee Recommendation: No action is necessary.

9/2010 Board Action: Adopt the Committee recommendation.

11/2010 Committee Discussion: Information has been received from the Pharmacy Board.

11/2010 Committee Recommendation: Table issue until the Board receives a response from the Nursing Board.

11/2010 Board Action: Adopt the Committee recommendation.

Joint Statement on Pain Management in End-of-Life Care
(Adopted by the North Carolina Medical, Nursing, and Pharmacy Boards)

Through dialogue with members of the healthcare community and consumers, a number of perceived regulatory barriers to adequate pain management in end-of-life care have been expressed to the Boards of Medicine, Nursing, and Pharmacy. The following statement attempts to address these misperceptions by outlining practice expectations for physicians and other health care professionals authorized to prescribe medications, as well as nurses and pharmacists involved in this aspect of end-of-life care. The statement is based on:

- the legal scope of practice for each of these licensed health professionals;
- professional collaboration and communication among health professionals providing palliative care; and
- a standard of care that assures on-going pain assessment, a therapeutic plan for pain management interventions; and evidence of adequate symptom management for the dying patient.

It is the position of all three Boards that patients and their families should be assured of competent, comprehensive palliative care at the end of their lives. Physicians, nurses and pharmacists should be knowledgeable regarding effective and compassionate pain relief, and patients and their families should be assured such relief will be provided.

Because of the overwhelming concern of patients about pain relief, the physician needs to give special attention to the effective assessment of pain. It is particularly important that the physician frankly but sensitively discuss with the patient and the family their concerns and choices at the end of life. As part of this discussion, the physician should make clear that, in some end of life care situations, there are inherent risks associated with effective pain relief. *The Medical Board will assume opioid use in such patients is appropriate if the responsible physician is familiar with and abides by acceptable medical guidelines regarding such use, is knowledgeable about effective and compassionate pain relief, and maintains an appropriate medical record that details a pain management plan.* Because the Board is aware of the inherent risks associated with effective pain relief in such situations, it will not interpret their occurrence as subject to discipline by the Board.

With regard to pharmacy practice, North Carolina has no quantity restrictions on dispensing controlled substances including those in Schedule II. This is significant when utilizing the federal rule that allows the partial filling of Schedule II prescriptions for up to 60 days. In these situations it would minimize expenses and unnecessary waste of drugs if the prescriber would note on the prescription that the patient is terminally ill and specify the largest anticipated quantity that could be needed for the next two months. The pharmacist could then dispense smaller quantities of the prescription to meet the patient's needs up to the total quantity authorized. Government-approved

labeling for dosage level and frequency can be useful as guidance for patient care. Health professionals may, on occasion, determine that higher levels are justified in specific cases. However, these occasions would be exceptions to general practice and would need to be properly documented to establish informed consent of the patient and family.

Federal and state rules also allow the fax transmittal of an original prescription for Schedule II drugs for hospice patients. If the prescriber notes the hospice status of the patient on the faxed document, it serves as the original. Pharmacy rules also allow the emergency refilling of prescriptions in Schedules III, IV, and V. While this does not apply to Schedule II drugs, it can be useful in situations where the patient is using drugs such as Vicodin for pain or Xanax for anxiety.

The nurse is often the health professional most involved in on-going pain assessment, implementing the prescribed pain management plan, evaluating the patient's response to such interventions and adjusting medication levels based on patient status. In order to achieve adequate pain management, the prescription must provide dosage ranges and frequency parameters within which the nurse may adjust (titrate) medication in order to achieve adequate pain control. Consistent with the licensee's scope of practice, the RN or LPN is accountable for implementing the pain management plan utilizing his/her knowledge base and documented assessment of the patient's needs. *The nurse has the authority to adjust medication levels within the dosage and frequency ranges stipulated by the prescriber and according to the agency's established protocols.* However, the nurse does not have the authority to change the medical pain management plan. When adequate pain management is not achieved under the currently prescribed treatment plan, the nurse is responsible for reporting such findings to the prescriber and documenting this communication. Only the physician or other health professional with authority to prescribe may change the medical pain management plan.

Communication and collaboration between members of the healthcare team, and the patient and family are essential in achieving adequate pain management in end-of-life care. Within this interdisciplinary framework for end of life care, effective pain management should include:

- thorough documentation of all aspects of the patient's assessment and care;
- a working diagnosis and therapeutic treatment plan including pharmacologic and non-pharmacologic interventions;
- regular and documented evaluation of response to the interventions and, as appropriate, revisions to the treatment plan;
- evidence of communication among care providers;
- education of the patient and family; and
- a clear understanding by the patient, the family and healthcare team of the treatment goals.

It is important to remind health professionals that licensing boards hold each licensee accountable for providing safe, effective care. Exercising this standard of care requires the application of knowledge, skills, as well as ethical principles focused on optimum patient care while taking all appropriate measures to relieve suffering. The healthcare team should give primary importance to the expressed desires of the patient tempered by the judgment and legal responsibilities of each licensed health professional as to what is in the patient's best interest.

(October 1999)

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
Medical, Nursing, Pharmacy Boards: Joint Statement on Pain Management in End-of-Life Care	Oct-99	Jan-11	Oct-99				
Office-Based Procedures	Sep-00	Jan-11	Jan-03				
HIV/HBV Infected Health Care Workers	Nov-92	Jan-11	Jan-05	May-96			
Writing of Prescriptions	May-91	Jan-11	Mar-05	Jul-02	Mar-02	May-96	Sep-92
Laser Surgery	Jul-99		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		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		

2. New Business:
    a. Position Statement Review
        i. HIV/HBV Infected Health Care Workers

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.

HIV/HVB infected health care workers

The North Carolina Medical Board supports and adopts the following rules of the North Carolina Department of Health and Human Services regarding infection control in health care settings and HIV/HBV infected health care workers.

10A NCAC 41A .0206: INFECTION CONTROL—HEALTH CARE SETTINGS

(a) The following definitions shall apply throughout this Rule:
- (1) "Health care organization" means hospital; clinic; physician, dentist, podiatrist, optometrist, or chiropractic office; home health agency; nursing home; local health department; community health center; mental health agency; hospice; ambulatory surgical center; urgent care center; emergency room; or any other health care provider that provides clinical care.
- (2) "Invasive procedure" means entry into tissues, cavities, or organs or repair of traumatic injuries. The term includes the use of needles to puncture skin, vaginal and cesarean deliveries, surgery, and dental procedures during which bleeding occurs or the potential for bleeding exists.

(b) Health care workers, emergency responders, and funeral service personnel shall follow blood and body fluid precautions with all patients.

(c) Health care workers who have exudative lesions or weeping dermatitis shall refrain from handling patient care equipment and devices used in performing invasive procedures and from all direct patient care that involves the potential for contact of the patient, equipment, or devices with the lesion or dermatitis until the condition resolves.

(d) All equipment used to puncture skin, mucous membranes, or other tissues in medical, dental, or other settings must be disposed of in accordance with 10A NCAC 36B after use or sterilized prior to reuse.

(e) In order to prevent transmission of HIV and hepatitis B from health care workers to patients, each health care organization that performs invasive procedures shall implement a written infection control policy. The health care organization shall ensure that health care workers in its employ or who have staff privileges are trained in the principles of infection control and the practices required by the policy; require and monitor compliance with the policy; and update the policy as needed to prevent transmission of HIV and hepatitis B from health care workers to patients. The health care organization shall designate a staff member to direct these activities. The designated staff member in each health care organization shall complete a course in infection control approved by the Department. The course shall address:
- (1) Epidemiologic principles of infectious disease;
- (2) Principles and practice of asepsis;
- (3) Sterilization, disinfection, and sanitation;
- (4) Universal blood and body fluid precautions;
- (5) Engineering controls to reduce the risk of sharp injuries;
- (6) Disposal of sharps; and
- (7) Techniques that reduce the risk of sharp injuries to health care workers.

(f) The infection control policy required by this Rule shall address the following components that are necessary to prevent transmission of HIV and hepatitis B from infected health care workers to patients:
- (1) Sterilization and disinfection, including a schedule for maintenance and microbiologic monitoring of equipment; the policy shall require documentation of maintenance and monitoring;
- (2) Sanitation of rooms and equipment, including cleaning procedures, agents, and schedules;
- (3) Accessibility of infection control devices and supplies;
- (4) Procedures to be followed in implementing 10A NCAC 41A .0202(4) and .0203(b)(4)when a health care provider or a patient has an exposure to blood or other body fluids of another person in a manner that poses a significant risk of transmission of HIV or hepatitis B.

History Note: *Authority G.S. 130A-144; 130A-145;*
Eff. October 1, 1992; Amended Eff. December 1, 2003; July 1, 1994; January 4, 1994.

10A NCAC 41A .0207: HIV AND HEPATITIS B INFECTED HEALTH CARE WORKERS

(a) The following definitions shall apply throughout this Rule:

(1) "Surgical or obstetrical procedures" means vaginal deliveries or surgical entry into tissues, cavities, or organs. The term does not include phlebotomy; administration of intramuscular, intradermal, or subcutaneous injections; needle biopsies; needle aspirations; lumbar punctures; angiographic procedures; endoscopic and bronchoscopic procedures; or placing or maintaining peripheral or central intravascular lines.

(2) "Dental procedure" means any dental procedure involving manipulation, cutting, or removal of oral or perioral tissues, including tooth structure during which bleeding occurs or the potential for bleeding exists. The term does not include the brushing of teeth.

(b) All health care workers who perform surgical or obstetrical procedures or dental procedures and who know themselves to be infected with HIV or hepatitis B shall notify the State Health Director. Health care workers who assist in these procedures in a manner that may result in exposure of patients to their blood and who know themselves to be infected with HIV or hepatitis B shall also notify the State Health Director. The notification shall be made in writing to the Chief, Communicable Disease Control Branch, 1902 Mail Service Center, Raleigh, NC 27699-1902..

(c) The State Health Director shall investigate the practice of any infected health care worker and the risk of transmission to patients. The investigation may include review of medical and work records and consultation with health care professionals who may have information necessary to evaluate the clinical condition or practice of the infected health care worker. The attending physician of the infected health care worker shall be consulted. The State Health Director shall protect the confidentiality of the infected health care worker and may disclose the worker's infection status only when essential to the conduct of the investigation or periodic reviews pursuant to Paragraph (h) of this Rule. When the health care worker's infection status is disclosed, the State Health Director shall give instructions regarding the requirement for protecting confidentiality.

(d) If the State Health Director determines that there may be a significant risk of transmission of HIV or hepatitis B to patients, the State Health Director shall appoint an expert panel to evaluate the risk of transmission to patients, and review the practice, skills, and clinical condition of the infected health care worker, as well as the nature of the surgical or obstetrical procedures or dental procedures performed and operative and infection control techniques used. Each expert panel shall include an infectious disease specialist, an infection control expert, a person who practices the same occupational specialty as the infected health care worker and, if the health care worker is a licensed professional, a representative of the appropriate licensure board. The panel may include other experts. The State Health Director shall consider for appointment recommendations from health care organizations and local societies of health care professionals.

(e) The expert panel shall review information collected by the State Health Director and may request that the State Health Director obtain additional information as needed. The State Health Director shall not reveal to the panel the identity of the infected health care worker. The infected health care worker and the health care worker's attending physician shall be given an opportunity to present information to the panel. The panel shall make recommendations to the State Health Director that address the following:

(1) Restrictions that are necessary to prevent transmission from the infected health care worker to patients;

(2) Identification of patients that have been exposed to a significant risk of transmission of HIV or hepatitis B; and

(3) Periodic review of the clinical condition and practice of the infected health care worker.

(f) If, prior to receipt of the recommendations of the expert panel, the State Health Director determines that immediate practice restrictions are necessary to prevent an imminent threat to the public health, the State Health Director shall issue an isolation order pursuant to G.S. 130A-145. The isolation order shall require cessation or modification of some or all surgical or obstetrical procedures or dental procedures to the extent necessary to prevent an imminent threat to the public health. This isolation order shall remain in effect until an isolation order is issued pursuant to Paragraph (g) of this Rule or until the State Health Director determines the imminent threat to the public health no longer exists.

(g) After consideration of the recommendations of the expert panel, the State Health Director shall issue an isolation order pursuant to G.S. 130A-145. The isolation order shall require any health care worker who is allowed to continue performing surgical or obstetrical procedures or dental procedures to, within a time period specified by the State Health Director, successfully complete a course in infection control procedures approved by the Department of Health and Human Services, General Communicable Disease Control Branch, in accordance with 10A NCAC 41A .0206(e). The isolation order shall require practice restrictions, such as cessation or modification of some or all surgical or obstetrical procedures or dental procedures, to the extent necessary to prevent a significant risk of transmission of HIV or hepatitis B to patients. The isolation order shall prohibit the performance of procedures that cannot be modified to avoid a significant risk of transmission. If the State Health Director determines that there has been a significant risk of transmission of HIV or hepatitis B to a patient, the State Health Director shall notify the patient or assist the health care worker to notify the patient.

(h) The State Health Director shall request the assistance of one or more health care professionals to obtain information needed to periodically review the clinical condition and practice of the infected health care worker who performs or assists in surgical or obstetrical procedures or dental procedures.

(i) An infected health care worker who has been evaluated by the State Health Director shall notify the State Health Director prior to a change in practice involving surgical or obstetrical procedures or dental procedures. The infected health care worker shall not make the proposed change without approval from the State Health Director. If the State Health Director makes a determination in accordance with Paragraph (c) of this Rule that there is a significant risk of transmission of HIV or hepatitis B to patients, the State Health Director shall appoint an expert panel in accordance with Paragraph (d) of this Rule. Otherwise, the State Health Director shall notify the health care worker that he or she may make the proposed change in practice.
(j) If practice restrictions are imposed on a licensed health care worker, a copy of the isolation order shall be provided to the appropriate licensure board. The State Health Director shall report violations of the isolation order to the appropriate licensure board. The licensure board shall report to the State Health Director any information about the infected health care worker that may be relevant to the risk of transmission of HIV or hepatitis B to patients.

History Note: *Authority G.S. 130A-144; 130A-145;*
Eff. October 1, 1992; Amended Eff. April 1, 2003.

(Adopted November 1992) (Amended May 1996; January 2005)

2. New Business:
    a. Position Statement Review
        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.

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, eg, 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)

2. New Business:
    b. Practice Drift Committee

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/ECU 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.