North Carolina Medical Board
Policy Committee Meeting
Wednesday, November 17, 2010

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

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

   b. Board Certification Distinction

      Issue: Rule hearing held on November 30, 2009 to receive comments.

      Task Force report and recommendation

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. Medical Supervisor-Trainee Relationship

         ii. The Treatment of Obesity

   b. Request from United Health Group

      Issue: Proposal for an internet based telemedicine service from United Health Group

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

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.

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)

1. Old Business
    b. Physician Advertising of Board Certification

7/2009 Board Action: Approve proposed rule. Proceed with rule-making process.

9/2009 Committee Discussion: It was reported that the following rule has been submitted to the Office of Administrative Hearings to be published in the NC Register. A public hearing for the purpose of collecting any comments will be held at the Board's office on November 30, 2009 at 11:00 am. The proposed rule will be submitted to the Board at its December meeting for adoption.

9/2009 Board Action: Accept as information.

11/2009 Committee Discussion: It was reported that the following rule has been submitted to the Office of Administrative Hearings and was published in the NC Register. A public hearing for the purpose of collecting any comments will be held at the Board's office on November 30, 2009 at 11:00 am. The Board continues to receive comments. The proposed rule and comments collected will be presented to the Board at its January 2010 meeting for consideration.

11/2009 Committee Recommendation: No action necessary.

11/2009 Board Action: No action necessary.

1/2010 Committee Discussion: A public hearing was held on November 30, 2009, for the purpose of receiving comments regarding the proposed rule. A taskforce is currently being assembled to further research and consider this issue. No action is necessary at this time.

1/2010 Committee Recommendation: For information only. No action necessary at this time.

1/2010 Board Action: Dr. Jablonski is to appoint a taskforce to further research and consider this issue.

5/2010 Committee Discussion: The taskforce has been created and its first meeting is scheduled for May 18th, 2010.

5/2010 Committee Discussion: The taskforce has been created and held its first meeting on May 18, 2010. The taskforce invited additional comments on the issue to those present and will table this matter until sufficient time has transpired to allow for additional comment.

5/2010 Committee Recommendation: For information only. No action necessary at this time.

5/2010 Board Action: Adopt Committee recommendation.

7/2010 Committee Discussion: Mrs. Apperson addressed the Committee regarding the May 18, 2010, taskforce meeting. It was suggested that the Committee consider adding criteria to the proposed rule in order to specify the requirements that the Board could consider in determining which certifying boards would be approved to use the term “Board Certified.” The Committee indicated that there seemed to be a consensus that a licensee must specify what area they are board certified in when advertising and identify the certifying Board. This would prohibit a licensee from advertising as being board certified and the board certification being in a field unrelated to the one being advertised. Additionally, the Committee pointed out that reporting board certifications for hospital credentialing purposes is not advertising. It was suggested that the Committee consider defining advertising. A representative of the NCMS suggested that the rule might work better in conjunction with a position statement. Dr. Walker pointed out that the Board originally had a position statement.

7/2010 Committee Recommendation: No action taken.

9/2010 Committee Discussion: Dr. Walker and Mrs. Apperson presented the Report of the Task Force on Physician Advertising of Board Certification, which included amendments to the proposed Board Rule 21 NCAC 32Y .0101 “Advertising of Specialty Board Certification. Mike Borden, NC Academy of Physician Assistants, suggested that the Committee consider including PAs in the rule. There was some discussion about board certification requirements for non-physician licensees. Representatives from various organizations thanked the Board for allowing them to have input during the process.

9/2010 Committee Recommendation: Present the Report of the Task Force on Physician Advertising of Board Certification and proposed amendments to 21 NCAC 32Y .0101 to the full Board and recommend approval and adoption. Limit proposed rule to physicians. Consider whether to adopt specific rules pertaining to advertisements by non-physician licensees.

9/2010 Board Action: Adopt the Committee recommendation.

Advertising and Publicity

It is the position of the North Carolina Medical Board that advertising or publicity that is deceptive, false, or misleading constitutes unprofessional conduct under the Medical Practice Act.*

The term "advertising" includes oral, written and other types of communication disseminated by or at the direction of a licensee for the purpose of encouraging or soliciting the use of the licensee's services. At issue is whether a member of the general public would be confused or deceived by the advertising in question. The following general principles are intended to assist licensees in meeting the Board's expectations: (1) advertisements should not contain false claims or misrepresentations of fact, either expressly or by implication; (2) advertisements should not omit material facts; and (3) licensees should be prepared to substantiate claims made in advertisements.

Licensees should avoid advertising and publicity that create unjustified medical expectations, that are accompanied by deceptive claims, or that imply exclusive or unique skills or remedies. Similarly, a statement that a licensee has cured or successfully treated a large number of patients suffering a particular ailment is deceptive if it implies a certainty of results and/or creates unjustified or misleading expectations. When using patient photographs, they should be of the licensee's own patients and demonstrate realistic outcomes. Likewise, when a change of circumstances renders advertising inaccurate or misleading, the licensee is expected to make reasonable efforts to correct the advertising within a reasonable time frame.

The advent of the Internet and the proliferation of websites purporting to "rate" healthcare providers mean that licensees cannot always control information about themselves in the public domain. However, a licensee is expected to exercise reasonable efforts to bring about the correction or elimination of false or misleading information when he or she becomes aware of it.

Physicians Advertising Board Certification

The term "board certified" is publicly regarded as evidence of the skill and training of a physician carrying this designation. Accordingly, in order to avoid misleading or deceptive advertising concerning board certification, physicians are expected to meet the following guidelines.

No physician should advertise or otherwise hold himself or herself out to the public as being "board certified" without proof of current certification by a specialty board approved by the (1) American Board of Medical Specialties (ABMS); (2) the Bureau of Osteopathic Specialists of the American Osteopathic Association (AOA-BOS); (3) the Royal College of Physicians and Surgeons of Canada (RCPSC); or (4) a board that meets the following requirements:

i. the organization requires satisfactory completion of a training program with training, documentation and clinical requirements similar in scope and complexity to ACGME- or AOA-approved programs, in the specialty or subspecialty field of medicine in which the physician seeks certification. Solely experiential or on-the-job training is not sufficient;

ii. the organization requires all physicians seeking certification to successfully pass a written or oral examination or both, which tests the applicant's knowledge and skill in the specialty or subspecialty area of medicine. All examinations require a psychometric evaluation for validation;

iii. the organization requires diplomates to recertify every ten years or less, and the recertification requires, at a minimum, passage of a written examination;

iv. the organization prohibits all certification and recertification candidates from attempting more than three times in three years to pass the examination;

v. the organization has written by-laws and a code of ethics to guide the practice of its members and an internal review and control process including budgetary practices to ensure effective utilization of resources;

vi. the organization has written proof of a determination by the Internal Revenue Service that the certifying organization is tax-exempt under Section 501(c) of the Internal Revenue Code; and

vii. the organization has a permanent headquarters and staff sufficient to respond to consumer and regulatory inquiries.

Any physician advertising or otherwise holding himself or herself out to the public as "board certified" should disclose in the advertisement the specialty board by which the physician was certified. A physician is expected to maintain and provide to the Board upon request evidence of current board certification. In the case of physicians who have been certified by non-ABMS, non-AOA and non-RCPSC boards, the physician is expected to maintain and provide to the Board upon request evidence that the certifying board meets the criteria listed above.

The above limitations are only intended to apply to physicians who advertise or otherwise hold themselves out to the public as being "board certified." The above criteria are not applicable in other instances, such as employment determinations, privileging or credentialing decisions, membership on insurance panels, or setting reimbursement rates.

*Business letterheads, envelopes, cards, and similar materials are understood to be forms of advertising and publicity for the purpose of this Position Statement.

North Carolina Medical Board
Task Force on Physician Advertising of Specialty Board Certification
Minutes of the Meeting of May 19, 2010

The Meeting of the Task Force on Specialty Board Certification was called to order by Chairman William Walker, M.D. at 6:00 PM Tuesday, May 19, 2010 in the Board Room of the North Carolina Medical Board, 1203 Front Street, Raleigh, NC.

The following Task Force members were present:

William Walker, MD, Chair, Member of the North Carolina Medical Board
Pamela Blizzard, Member of the North Carolina Medical Board
Ralph Loomis, MD, Member of the North Carolina Medical Board
Craig Burkhart, MD(Chapel Hill)
Edward Ermini, MD (Lumberton)
John Fagg, MD (Winston-Salem)
Brian Forrest, MD (Apex)
Cynthia Gregg, MD (Cary)
Paul Francis Malinda, MD (Kernersville)
Warren Pendergast, MD (Raleigh)
John C. Pittman, MD (Raleigh)
Vivek Tayal, MD (Charlotte & Washington, DC)

Dr. Walker explained the purpose and need for the Task Force. The North Carolina Medical Board selected the Task Force members to serve as a panel of experts to review materials, hear presentations and discuss appropriate standards for physicians who advertise they are board certified. Dr. Walker cautioned the group that the Task Force meeting was not intended as a forum to debate the relative merits of various certifying organizations but rather to define the appropriate use of the term "board certified" in advertising.

The Task Force heard a briefing from Medical Board attorney Todd Brosius on the Board's work on the issue. The Board has broad general authority under N.C.G.S. 90-14(a)(1) to discipline its licensees for unprofessional conduct such as false or misleading advertising. In November 1999 the Board first adopted a Position Statement entitled "Advertising and Publicity" generally cautioning licensees against false advertising and providing guidelines with which to assess the propriety of certain kinds of ads. (Position Statement adopted November 1999; amended March 2001; and revised September 2005). The Board revisited physician board certification advertising standards three years ago when the Board disciplined a physician for advertising his board certification by a patently illegitimate board. The Medical Board subsequently issued proposed rule 21 NCAC 32Y .0101 "Advertising of Specialty and Board Certification" which set criteria that a board must meet before a physician could advertise board-certified status. The Medical Board received 77 letters of public comment at the November 2009 rule hearing, which prompted the Board to delay the rulemaking process pending further solicitation of public input and in-depth discussion with stakeholders. This need for more information precipitated the Task Force's creation.

The Task Force was reminded of the reading materials sent for review prior to the meeting. The group then heard formal presentations concerning board certification criteria and operations from the following individuals representing the following organizations: Cheryl Gross of the American Osteopathic Association Bureau of Osteopathic Specialties; William Carbone, MD, of the American Board of Physician Specialists; Kevin Weiss, MD, of the American Board of Medical Specialties; Scott Fintzen, JD and Michael Will, MD, DDS of the American Board of Cosmetic Surgery; and Janice Ramquist of the North Carolina Integrative Medical Society. The Task Force engaged in conversation with each of the speakers.

Dr. Walker then led a discussion among the Task Force members concerning the evening's presentations. One member suggested the NCMB require physicians who advertise to list board certification and the name of the certifying board. The NCMB should also provide guidelines to assist in identifying legitimate boards. "Board certification" should be meaningful. It should reflect rigorous training and viable testing in a specialty. NCMB should serve as a safety net to discern legitimate boards from illegitimate boards but should allow for some expansion and innovation in the development of new specialty boards as medicine evolves.

Another opined that "board certified" is a widely understood term. A possible alternative would be to permit physicians to advertise that they are "trained in a certain procedure" or "certified to do a certain procedure."

Another task force member recommended that the language of proposed rule 21 NCAC 32Y .0101(a)(4) be amended to require training in the area of specialization. The NCMB needs to educate the public about the significance of "board certification." Yellow pages and internet sites often erroneously designate a physician as a specialist or attribute board certification when a physician is unaware that his/her information is included an advertisement or listing. It is impossible for a physician to prevent its occurrence and it would be inequitable for the NCMB to punish in those circumstances. It was further suggested that the NCMB Licensee Information Page would be an ideal site to allow for this information.

It was noted that the proposed rule is more lenient than the current Position Statement in that it permits advertisement of board certification by organizations "equivalent to" ABMS-recognized boards. NCMB needs to clarify what is meant by "equivalent" and reference was made to the Texas Medical Board's rule.

It was noted that it will be a time- and resource-intensive undertaking for the NCMB to determine which certifying boards are legitimate and which are not. It was again suggested that if a physician's residency training differs from his board certification, both should be included in an advertisement.

Others suggested looking at Florida's and Texas' approach to advertising of board certification. Another suggestion was to develop a logo to be used in advertisements that signifies the NCMB has approved the board.

Dr. Walker summarized the evening's discussion and added that NCMB policy also needs to recognize the international practice of medicine and foreign-trained physicians with distinguished international credentials cannot be unfairly proscribed from advertising their board certifications because the NCMB was provincial in its approach to policymaking.

Dr. Walker, aware of the issue's inherent complexity and mindful of the late hour, invited interested parties to submit additional written comments on the narrow issue of physician advertising of board certification before June 18. The meeting was adjourned at 9 PM.

Recommendations of the North Carolina Medical Board Task Force on Physician Advertising of Board Certification

The Task Force met at 6 PM on Tuesday, May 18, 2010 in the Board Room of the North Carolina Medical Board, 1203 Front Street, Raleigh, North Carolina. The "Minutes of the Meeting of the North Carolina Medical Board Task Force on Physician Advertising of Board Certification" are incorporated as Attachment 1. The Task Force was charged with discussing and identifying standards for the state's physicians advertising to the public that they are "board certified."

Defining "Board Certified"

"Board certified" has a special meaning within the health care industry and to the general public. Board Certification requires completion of a residency, licensure by a state medical board, and passing additional examinations in the specialty field. Board certification further assures the public that a physician remains dedicated to lifelong learning and mastery of the specialty field. Board certification connotes that a physician has advanced knowledge and expertise.

The general public relies on the term "board certified" as a means of assessing a physician's clinical ability. Patients who select a board certified physician as their health care professional historically have been safe in assuming that the physician had met rigorous educational, training and testing requirements. (ABMS letter to NCMB Task Force, May 10, 2010.) A physician's board certification may be used to determine eligibility to contract with managed care entities, for credentialing to serve on hospital staffs, to obtain other clinical privileges, to ascertain competence to practice medicine or for other purposes. (AMA Policy H-275.944 Board Certification and Discrimination (Sub. Res. 701, I-95, Reaffirmed: CME Rep. 7, A-07)) However, the Task Force is focused only on the issue of physician advertising of board certification to the public.

History of Board Certification

In the early 1900's advances in medical science vastly improved the delivery of health care. Unfortunately this era of rapid medical advancement also allowed less well trained or less well qualified physicians to make claims concerning the extent of their knowledge and training that could not be substantiated. With no formal system in place to validate these claims, neither the public nor the medical profession could trust that a self-designated specialist had the appropriate qualifications. This uncertainty prompted the rise of the specialty board movement.

In 1908 the American Academy of Ophthalmology and Otolaryngology first proposed the notion of specialized training followed by an examination in order to determine a physician's competence in a particular field. The National Board of Medical Examiners and the American Medical Association, among others, worked together to implement standards for graduate medical school education and the recognition of physician specialists which was largely accomplished during the 1920s and 1930s. National specialty boards designated certain clinical and practical experiences as well as graduate course requirements as prerequisites to sit for the examinations. Eventually specialty boards established a uniform system to administer examinations conducted by a group of peers selected by the boards. The rapid and widespread acceptance of specialty boards by the profession began to restrain physicians with little or no formal education in the specialty from designating themselves as specialists. (www.ABMS.org)

There are currently approximately 100 to 200 organizations claiming to certify physicians as specialists. (ABMS letter to NCMB Task Force, May 10, 2010) These certifying boards have a broad spectrum of intellectual, clinical, and academic requirements to achieve certification status. Some boards have been criticized for lacking intellectual rigor and designating physicians as "board certified" without meeting any real standards other than paying the certifying board's fees. These "bogus boards" have degraded the term "board certified" as a measure of reliability. A significant conflict exists between the well established certifying organizations (ABMS and AOA) and newer organizations wishing to become certifying boards. The conflict revolves around a perception of prejudice on the part of the established organizations against newcomers on the grounds of economic issues and differences regarding the quality of the programs and the appropriateness of subdivisions of medical training. There may be varying degrees of truth in the claims made on all sides of the debate. Regardless, the public can no longer safely assume that "board certified" means what it once did. The North Carolina Medical Board wishes to establish guidelines for its physician licensees to avoid misleading the public when advertising "board certification."

NCMB and Standards for Physician Advertising of Board Certification

The Board has broad general authority under N.C.G.S. 90-14(a)(1) to discipline its licensees for conduct such as false or misleading advertising. In November 1999 the Board first adopted a Position Statement entitled "Advertising and Publicity" generally cautioning licensees against false advertising and providing guidelines to assess the propriety of certain kinds of ads. (Position Statement adopted November 1999; amended March 2001; revised September 2005). The Board revisited physician board certification advertising standards three years ago when the Board disciplined a physician for publicly advertising his board certification by a patently "bogus" board and failing to disclose in advertising that his post graduate training was done in another specialty field. The NCMB felt that its licensees would benefit from more robust advertising guidelines. Accordingly, the NCMB issued proposed rule 21 NCAC 32Y .0101 "Advertising of Specialty and Board Certification" which set criteria that a board must meet before a physician could advertise board-certified status. The Medical Board received 77 letters of public comment at the November 2009 rule hearing, prompting the Board to delay the rulemaking process to create this Task Force to allow for additional public input and discussion among stakeholders.

Background

The issue of defining the parameters of appropriate advertising of board certification by physician licensees began when the California Board studied the issue in 1990 at the request of the California state legislature. Since then the Texas, Florida and Oklahoma boards have each labored to adopt criteria for distinguishing "bogus" or "sham" certifying boards from their legitimate counterparts. These efforts have given rise to expensive and protracted litigation as well as aggressive lobbying efforts by specialty boards which do not meet the criteria of the various state licensing Boards. At its 2010 Annual Meeting, the Federation of State Medical Boards declined to adopt a resolution asking the FSMB to study advertising standards regarding board certification. The North Carolina Medical Board and the Task Force have endeavored to find a solution that will adequately protect the public.

Task Force Recommendations

The issue of advertising board certification is complex and contentious. To fully understand board certification requires a working knowledge of physician residency and fellowship training, the taxonomy of physician specialty designations, and specialty certification boards. Constitutional law concerning commercial free speech, state physician regulatory law and physician specialty politics all relate to the issue of advertising. Consequently the Task Force recommends that the Medical Board adopt a strategy to regulate and educate its physician licensees and educate the general public. First, the Task Force recommends amendments to proposed Rule 21 NCAC 32Y .0101 "Advertising of Specialty and Board Certification." The Board should also amend its current Position Statement, "Advertising and Publicity" (adopted Nov. 1, 1999) to better inform both licensees and the general public in specific terms what the Boards expectations are for specialty and board certification advertising by physicians. Finally, the Board should provide consumer education regarding "board certification" on the Board website with links to appropriate resources.

Changes to Proposed NCMB Rule 21 NCAC 32Y .0101

The proposed rule, Attachment 2, precludes advertisement of board certification unless the board in question has been approved by the American Board of Medical Specialties; the Bureau of Osteopathic Specialists of the American Osteopathic Association; the Royal College of Physicians and Surgeons of Canada; or a board or association fulfilling the characteristics listed in the rule. The proposed rule further requires that a physician advertising board certification disclose the name of the specialty board granting certification. Finally, the proposed rule requires that if a physician is board-certified in a specialty different than the one in which he or she is residency- or fellowship-trained, the physician must note that with equal prominence in the advertising materials.

The Task Force recommends against the Medical Board's implementation of any rule, policy or procedure that would require the Medical Board to individually assess the legitimacy of specialty boards that grant board certification status to physicians. The leadership, management, board certification requirements and membership requirements in such organizations are in a state of

flux. Assessing specialty boards is a data-intensive, time-intensive and resource-intensive undertaking and requires special expertise. Other state medical boards with such review mechanisms report substantial litigation by certifying boards which do not met the various state licensing boards' criteria. While litigation risk should not prevent the adoption of policies, the cost in time and resources must be considered.

Amendments to the NCMB Position Statement "Advertising and Publicity"

The Task Force recommends amendments to the Position Statement. The Task Force believes that the statement in its present form lacks the specific detail that licensees may rely on when crafting their advertisements to comport with the Board's expectations. The Task Force believes specific guidance serves the licensees and the public better. The statement should reflect NCMB's opinions concerning consumer advertising. The statement should reflect the reality that physicians often cannot control information on the internet in physician listings, consumer rating services and other media. The statement should also encourage physicians to provide accurate current information on the North Carolina Medical Board's Licensee Information Pages. Consideration should be given to the Constitutional protections afforded commercial speech in crafting the Position Statement.

Consumer Education on the NCMB Website

The Task Force recommends that the North Carolina Medical Board expand the use of the North Carolina Medical Board website as a consumer resource center. The Board should direct its staff to provide educational materials in laymen's terms that explain the significance of the term "board certified." The materials should explain how certifying boards differ from state licensing agencies and give a brief explanation of the history of the development of certifying boards. It should be noted that board certification is used for assessment purposes by a variety of organizations, including insurance panels, hospital privileging committees, and Medicare and Medicaid, among others. The information should include recognition that ABMS- and AOA-recognized board certifications are acknowledged by industry experts to represent the "gold standard" for physicians but that other legitimate and credible boards exist. Likewise, the public should be informed that Boards requiring completion of a specialty-specific ACGME-approved postgraduate training program represent the highest standard of physician training and certification. The public should also be informed that there are viable reasons why such board certification is not open to everyone, for example, emergency physicians who graduated from medical school prior to the formal recognition of emergency medicine as an independent specialty. The public should also be afforded a list of criteria the NCMB feels are essential components of a legitimate certifying board. NCMB should also provide a list of "red flags" that identify "bogus" or "sham" boards.

The consumer education page should make clear that the Board's rules governing physician advertising of board certification apply to the limited instance of consumer advertising and do not serve as a referendum on the legitimacy of various certifying boards. The standards should not be used as a benchmark or controlling authority for credentialing organizations or for privileging purposes. Likewise, the Board's approval of advertising of board certification by

boards other than those traditional ABMS- or AOA-approved boards should not be misconstrued as tacit approval of diminution of standards for certifying boards.

Conclusion

The North Carolina Medical Board Task Force on Physician Advertising of Specialty Board Certification hereby presents this report for consideration by the Policy Committee of the North Carolina Medical Board at the Board's September, 2010 meeting.

Proposed 21 NCAC 32Y .0101 Advertising of Specialty and Board Certification*

(a) No physician shall advertise or otherwise hold himself or herself out to the public as being "Board Certified" without proof of current certification by a specialty board approved by the (1) American Board of Medical Specialties; (2) the Bureau of Osteopathic Specialists of the American Osteopathic Association; (3) the Royal College of Physicians and Surgeons of Canada; a board or association that meets the following requirements:

(1) the organization requires all physicians seeking certification to successfully pass a written or oral examination or both, which tests the applicant's knowledge and skill in the specialty or subspecialty area of medicine. All examinations require a psychometric evaluation for validation;[i]
(2) the organization requires diplomates to recertify every ten years or less, which requires passage of a valid written examination;
(3) the organization prohibits all certification and recertification candidates from attempting more than three times in three years to pass the examination;
(4) the organization has written proof of a determination by the Internal Revenue Service that the certifying board is tax-exempt under Section 501(c) of the Internal Revenue Code;
(5) the organization has a permanent headquarters and staff sufficient to respond to consumer and regulatory inquiries;
(6) the organization has written by-laws and a code of ethics to guide the practice of its members and an internal review and control process including budgetary practices to ensure effective utilization of resources; and
(7) the organization requires all physicians seeking certification to have satisfactorily completed identifiable and substantial training (not consisting solely of experiential or "on the job" training) in the specialty or subspecialty area of medicine in which the physician is seeking certification.

(b) Any physician advertising or otherwise holding himself or herself out to the public as "Board Certified" as contemplated in paragraph (a) shall disclose in the advertisement the specialty board by which the physician was certified.

(c) A physician that completed his or her training in a specialty or sub-specialty different from the specialty or sub-specialty in which he or she is "Board Certified" as contemplated in paragraph (a) shall note in any advertisements or other public announcements the specialty or sub-specialty in which the physician's residency training or fellowship training was completed. Such advertisements or other public announcements shall list the residency training or fellowship training completed by the physician and the specialty or sub-specialty in which he or she is Board Certified with equal prominence.

(d) The licensee shall maintain and provide to the Board upon request evidence of current board certification and, in the case of non-ABMS, non-AOA and non-RCPSC boards, evidence that the certifying board meets the criteria listed in paragraph (a).

Original proposed rule:

21 NCAC 32Y .0101 is proposed for adoption as follows:

Subchapter 32Y – SPECIALTY AND BOARD CERTIFICATION ADVERTISING

21 NCAC 32Y .0101 ADVERTISING OF SPECIALTY AND BOARD CERTIFICATION

(a) No physician shall advertise or otherwise hold himself or herself out to the public as being "Board Certified" without proof of current certification by a specialty board approved by (1) the American Board of Medical Specialties; (2) the Bureau of Osteopathic Specialists of American Osteopathic Association; (3) the Royal College of Physicians and Surgeons of Canada; (4) a board or association with an Accreditation Council for Graduate Medical Education approved postgraduate training program that provides complete training in that specialty or subspecialty; or (5) a board or association with equivalent requirements approved by the North Carolina Medical Board.

(b) Any physicians advertising or otherwise holding himself or herself out to the public as "Board Certified" as contemplated in paragraph (a) shall disclose in the advertisement the specialty board by which the physician was certified.

(c) Physicians shall not list their names under a specific specialty in advertisements, including but not limited to, classified telephone directories and other directories unless: (1) they are board certified as defined in paragraph (a); or (2) they have successfully completed a training program in the advertised specialty that is accredited by the Accreditation Council for Graduate Medical Education or approved by the Council on Postdoctoral Training of the American Osteopathic Association.

History Note: Authority G.S.90-5.1, 90-5.2, 90-14.

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
Professional Obligation to Report Incompetence, Impairment, and Unethical Conduct	Nov-98	March 2010	Nov-98				
Medical, Nursing, Pharmacy Boards: Joint Statement on Pain Management in End-of-Life Care	Oct-99	May 2010	Oct-99				
What Are the Position Statements of the Board and To Whom Do They Apply?	Nov-99	May 2010	Nov-99				
Contact With Patients Before Prescribing	Nov-99	July 2010	Feb-01				
Guidelines for Avoiding Misunderstandings During Physical Examinations	May-91	July 2010	Oct-02	Feb-01	Jan-01	May-96	May-93
Office-Based Procedures	Sep-00	Sept 2010	Jan-03				
Access to Physician Records	Nov-93	Sept 2010	Aug-03	Mar-02	Sep-97	May-96	
Medical Supervisor-Trainee Relationship	Apr-04	Nov 2010	Apr-04				
The Treatment of Obesity	Oct-87	Nov 2010	Jan-05	Mar-96			
HIV/HBV Infected Health Care Workers	Nov-92		Jan-05	May-96			
Writing of Prescriptions	May-91		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	
Advertising and Publicity	Nov-99		Sep-05	Mar-01			

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			
Unethical Agreements in Complaint Settlements	Nov-93		Mar-10	May-96			

2. New Business:
    a. Position Statement Review
        i. Medical Supervisor-Trainee Relationship

    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.

The medical supervisor-trainee relationship

It is the position of the North Carolina Medical Board that the relationship between medical supervisors and their trainees in medical schools and other medical training programs is one of the most valuable aspects of medical education. We note, however, that this relationship involves inherent inequalities in status and power that, if abused, may adversely affect the educational experience and, ultimately, patient care. Abusive behavior in the medical supervisor-trainee relationship, whether physical or verbal, is a form of unprofessional conduct. However, criticism and/or negative feedback that is offered with the aim of improving the educational experience and patient care should not be construed as abusive behavior.

(Adopted April 2004)

2. New Business:
    a. Position Statement Review
        ii. The Treatment of Obesity

    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.

The treatment of obesity

It is the position of the North Carolina Medical Board that the cornerstones of the treatment of obesity are diet (caloric control) and exercise. Medications and surgery should only be used to treat obesity when the benefits outweigh the risks of the chosen modality.

The treatment of obesity should be based on sound scientific evidence and principles. Adequate medical documentation must be kept so that progress as well as the success or failure of any modality is easily ascertained.

(Adopted [as The Use of Anorectics in Treatment of Obesity] October 1987) (Amended March 1996) (Amended and retitled January 2005)

2. New Business:
    b. Request from United Health Group

        Issue: Proposal for an internet based telemedicine service from United Health Group

OptumHealth℠

Optimizing Health and Well-Being℠

October 7, 2010

Scott Kirby, M.D.
Medical Director
North Carolina Medical Board
1203 Front Street
Raleigh, NC 27609

Dear Dr. Kirby:

OptumHealth is a division of UnitedHealth Group and provides health care services to consumers, such as Disease Management, Case Management, Health and Wellness coaching and the like. One of our exciting new offerings for physicians and patients is an online telemedicine tool, known as "NowClinic". I appreciate the time you spent with Dr. John Rennick and me on September 23 discussing OptumHealth's intent to offer this tool to North Carolina physicians for use with their patients.

NowClinic gives physicians an opportunity to offer patients access to online encounters in addition to in-office services. NowClinic's software, powered by American Well® technology, does not use questionnaires for diagnosis and treatment, but instead allows patients and physicians to engage in live, "face-to-face" encounters through webcam enabled technology. Doctors and patients can see each other, hear each other, chat online with each other, and even reach each other by telephone if they desire. This direct doctor-patient interaction is documented in a full electronic medical record which is accessible to patients and physicians alike. This medical record has capabilities allowing the import of additional past medical history, patient personal health records, medications, allergies, etc., and represents a significant clinical tool supporting the patient's encounter with a NowClinic physician.

To be clear, though, this telemedicine application does not support a traditional, complete physical examination.

NowClinic will categorically not allow any treatment to include the prescription of controlled substances from within its borders, but hopes to allow other medication prescriptions subject to the licensee's independent medical judgment under applicable standards of care. NowClinic's prescription software is powered by SureScripts and is pre-set to block the prescription of any controlled substance. To date, only 30% of online encounters in other states using this software have resulted in any medication recommendation, and many of those recommendations are for OTC products. Thus, NowClinic is not a "pill-mill". Rather, NowClinic is meant to supply greater access, convenience and continuity to established patients in physician practices, as well as to give North Carolina residents without access to physicians an opportunity to interact with North Carolina licensed doctors. Physicians are reimbursed modestly, generally by the patient, for each online encounter they provide, with no distinction in reimbursement made on the basis of whether or not a prescription is issued.

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We are mindful of North Carolina Medical Board authorities on telemedicine, particularly around (1) the establishment of a physician-patient relationship and (2) the prescription of medications without an *appropriate* physical examination.

1) With respect to whether a physician-patient relationship is established in the NowClinic environment, the following observations seem to us to be relevant:
   a) Through the NowClinic software, the patient has the opportunity to individually select the physician of his/her choice with whom they wish to speak. The physician likewise has the ability to accept or decline an online encounter. The identity of each party is known to the other. Thus, the relationship established is both open and consensual.
   b) Patients and physicians have the opportunity to see and hear each other, and an interactive medical history takes place in real time. Clinical recommendations are made by physicians on the basis of this real time clinical exchange.
   c) The physician is paid for his/her clinical advice.
   d) The physician is assumed liable for any negligence committed in this environment. (NowClinic pays for professional liability coverage for physicians on an encounter-by-encounter basis).
2) Since we do not allow the prescription of controlled substances in this environment, we are interested in the Medical Board's stance on the prescription of non-controlled medications. We read the authorities such that this would be permissible as long as the treating physician performs an *appropriate* physical examination. Since there are a number of clinical scenarios where the standard of care does not require an examination - as, for example, in the treatment of H1N1 symptoms, or the treatment of uncomplicated urinary tract infections in adult females - we presume that the Medical Board would allow the prescription of non-controlled substances in these situations. The North Carolina Medical Board appears to recognize this principle in certain clinical circumstances, such as in the treatment of Sexually Transmitted Diseases (e.g. http://www.ncmedboard.org/position_statements/detail/contact_with_patients_before_prescribing/).

Where the standard of care requires a physical examination, however, physicians should be expected to meet the standard of care and request/arrange for an appropriate physical examination prior to the issuance of a prescription. We fully support the idea that physicians should ask patients to schedule an in-office follow up examination so that an accurate diagnosis can be made and appropriate treatment recommended. We intend to counsel North Carolina physicians directly to this effect.

We'd like to begin offering NowClinic to North Carolina physicians and residents in the near future in full compliance with North Carolina law. We are hopeful the Board will allow the full capabilities of NowClinic, including the prescription of non-controlled substances in appropriate circumstances, to be offered to North Carolina residents. I'd be happy to come to Raleigh again

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to personally demonstrate our software, discuss our plans, ask our questions and address any concerns your larger Board may have.

You may find a brief overview of NowClinic at http:/www.myNowClinic.com.

Please let us know your thoughts and next steps.

Sincerely,

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