

# Position Statements North Carolina Medical Board

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[The principles of professionalism and performance expressed in the position statements of the North Carolina Medical Board apply to all persons licensed and/or approved by the Board to render medical care at any level.

The words "physician" and "doctor" as used in the position statements of the North Carolina Medical Board refer to persons who are MDs or DOs licensed by the Board to practice medicine and surgery in North Carolina.]

#### Disclaimer

The North Carolina Medical Board makes the information in this publication available as a public service. We attempt to update this printed material as often as possible and to ensure its accuracy. However, because the Board's position statements may be revised at any time and because errors can occur, the information presented here should not be considered an official or complete record. Under no circumstances shall the Board, its members, officers, agents, or employees be liable for any actions taken or omissions made in reliance on information in this publication or for any consequences of such reliance. A more current version of the Board's position statements will be found on the Board's Web site: www.ncmedboard.org, which is usually updated shortly after revisions are made. In no case, however, should this publication or the material found on the Board's Web site substitute for the official records of the Board.

# What Are the Position Statements of the Board and to Whom Do They Apply?

The North Carolina Medical Board's Position Statements are interpretive statements that attempt to define or explain the meaning of laws or rules that govern the practice of physicians,\* physician assistants, and nurse practitioners in North Carolina, usually those relating to discipline. They also set forth criteria or guidelines used by the Board's staff in investigations and in the prosecution or settlement of cases.

When considering the Board's Position Statements, the following four points should be kept in mind.

- In its Position Statements, the Board attempts to articulate some of the standards it believes applicable to the medical profession and to the other health care professions it regulates. However, a Position Statement should not be seen as the promulgation of a new standard as of the date of issuance or amendment. Some Position Statements are reminders of traditional, even millennia old, professional standards, or show how the Board might apply such standards today.
- The Position Statements are not intended to be comprehensive or to set out exhaustively every standard that might apply in every circumstance. Therefore, the absence of a Position Statement or a Position Statement's silence on certain matters should not be construed as the lack of an enforceable standard.
- The existence of a Position Statement should not necessarily be taken as an indication of the Board's enforcement priorities.
- A lack of disciplinary actions to enforce a particular standard mentioned in a Position Statement should not be taken as an abandonment of the principles set forth therein.

The Board will continue to decide each case before it on all the facts and circumstances presented in the hearing, whether or not the issues have been the subject of a Position Statement. The Board intends that the Position Statements will reflect its philosophy on certain subjects and give licensees some guidance for avoiding Board scrutiny. The principles of professionalism and performance expressed in the Position Statements apply to all persons licensed and/or approved by the Board to render medical care at any level.

\*The words "physician" and "doctor" as used in the Position Statements refer to persons who are MDs or DOs licensed by the Board to practice medicine and surgery in North Carolina.

(Adopted November 1999) (Reviewed May 2010; November 2017)

# The Physician-Patient Relationship

A physician's first responsibility is to his or her patients. Having assumed care of a patient, the physician's responsibility is to provide competent, compassionate, and economically prudent care within the standards of acceptable medical practice and to make treatment decisions that are in the best interest of the patient. It is the Board's position that it is unethical for a physician to allow financial incentives or other interests to adversely affect or influence his or her medical judgment or patient care. Patient advocacy is a fundamental element of the patient-physician relationship and should not be altered by the health care system or setting in which a physician practices. All physicians should exercise their best professional judgement when making patient care decisions. When economic or other interests are in conflict with patient welfare, the patient's welfare must take priority. Physicians who hold administrative leadership positions should foster policies that support the physician-patient relationship and enhance the quality of patient care.

# Elements of the Physician-Patient Relationship

Receiving a license to practice medicine grants the physician privileges and imposes great responsibilities. The people of North Carolina expect a licensed physician to be competent and worthy of their trust. As patients, they come to the physician in a vulnerable condition, believing the physician has knowledge and skill that will be used for their benefit.

Mutual trust is fundamental to the physician-patient relationship and requires that:

- there be appropriate professional communication between the physician and the patient;
- the physician timely report all significant findings to the patient or the patient's legally designated surrogate/guardian/personal representative;
- conflict of interest between the patient and the physician or third parties be resolved to the benefit of the patient;
- personal details of the patient's life shared with the physician are held in confidence;
- the physician maintain competence, professional knowledge, and skills:
- there is respect for the patient's autonomy;
- the physician maintains a compassionate and professional demeanor;
- the physician respect the patient's right to request restrictions on medical information disclosure;
- the physician be an advocate for appropriate medical care;
- patient advocacy remains unaltered by the health care system or setting; and
- the physician provide neither more nor less than the medical problem requires.

The Board believes the interests and health of the people of North Carolina are best served when the physician-patient relationship, founded on patient trust and fostered by professional communication, patient primacy, confidentiality, competence, patient autonomy, compassion, selflessness, and appropriate care are foremost considerations of physicians.

This same fundamental physician-patient relationship also applies to all licensees of this Board.

## Termination of the Physician-Patient Relationship

The Board recognizes the physician's right to choose patients and to terminate the professional relationship with them when he or she believes it is best to do so. That being understood, the Board maintains that termination of the physicianpatient relationship must be done in accord with the physician's underlying obligation to support continuity of care.

Patient termination must be accompanied by appropriate written notice provided to the patient or the patient's representative sufficiently far in advance (at least 30 days) to allow other medical care to be secured. A copy of such notification is to be included in the medical record. Should the physician be a member of a group or an employee of a large practice, the notice of termination must also state clearly whether the termination involves only the individual physician, other physicians in the practice, or the entire practice. In the latter case, those members of the group joining in the termination must be designated. It is advisable that the notice of termination also include instructions for transfer of or access to the patient medical records.

When a physician's employment status is terminated by an employer, the physician or his or her employer should notify the physician's patients that the physician will no longer be working with the employer and should provide them with the physician's new contact information. Patients should be given the choice to continue to be seen by the physician in his or her new practice setting or to be treated by another physician still working with the employer.

(Adopted July 1995) (Amended July 1998; January 2000; March 2002; August 2003; September 2006; July 2012; September 2016)

# MEDICAL RECORDS - Documentation, Electronic Health Records, Access, and Retention

#### Documentation

The North Carolina Medical Board takes the position that an accurate, current, and complete medical record is an essential component of patient care. Licensees should maintain a medical record for each patient to whom they provide care. The medical record should be legible. When the caregiver does not write legibly, notes should be dictated, transcribed, reviewed, and signed within a reasonable time. It is incumbent upon the licensee to ensure that the transcription of notes is accurate (particularly in those instances where dictation software is utilized).

The medical record is a chronological document that:

- Records pertinent facts about an individual's health and wellness;
- Enables the treating care provider to plan and evaluate treatments or interventions:
- Enhances communication between professionals, assuring the patient optimum continuity of care;
- Assists both patient and physician in communication with third party participants;
- Allows the physician to develop an ongoing quality assurance program;
- Provides a legal document to verify the delivery of care; and
- Is available as a source of clinical data for research and education.

The following required elements should be present in all medical records:

- The purpose of each patient encounter and appropriate information about the patient's history and examination, plan for any treatment, and the care and treatment provided;
- The patient's past medical history including serious accidents, operations, significant illnesses, and other appropriate information;
- Prominent notation of medication and other significant allergies, or a statement of their absence;
- Clearly documented informed consent obtained from the patient when appropriate; and
- Date of each entry.

The following additional elements reflect commonly accepted standards for medical record documentation:

- Each page in the medical record contains the patient's name or ID number.
- Personal biographical information such as home address, employer, marital status, and all telephone numbers. including home, work, and mobile phone numbers.
- All entries in the medical record contain the author's identification. Author identification may be a handwritten signature, initials, or a unique electronic identifier.
- All drug therapies are listed, including dosage instructions and, when appropriate, indication of refill limits. Prescription refills should be recorded.
- Encounter notes should include appropriate arrangements and specified times for follow-up care.
- All consultation, laboratory, and imaging reports should be entered into the patient's record, reviewed, and the review documented by the practitioner who ordered them. Abnormal reports should be noted in the record, along with corresponding follow-up plans and actions taken.
- An appropriate immunization record is evident and kept up to date.
- Appropriate preventive screening and services are offered in accordance with the accepted practice guidelines.

## **Electronic Health Records**

The Board recognizes and encourages the trend towards the use of electronic health records ("EHR"). The promise and potential of information technology in health care, particularly the use of EHR presents providers with distinct challenges. While the Board encourages the adoption and appropriate use of various forms of EHR, there are some unique aspects and problems associated with EHR that have been repeatedly encountered by the Board, some of which are discussed below. This subsection is meant to identify issues which the Board has repeatedly found to be problematic in malpractice and complaint cases coming to the Board's attention. It is important to recognize that this, and other Board position statements, are not comprehensive and do not describe exhaustively every standard that might apply in every circumstance. Basic, well-established principles of medical record documentation, as outlined above, apply to all forms of medical record documentation, including EHR.

The following guidelines are offered to assist licensees in meeting their ethical and legal obligations:

- EHR Deficiencies. Providers, on occasion, attribute errors or lack of follow-up, such as missed or lost abnormal laboratory results or x-ray reports, to deficiencies in their EHR. This is not acceptable. Providers must be aware of the idiosyncrasies and weaknesses of the EHR system they are using and adjust their practice accordingly. Providers are ultimately responsible for the adequate oversight and monitoring of the EHR.
- Responsibility of Licensees. EHR are becoming increasing sophisticated and may provide flags for follow-up care or other clinical decision-making support, such as health maintenance recommendations. While an EHR system may assist in the clinical decision-making process, it is not responsible for decision making. For example, it is not acceptable to blame an EHR because it failed to recommend particular testing. Increasingly elaborate documentation, clinical management, and productivity tools may also result in increased opportunities for errors or omissions. These errors are a failure of the provider to assume appropriate responsibility for the care of the patient. In the end, decision-making responsibility rests solely with the provider; regardless of the information or notices provided by the EHR.
- Use of Templates. The Board cautions against overuse of template content or reliance on EHR software which pre-populates, carries forward, or clones information from one encounter to the next, or from different providers. without the provider carefully reviewing and updating all information. Documentation of clinical findings for each patient encounter must accurately and contemporaneously reflect the actual care provided.
- Availability of, or Access to, EHR. Physicians must be able to provide patient medical records in a timely manner for various situations, such as consultations, transfer of care to another provider, or practice closure. The Board has encountered situations where providers were unable to access their patients' medical records due to fee or other disputes with the EHR vendor. This is particularly true when the medical records are maintained off site (cloud storage). Providers must understand provisions of their contract with the EHR vendor in this regard. These principles of medical record access apply as well to telemedicine providers.
- Breakdown of Patient-Provider Communication. Misunderstandings and miscommunications between patients, patient family members, practitioners, and office staff generate a substantial percentage of complaints received by the Board. Many EHR systems allow direct patient-provider communication (i.e. "patient portal"). While this form of communication can facilitate communication, such as follow-up of lab or x-ray results or medication refills, they also place a responsibility on the provider to provide timely responses to legitimate requests from patients for feedback or information.
- Employed Licensees and Independent Contractors. The Board recommends all employed licensees/independent contractors review their employment agreements regarding ownership of the EHR. There should be explicit provisions which set forth the rights and duties of the practice and the licensee upon termination of employment, with regards to notification of patients and access to medical records.

#### Access to Medical Records

A licensee's policies and practices relating to medical records under his or her control should be designed to benefit the health and welfare of patients, whether current or past, and should facilitate the transfer of clear and reliable information about a patient's care. Such policies and practices should conform to applicable federal and state laws governing health information.

It is the position of the North Carolina Medical Board that notes made by a licensee in the course of diagnosing and treating patients are primarily for the licensee's use and to promote continuity of care. Patients, however, have a substantial right of access to their medical records and a qualified right to amend their medical records pursuant to HIPAA privacy regulations.

Medical records are confidential documents and should only be released when permitted by law or with proper written authorization of the patient. Licensees are responsible for safeguarding and protecting the medical record and for providing adequate security measures.

Each licensee has a duty on the request of a patient or the patient's representative to release a copy of the record in a timely manner to the patient or the patient's representative, unless the licensee believes that such release would endanger the patient's life or cause harm to another person. This includes medical records received from other licensees' offices or health care facilities. A summary may be provided in lieu of providing access to or copies of medical records only if the patient agrees in advance to such a summary and to any fees imposed for its production.

Licensees may charge a reasonable fee for the preparation and/or the photocopying of medical records, keeping in mind that state law limits fees a licensee can charge for copies of medical records in certain cases, including liability claims for personal injury, social security disability claims, and workers' compensation claims. To assist in avoiding

misunderstandings, and for a reasonable fee, the licensee should be willing to review the medical records with the patient at the patient's request. Medical records should not be withheld because an account is overdue or a bill is owed (including charges for copies or summaries of medical records).

Should it be the licensee's policy to complete insurance or other forms for established patients, it is the position of the Board that the licensee should complete those forms in a timely manner. If a form is simple, the licensee should perform this task for no fee. If a form is complex, the licensee may charge a reasonable fee.

To prevent misunderstandings, the licensee's policies about providing copies or summaries of medical records and about completing forms should be made available in writing to patients when the licensee-patient relationship begins.

Licensees should not relinquish control over their patients' medical records to third parties unless there is an enforceable agreement that includes adequate provisions to protect patient confidentiality and to ensure access to those medical records.\*

When responding to subpoenas for medical records, unless there is a court or administrative order, licensees should follow the applicable federal regulations.

#### Retention of Medical Records

Licensees have both a legal and ethical obligation to retain patient medical records. The Board, therefore, recognizes the necessity and importance of a licensee's proper maintenance, retention, and disposition of medical records. Patient interests related to present and future healthcare needs should be a licensee's primary consideration when determining how long to retain medical records.

Other Considerations and Board Expectations:

- Patients should be notified regarding how long the licensee will retain medical records.
  - In order to preserve confidentiality when discarding old medical records, all medical records should be retained and destroyed in a HIPAA compliant manner, including both paper medical records and EHR. If it is feasible, patients should be given an opportunity to claim the medical records or have them sent to another care provider before old medical records are discarded.
- The licensee should respond in a timely manner to requests from patients for access to, or copies of, their medical
- Licensees should notify patients of the amount, and under what circumstances, the licensee will charge for copies of a patient's medical record.
- Those licensees providing episodic care should attempt to provide a copy of the patient's medical record to the patient, the patient's primary care provider, or, if applicable, the referring licensee.

It should be noted that these expectations relate solely to Board inquiries and do not preempt other legal or ethical record retention requirements. Licensees are encouraged to seek advice from private legal counsel and/or their malpractice insurance carrier.

\*NOTE: Refer also to the Board's Position Statement on Departures from or Closings of Medical Practices.

(Adopted July 2018) (Replaced Medical Record Documentation; Access to Medical Records; and Retention of Medical Records)

# **Departures from or Closings of Medical Practices**

Practitioners may have continuing obligations toward patients during and after their departure from or closing of a medical practice. A practitioner's specific obligations will vary depending on several factors including employment or practice partnership status, contractural based obligations, practice venue, and other considerations. Nevertheless, the patient's welfare, autonomy, and continuity of care must be the foremost consideration for all parties involved. Patients should therefore be given reasonable advance notice (at least 30 days) to allow other medical care to be secured. Good continuity of care includes preserving and providing appropriate access to medical records and may include making appropriate referrals. The practitioner(s) and other parties, such as group practices or physician employers, should work cooperatively to ensure requirements for continuity of care and patient autonomy are effectively attended to.

During these times practitioners and other parties involved must consider how their actions affect patients. In particular, practitioners and other parties have the following obligations.

It is the patient's decision from whom to receive care. Therefore, it is the responsibility of all practitioners and other parties to ensure that:

- Patients are notified in a timely fashion of changes in the practice and given the opportunity to seek other medical care, sufficiently far in advance (at least 30 days), to allow other medical care to be secured. The Board does not have specific rules on which patients should receive this notification or how it should be accomplished, but a reasonable option would be to notify active patients the physician has seen within the past 1-2 years. Methods of notification which might be considered include newspaper notices, posting an announcement in public locations in the office, website announcements, front desk flyers, etc. Each medical practice and patient population is unique and the Board would expect practitioners to utilize the most effective means of patient notification for their particular situation.
- Patients should clearly understand they have a choice of health care providers and notice to patients of the departing physician should include an unambiguous statement that patients have a choice of from whom to receive medical care. It is unethical to withhold information upon request of a patient. If the responsibility for notifying patients falls to the departing practitioner rather than to the group or employer there should be no interference in discharge of this responsibility by withholding essential information.
- Patients should be told both how to contact practitioner(s) remaining in practice, and when specifically requested, how to contact departing practitioners.
- Patients are told how to obtain copies of or transfer their medical records and how long their medical records will be available.

#### **Written Policies:**

The Board recommends that practitioners and practices prepare written policies regarding the secure maintenance, storage, transfer, data sharing, and retrieval of patient medical records recognizing that separate policies may be necessary for the storage of and access to paper and electronic medical records. Practitioners and practices should notify patients of these policies. At a minimum, the Board recommends that such written policies include:

- A procedure and timeline that describes how the practitioner or practice will notify each patient about (1) a pending practice closure or practitioner departure, (2) how medical records are to be accessed, and (3) how future notices of the location of the practice's medical records will be provided.
- How long medical records will be retained and the procedure by which the practitioner or practice will dispose of unclaimed medical records.
- How the practitioner or practice will respond to requests from patients for copies of or access to their medical records.
- In the event of a practitioner's death or incapacity, how the deceased practitioner's executor, administrator, personal representative, or survivor will notify patients of the location of their medical records, how patients can access those records, and how and when unclaimed medical records will be destroyed after a specified period of time.

The procedure by which the practitioner or practice will maintain medical record confidentiality and data integrity. Practice transitions are also times when there is increased risk of privacy breaches or inappropriate disclosure. HIPAA rules require that patients must be promptly informed about any security breach or unauthorized disclosure describing what information was breached, what steps patients may take to minimize adverse consequences of inappropriate disclosure of their personal health information placing the interests of patients above those of the physician, medical practice, or institution.

The Board further expects its licensees to comply with all applicable state and federal laws and regulations pertaining to a patient's protected healthcare information.

\*NOTE: The Board's Position Statement on the Retention of Medical Records applies, even when practices close permanently due to the retirement or death of the practitioner.

Additional Resources: The Board has published a guide to closing a medical practice to assist licensees with meeting their professional obligations.

(Adopted January 2000) (Amended August 2003; July 2009; March 2018) (Reviewed May 2014)

# The Retired Physician/Licensee

The retirement of a licensee is defined by the North Carolina Medical Board as the total and complete cessation of the practice of medicine and/or surgery by the licensee in any form or setting. According to the Board's definition, the retired licensee is not required to maintain a currently registered license and SHALL NOT:

- provide patient services;
- order tests or therapies;
- prescribe, dispense, or administer drugs;
- perform any other medical and/or surgical acts; or
- receive income from the provision of medical and/or surgical services performed following retirement.

The North Carolina Medical Board is aware that a number of licensees consider themselves "retired," but still hold a currently registered medical license (full, volunteer, or limited) and provide professional medical and/or surgical services to patients on a regular or occasional basis. Such licensees customarily serve the needs of previous patients, friends, nursing home residents, free clinics, emergency rooms, community health programs, etc. The Board commends those licensees for their willingness to continue service following "retirement," but it recognizes such service is not the "complete cessation of the practice of medicine" and therefore must be joined with an undiminished awareness of professional responsibility. That responsibility means that such licensees SHOULD:

- practice within their areas of professional competence;
- prepare and keep medical records in accord with good professional practice; and
- meet the Board's continuing medical education requirement.

The Board also reminds "retired" licensees with currently registered licenses that all federal and state laws and rules relating to the practice of medicine and/or surgery apply to them, that the position statements of the Board are as relevant to them as to licensees in full and regular practice, and that they continue to be subject to the risks of liability for any medical and/or surgical acts they perform.

(Adopted January 1997) (Amended September 2006; July 2012) (Reviewed May 2016)

# **Advance Directives and Patient Autonomy**

Licensees must be aware that North Carolina law specifically recognizes the individual's right to a peaceful and natural death. NC Gen Stat § 90-320 (a) (2007) reads:

The General Assembly recognizes as a matter of public policy that an individual's rights include the right to a peaceful and natural death and that a patient or the patient's representative has the fundamental right to control the decisions relating to the rendering of the patient's own medical care, including the decision to have life-prolonging measures withheld or withdrawn in instances of a terminal condition.

Licensees must also be aware that North Carolina law empowers any adult individual with capacity to make a Health Care Power of Attorney (N.C. Gen. Stat. § 32A-17 (2007)) and stipulates that, when a patient lacks understanding or capacity to make or communicate health care decisions, the instructions of a duly appointed health care agent are to be taken as those of the patient unless evidence to the contrary is available (N.C. Gen. Stat. § 32A-24(b)(2007)).

It is the position of the North Carolina Medical Board that it is in the best interest of the patient and of the licensee/patient relationship to encourage patients to complete or authorize documents that express their wishes for the kind of care they desire at the end of their lives. Licensees should encourage their patients to appoint a health care agent to act through the execution of a Health Care Power of Attorney and to provide documentation of the appointment to the responsible licensee(s). Further, licensees should provide full information to their patients in order to enable those patients to make informed and intelligent decisions preferably prior to a terminal illness. The Board also encourages the use of portable licensee orders to improve the communication of the patient's wishes for treatment at the end of life from one care setting to another.

It is also the position of the Board that licensees are ethically obligated to follow the wishes of the terminally ill or incurable patient as expressed by and properly documented in a declaration of a desire for a natural death; however, when the wishes of a patient are contrary to what a licensee believes in good conscience to be appropriate care, the licensee may withdraw from the case once continuity of care is assured.

It is also the position of the Board that withholding or withdrawal of life-prolonging measures is in no manner to be construed as permitting diminution of nursing care, relief of pain, or any other care that may provide comfort for the patient.

(Adopted July 1993) (Amended May 1996; March 2008; November 2012) (Reviewed July 2016)

# **Availability of Licensees to Their Patients**

It is the position of the North Carolina Medical Board that once a relationship between a licensee and a patient is created, it is the duty of the licensee to provide care whenever it is needed or to assure that proper backup by a healthcare provider is available to take care of the patient during or outside normal office hours.

If the licensee is not going to be available after hours, the licensee must provide clear instructions to the patient for securing after-hours care. It is the responsibility of the licensee to ensure that the patient has sufficient information regarding how to secure after-hours care.

It should be noted that these duties are applicable to a licensee whether the licensee is practicing telemedicine or practicing medicine through traditional means.

(Adopted July 1993) (Amended May 1996; January 2001; October 2003; July 2006; May 2012) (Reviewed January 2016)

# **Guidelines for Avoiding Misunderstandings During Patient Encounters and Physical Examinations**

It is the position of the North Carolina Medical Board that respect, empathy, and sensitivity to the vulnerability of patients are needed at all times during a patient encounter in order to avoid misunderstandings that could lead to charges of boundary violation or sexual misconduct against licensees. The Board offers the following guidelines to assist licensees in reducing the possibility of such misunderstandings.

- Licensees should recognize that misunderstandings regarding boundaries may occur at any time during a patient encounter, but particularly during disclosure of private information by the patient about symptoms, prior personal experiences, or during the physical examination. The licensee should maintain a professional demeanor at all times. While some licensees have adopted a more informal approach to patient interactions, such as use of first names for both patients and the licensee, this may blur boundaries and result in later misunderstandings.
- Sensitivity to patient modesty and dignity must be maintained at all times. The patient should be assured of adequate privacy and should never be asked to disrobe in the presence of the licensee. Examining rooms should be well maintained and equipped with appropriate furniture and supplies for examination and treatment. Gowns, sheets, and/or other appropriate apparel should be made available to the patient.
- Regardless of the patient's gender, a third party, usually a staff member, should be readily available at all times during a physical examination, and it is strongly advised that a third party be present when the licensee performs an examination of the breasts, genitalia, or rectum. It is the licensee's responsibility to have a staff member available at any point during the examination. If no chaperone is available, the patient should be clearly advised of what will occur during the examination and provide verbal informed consent for an unchaperoned examination.
- The licensee should individualize the approach to physical examinations so that each patient's sense of vulnerability, apprehension, fear, and embarrassment are diminished to the extent possible. An explanation of the necessity of a complete physical examination, the components of that examination, and the purpose of disrobing may be necessary in order to minimize the patient's apprehension.
- The licensee and staff should exercise the same degree of professionalism and care when performing diagnostic procedures (e.g., electrocardiograms, electromyograms, endoscopic procedures, and radiological studies, etc.), as well as during surgical procedures and postsurgical follow-up examinations when the patient is in varying stages of consciousness.
- Sexual impropriety by the licensee may include behavior, gestures, comments, or expressions that are seductive, sexually suggestive, disrespectful of patient privacy, or sexually demeaning to a patient, and may include, but are not limited to:
  - Neglecting to employ disrobing or draping practices that respect patient privacy or deliberately watching a patient dress or undress.
  - Subjecting a patient to an intimate examination in the presence of medical students or other persons without the patient's consent.
  - Examination or touching of genital mucosal areas without the use of gloves.
  - Unprofessional comments made at any time during the encounter about or to the patient, including making sexual comments about a patient's appearance, body, or clothing or offering demeaning observations about the patient or others.
  - Using a physician-patient encounter to solicit a date or romantic relationship.
  - Conversations or comments regarding the sexual problems, preferences, or fantasies of the licensee.
  - Performing an examination without clinical justification or without explaining to the patient the need for such examination.

- Requesting details of the patient's sexual history or sexual preferences when not clinically indicated.
- The licensee should also be alert for suggestive or flirtatious behavior or mannerisms on the part of the patient and should not permit a compromising situation to develop.

(Adopted May 1991) (Amended May 1993; May 1996; January 2001; February 2001; October 2002; July 2010; November 2017; March 2019) (Reviewed January 2014)

# **Sexual Exploitation of Patients**

It is the position of the North Carolina Medical Board that sexual exploitation of a patient is unprofessional conduct and undermines the public trust in the medical profession and harms patients both individually and collectively. This Position Statement is based, in part, upon the Federation of State Medical Board's guidelines regarding sexual boundaries ("FSMB Guidelines").

Sexual behavior between a licensee and a patient is never diagnostic or therapeutic. Such behavior may be verbal or physical and may include expressions of thoughts and feelings or gestures that are sexual or that reasonably may be construed by the patient as sexual.

The FSMB Guidelines define and distinguish between two types of professional sexual misconduct: sexual impropriety and sexual violation. Both types of sexual misconduct could constitute a basis for disciplinary action by the Board.

Sexual impropriety may comprise behavior, gestures, or communications, whether they be made in person, electronically or by other means, that are seductive, sexually suggestive, disrespectful of patient privacy, or sexually demeaning to a patient, that may include, but are not limited to:

- Neglecting to employ disrobing or draping practices respecting the patient's privacy, or deliberately watching a patient dress or undress:
- 2. Subjecting a patient to an intimate examination in the presence of medical students or other parties without the patient's informed consent or in the event such informed consent has been withdrawn;
- Examination or touching of genital mucosal areas without the use of gloves;
- Inappropriate comments about or to the patient, including but not limited to, making sexual comments about a patient's body or underclothing, making sexualized or sexually demeaning comments to a patient, criticizing the patient's sexual orientation, making comments about potential sexual performance during an examination;
- Using the physician-patient relationship to solicit a date or romantic relationship;
- Initiation by the physician of conversation regarding the sexual problems, preferences, or fantasies of the physician;
- Performing an intimate examination or consultation without clinical justification;
- 8. Performing an intimate examination or consultation without explaining to the patient the need for such examination or consultation even when the examination or consultation is pertinent to the issue of sexual function or dysfunction; and
- Requesting details of sexual history or sexual likes or dislikes when not clinically indicated for the type of examination or consultation.

Sexual violation may include physical sexual contact between a physician and patient, whether or not initiated by the patient, and engaging in any conduct with a patient that is sexual or may be reasonably interpreted as sexual, including but not limited to:

- Sexual intercourse, genital to genital contact;
- Oral to genital contact;
- Oral to anal contact and genital to anal contact; 3.
- Kissing in a romantic or sexual manner;
- Touching breasts, genitals, or any sexualized body part for any purpose other than appropriate examination or treatment, or where the patient has refused or has withdrawn consent;
- Encouraging the patient to masturbate in the presence of the physician or masturbation by the physician while the patient is present: and
- Offering to provide practice-related services, such as drugs, in exchange for sexual favors.

The Board also refers its licensees to the Board's Position Statement entitled "Guidelines for avoiding misunderstandings during physical examinations."

(Adopted May 1991) (Amended April 2012; March 2016)

# **Contact with Patients Before Prescribing**

It is the position of the North Carolina Medical Board that prescribing drugs to an individual the prescriber has not examined to the extent necessary for an accurate diagnosis is inappropriate except as noted in the paragraphs below. Before prescribing a drug, a licensee should make an informed medical judgment based on the circumstances of the situation and on his or her training and experience. Ordinarily, this will require that the licensee perform an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan, a part of which might be a prescription. This process must be documented appropriately.

Prescribing for a patient whom the licensee has not personally examined may be suitable under certain circumstances. These may include admission orders for a newly hospitalized patient, interim medication orders or prescriptions, including pain management, from a hospice physician for a patient admitted to a certified hospice program, prescribing for a patient of another licensee for whom the prescriber is taking call, continuing medication on a short-term basis for a new patient prior to the patient's first appointment, an appropriate prescription in a telemedicine encounter where the threshold information to make an accurate diagnosis has been obtained, prescribing an opiate antagonist to someone in a position to assist a person at risk of an opiate-related overdose, or an appropriate prescription in anticipation of a diagnostic test consistent with the standard of care in that particular specialty. Established patients may not require a new history and physical examination for each new prescription, depending on good medical practice.

Prescribing for an individual whom the licensee has not met or personally examined may also be suitable when that individual is the partner of a patient whom the licensee is treating for gonorrhea or chlamydia. Partner management of patients with gonorrhea or chlamydia should include the following items:

- Signed prescriptions of oral antibiotics of the appropriate quantity and strength sufficient to provide curative treatment for each partner named by the infected patient. Notation on the prescription should include the statement: "Expedited partner therapy."
- Signed prescriptions to named partners should be accompanied by written material that states that clinical evaluation is desirable; that prescriptions for medication or related compounds to which the partner is allergic should not be accepted; and that lists common medication side effects and the appropriate response to them.
- Prescriptions and accompanying written material should be given to the licensee's patient for distribution to named partners.
- The licensee should keep appropriate documentation of partner management. Documentation should include the names of partners and a copy of the prescriptions issued or an equivalent statement.

It is the position of the Board that prescribing drugs to individuals the licensee has never met based solely on answers to a set of questions, as is common in Internet or toll-free telephone prescribing, is inappropriate and unprofessional.

(Adopted November 1999) (Amended February 2001; November 2009; May 2013; November 2014; March 2015; July 2015)

# **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 issued and should be signed by the licensee at time of issuance. Prescriptions that are handwritten should indicate the quantity in both numbers AND words, e.g., 30 (thirty).

Each handwritten prescription for a DEA controlled substance (2, 2N, 3, 3N, 4 and 5) should be written on a separate prescription blank. Each electronic prescription for a DEA controlled substance (2, 2N, 3, 3N, 4 and 5) should be issued separately and comply with DEA regulations. 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 licensee-patient relationship.

Any prescriptions written by licensees for their personal use should comply with the Board's position statement on "Self Treatment and Treatment of Family Members." As noted in that position statement, it is the Board's position that it is not appropriate for licensees to write prescriptions for controlled substances for themselves or their family members.

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 website, www.ncmedboard.org

(Adopted May 1991) (Amended May 1996; March 2002; July 2002; March 2011; July 2012) (Reviewed March 2005; January 2015)

# **Self-Treatment and Treatment of Family Members**

It is the Board's position that it is not appropriate for licensees to write prescriptions for controlled substances or to perform procedures on themselves or their family members. Rules 32B.1001, 32S.0212, and 32M.0109 prohibit licensees from prescribing controlled substances (including all narcotics) to themselves or immediate family members. In addition, licensees should not treat their own chronic conditions or those of their immediate family members or others with whom the licensee has a significant emotional relationship. In such situations, professional objectivity may be compromised, and the licensee's personal feelings may unduly influence his or her professional judgment, thereby interfering with care.

There are, however, certain limited situations in which it may be appropriate for licensees to treat themselves, their family members, or others with whom the licensee has a significant emotional relationship.

- Emergency Conditions. In an emergency situation, when no other qualified licensee is available, it is acceptable for licensees to treat themselves or their family members until another licensee becomes available.
- Urgent Situations. There may be instances when licensees or family members do not have their prescribed medications or easy physician access. It may be appropriate for licensees to provide short term prescriptions.
- Acute Minor Illnesses Within Clinical Competence. While licensees should not serve as primary or regular care providers for themselves or their family members, there are certain situations in which care may be acceptable. Examples would be treatment of antibiotic-induced fungal infections or prescribing ear drops for a family member with external otitis. It is the expectation of the Board that licensees will not treat recurrent acute problems.
- Over the Counter Medication. This position statement is not intended to prevent licensees from suggesting over the counter medications or other non-prescriptive modalities for themselves or family members, as a lay person might.

Licensees who act in accord with this position statement will be held to the same standard of care applicable to licensees providing treatment for patients who are unrelated to them. Thus, licensees should not treat problems beyond their expertise or training.

The Board expects licensees to maintain an appropriate medical record documenting any care that is given. It is also prudent for the licensee to provide a copy of the medical record to the patient's primary care provider.

Licensees who inappropriately treat themselves, their family members or others with whom they have a significant emotional relationship should be aware that they may be subject to disciplinary action by the Board.

(Adopted May 1991) (Amended May 1996: May 2000: March 2002: September 2005: March 2012) (Reviewed November 2015)

# The Treatment of Obesity

Repealed July 2019.

(Adopted [as The Use of Anorectics in Treatment of Obesity] October 1987) (Amended March 1996; January 2005 [retitled]; May 2013; March 2014)

# Prescribing Controlled Substances for Other Than Validated Medical or Therapeutic Purposes, with Particular Reference to Substance or Preparations with Anabolic **Properties**

#### General

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

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

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

## **Substances/Preparations with Anabolic Properties**

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

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

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

(Adopted May 1998) (Amended July 1998; January 2001; September 2011) (Reviewed November 2005; July 2015)

# Policy for the Use of Opioids for the Treatment of Pain

The Board believes that a fundamental component of good medical practice includes the appropriate evaluation and management of pain. Responsibly prescribed opioid medications may help North Carolina licensees treat their patients' pain safely and effectively, and improve their quality of life. It is the duty of any licensee prescribing opioid medications to be knowledgeable of both the therapeutic benefits, risks, and potential harm associated with opioid treatment. The Board expects any licensee prescribing opioids for the treatment of pain to provide diagnoses, treatments, and medical record documentation that are consistent with the standard of care in North Carolina. The Board notes that a failure to provide opioid treatment consistent with the standard of care in North Carolina may subject a licensee to disciplinary action by the Board.

The Board has previously attempted to provide guidance regarding opioid treatment of pain to its licensees through guidance documents generated and maintained by the Board. However, in order to provide its licensees with guidance that reflects the most current medical and scientific research and recommended practices, the Board has decided to adopt and endorse the CDC Guideline for Prescribing Opioids for Chronic Pain written and maintained by the Center for Disease Control and Prevention ("CDC"). While these guidelines do not constitute regulations or necessarily state the standard of care in North Carolina in every context, the Board's believes that these guidelines can provide useful information to licensees related to the appropriate considerations to be made prior to and during treatment plans involving opioids.

The CDC Guideline for Prescribing Opioids for Chronic Pain can be found at the following link: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm In addition to its Guideline, the CDC has also provided a number of useful clinician resources related to opioid treatment of pain covering topics such as Nonopioid Treatments, Assessing Benefits and Harms, Calculating Dosage, and Tapering. These documents can be found at the following link: https://www.cdc.gov/drugoverdose/prescribing/resources.html

It is the Board's hope that familiarity with the concepts included in the documents above will help licensees provide safe and effective care for their North Carolina patients.

(Adopted July 2005) (Amended May 2013; January 2017)

# Palliative Care and End-of-life Responsibilities

#### **Assuring Patients**

When appropriate processes have determined that the use of life prolonging measures or invasive interventions will only prolong the dying process, it is incumbent on licensees to accept death "not as a failure, but the natural culmination of our lives."\*

It is the position of the North Carolina Medical Board that patients and their families should be assured of competent, timely, comprehensive palliative care along the continuum of a chronic disease diagnosis up unto the end of life. Licensees should be knowledgeable regarding means to maximize quality of life and function, including effective and compassionate pain relief. Licensees should, for all patients, at age appropriate intervals, address Advanced Care Planning including the establishing of a Health Care Power of Attorney and Advanced Directives.\*\* The Board recognizes there are times when a hospice patient needs medications to manage pain or other symptoms in an urgent situation. Under these circumstances a hospice physician who is an employee of, under contract with, or a volunteer with a Medicare-certified hospice may prescribe medications to a patient admitted to the hospice program who he has not seen when the needs of the patient dictate.

#### **Palliative Care**

Palliative care is specialized medical care for people with serious illnesses. It is focused on providing patients with relief from the symptoms, pain, and stress of a serious illness—whatever the diagnosis. The goal is to improve quality of life for both the patient and the family.

Palliative care is provided by healthcare providers who work together with a patient's other caregivers to provide an extra layer of support. It is appropriate at any age and at any stage in a serious illness and can be provided along with curative treatment.\*\*\*

#### Palliative care:

- provides relief from pain and other distressing symptoms;
- affirms life and regards dying as a normal process;
- intends neither to hasten nor postpone death;
- integrates the psychological and spiritual aspects of patient care;
- offers a support system to help patients live as actively as possible until death;
- offers a support system to help the family cope during the patient's illness and in their own bereavement;
- uses a team approach to address the needs of patients and their families, including bereavement counseling, if indicated;
- will enhance quality of life, and may also positively influence the course of illness;
- Imay be applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to better understand and manage distressing clinical complications.\*\*\*\*

#### **Opioid Use**

The Board will assume opioid use in such patients is appropriate if the responsible licensee 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 documents a palliative care diagnosis and details of any pain management plan. (See the Board's position statement on the Policy for the Use of Controlled Substances for the Treatment of Pain for an outline of what the Board expects of licensees in the management of pain.) Because the Board is aware of the inherent risks associated with effective symptom relief in such situations, it will not interpret their occurrence as subject to discipline by the Board.

\*Steven A. Schroeder, MD, President, Robert Wood Johnson Foundation.

\*\*See also the Board's position statement on "Advance Directive and Patient Autonomy."

\*\*\*Taken from the Center to Advance Palliative Care (2012) <a href="http://www.capc.org/building-a-hospital-based-palliative-">http://www.capc.org/building-a-hospital-based-palliative-</a> care-program/case/definingpc

\*\*\*\*Taken from the World Health Organization definition of Palliative Care (2002) http://www.who.int/cancer/palliative/definition/en

(Adopted October 1999) (Amended May 2007; March 2008; January 2013; November 2014; November 2016)

# Joint Statement on Medication Management of Pain 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 licensees 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. Healthcare providers, including physicians, physician assistants, advanced practice registered nurses, 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 or other prescriber needs to give special attention to the effective assessment of pain. It is particularly important that the prescriber frankly but sensitively discuss with the patient and the family their concerns and choices for the end of life. As part of this discussion, the prescriber should make it clear that, in some end of life care situations, there are inherent risks associated with effective pain relief. The Medical and Nursing Boards will assume opioid use in such patients is appropriate if the responsible prescriber 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 Boards are aware of the inherent risks associated with effective pain relief in such situations, they will not interpret their occurrence as subject to discipline by the Boards.

With regard to pharmacy practice, in general North Carolina has no quantity restrictions on dispensing controlled substances—including those in Schedule II. The STOP Act limits initial prescriptions for opioid medications in Schedules II and III to five- and seven-day supplies when prescribed for acute pain or post-operative acute pain, respectively. But those limitations do **not** apply to treatment of chronic pain or pain being treated as a component of hospice or palliative care.

Federal law allows partial filling of Schedule III and IV prescriptions for up to six months, and, for terminally ill patients, partial filing of Schedule II prescriptions for up to 60 days. This allows the pharmacist to dispense smaller quantities of the prescription to meet the patient's needs, thereby minimizing patient expenses and unnecessary waste of drugs. The prescriber should note on the prescription that the patient is terminally ill to facilitate these partial fills.

Transmission of prescriptions for terminally ill patients is often a matter of urgency. Federal and state law allow the fax transmittal of all schedules of controlled substances. For Schedule III, IV, and V prescriptions, the fax serves as the original. For a Schedule II prescription, the fax serves as the original if the prescriber notes on the face of the prescription that it is for a patient receiving hospice care or who is a resident of a long-term care facility.

Federal and state law allow electronic transmission of prescriptions for all schedules of controlled substances using an eprescribing tool that meets DEA security requirements. E-prescribing is often the quickest, most secure way to meet a patient's urgent needs.

The nurse (RN or LPN) is often the health professional most involved in assessment of pain and in the on-going management of pain, through implementing the prescribed/ordered pain management plan, evaluating the patient's response to such interventions, and adjusting medication levels based on prescriptions/orders and patient status. 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 through the use of designated pain evaluation tools.

If, in order to achieve adequate pain management, prescriptions/orders include a medication dose and/or frequency range, the instructions on how the nurse determines the appropriate administration dose or time frame should be included in the order. In the absence of such instructions, the nurse has the authority to adjust medication levels within the dose and frequency ranges stipulated, in accordance with the agency's established protocols. However, the RN or LPN does not have the authority to change the medical pain management plan. When adequate pain management is not achieved under the currently prescribed/ordered treatment plan, the nurse is responsible for reporting such findings to the prescriber and documenting this communication. Only the licensee or other health professional with authority to prescribe/order 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 health care 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 health care 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.

(Adopted October 1999) (Amended January 2011; November 2014; May 2019)

## **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 officebased 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:

- state licensure: 1.
- procedure specific education, training, experience and successful evaluation appropriate for the patient 2. population being treated (i.e., pediatrics):
- for physicians, board certification, board eligibility or completion of a training program in a field of specialization 3. recognized by the ACGME or AOA or by a national medical specialty board that is recognized by the ABMS or AOA 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;
- professional misconduct and malpractice history; 4.
- participation in peer and quality review;
- participation in continuing education consistent with the statutory requirements and requirements of the physician's professional organization;
- to the extent such coverage is reasonably available in North Carolina, malpractice insurance coverage for the 7. surgical or special procedures being performed in the office;
- procedure-specific competence (and competence in the use of new procedures and technology), which should 8. encompass education, training, experience and evaluation, and which may include the following:
  - a. adherence to professional society standards;
  - b. credentials approved by a nationally recognized accrediting or credentialing entity; or
  - c. didactic course complemented by hands-on, observed experience; training is to be followed by a specified number of cases supervised by a practitioner already competent in the respective procedure, in accordance with professional society standards.

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

#### Accreditation

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

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

#### **Patient Selection**

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

## **ASA Physical Status Classifications**

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

#### **Candidates for Level II Procedures**

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

#### **Candidates for Level III Procedures**

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

## **Surgical or Special Procedure Guidelines**

# **Patient Preparation**

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

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

The physician performing the surgical or special procedure also should:

- 1. ensure that an appropriate pre-anesthetic examination and evaluation is performed proximate to the procedure:
- 2. prescribe the anesthetic, unless the anesthesia is administered by an anesthesiologist in which case the anesthesiologist may prescribe the anesthetic;
- 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
- 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;
- resolving neural blockade, resolution of the neuraxial blockade; and
- 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 postoperative 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;
- 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:

- physician's name and license number;
- date and time of the occurrence;
- 3. office where the occurrence took place:
- name and address of the patient;
- surgical or special procedure involved:
- type and dosage of sedation or anesthesia utilized in the procedure; and
- 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 officebased 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
- 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.

## **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:

- 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):
- 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;
- emergency power source able to produce adequate power to run required equipment for a minimum of two (2) 3. hours:
- electrocardiographic monitor;
- noninvasive blood pressure monitor:
- pulse oximeter:
- continuous suction device;
- endotracheal tubes, larvngoscopes;
- positive pressure ventilation device (e.g., Ambu);
- 10. reliable source of oxygen;
- 11. emergency intubation equipment;
- 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
- 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 analysesia, 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:

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;
- emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours:
- electrocardiographic monitor;
- noninvasive blood pressure monitor; 5.
- pulse oximeter;
- continuous suction device;
- endotracheal tubes, and larvngoscopes:
- 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:

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

Level II procedures – any surgical or special procedures:

- that require the administration of local or peripheral nerve block, minor conduction blockade, Bier block, minimal sedation, or conscious sedation; and
- 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:

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

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

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

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

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

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

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

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

OSHA – the Occupational Safety and Health Administration.

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

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

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

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

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

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

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

Surgical procedure - the revision, destruction, incision, or structural alteration of human tissue performed using a variety of methods and instruments and includes the operative and non-operative care of individuals in need of such intervention, and demands preoperative 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.]

(Adopted September 2011) (Amended January 2003; May 2011; May 2015) (Reviewed March 2016)

# **Laser Surgery**

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

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

## Laser Hair and Tattoo Removal \*\*

Lasers are employed in certain hair and tattoo-removal procedures, as are various devices that (1) manipulate and/or pulse light causing it to penetrate human tissue and (2) are classified as "prescription" by the U.S. Food and Drug Administration. Hair and tattoo-removal procedures using such technologies should be performed only by a physician or by an individual designated as having adequate training and experience by a physician who bears full responsibility for the procedure. Additionally, electrologists who are licensed as laser hair practitioners may perform laser hair removal (but not tattoo removal) under the supervision of a physician.

The physician who provides medical supervision is expected to provide adequate oversight of licensed and non-licensed personnel both before and after the procedure is performed. The Board believes that the guidelines set forth in this Position Statement are applicable to every licensee of the Board involved in laser hair and tattoo removal.

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

The responsible supervising physician should be on site or readily available to the person actually performing the procedure. What constitutes "readily available" will depend on a variety of factors. Those factors include the specific types of procedures and equipment used; the level of training of the persons performing the procedure; the level and type of licensure, if any, of the persons performing the procedure; the use of topical anesthetics; the quality of written protocols for the performance of the procedure; the frequency, quality and type of ongoing education of those performing the procedures; and any other quality assurance measures in place. In all cases, the Board expects the physician to be able to respond quickly to patient emergencies and questions by those performing the procedures.

\*Definition of surgery as adopted by the NCMB, November 1998: Surgery, which involves the revision, destruction, incision, or structural alteration of human tissue performed using a variety of methods and instruments, is a discipline that includes the operative and non-operative care of individuals in need of such intervention, and demands pre-operative assessment, judgment, technical skills, post-operative management, and follow up.

\*\*For more information regarding the involvement of unlicensed persons in laser hair and tattoo removal, see the Board's Guidance Document with FAOs.

(Adopted July 1999) (Amended January 2000; March 2002; August 2002; July 2005; March 2012) (Reviewed March 2011; March 2015)

# Care of the Patient Undergoing Surgical or Other Invasive Procedure\*

The evaluation, diagnosis, and care of the surgical patient is primarily the responsibility of the surgeon. The surgeon bears responsibility for ensuring the patient undergoes a preoperative assessment appropriate to the procedure. The assessment shall include a review of the patient's data relevant to the procedure. The operating surgeon shall have a detailed discussion with each patient regarding the diagnosis and the nature of the surgery, advising the patient fully of the risks involved. It is also the responsibility of the operating surgeon to reevaluate the patient immediately prior to the procedure.

It is the responsibility of the operating surgeon to assure safe and readily available postoperative care for each patient on whom he or she performs surgery. It is not improper to involve other licensed health care practitioners in postoperative care so long as the operating surgeon maintains responsibility for such care. The postoperative note must reflect the findings encountered in the individual patient and the procedure performed.

When identical procedures are done on a number of patients, individual notes should be done for each patient that reflect the specific findings and procedures of that operation.

(Invasive procedures includes, but is not limited to, endoscopies, cardiac catheterizations, interventional radiology procedures, etc. Surgeon refers to the provider performing the procedure.)

\*This position statement was formerly titled, "Care of the Surgical Patient."

(Adopted September 1991) (Amended March 2001; September 2006; July 2012) (Reviewed March 2016)

# **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 PREVENTION – HEALTH CARE SETTINGS

- (a) The following definitions apply throughout this Rule:
  - (1) "Health care organization" means a hospital; clinic; physician, dentist, podiatrist, optometrist, or chiropractic office; home care agency; nursing home; local health department; community health center; mental health facility; hospice; ambulatory surgical facility; urgent care center; emergency room; Emergency Medical Service (EMS) agency; pharmacies where a health practitioner offers clinical services; or any other organization 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.
  - (3) "Non-contiguous" means not physically connected.
- (b) In order to prevent transmission of HIV, hepatitis B, hepatitis C and other bloodborne pathogens 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, hepatitis B, hepatitis C and other bloodborne pathogens. The health care organization shall designate one on-site staff member for each noncontiguous facility to direct these activities The designated staff member in each health care facility shall complete a course in infection control approved by the Department The Department shall approve a course that addresses:
  - (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) Safe injection practices:
  - (6) Engineering controls to reduce the risk of sharp injuries:
  - (7) Disposal of sharps; and
  - (8) Techniques that reduce the risk of sharp injuries to health care workers.
- The infection control policy required by this Rule shall address the following components that are necessary to prevent transmission of HIV, hepatitis B, hepatitis C and other bloodborne pathogens:
  - (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; and
  - (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.
- (d) Health care workers and emergency responders shall, with all patients, follow Centers for Disease Control and Prevention Guidelines on blood and body fluid precautions incorporated by reference in 10A NCAC 41A .0201.
- (e) 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.
- (f) All equipment used to puncture skin, mucous membranes, or other tissues in medical, dental, or other settings must be disposed of in accordance with 15A NCAC 13B .1200 after use or sterilized prior to reuse.
- 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:
  - "Surgical or obstetrical procedures" means vaginal deliveries or surgical entry into tissues, cavities, or (1) 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:
  - Restrictions that are necessary to prevent transmission from the infected health care worker to patients; (1)
  - (2)Identification of patients that have been exposed to a significant risk of transmission of HIV or hepatitis
  - 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; March 2015) (Reviewed January 2011)

# Professional Obligations Pertaining to Incompetence, Impairment, or Unethical Conduct of Licensees

It is the position of the North Carolina Medical Board that its licensees have a professional obligation to act when confronted with an impaired or incompetent colleague or one who has engaged in unethical conduct.

When appropriate, an offer of personal assistance to the colleague may be the most compassionate and effective intervention. When this would not be appropriate or sufficient to address the problem, licensees have a duty to report the matter to the institution best positioned to deal with the problem. For example, impaired licensees should be reported to the North Carolina Physicians Health program. Incompetent licensees should be reported to the clinical authority empowered to take appropriate action. Licensees also may report to the North Carolina Medical Board, and when there is no other institution reasonably likely to be able to deal with the problem, this will be the only way of discharging the duty to report.

This duty is subordinate to the duty to maintain patient confidences. In other words, when the colleague is a patient or when matters concerning a colleague are brought to the licensee's attention by a patient, the licensee must give appropriate consideration to preserving the patient's confidences in deciding whether to report the colleague.

(Adopted November 1998) (Amended May 2010) (Reviewed September 2013; September 2017)

# 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 creates 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:

- 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-iob training is not sufficient:
- 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;
- the organization requires diplomates to recertify every ten years or less, and the recertification requires, at a minimum, passage of a written examination;
- the organization prohibits all certification and recertification candidates from attempting more than three times in three years to pass the examination:
- 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;
- 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
- the organization has a permanent headquarters and staff sufficient to respond to consumer and regulatory inquiries.

The Board expects any physician advertising or otherwise holding himself or herself out to the public as "board certified" to 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.

(Adopted November 1999) (Amended March 2001; November 2010; March 2012) (Reviewed September 2014; May 2018)

# Sale of Goods from Physician Offices

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

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

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

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

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

(Adopted March 2001) (Amended March 2006) (Reviewed May 2011: March 2015)

# **Referral Fees and Fee Splitting**

Payment by or to a licensee solely for the referral of a patient is unethical. A licensee may not accept payment of any kind, in any form, from any source, such as a pharmaceutical company or pharmacist, an optical company, or the manufacturer of medical appliances and devices, for prescribing or referring a patient to said source. In each case, the payment violates the requirement to deal honestly with patients and colleagues. The patient relies upon the advice of the licensee on matters of referral. All referrals and prescriptions must be based on the skill and quality of the licensee to whom the patient has been referred or the quality and efficacy of the drug or product prescribed.

It is unethical for licensees to offer financial incentives or other valuable considerations to patients in exchange for recruitment of other patients. Such incentives can distort the information that patients provide to potential patients, thus distorting the expectations of potential patients and compromising the trust that is the foundation of the patientphysician licensee relationship. Furthermore, referral fees are prohibited by state law pursuant to N.C. Gen. Stat. Section 90-401. Violation of this law may result in disciplinary action by the Board.

Except in instances permitted by law (N.C. Gen. Stat. § 55B-14(c)), it is the position of the Board that a licensee cannot share revenue on a percentage basis with a non-licensee. To do so is fee splitting and is grounds for disciplinary action.

#### **Voucher Advertising**

It is the Board's position that, so long as certain conditions are followed, advertising involving the utilization of vouchers does not constitute unethical fee-splitting or a prohibited solicitation or referral fee under North Carolina law. Those conditions include: (1) ensuring that the negotiated fee between the voucher advertising company and the licensee represents reasonable compensation for the cost of advertising; and (2) incorporating the following terms and conditions in a clear and conspicuous manner in all advertisements:

- (a) A description of the discounted price in comparison to the actual cost of services:
- (b) A disclosure that all patients may not be eligible for the advertised medical service and that decisions about medical care should not be made in haste. Determinations regarding the medical indications for individual patients will be made on an individual basis by applying accepted and prevailing standards of medical practice; and
- (c) A disclosure to prospective patients that, if it is later decided that the patient is not a candidate for the previously purchased medical service, the patient's purchase price will be refunded in its entirety. If the patient does not claim the service, then the patient's purchase price must still be refunded in its entirety. In the event that the voucher advertising company does not refund the purchase price in its entirety, it will be the sole obligation of the licensee to refund the entire purchase price.

(Adopted November 1993) (Amended May 1996; July 2006; January 2013) (Reviewed 2015)

# **Unethical Agreements in Complaint Settlements**

It is the position of the North Carolina Medical Board that it is unethical for a licensee to settle any complaint if the settlement contains an agreement by a patient not to complain or provide information to the Board.

(Adopted November 1993) (Amended May 1996; March 2010) (Reviewed September 2013; September 2017)

# 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) (Reviewed July 2014; May 2018)

# Competence and Reentry to the Active Practice of Medicine

Repealed May 2016 in light of administrative rule **21 NCAC 32B .1370** 

(Adopted July 2006) (Repealed May 2016)

# **Capital Punishment**

In North Carolina Dept. of Correction v. North Carolina Medical Board, the North Carolina Supreme Court ruled that while the North Carolina Medical Board does "retain disciplinary power over a licensed medical doctor who participates in an execution," the Board "may not discipline or threaten discipline against its licensees solely for participating in the execution alone." Since the Supreme Court's ruling the North Carolina General Assembly enacted N.C. Gen. Stat. § 15-188.1 (https://www.ncga.state.nc.us/GS 15-188.1.html) which provides similar limitations on the Board's authority to discipline a physician for participating in an execution. Consistent with the Supreme Court's ruling and § 15-188.1, the Board will not take any disciplinary action against a physician for participation in an execution.

The North Carolina Medical Board does, however, continue to take the position that physician participation in capital punishment is a departure from the ethics of the medical profession. The North Carolina Medical Board cites the provisions of AMA Code of Medical Ethics 9.7.3 (https://www.ama-assn.org/delivering-care/capital-punishment) as an accurate statement of the professional ethics of physician participation in executions.

(Adopted January 2007) (Amended July 2009; November 2009; November 2017) (Reviewed July 2013)

# Physician Supervision of Other Licensed Health Care Practitioners

The physician who provides medical supervision of other licensed healthcare practitioners is expected to provide adequate oversight. The physician must always maintain the ultimate responsibility to assure that high quality care is provided to every patient. In discharging that responsibility, the physician should exercise the appropriate amount of supervision over a licensed healthcare practitioner which will ensure the maintenance of quality medical care and patient safety in accord with existing state and federal law and the rules and regulations of the North Carolina Medical Board. What constitutes an "appropriate amount of supervision" will depend on a variety of factors. Those factors include, but are not limited to:

- The number of supervisees under a physician's supervision
- The geographical distance between the supervising physician and the supervisee
- The supervisee's practice setting
- The medical specialty of the supervising physician and the supervisee
- The level of training of the supervisee
- The experience of the supervisee
- The frequency, quality, and type of ongoing education of the supervisee
- The amount of time the supervising physician and the supervisee have worked together
- The quality of the written collaborative practice agreement, supervisory arrangement, protocol or other written guidelines intended for the guidance of the supervisee
- The supervisee's scope of practice consistent with the supervisee's education, national certification and/or collaborative practice agreement

Physicians should also be cognizant of maintaining appropriate boundaries with their supervisees, including refraining from requesting medical treatment by the physician's supervisee. Physician assistants and nurse practitioners are specifically prohibited from prescribing controlled substances for the use of their supervising physicians.

Practices owned solely by physician assistants or nurse practitioners may not hire or contract with physicians to practice medicine on behalf of the physician assistant or nurse practitioner owned practice. The physician assistant or nurse practitioner may contract with a physician to provide the legally required supervision of the physician assistant or nurse practitioner.

(Adopted July 2007) (Reviewed September 2012) (Amended November 2015)

<sup>&</sup>lt;sup>1</sup> See also the Board's position statement on "Self-treatment and Treatment of Family Members."

# **Drug Overdose Prevention**

The Board is concerned about the rise in overdose deaths over the past decade in the State of North Carolina as a result of both prescription and non-prescription drugs. The Board is encouraged by programs that are attempting to reduce the number of drug overdoses by making available or prescribing an opioid antagonist such as naloxone to someone in a position to assist a person at risk of an opiate-related overdose. The Board therefore encourages its licensees to cooperate with programs in their efforts to make opioid antagonists available to persons at risk of suffering an opiate-related overdose.

The prevention of drug overdoses is consistent with the Board's statutory mission to protect the people of North Carolina. Other efforts the Board has made in this regard include the Board's Safe Opioid Prescribing Initiative and the implementation of continuing medical education requirements for those licensees prescribing controlled substances.

(Adopted September 2008) (Amended March 2013; January 2017)

# **Medical Testimony**

The Board recognizes that medical testimony is vital to the administration of justice in both judicial and administrative proceedings. In order to provide further guidance to those licensees called upon to testify, the Board adopts and endorses the AMA Code of Medical Ethics Opinion 9.7.1 entitled "Medical Testimony." In addition to AMA Ethics Opinion 9.7.1, the Board provides the following guidelines to those licensees testifying as medical experts:

- Licensee expert witnesses are expected to be impartial and should not adopt a position as an advocate or partisan in the legal proceedings.
- The licensee expert witness should review all the relevant medical information in the case and testify to its content fairly, honestly, and in a balanced manner. In addition, the licensee expert witness may be called upon to draw an inference or an opinion based on evidence presented in the case. In doing so, the licensee expert witness should apply the same standards of fairness and honesty.
- The licensee expert witness is ethically and legally obligated to tell the truth. The licensee expert witness should be aware that failure to provide truthful testimony constitutes unprofessional conduct and may expose the licensee expert witness to disciplinary action by the Board pursuant to N.C. Gen Stat. § 90-14(a)(6).
- \* The language of AMA Code of Medical Ethics Opinion 9.7.1 provides:

#### **Medical Testimony** 9.7.1

Medical evidence is critical in a variety of legal and administrative proceedings. As citizens and as professionals with specialized knowledge and experience, physicians have an obligation to assist in the administration of justice.

Whenever physicians serve as witnesses they must:

- (a) Accurately represent their qualifications.
- (b) Testify honestly.
- (c) Not allow their testimony to be influenced by financial compensation. Physicians must not accept compensation that is contingent on the outcome of litigation.

Physicians who testify as fact witnesses on legal claims involving a patient they have treated must hold the patient's medical interests paramount by:

- (d) Protecting the confidentiality of the patient's health information, unless the physician is authorized or legally compelled to disclose the information.
- (e) Delivering honest testimony. This requires that they engage in continuous self-examination to ensure that their testimony represents the facts of the case.
- Declining to testify if the matters could adversely affect their patients' medical interests unless the patient (f) consents or unless ordered to do so by legally constituted authority.
- Considering transferring the care of the patient to another physician if the legal proceedings result in placing the (g) patient and the physician in adversarial positions.
  - Physicians who testify as expert witnesses must:
- (h) Testify only in areas in which they have appropriate training and recent, substantive experience and knowledge.
- (i) Evaluate cases objectively and provide an independent opinion.
- (j) Ensure that their testimony:

- (i) reflects current scientific thought and standards of care that have gained acceptance among peers in the relevant field;
- (ii) appropriately characterizes the theory on which the testimony is based if the theory is not widely accepted in the profession;
- considers standards that prevailed at the time the event under review occurred when testifying about a (iii) standard of care.

Organized medicine, including state and specialty societies and medical licensing boards, has a responsibility to maintain high standards for medical witnesses by assessing claims of false or misleading testimony and issuing disciplinary sanctions as appropriate.

(Adopted March 2008) (Amended September 2012; September 2016)

#### **Professional Behavior Within the Healthcare Team**

The North Carolina Medical Board ("the Board") recognizes that the manner in which its licensees interact with others can significantly impact patient care.

The Board strongly urges its licensees to fulfill their obligations to maximize the safety of patient care by behaving in a manner that promotes both professional practice and a work environment that ensures high standards of care. Licensees should consider it their ethical duty to foster respect among all health care professionals as a means of ensuring good patient care.

Disruptive behavior is a style of interaction between licensees, hospital personnel, patients, family members, or others that interferes with patient care. Behaviors such as rude, loud, or offensive comments; sexual harassment or other inappropriate physical contact; and intimidation of staff, patients, and family members are commonly recognized as detrimental to patient care. The Board distinguishes disruptive behavior from: (1) constructive criticism that is offered in a professional manner with the aim of improving patient care; or (2) reasonably direct or blunt communication that may be appropriate to protect the health of a patient in urgent or emergency situations.

It has been the Board's experience that disruptive behavior may be a marker for underlying concerns that can range from a lack of interpersonal skills to deeper problems, such as depression, work-related burnout, or substance use disorder. Licensees suffering such symptoms are encouraged to seek the support needed to help them regain their equilibrium.

Disruptive behavior by licensees may also constitute grounds for further inquiry by the Board to determine the potential underlying causes of such behavior. Additionally, such behavior may ultimately constitute grounds for Board discipline.

Finally, licensees, in their role as patient and peer advocates, are obligated to take appropriate action when observing disruptive behavior on the part of other licensees. The Board urges its licensees to support their hospital, practice, or other healthcare organization in their efforts to identify and manage disruptive behavior, by taking a role in the process of addressing behavior when appropriate.

(Adopted January 2010) (Amended July 2019)

#### **Telemedicine**

"Telemedicine" is the practice of medicine using electronic communication, information technology, or other means between a licensee in one location and a patient in another location with or without an intervening health care provider. The term telemedicine incorporates the practices of telehealth.

The Board recognizes that technological advances have made it possible for licensees to provide medical care to patients who are separated by some geographical distance. As a result, telemedicine is a useful practice model that, if employed appropriately, can provide important benefits to patients, including: increased access to health care, expanded utilization of specialty expertise, rapid availability of patient records, and the potential of reduced healthcare costs, increased efficiency, and improved overall healthcare outcomes. The call for ongoing research and formal training in the care models and technologies associated with telemedicine reflects the evolving nature of telemedicine practice.

The Board cautions, however, that licensees providing care to North Carolina patients via telemedicine will be held to the same established standard of care as those practicing in traditional in-person medical settings. The Board does not endorse a separate standard of care for telemedicine. Licensees, who fail to conform to the North Carolina statewide standard of care, may be subject to discipline by this Board.

The Board provides the following considerations to its licensees as guidance in providing medical services via telemedicine:

#### **Training of Staff**

Staff involved in the telemedicine visit should be trained in the use of the technology being used to deliver care and competent in its operation.

#### **Evaluations and Examinations**

Licensees using telemedicine technologies to provide care to patients located in North Carolina must provide, or rely upon, an appropriate evaluation prior to diagnosing and/or treating the patient. This evaluation need not be in-person if the licensee employs technology sufficient to accurately diagnose and treat the patient in conformity with the applicable standard of care. A diagnosis should be established using accepted medical practices, i.e., a patient history, mental status evaluation, physical examination, and appropriate diagnostic and laboratory testing.

Evaluations may also be considered appropriate if a licensed health care professional is able to facilitate aspects of the patient assessment needed to render reasonable diagnostic possibilities and care plans. On the other hand, a simple questionnaire without an appropriate evaluation may be a violation of law and/or subject the licensee to discipline by the Board.

## **Licensee-Patient Relationship**

The Board stresses the importance of proper patient identification prior to any telemedicine encounter. Failure to verify the patient's identity may lead to fraudulent activity or the improper disclosure of confidential patient information. The licensee using telemedicine should verify the identity and location of the patient. Furthermore, the licensee's name, location, and professional credentials should be provided to the patient. Licensees using telemedicine should also ensure the availability for appropriate follow-up care and maintain a complete medical record that is available to the patient and other treating health care providers.

#### **Prescribing**

Licensees are expected to practice in accordance with the Board's Position Statement "Contact with Patients Before Prescribing." It is the position of the Board that it is not consistent with the current standard of care to prescribe controlled substances for the treatment of pain in which the only patient encounter is by means of telemedicine and there are no other licensed healthcare providers involved in the initial and ongoing evaluations of the patient. Licensees prescribing controlled substances by means of telemedicine for other conditions should comply with all relevant federal and state laws and are expected to participate in the Controlled Substances Reporting System.

#### **Medical Records**

The licensee treating a patient via telemedicine must maintain a complete record of the telemedicine patient's care consistent with the prevailing medical record standards. The medical record should clearly document all aspects of care including email, text, photos, phone contact, and other forms of communication. HIPAA and related privacy and security documents should be present and signed where appropriate. Appropriate informed consent documents acknowledging the risks, limitations, alternatives, and benefits of the telemedicine encounter should be included.

The licensee must maintain the medical record's confidentiality and provide a copy of the medical record to the patient in a manner consistent with state and federal law. If the patient has a primary care provider and a telemedicine provider for the same ailment, then the primary care provider's medical record and the telemedicine provider's medical record constitute one complete patient record. Licensees practicing via telemedicine will be held to the same standards of professionalism concerning the transfer of medical records and communications with the patient's primary care provider and medical home as those licensees practicing via traditional means.

#### **Disclaimers**

Practitioners of telemedicine should consider providing a statement identifying any unique limitations of the electronic model by which care is being provided. Such patient notification can be distributed prior to providing services and included in all direct advertising to the public.

#### Licensure

The Board deems the practice of medicine to occur in the state where the patient is located. Therefore, any licensee using telemedicine to regularly provide medical services to patients located in North Carolina should be licensed to practice medicine in North Carolina. Licensees need not reside in North Carolina if they have a valid, current North Carolina license.

North Carolina licensees intending to practice medicine via telemedicine technology to treat or diagnose patients outside of North Carolina should check with other state licensing boards. Most states require physicians to be licensed, and some have enacted limitations on telemedicine practice or require or offer a special registration. A directory of all U.S. medical boards may be accessed at the Federation of State Medical Boards web site: http://www.fsmb.org/directory\_smb.html.

(Adopted July 2010) (Amended November 2014; March 2019)

# **Physician Practice Drift**

When physicians are granted a license by the Board, they are generally given the privilege of practicing the full breadth of medicine and are not limited to a particular specialty. This general medical license allows physicians a certain degree of discretion to expand or shift their practice areas. 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.

When considering changes to one's area of practice, physicians have a professional and ethical duty to put their patients' interests first and only offer medical care that the physician is competent to provide. Patient harm can occur when physicians practice outside of areas in which they have been adequately trained.

Physicians intending to expand their practice to a new area should ensure that they have acquired the appropriate level of education and training. This may involve seeking additional training by attending appropriate educational programs. Physicians should be prepared to provide information about their qualifications and any additional training that has prepared them to provide medical care outside the physician's original area of practice. It may also be prudent for physicians to confirm that their liability insurance provides coverage for the procedures they intend to perform.

It is the Board's position that all physicians, irrespective of their area of training, will be held to the standard of acceptable and prevailing medical practice in the specialty area that the care was rendered as set forth in N.C. Gen. Stat. § 90-14(a)(6).

The Board also refers its licensees to the Board's Position Statement entitled "Physician Supervision of Other Licensed Health Care Practitioners" and Board rules 21 NCAC 32S .0213 (addressing physician supervision of physician assistants) and 21 NCAC 32M .0102 (addressing the scope of practice of nurse practitioner).

(Adopted March 2011) (Amended November 2019)

#### Professional Use of Social Media

The Board recognizes that social media has increasing relevance to professionals and supports its responsible use. However, health care practitioners are held to a higher standard than others with respect to social media because health care professionals, unlike members of the lay public, are bound by ethical and professional obligations that extend beyond the exam room.

The informality of social media sites may obscure the serious implications and long term consequences of certain types of postings. The Board encourages its licensees to consider the implications of their online activities including, but not limited to, the following:

- Licensees must understand that the code of conduct that governs their face to face encounters with patients also extends to online activity. As such, licensees interacting with patients online must maintain appropriate boundaries in accordance with professional ethical guidelines, just as they would in any other context.
- Licensees have an absolute obligation to maintain patient privacy and must refrain from posting identifiable patient information online regardless of the practice location or circumstance, i.e. volunteer services or services provided abroad.
- A licensee's publicly available online content directly reflects on his or her professionalism. It is advisable that licensees separate their professional and personal identities online (maintain separate email accounts for personal and professional use; establish a social media presence for professional purposes and one for personal use, etc.).
- Because privacy is never absolute, considerations of professionalism should also extend to a licensee's personal accounts. Posting of material that demonstrates, or appears to demonstrate, behavior that might be considered unprofessional, inappropriate or unethical should be avoided.
- The online use of profanity, disparaging or discriminatory remarks about individual patients or types of patients is unacceptable.
- Licensees should routinely monitor their own online presence to ensure that the personal and professional information on their own sites is accurate and appropriate.

The Board also endorses the Model Policy Guidelines for the Appropriate Use of Social Media and Social Networking in Medical Practice adopted by the Federation of State Medical Boards which can be accessed at http://www.fsmb.org/pdf/pub-social-media-guidelines.pdf. Further discussion of this issue by the Board's Medical Director can be found at http://tinyurl.com/jse62lt.

(Adopted September 2008) (Amended March 2013; January 2017)

#### **Child Maltreatment**

It is the position of the North Carolina Medical Board that child maltreatment (abuse and neglect) presents a significant risk to the health and well-being of North Carolinians. The Board's licensees have a legal responsibility to report as soon as practicable "cases involving recurrent illness or serious physical injury to any child under the age of 18 years where the illness or injury appears, in the physician's professional judgment, to be the result of non-accidental trauma." N.C. Gen. Stat. § 90-21.20(c1).\* It should also be noted that the statute provides civil and criminal immunity for reports made in good faith by physicians and other related personnel or institutions.

This legal and ethical obligation to report requires a licensee to recognize the signs, symptoms, and etiology of child maltreatment. Licensees are also encouraged to learn how to refer children for expert medical evaluations of possible maltreatment.

The following links provide detailed information on the state's reporting requirements and web-based training on recognition of child maltreatment:

https://www.sog.unc.edu/sites/www.sog.unc.edu/files/full text books/2016-11-01%202006087%20Abuse Mason%20TEXT%20with%20supplement 0.pdf

http://www.preventchildabusenc.org/services/trainings-and-professional-development/rrcourse

\*This obligation specific to physicians is in addition to the legal requirement that any person or institution in North Carolina "who has cause to suspect that any juvenile is abused, neglected, or dependent, as defined by N.C. Gen. Stat. § 7B-101, or has died as the result of maltreatment, shall report the case of that juvenile to the director of the department of social services in the county where the juvenile resides or is found." N.C. Gen. Stat. § 7B-301(a). This statute also provides criminal penalties for "knowingly or wantonly failing to make a report, or preventing someone else from making a report" when required by law.

(Adopted September 2014) (Amended November 2019)

# **Corporate Practice of Medicine**

It is the position of the Board that, except as discussed below, businesses practicing medicine in North Carolina must be owned in their entirety by persons holding active North Carolina licenses. The owners of a business engaged in the practice of medicine must be licensees of this Board or one of the combinations permitted in N.C. Gen. Stat. § 55B-14. Licensees of the Board providing medical services on behalf of businesses engaged in the corporate practice of medicine may be subject to disciplinary action by the Board. Whether a licensee of the Board is an employee or independent contractor is not determinative of whether a physician is aiding and abetting the corporate practice of medicine. In addition, the Board may seek injunctive relief against lay owners of businesses engaged in the corporate practice of medicine.

The Board does recognize certain exceptions to the corporate practice of medicine, including hospitals and health maintenance organizations. Such exceptions are premised on the notion that these entities are statutory creations intended for the public welfare and regulated by the government, thus ameliorating the inherent conflict between profitmaking and good medical care. Under a similar rationale, public health clinics and charitable nonprofits are also considered exceptions to the prohibition on the corporate practice of medicine.

### **Hospital-owned** practices

As mentioned above, the Board recognizes an exception to the prohibition on the corporate practice of medicine for nonprofit hospitals and in turn medical practices that are owned by such hospitals. The policy underlying this exception is that non-profit hospitals are charged with the same mission as the Board in protecting the well-being of the citizens of North Carolina. In keeping with this policy, it is the Board's expectation that hospital-owned practices will recognize the ethical obligations that their physician employees have to their patients and allow them to discharge such obligations. For example, it is the position of the Board that physicians who depart such practices for reasons other than safety concerns be permitted to provide appropriate notice to their patients, ensure continuity of care, and allow patient selection.

(Adopted March 2016)

# Policy for the Use of Audio or Visual Recordings in Patient Care

The Board recognizes that there may be valid reasons for licensees to make audio or visual recordings of patients during a healthcare encounter. However, such recordings must be made for appropriate professional reasons and should employ safeguards that protect a patient's autonomy, privacy, confidentiality, and dignity. **In instances where a patient may** be asked to disrobe, the patient should be provided an opportunity to disrobe beyond the view of any camera.

Prior to an audio or visual recording being made of a patient, licensees should ensure that they have obtained the patient's informed consent. The informed consent should be documented in the medical record and should allow the patient an opportunity to discuss any concerns before and after the recording.

Recordings that could lead to disclosure of the patient's identity constitute protected health information and must be managed and transmitted in a manner that complies with HIPAA requirements.

(Adopted July 2017)

# Clinician Obligation to Complete a Certificate of Death

North Carolina law requires that when a death does not meet criteria for jurisdiction by the Medical Examiner (N.C. Gen. Stat. § 130A-383) the death certificate shall be completed and signed by the physician, physician assistant, or nurse practitioner ("clinician") in charge of the patient's care for the illness or condition which resulted in death. Delaying the completion of a death certificate or refusing to sign a death certificate makes an already difficult time for surviving family members and other loved ones even more so and may result in unnecessary complications with funeral arrangements, estate proceedings, and other legal and personal matters.

The Board recognizes that clinicians may not be comfortable with uncertainty, however, a clinician should not decline to sign a death certificate simply because the exact anatomic or physiologic cause of death is uncertain. Less than 10% of deaths result in an autopsy. Clinicians are not expected or required to establish beyond a doubt the specific cause of death but should exercise their best judgment under the circumstances using available information.2

Review of the patient's medical history should provide adequate information to state a reasonable or likely cause of death. Examples of acceptable causes of death may include arteriosclerotic cardiovascular disease, hypertension, Alzheimer's disease, or complications of diabetes mellitus. Furthermore, it is acceptable to use "probable" or "possible" to identify a suspected cause of death. In the end, a clinician's determination of the cause of death is a medical opinion and is based on the best available medical evidence, which may include the cumulative effects of multiple risk factors or a previously known disease process. Use of standard nomenclature without abbreviations and legible writing is encouraged.

The Board will not pursue disciplinary action against clinicians who complete death certificates in good faith and to the best of their ability in accord with the information available — even if that information is limited. The clinician completing the death certificate is only asked to provide a cause of death "to the best of [his or her] knowledge," not to a medical certainty (which is not possible in many instances). The Board also recognizes that clinicians may believe, for a variety of reasons, they were not "in charge of the patient's care for the illness or condition which resulted in death." This is often because death has occurred weeks or months after the last contact with the patient. The Board encourages clinicians to undertake completion of death certificates for patient's (current, recent, or remote) under these circumstances as a professional, ethical, civic, and public health responsibility. Failure or refusal to complete a death certificate, when the licensee clearly has a responsibility to do so, could lead the Board to consider disciplinary action.

Licensees should perform this final aspect of patient care promptly and with consideration for the decedent and his or her loved ones. Questions or concerns by clinicians regarding medical examiner responsibilities in a particular case or for advice on the completion of a death certificate may be discussed in a collegial and professional manner with the county medical examiner or Chief Medical Examiner's office. Legal requirements regarding completion of a death certificate may be found at N.C. Gen. Stat. § 130A-115. Additional guidance on the proper completion of death certificates is available at https://www.cdc.gov/nchs/data/misc/hb cod.pdf (Physicians' Handbook on Medical Certification of Death).

(Adopted March 2019)

<sup>&</sup>lt;sup>2</sup> The Board is aware that N.C. Gen. Stat. § 130A-115(c) requires that the practitioner "state the cause of death in definite and precise terms." (emphasis added) It is the Board's interpretation of this statute that the terms describing the cause of death must be definite and precise, not that the cause of death be definite, as this would be inconsistent with other language in N.C. Gen. Stat. § 130A-115(c) and, as previously mentioned, is not possible in some instances.