



# **Position Statements**

## **North Carolina Medical Board**

**Updated March 2016**

## Table of Contents

|                                                                                                                                                                                     |    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| What Are the Position Statements of the Board and<br>To Whom Do They Apply? .....                                                                                                   | 3  |
| The Physician-Patient Relationship .....                                                                                                                                            | 4  |
| Medical Record Documentation.....                                                                                                                                                   | 5  |
| Access to Medical Records .....                                                                                                                                                     | 6  |
| Retention of Medical Records .....                                                                                                                                                  | 7  |
| Departures from or Closings of Medical Practices .....                                                                                                                              | 8  |
| The Retired Physician .....                                                                                                                                                         | 9  |
| Advance Directives and Patient Autonomy .....                                                                                                                                       | 10 |
| Availability of Licensees to Their Patients .....                                                                                                                                   | 11 |
| Guidelines for Avoiding Misunderstandings During<br>Physical Examinations .....                                                                                                     | 12 |
| Sexual Exploitation of Patients .....                                                                                                                                               | 13 |
| Contact With Patients Before Prescribing .....                                                                                                                                      | 14 |
| Writing of Prescriptions .....                                                                                                                                                      | 15 |
| Self- Treatment and Treatment of Family Members .....                                                                                                                               | 16 |
| The Treatment of Obesity .....                                                                                                                                                      | 17 |
| Prescribing controlled substances for other than validated medical or therapeutic purposes, with particular<br>reference to substance or preparations with anabolic properties..... | 18 |
| Policy for the Use of Opiates for the Treatment of Pain .....                                                                                                                       | 19 |
| End-of-Life Responsibilities and Palliative Care .....                                                                                                                              | 47 |
| Medical, Nursing, Pharmacy Boards: Joint Statement on Pain Management in End-of-Life Care .....                                                                                     | 48 |
| Office-Based Procedures .....                                                                                                                                                       | 50 |
| Laser Surgery .....                                                                                                                                                                 | 59 |
| Care of the Patient Undergoing Surgery or Other Invasive Procedure .....                                                                                                            | 60 |
| HIV/HBV Infected Health Care Workers .....                                                                                                                                          | 61 |
| Professional Obligation to Report Incompetence,<br>Impairment, and Unethical Conduct .....                                                                                          | 63 |
| Advertising and Publicity .....                                                                                                                                                     | 64 |
| Sale of Goods From Physician Offices .....                                                                                                                                          | 66 |
| Referral Fees and Fee Splitting .....                                                                                                                                               | 67 |
| Unethical Agreements in Complaint Settlements .....                                                                                                                                 | 68 |
| Medical Supervisor-Trainee Relationship .....                                                                                                                                       | 69 |
| Competence and Reentry to the Active Practice of Medicine .....                                                                                                                     | 70 |
| Capital Punishment.....                                                                                                                                                             | 71 |
| Physician Supervision of Other Licensed Health Care Practitioners .....                                                                                                             | 72 |
| Drug Overdose Prevention .....                                                                                                                                                      | 73 |
| Medical Testimony .....                                                                                                                                                             | 74 |
| Collaborative Care within the Health Care Team.....                                                                                                                                 | 75 |
| Telemedicine .....                                                                                                                                                                  | 76 |
| Physician Scope of Practice .....                                                                                                                                                   | 78 |
| Professional Use of Social Media .....                                                                                                                                              | 79 |
| Child Maltreatment.....                                                                                                                                                             | 80 |
| Corporate practice of medicine.....                                                                                                                                                 | 81 |

*[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](http://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.

- 1) 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.
- 2) 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.
- 3) The existence of a Position Statement should not necessarily be taken as an indication of the Board's enforcement priorities.
- 4) 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)

## **The physician-patient relationship**

The duty of the physician is to provide competent, compassionate, and economically prudent care to all his or her patients. Having assumed care of a patient, the physician may not neglect that patient nor fail for any reason to prescribe the full care that patient requires in accord with the standards of acceptable medical practice. Further, it is the Board's position that it is unethical for a physician to allow financial incentives or contractual ties of any kind to adversely affect his or her medical judgment or patient care.

Therefore, it is the position of the North Carolina Medical Board that any act by a physician that violates or may violate the trust a patient places in the physician places the relationship between physician and patient at risk. This is true whether such an act is entirely self-determined or the result of the physician's contractual relationship with a health care entity. The Board believes the interests and health of the people of North Carolina are best served when the physician-patient relationship remains inviolate. The physician who puts the physician-patient relationship at risk also puts his or her relationship with the Board in jeopardy.

### **Elements of the Physician-Patient Relationship**

The North Carolina Medical Board licenses physicians as a part of regulating the practice of medicine in this state. 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.

Patient trust is fundamental to the relationship thus established. It requires that:

- there be adequate communication between the physician and the patient;
- the physician report all significant findings to the patient or the patient's legally designated surrogate/guardian/personal representative;
- there be no conflict of interest between the patient and the physician or third parties;
- personal details of the patient's life shared with the physician be held in confidence;
- the physician maintain professional knowledge and skills;
- there be respect for the patient's autonomy;
- the physician be compassionate;
- the physician respect the patient's right to request further restrictions on medical information disclosure and to request alternative communications;
- the physician be an advocate for needed medical care, even at the expense of the physician's personal interests; 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, is considered sacred, and when the elements crucial to that relationship and to that trust—communication, patient primacy, confidentiality, competence, patient autonomy, compassion, selflessness, appropriate care—are foremost in the hearts, minds, and actions of the physicians licensed by the Board.

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

### **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 physician-patient relationship must be done in compliance with the physician's obligation to support continuity of care for the patient.

The decision to terminate the relationship must be made by the physician personally. Further, termination must be accompanied by appropriate written notice given by the physician 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, the notice of termination must state clearly whether the termination involves only the individual physician or includes other members of the group. 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's medical records.

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

## Medical record 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 contain an appropriate history and physical examination, results of ancillary studies, diagnoses, and any plan for treatment. The medical record should be legible. When the care giver does not handwrite legibly, notes should be dictated, transcribed, reviewed, and signed within a reasonable time. The Board recognizes and encourages the trend towards the use of electronic medical records ("EMR"). However, the Board cautions against relying upon software that pre-populates particular fields in the EMR without updating those fields in order to create a medical record that accurately reflects the elements delineated in this Position Statement.

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 to communicate to 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:

1. The record reflects the purpose of each patient encounter and appropriate information about the patient's history and examination, and the care and treatment provided are described.
2. The patient's past medical history is easily identified and includes serious accidents, operations, significant illnesses and other appropriate information.
3. Medication and other significant allergies, or a statement of their absence, are prominently noted in the record.
4. When appropriate, informed consent obtained from the patient is clearly documented.
5. All entries are dated.

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

1. Each page in the medical record contains the patient's name or ID number.
2. Personal biographical information such as home address, employer, marital status, and all telephone numbers, including home, work, and mobile phone numbers.
3. All entries in the medical record contain the author's identification. Author identification may be a handwritten signature, initials, or a unique electronic identifier.
4. All drug therapies are listed, including dosage instructions and, when appropriate, indication of refill limits. Prescriptions refilled by phone should be recorded.
5. Encounter notes should include appropriate arrangements and specified times for follow-up care.
6. 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.
7. An appropriate immunization record is evident and kept up to date.
8. Appropriate preventive screening and services are offered in accordance with the accepted practice guidelines.

(Adopted May 1994) (Amended May 1996, May 2009)(Reviewed May 2013)

## 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 records pursuant to the 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 licensee 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 and other records. 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 records.\*

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

*[\*] See also Position Statement on Departures from or Closings of Medical Practices.*

(Adopted November 1993) (Amended May 1996, September 1997, March 2002, August 2003, September 2010) (Reviewed May 2014)

## Retention of medical records

Physicians have both a legal and ethical obligation to retain patient records. The Board, therefore, recognizes the necessity and importance of a licensee's proper maintenance, retention, and disposition of medical records. The following guidelines are offered to assist licensees in meeting their ethical and legal obligations:

- State and federal laws require that records be kept for a minimum length of time including but not limited to:
  1. Medicare and Medicaid Investigations (up to 7 years);
  2. HIPAA (up to 6 years);
  3. Medical Malpractice (varies depending on the case but should be measured from the date of the last professional contact with the patient)—physicians should check with their medical malpractice insurer); North Carolina has no statute relating specifically to the retention of medical records;
  4. Immunization records always must be kept.
- In addition to existing state and federal laws, medical considerations may also provide the basis for deciding how long to retain medical records. Patients should be notified regarding how long the physician will retain medical records.
- In deciding whether to keep certain parts of the record, an appropriate criterion is whether a physician would want the information if he or she were seeing the patient for the first time. The Board, therefore, recognizes that the retention policies of physicians giving one-time, brief episodic care may differ from those of physicians providing continuing care for patients.
- In order to preserve confidentiality when discarding old records, all records should be destroyed, including both paper and electronic medical records.
- Those licensees providing episodic care should attempt to provide a copy of the patient's record to the patient, the patient's primary care provider, or, if applicable, the referring physician.
- If it is feasible, patients should be given an opportunity to claim the records or have them sent to another physician before old records are discarded.
- The physician should respond in a timely manner to requests from patients for copies of their medical records or to access to their medical records.
- Physicians should notify patients of the amount, and under what circumstances, the physician will charge for copies of a patient's medical record, keeping in mind that N.C. Gen. Stat. 90-411 provides limits on the fee a physician can charge for copying of medical records.

*1 Physicians should retain medical records as long as needed not only to serve and protect patients, but also to protect themselves against adverse actions. The times stated may fall below the community standard for retention in their communities and practice settings and for the specific needs. Physicians are encouraged (may want to) seek advice from private counsel and/or their malpractice insurance carrier.*

(Adopted May 1998) (Amended May 2009) (Reviewed July 2013)

## Departures from or closings of medical practices

Departures from or closings of medical practices are trying times. If mishandled, they can significantly disrupt continuity of care and endanger patients.

### Provide Continuity of Care

Practitioners continue to have obligations toward their patients during and after the departure from or closing of a medical practice. Practitioners may not abandon a patient or abruptly withdraw from the care of a patient. 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.\* Also, good continuity of care may often include making appropriate referrals. The practitioner(s) and other parties that may be involved should ensure that the requirements for continuity of care are effectively addressed.

It is the position of the North Carolina Medical Board that during such times practitioners and other parties that may be involved in such processes must consider how their actions affect patients. In particular, practitioners and other parties that may be involved have the following obligations.

### Permit Patient Choice

It is the patient's decision from whom to receive care. Therefore, it is the responsibility of all practitioners and other parties that may be involved 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, which is often done by newspaper advertisement and by letters to patients currently under care;
- Patients clearly understand that they have a choice of health care providers;
- Patients are told how to reach any practitioner(s) remaining in practice, and when specifically requested, are told how to contact departing practitioners; and
- Patients are told how to obtain copies of or transfer their medical records.

No practitioner, group of practitioners, or other parties involved should interfere with the fulfillment of these obligations, nor should practitioners put themselves in a position where they cannot be assured these obligations can be met.

### Written Policies

The Board recommends that practitioners and practices prepare written policies regarding the secure storage, transfer and retrieval of patient medical records. Practitioners and practices should notify patients of these policies. At a minimum, the Board recommends that such written policies specify:

- A procedure and timeline that describes how the practitioner or practice will notify each patient when appropriate 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;
- The procedure by which the practitioner or practice will dispose of unclaimed medical records after a specified period of time;
- How the practitioner or practice shall timely respond to requests from patients for copies of their medical records or to access to their medical records; In the event of the 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 and how patients can access those records; and
- The procedure by which the deceased or incapacitated practitioner's executor, administrator, personal representative or survivor will dispose of unclaimed medical records after a specified period of time.

The Board further expects that its licensees comply with any applicable state and/or federal law or regulation 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.

(Adopted January 2000) (Amended August 2003, July 2009)

### **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)

### **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)

### **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 physical examinations**

It is the position of the North Carolina Medical Board that proper care and sensitivity are needed during physical examinations to avoid misunderstandings that could lead to charges of sexual misconduct against licensees. In order to prevent such misunderstandings, the Board offers the following guidelines.

- 1) Sensitivity to patient dignity should be considered by the licensee when undertaking a physical examination. The patient should be assured of adequate auditory and visual privacy and should never be asked to disrobe in the presence of the licensee. Examining rooms should be safe, clean, and well maintained, and should be equipped with appropriate furniture for examination and treatment. Gowns, sheets and/or other appropriate apparel should be made available to protect patient dignity and decrease embarrassment to the patient while a thorough and professional examination is conducted.
- 2) Whatever the sex of the patient, a third party, 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 breast(s), genitalia, or rectum. It is the licensee's responsibility to have a staff member available at any point during the examination.
- 3) The licensee should individualize the approach to physical examinations so that each patient's apprehension, fear, and embarrassment are diminished as much as 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 possible misunderstanding.
- 4) The licensee and staff should exercise the same degree of professionalism and care when performing diagnostic procedures (eg, electro-cardiograms, 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.
- 5) The licensee should be on the 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; 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:

1. 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;
3. Examination or touching of genital mucosal areas without the use of gloves;
4. 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;
5. Using the physician-patient relationship to solicit a date or romantic relationship;
6. Initiation by the physician of conversation regarding the sexual problems, preferences, or fantasies of the physician;
7. 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
9. 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:

1. Sexual intercourse, genital to genital contact;
2. Oral to genital contact;
3. Oral to anal contact and genital to anal contact;
4. Kissing in a romantic or sexual manner;
5. 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;
6. Encouraging the patient to masturbate in the presence of the physician or masturbation by the physician while the patient is present; and
7. 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 19991)(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, 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, or prescribing an opiate antagonist to someone in a position to assist a person at risk of an opiate-related overdose. 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.

Created: Nov 1, 1999

Modified: February 2001; November 2009, May 2013, November 2014

## 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](http://www.ncmedboard.org)

(Adopted May 1991, September 1992) (Amended May 1996, March 2002, July 2002, March 2011, July 2012) (Reviewed March 2005)

## **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.

1. **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.
2. **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.
3. **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.
4. **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**

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

The treatment of obesity should be based on sound scientific evidence and principles. Treatment modalities and prescription medications that have not been proven to have beneficial effects should not be used.

Adequate medical documentation must be kept so that progress as well as the success or failure of any modality is easily ascertained.

(Adopted [as The Use of Anorectics in Treatment of Obesity] October 1987) (Amended March 1996, 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 or legend substance for other than a validated medical or therapeutic purpose is unprofessional conduct.

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

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

**Substances/Preparations with Anabolic Properties**

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

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

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

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

## **POLICY FOR THE USE OF OPIATES FOR THE TREATMENT OF PAIN**

### **Introduction**

Since the 2004 publication of the North Carolina Medical Board's Policy for the Use of Controlled Substances for the Treatment of Pain, a considerable body of research and experience has made it evident that the Board's 2004 Policy required revision. The updated policy presented here takes into consideration recent evidence that risk associated with opiates has surged, while evidence for benefits has remained controversial and insufficient. Over the last decade opioid sales have increased in parallel with an increase in the morbidity and mortality associated with these drugs. At the same time approximately one in four patients seen in primary care settings suffers from pain that interferes with the activities of daily living (1).

The challenges faced by North Carolina Medical Board licensees who care for patients taking opiates for pain are significant. The North Carolina Medical Board is committed to helping its licensees meet those challenges successfully. By doing so the Board and its licensees will help promote public health and the individual well-being of the citizens of our state. For the sake of simplicity, in the document that follows the word "physician" is used to represent all North Carolina Medical Board Licensees who use opiates for the treatment of pain.

The majority of this updated policy applies to the treatment of chronic pain and the use of opioid analgesics. Guidance for assessing and managing acute pain in primary care is also provided. The Board recognizes that the use of opiates in end of life and palliative care may present unique benefits and risks. Concepts and guidelines presented in this policy will be useful and generally apply to the use of opiates for end of life and palliative care. However, the Board's Position Statements on end of life and palliative care take precedence over information presented here.

The updated policy contains three sections. Section 1 begins with a preamble of information and a statement of the Board's goals. The preamble is followed by conceptual overviews discussing responsibility for appropriate pain management and opiate prescribing, and prevention of opiate diversion and abuse. Section 2 provides guidelines to physicians that are linked to concepts presented in Section 1. The guidelines provide information that physicians can use to help them evaluate and manage pain appropriately and prescribe opiates responsibly. The guidelines provide the Board a framework to assess physicians' treatment of pain, and a means to determine whether opiate medications are used in a manner that is medically appropriate and in compliance with North Carolina State and federal laws and regulations. Section 3 contains a glossary of terms.

In developing this updated policy the Board has relied heavily on the Federation of State Medical Board's 2013 Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain. The Board also acknowledges the work of, and extends its thanks to the Indiana Medical Licensing Board, and the efforts of the State of Indiana's Attorney General, the Indiana State Department of Health's Chief Medical Officer, and the Indiana Prescription Drug Abuse Task Force. As the North Carolina Medical Board has developed this updated policy, it has borrowed freely and taken material verbatim, with permission, from "*First Do No Harm, The Indiana Healthcare Providers Guide to the Safe, Effective Management of Chronic Non-Terminal Pain*."

The Board encourages all physicians to review the Federation of State Medical Board's 2013 Model Policy at [http://www.fsmb.org/pdf/pain\\_policy\\_july2013.pdf](http://www.fsmb.org/pdf/pain_policy_july2013.pdf), and the State of Indiana's "*First Do No Harm*" document at [http://www.in.gov/bitterpill/docs/First\\_Do\\_No\\_Harm\\_V\\_1\\_0.pdf](http://www.in.gov/bitterpill/docs/First_Do_No_Harm_V_1_0.pdf) for additional helpful information.

### **SECTION I - Preamble**

The North Carolina Medical Board is obligated under the laws of the State of North Carolina to protect public health and safety. This obligation is reflected in the Board's mission statement to "...regulate the practice of medicine and surgery for the benefit and protection of the people of North Carolina." The Board believes that a fundamental component of good medical practice includes the appropriate evaluation and management of pain. Responsibly prescribed opiate medications may help North Carolina physicians treat their patients' pain safely and effectively, and improve their quality of life. The Board is aware that the undertreatment of pain is recognized as a serious public health problem that compromises patients' function and quality of life (2, 3). However, it must be understood that chronic pain is often intractable, and that in most cases the current state of medical knowledge and medical therapies, including the use of opioid analgesics, does not provide for the complete elimination of chronic pain (4, 5, 6). Furthermore, chronic pain and its attendant opioid use have become an enormous burden to patients, medical institutions and our society. There are over 50 million estimated chronic pain patients in the United States. Medical expense data places the cost of chronic pain, including direct and indirect costs, at well over \$100 billion per year. As many as 15-20% of primary care visits result in a prescription being given for opioids. However, despite the increased use of pain interventions, including opioids, many patients are dissatisfied and report inadequate pain control. The aggressive use of pain intervention resources has not

been associated with commensurate clinical benefit. Robust increases in pain expenditures from 1997 to 2005 did not translate into improvements in self-assessed health status and pain (7).

Persistent pain, like all chronic illnesses, is managed optimally with a bio-psychosocial model and not with the opio-centric practices of the past. Data from a large population-based study suggests that those on chronic high-dose opioids may fare worse over time than those on lower doses or none at all. Quality of life measures for patients in the study using high-dose opioids were lower than those on a low dose regimen, and patients were four times less likely to “recover” significantly during the five years of the study (8).

Between 1997 and 2010, opioid use increased dramatically. However, increased use of opioids has not been accompanied by adequate evidence to support the effectiveness and safety of long-term opioid therapy, and has been complicated by opioid-related overdoses, substance abuse, and prescription costs to society that have escalated to unacceptable levels. Leonard J. Paulozzi, a medical epidemiologist at the Center for Disease Control and Prevention (CDC), during congressional testimony reported that “the number of deaths in the narcotics category that involved prescription opioid analgesics increased from 2,900 in 1999 to at least 7,500 in 2004, an increase of 160% in just five years.” Accidental drug overdose is currently the leading cause of injury-related death in the United States for people between the ages of 35-54 (9). In addition to nearly 16,000 prescription opioid-related deaths in 2010, the rise in opioid use has fueled a substantial increase in substance use disorders. Approximately nine people are admitted for prescription opioid abuse treatment for every one opioid prescription-related death (10).

An analysis on 2006 data related to the cost of nonmedical use of prescription opioids placed the total at \$53.4 billion (11). The CDC’s estimate on those same costs in 2009 was over \$70 billion. Lost productivity was the largest single contributing factor, contributing to 79% of this cost. Clearly, suboptimal risk stratification and monitoring of patients prior to opioid therapy, combined with current practices of prescription writing, are creating enormous emotional and financial burdens on a national level.

In North Carolina, six-hundred and seventy three North Carolinians were reported to have died in 2012 from unintentional poisoning by opioids other than opium and heroin (12). Extrapolating data from the 2011 and 2012 National Survey on Drug Use and Health suggests that as many as 70% of these opiate related deaths are associated with a prescription medication shared by or stolen from the individual for whom the drug was prescribed.

In presenting this Policy for the Use of Opiates for the Treatment of Pain, it is the North Carolina Medical Board’s goal to provide guidelines that may help to improve the quality of life for those North Carolinians who suffer from pain, and reduce the morbidity and mortality associated with the inappropriate use of opiates and other controlled substances prescribed to treat pain.

#### ***Responsibility for Appropriate Pain Management and Opiate Prescribing:***

The evaluation and management of pain is integral to the practice of medicine. All physicians should be knowledgeable about the process of evaluating their patients’ pain and function, and be familiar with methods of managing pain safely and effectively. The process of evaluation and management of a patient’s pain should be based on an established physician-patient relationship. Patients with chronic pain should be assessed for the potential for substance abuse and coexistent mental health conditions. Objective and verifiable goals that incorporate physical, functional and social domains should be prominent components of a patient’s treatment plan. Non- pharmacologic treatment interventions and use of non-opiate pain medications should be explored before beginning opioid medications. When controlled substances are to be used to treat chronic pain, their use should be accompanied by informed consent and treatment agreements. If opiate medications are part of a treatment plan, they should be prescribed or administered in response to an identified medical condition that qualifies for treatment with a controlled substance. Physicians should be aware that there is very little data to support the use of long term opioid therapy for common causes of chronic pain such as fibromyalgia, low back pain, pelvic pain, functional bowel disorders and chronic headache. Physicians prescribing controlled substances should understand and comply with applicable federal and North Carolina State requirements. Follow up monitoring of a patient’s response to treatment should include the patient’s progress in achieving objective and verifiable goals, and should insure that the patient is using prescribed medications safely. Treatment plans and prescribed medications should be adjusted as needed, and referral to consultants made when necessary. Opioids should be tapered or discontinued when a patient’s pain is poorly controlled on appropriate doses of medication or if there is no physical, functional, and psychosocial improvement with opioid treatment. The medical record should provide documentation of all relevant aspects of the physician’s evaluation and management, including diagnoses and treatment plans, periodic assessment of the patient’s progress toward identified goals, medications prescribed and results of medication monitoring, evidence of compliance with treatment agreements, and pertinent results of laboratory, radiographic and ancillary services, including consultations and referrals.

#### ***Preventing Opioid Diversion and Abuse:***

The Board recognizes that patients and other individuals who inappropriately use opiates place their own health in jeopardy and create a public health problem (13). Physicians who fail to prescribe opiates responsibly may contribute to patients’ and other individuals’ drug misuse and diversion (14, 15, 16). The Board expects physicians to incorporate

safeguards into their practices to minimize the risk of misuse and diversion of opiates as well as other controlled substances (17, 18, 19, 20, 21, 22, 23, 24).

The appropriate evaluation and management of a patient's pain, including the prescribing of opiate medications is the treating physician's responsibility. Physicians who prescribe, order, dispense, or administer controlled substances using evidence based or current best clinical practices should not fear disciplinary action from the Board. Conversely, the Board will consider the failure to prescribe controlled substances responsibly to be a departure from the standards of practice and will investigate such allegations, utilizing current clinical practice guidelines and expert review in determining whether or not standards of care have been met. Allegations of inappropriate pain management, including the failure to prescribe controlled substances responsibly, will be evaluated on an individual basis. The Board may use a variety of sources to determine the appropriateness of treatment including prescribing information obtained from the North Carolina Controlled Substance Reporting System (NCCSRS). The Board will not take disciplinary action against a physician for deviating from this Policy when the physician can establish a reasonable cause for the deviation.

The Board will judge the validity of the physician's treatment of a patient on the basis of available documentation. Goals of treatment are the effective control of the patient's pain using appropriate doses of medication, achieving improved physical, functional, and psychosocial activities, and mitigating risk of misuse, abuse, diversion, and overdose (25, 26, 27).

The Board will consider the unsafe or otherwise inappropriate treatment of pain to be a departure from best clinical practice, taking into account whether the treatment is appropriate to the diagnosis and the patient's level of risk.

## **SECTION II – Guideline**<sup>28</sup>

### **Overview:**

The guidelines in the North Carolina Medical Board's Policy on the Use of Opiates for the Treatment of Pain are meant to help physicians evaluate and manage pain appropriately, prescribe opiates responsibly, and prevent opioid diversion and abuse. Incorporating the guidelines into best practices behavior will help physicians mitigate some of the burdens that pain and its attendant opiate use place on patients, physicians, medical institutions, and society. The Board recommends the following as best practices behavior when using opiates to treat pain.

### ***Patient Evaluation and Risk Stratification***

The physician should personally participate in the process of every patient's evaluation. The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For example, meaningful assessment of chronic pain demands a more detailed evaluation than an assessment of acute pain. Assessment of a patient's pain should include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical, functional and psychosocial activities (29).

For every patient with pain, the initial work-up should include a systems review and relevant physical examination, and laboratory investigations as indicated (30, 31, 32, 33). Such investigations help the physician address the nature and intensity of the pain, and its impact on the patient's physical, functional and psychosocial activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation. For example, does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing (34)? When applicable, the patient's evaluation should include information from family members and/or significant others (35, 36, 37, 38).

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse should be part of the initial evaluation (39, 40, 41, 42, 43, 44). These assessments, should ideally be completed prior to a decision to prescribe opioid analgesics, and should inquire into any history of physical, emotional or sexual abuse, which are risk factors for substance misuse (45, 46, 47, 48). Use of a validated screening tool, such as the Screener and Opioid Assessment for Patients with Pain (SOAPP-R; 49) or the Opioid Risk Tool (ORT; 50) can save time in collecting and evaluating information and determining the patient's level of risk.

Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy and are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse (51, 52, 53). Whenever possible treatment of a patient who has a history of substance use disorder should involve consultation with an addiction specialist before opioid therapy is initiated and include follow-up as needed. Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program (54), or alternatives such as co-management with an addiction professional are established. Physicians who treat patients with chronic pain are strongly encouraged to be knowledgeable about addiction, including recognizing behaviors that indicate addiction, and how and when to refer patients for addiction evaluation and treatment.

All patients should be screened for depression and other mental health disorders as part of risk evaluation. There is a clear association between mental illness and opioid related morbidity and mortality. Patients with untreated depression and

other mental health problems are at increased risk for misuse or abuse of controlled medications, addiction, and overdose (55).

Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers. Patients occasionally provide fraudulent records. If there is reason to question the truthfulness of a patient's report, records should be requested directly from the patient's other providers (56, 57).

Information from the North Carolina Controlled Substance Reporting System (NCCSRS) should be part of every patient's initial evaluation and subsequent monitoring program. Physicians should register with the NCCSRS and become familiar with analyzing and using NCCSRS data. Information from the NCCSRS should be used to help confirm each patient's compliance with treatment plans and opiate medication agreements. Relevant information from the NCCSRS should become part of the patient's medical record.

Obtaining a toxicology screen, such as a urine drug screen, is a useful tool in the setting of risk assessment prior to prescribing opioids. It may reveal the use of controlled medications such as opioids or benzodiazepines other than those prescribed or may reveal the use of other illicit drugs.

In dealing with a patient who is taking opioids prescribed by another physician—particularly a patient on high doses—evaluation and risk stratification assume even greater importance (58, 59, 60). As with all patients the physician's decision to prescribe opioid analgesics should reflect the totality of the information collected, the physician's own knowledge and comfort level in prescribing and the resources for patient support that are available in the community (61, 62, 63).

### ***Development of a Treatment Plan and Goals:***

In chronic pain the goals of treatment include reasonably attainable improvement in pain and activity; improvement in pain-associated problems such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications (64, 65). According to the International Association of the Study of Pain, activity goals should be set in three separate domains. The physical domain is the exercise program the patient follows. The functional domain involves tasks of everyday living. The social domain relates to pleasurable social activities (66). Effective means of achieving treatment goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient.

Early treatment with non-pharmacologic interventions including physical therapy, exercise, and cognitive behavioral techniques, should be employed whenever possible. First line pharmacotherapy should be the appropriate use of non-opioid analgesics including over the counter medications, non-steroidal anti-inflammatory drugs, and acetaminophen. Other treatment modalities including minor interventions such as anesthetic and steroid joint injections, cutaneous stimulators, topical anesthetics, and local therapies employing heat, massage, and manipulations should be considered before using opiates.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly. Clear-cut, individualized goals for pain relief and improved physical, functional and psychosocial activity should be set to help guide the choice and response to treatment (67). The treatment plan should contain information supporting the selection of pharmacologic and nonpharmacologic therapies. The plan should specify the objectives that will be used to evaluate the control of pain and achievement of specific physical, functional and psychosocial activity goals (68, 69, 70, 71). The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered (72, 73, 74, 75).

### ***Informed Consent and Treatment Agreement:***

The decision to initiate opioid therapy should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient, with persons designated by the patient, or with the patient's surrogate or guardian if the patient is without medical decision-making capacity (76, 77). If opioids are prescribed, the patient (and possibly family members) should be counseled on safe ways to store and dispose of medications (78, 79).

When treating chronic pain, use of a written informed consent, and a treatment agreement are recommended (80, 81, 82, 83, 84). They may be combined into one document for convenience.

*Informed consent* documents typically address:

- The potential risks and anticipated benefits of chronic opioid therapy.
- Potential side effects (both short- and long-term) of the medication, such as constipation and cognitive impairment.
- The likelihood that tolerance to and physical dependence on the medication will develop.
- The risk of drug interactions and over-sedation, including the increased risk of using opiates in diseases and conditions such as obesity and sleep apnea.
- The risk of impaired motor skills (affecting driving and other tasks).
- The risk of opioid misuse, dependence, addiction, and overdose.
- The limited evidence as to the benefit of long-term opioid therapy.
- The physician's prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications.

- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).

*Treatment agreements* outline the joint responsibilities of physician and patient in the management of chronic pain (85, 86, 87) and may be applicable in some cases of acute pain. Treatment agreements are indicated when opioid or other abusable medications are prescribed. Agreements typically discuss:

- The goals of treatment, in terms of pain management, restoration of activities, and safety.
- The patient's responsibility for using medication safely (e.g., not using more medication than prescribed, not using an opioid in combination with alcohol or other potentially dangerous substances; storing medications in a secure location; and safely disposing of unused medication).
- The patient's responsibility to obtain prescribed opioids from only one physician or practice.
- The patient's agreement to periodic drug testing of blood, urine, hair, saliva, or other body material.
- The physician's responsibility to be available or to have a covering physician be available to care for unforeseen problems and to prescribe scheduled refills.

### ***Initiating an Opioid Trial:***

Generally, safer alternative treatments including non-pharmacologic and minor interventions and first line pharmacotherapy with over the counter medications, non-steroidal anti-inflammatory drugs, and acetaminophen should be considered before initiating opioid therapy. When the decision to use an opiate has been made, it should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 90 days) and with specified evaluation points. The physician should explain that progress will be carefully monitored for benefit and harm in terms of the effects of opioids on the patient's level of pain, and on the patient's physical, functional and psychosocial activities. Attention will be focused on adverse events and risks to safety (88). Patients at risk of an opiate overdose should be identified. The Board expects physicians who prescribe opiates to help insure that naloxone is readily available to patients who are identified as being at risk of an opiate overdose. Readers are referred to the Board's Position Statement, "Drug overdose prevention."

When initiating opioid therapy, the lowest dose possible should be given to an opioid naïve patient and titrated to affect while monitoring for complications. Opioid therapy should begin with a short acting drug and rotate to a long acting/extended release if indicated. A decision to continue opioid therapy beyond the trial period should reflect a careful evaluation of benefits, adverse events, and potential risks (89).

### ***Ongoing Monitoring and Adapting the Treatment Plan:***

The physician should regularly review the patient's progress, including any new information about the etiology of the pain or the patient's overall health and level of activities (90, 91, 92). When possible, collateral information about the patient's response to opioid therapy including the medications' effects on physical, functional, and psychosocial activities, as well as signs of adverse effects such as sedation or other impairment should be obtained from family members or other close contacts. The physician should regularly review North Carolina Controlled Substance Reporting System data. The patient should be seen more frequently while the treatment plan is being initiated and when the opioid dose is being adjusted (93 - 100). As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently.

At each visit, the results of chronic opioid therapy should be monitored by assessing what have been called the "5As" of chronic pain management. These include a determination of whether the patient has had a reduction in pain (Analgesia), improved physical, functional and psychosocial Activity, the presence of Adverse effects, evidence of Aberrant substance-related behaviors, and a change in Affect (101, 102). Validated brief assessment tools that measure pain and physical, functional and psychosocial activities, such as the three- question "Pain, Enjoyment and General Activity" (PEG) scale (103) may be helpful and more time efficient in general medical settings.

Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of the patient's progress toward treatment goals and assessment of substantial risks or adverse events (104, 105, 106, 107). A satisfactory response to treatment would be indicated by a reduced level of pain, and improved physical, functional and psychosocial activities (108, 109). Information from family members or other caregivers should be considered in evaluating the patient's response to treatment (110, 111, 112). Use of measurement tools to assess the patient's level of pain, activity, and quality of life (such as a visual analog or numerical scale) can be helpful in documenting therapeutic outcomes (113, 114).

Risks associated with opioids increase with escalating doses. The physician should avoid opiate dose escalation without adequate attention to risks or alternative treatments. Clinicians should avoid over-reliance on opioids as the primary or only treatment modality, including using opioid dose escalation as the only response to a complaint of inadequate pain relief. The physician should be continuously attentive to the use of opiates with other respiratory depressants such as benzodiazepines or alcohol, and using opiates in the setting of other comorbidities such as mental illness, respiratory disorders and sleep apnea, and a pre-existing substance use disorder.

### ***Periodic Drug Testing:***

Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs (115, 116). Drug testing is an important monitoring tool because self-reports of medication use and behavioral observations are not always reliable (117, 118, 119, 120, 121). Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing (122). When testing is conducted as part of pain treatment, forensic standards are generally not employed. Sample collection may not need to be observed, and chain-of-custody protocols are not customarily followed. Initial testing may be done using class-specific immunoassay point-of-care or laboratory-based tests. These tests do not typically identify a particular specific drug within a class. However, the tests are available as panels and immunoassays for specific drugs can be included. It is important that the clinician formulate these panels to include the specific medications being prescribed, and, if possible, the drugs commonly abused in the local community. If necessary, initial testing can be followed with more specific techniques, including gas chromatography/mass spectrometry (GC/MS) or other chromatographic tests (123). In drug testing in a pain practice, it is important to identify the specific drug not just the class of the drug.

Physicians should be knowledgeable about the specific drug tests they order. They should be aware of the limitations, sensitivity and specificity of the tests they order, and take care to order tests appropriately (124). When a drug test is ordered, it is important to specify that it include the opioid being prescribed (125). Because of the complexities involved in interpreting drug test results appropriately, it is advisable to confirm significant or unexpected results with the testing laboratory's toxicologist or a clinical pathologist (126, 127).

While immunoassay, point of care (POC) testing has utility in the making of temporary and "on the spot" changes in clinical management, its limitations with regard to accuracy have recently been the subject of study. The use of point of care testing for making long term and permanent changes in patient management may not be justified until the results of confirmatory testing with more accurate methods such as LC-MS/MS are obtained. A recent study on LC-MS/MS results following immunoassay POC testing in addiction treatment settings found very high rates of "false negatives and positives" (128, 129).

Test results that suggest illicit or prescribed medication misuse should be discussed with the patient. The discussion should occur in a positive, supportive fashion, to strengthen the physician-patient relationship, encourage healthy behaviors, and produce behavioral change when needed. Results of drug testing and subsequent discussion with the patient should be documented in the medical record (130). Periodic pill counting is a useful strategy to confirm medication adherence and minimize diversion. Data from the North Carolina Controlled Substance Reporting System (NCCSRS) should be reviewed before beginning opiates and as a routine part of monitoring and adapting a patient's treatment plan. (131, 132, 133, 134, 135). If the patient's progress is unsatisfactory, the physician must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach—possibly involving referral to a pain specialist or other health professional—should be employed (136, 137, 138, 139, 140).

Evidence of misuse of prescribed opioids demands prompt intervention by the physician (141, 142, 143, 144, 145, 146). Patient behaviors that require such intervention typically involve recurrent early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the physician's knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors (147). The presence of illicit or un-prescribed drugs, (drugs not prescribed by a physician) in drug tests requires action on the part of the prescriber. Some aberrant behaviors are more closely associated with medication misuse than others (148, 149). Most worrisome are patterns of behavior that suggests recurring misuse, such as unsanctioned dose escalations, deteriorating physical, functional or psychosocial activities, and failure to comply with a treatment plan (150).

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response (151, 152, 153, 154). Failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempt, arrest and incarceration, or death (155, 156, 157, 158). For this reason, physicians who prescribe chronic opioid therapy should be knowledgeable about substance use disorders and be able to distinguish substance use disorders from physical dependence on opiates.

### ***Tips on Diversion:***<sup>159</sup>

One of the most difficult duties that a physician has as it relates to the prescribing of opioids to patients with chronic pain is the issue of opioid diversion. Even in light of a failed urine drug screen (UDS) with confirmation, an inconsistent NCCSRS report, and or noncompliance (not attending physical therapy, failure to obtain prescribed imaging, failure to attend appropriate interventional procedures, etc.) it is difficult to know when a patient is diverting prescription opioids. However, the prescriber may feel the patient is diverting after ascertaining a history, or the medical office receives a phone call from an anonymous source that the patient is selling his/her opioid medication. Perhaps the most effective way to appropriately decide if the patient is diverting is the combination of a random pill count and a concomitant UDS with a confirmation.

If you believe a patient may be diverting a medication, he or she should be notified to come in to the office between scheduled appointments for a random pill count. This is one reason that it is of vital importance that a random pill count be part of the Physician-Patient Informed Consent and Treatment Agreement and be reviewed with the patient at the time the agreement is signed. If a random pill count reveals medication quantities that fall short of amounts expected from

prescribing instructions, it is vital to perform at that exact point in time a urine drug screen with confirmation. If the patient's UDS confirmation is negative for the prescribed opioid, it is very strong evidence that the patient is diverting, and it is safe to stop prescribing. If the UDS confirmation comes back with the appropriate medication in the patient's urine, but the random pill count is short, it is highly likely that the patient is either taking more medication than prescribed, or the patient is taking some of the medication but is diverting a portion of the prescription. At this point, a conversation with the patient should occur. If the patient is over-taking the medication, it may be a good idea to seek a pain management consultation to get a reassessment of the true pain generator(s). If you believe the patient is diverting or abusing medication, a referral to an addiction specialist is in order. If you have strong evidence that the patient is diverting opioid medication, the medication should be discontinued and alternative treatments initiated. If the physician believes the diversion represents a significant risk to public health, consideration should be given to reporting the individual to law enforcement or asking the NCCSRS for assistance.

A list of items that should raise the physician's awareness about the possibility that a patient is seeking opioid medications for reasons other than legitimate pain relief includes:

**Suspicious history:**

- Patient referred is already taking controlled substances; especially combinations of narcotics, muscle relaxants, use of sedative/hypnotics
- Soft diagnosis – perhaps based solely on chief complaint
- Multiple doctors and pain physicians in the past
- Patient travelled out of the way to come to your clinic
- Solicitous behavior frequently heard: "You're the best. I always wanted to come to you."
- No past medical records; unable to obtain records from "referring doctor"
- Patient brings records that look old, tattered or suspicious in some other way
- Patient asks for a specific controlled substance (example: prefers Lortab® over Norco )

**Suspicious physical exam:**

- No abnormal findings
- Abnormal findings in exam room inconsistent with witnessed behavior (patient has normal gait from car to office door, but limps once inside door)
- Exaggerative behaviors, pain is always a 10 on a scale of 1 to 10.
- Unimpressive imaging
- Presence of injecting behavior (old or recent "track marks" or multiple healed or current abscesses) or marked nasal erythema from insufflation ("snorting")
- Patient smells like marijuana smoke

**Equivocal compliance:**

- NCCSRS shows multiple providers, multiple pharmacies, prescriptions for multiple types and of medications, out of the area doctors, etc.
- UDS is refused or abnormal; patient offers multiple excuses; presence of any illegal substances (marijuana)
- Inconsistent test results over time
- Patient seeks recurrent early refills for lost or stolen prescriptions or for increased opioid use without consultation with prescriber
- Patient has excuses for lost pills (lost my prescription, my dog ate my pills, etc.)

**No or equivocal clinical improvement:**

- Subjective improvement alone does not count
- Lack of evidence of objective improvement in physical, functional and psychosocial activities,
- Lack of evidence of decreasing use of opioid medications, decreasing visits to emergency rooms, etc.

**What you should do when the clinician suspects misuse, abuse or addiction:**

- Request picture I.D. or other I.D. and a Social Security number. Photocopy these documents and include in the patient's record.
- Call a previous practitioner, pharmacist or hospital to confirm the patient's story.
- Confirm a telephone number, if provided by the patient.
- Confirm the current address at each visit.
- Investigate suspicions further by presenting and discussing specific concerns with the patient, re-checking NCCSRS information, increase the use of drug screens, talk with family members
- Write prescriptions for limited quantities until concerns are resolved and it is safe to do so, and increase frequency of visits and drug screens.

***Consultation and Referral:***

The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, addiction, or mental health specialist as needed (160, 161). For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment (162, 163).

Physicians who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed (164, 165, 166, 167).

***Discontinuing Opioid Therapy:***

Throughout the course of opioid therapy, the physician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate (168). Opioids should be tapered or discontinued when a patient's pain is poorly controlled on appropriate doses of medication OR if there is no improvement in physical, functional or psychosocial activity with opioid treatment. Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, deteriorating physical, functional or psychosocial activities, or significant aberrant medication use (169, 170).

If opioid therapy is discontinued, in the setting of appropriate use but inadequate response and the patient has become physically dependent, they should be provided with a safely structured tapering regimen. In the setting of abuse or addiction, when it is necessary to discontinue opioids quickly because of safety, withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist (171). The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate (172, 173, 174).

***Medical Records:***

Every physician who treats patients for chronic pain must maintain accurate and complete medical records. The medical record should include the following (175, 176, 177, 178):

- Copies of the signed informed consent and treatment agreement.
- The patient's medical history.
- Results of the physical examination and all laboratory tests.
- Results of the risk assessment, including results of any screening instruments used.
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.
- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and physician, functional and psychosocial improvement.
- Notes on evaluations by and consultations with specialists.
- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors (179, 180, 181, 182, 183, 184, 185). These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
- Authorization for release of information to other treatment providers.
- The medical record must include all prescription orders for opioid analgesics and other controlled substances, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record (186). The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed (187). Records should be up-to-date and maintained in an accessible manner so as to be readily available for review (188).
- Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient (189, 190, 191, 192).

***Assessing and Managing Pain in Primary Care***<sup>193</sup>

Acute pain was once defined simply in terms of duration. It is now viewed as a complex, unpleasant experience with emotional and cognitive, as well as sensory features that occur in response to tissue trauma. In contrast to chronic pain, relatively high levels of pathology usually accompany acute pain. The pain resolves with healing of the underlying injury. Acute pain is usually nociceptive, but may be neuropathic. Common sources of acute pain include trauma, surgery, labor, medical and dental procedures and acute disease states.

Acute pain serves an important biological function, as it warns of the potential for, or extent of, injury. A host of protective reflexes (e.g., withdrawal of a damaged limb, muscle spasm, autonomic responses) often accompany it. Acute pain might be mild and last just a moment, or it might be severe and more prolonged. Acute pain, by definition, does not

last longer than six months and it resolves when the underlying cause of pain has been treated or has healed. An accurate assessment of acute pain should be performed when a patient presents with pain to the healthcare setting. A solid understanding of the person and the etiology of the pain are essential for the development of an effective and appropriate short-term pain management plan.

#### Recommendations For Primary Care

- Develop an office policy for opioid prescribing and have this clearly posted and available for patients.
- Perform a thorough history and physical at the onset.
- Acute pain patients should be frequently evaluated for physical, functional and psychosocial improvement, with adjustments to treatment as needed. It is almost always contraindicated to include refills on opioid prescriptions for acute pain.
- Educate your patients about pain and analgesia. Explain the underlying diagnosis causing the pain, the natural history of the condition, and how your patient can help the healing process.
- If medically possible, exhaust non-opioid medications and collaborate with other professionals, including physical therapists and pain specialists. Consider nontraditional therapies such as acupuncture and massage therapy.
- Opioids are often not required for acute pain. If you feel a brief course of opioids are indicated and appropriate, be thoughtful and thorough in your discussions and practice.
- Always prescribe a complete pain management program when an opioid is used to treat acute pain:
  - utilize NSAIDS
  - develop and recommend specific exercises
  - utilize other modalities (e.g. heat, ice, massage, topical medications)
- Prescribe opioids intentionally. With the first opioid prescription, set patient responsibilities and the expectation that opioids will be discontinued when the pain problem has resolved or is not responding to what you are doing.
- Write the taper on the prescription (e.g. 1 po every 6 hours for 3 days, 1 po every 8-12 hr for 3 days, 1 po every 24 hr for 3 days, stop).
- Do not prescribe long-acting or controlled-release opioids (e.g., long-acting oxycodone and oxymorphone, fentanyl patches, long-acting hydromorphone and morphine or methadone) for acute pain.
- Consider performing risk stratification, urine drug monitoring and have a low threshold for accessing and monitoring the NCCSRS at the onset of pain care.
- Give clear instructions to take opiates only as prescribed, not more frequently or in greater quantities. Educate your patients about the risks of taking opioid analgesics, including, but not limited to: overdose that can slow or stop their breathing and even lead to death; fractures from falls, especially in patients aged 60 years and older; drowsiness leading to injury, especially when driving or operating heavy or dangerous equipment; and tolerance and addiction. Educate your patients about acute pain – tell them it is likely that their acute pain will diminish and resolve, and tell them that prolonged (several weeks of) scheduled opioids may actually impair their ability to fully recover.
- Patients should be advised to avoid medications that are not part of their treatment plan because they may worsen the side effects and increase the risk of overdose from opiates.
- Prepare patients that it may be difficult to taper off opioids, particularly from higher dose regimens, even when they are eager to do so.
- Consider referrals and consultations with a pain specialist if the patient is not responding to your treatment plan. You may want to do this early in the course of treatment if the patient does not respond to standard first line medications and before you prescribe narcotics. Pain specialists may offer procedures or other interventions that will help your patient improve and avoid unnecessary opiate use.
- It is critical to assure that patients are provided with easy to follow and graduated activity instructions that help them quickly improve their quality of life in physical, functional and social domains.

#### Recommendations for Emergency Departments

- Emergency medical physicians should not provide replacement prescriptions for controlled substances that were lost, destroyed or stolen.

- Emergency medical physicians should not provide replacement doses of methadone for patients in a methadone treatment program.
- Long-acting or controlled-release opioids (such as OxyContin®, fentanyl patches and methadone) should not be prescribed by emergency department physicians.
- Emergency department physicians are encouraged to use information from the NCCSRS before prescribing opioids.
- Physicians who manage patients with chronic pain should be encouraged to send patient pain agreements to local emergency departments for reference, and work to develop appropriate plans for the evaluation and management of their patients in the emergency department in conjunction with emergency department physicians.
- Whenever possible when evaluating a patient with an exacerbation of chronic pain, the emergency medicine physician should contact the patient's primary opioid prescriber and access the NCCSRS. If analgesics are to be prescribed, only enough pills to last until the office of the primary opioid prescriber's opens should be provided.
- Prescriptions for controlled substances from emergency department physicians should state the patient is required to provide a government issued picture identification (ID) to the pharmacy filling the prescription.
- Prescriptions for opioid pain medication from emergency department physicians for acute injuries, such as fractured bones, in most cases should not exceed 30 pills.
- When appropriate, emergency department patients should be screened for substance abuse prior to prescribing opioid medication for acute pain.

#### ***Compliance with Controlled Substance Laws and Regulations:***

To prescribe, dispense or administer controlled substances, the physician must be registered with the DEA, licensed by the state in which he or she practices, and in compliance with applicable federal and state regulations (194).

Physicians are referred to the *Physicians' Manual of the U.S. Drug Enforcement Administration* for specific rules and regulations governing the use of controlled substances. Additional resources are available on the DEA's website at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov).

### **SECTION III: Definitions**<sup>195</sup>

For the purposes of these guidelines, the following terms are defined as follows:

**Aberrant drug-related behaviors:** Actions that indicate addiction, including the following: rapidly escalating drug dosage, running out of prescriptions early, acquiring prescription drugs from outside sources, inconsistent UDS, multiple providers from NCCSRS data, stolen medications, chewing/snorting/injecting medications, and altering/stealing/selling prescriptions.

**Abuse:** A term with a wide array of definitions, depending on context. The American Psychiatric Association defines drug abuse as "a maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by one or more behaviors." DSM-V replaces the term "abuse" with "misuse" (196) In addition; **Substance abuse (SA)** can mean the use of any substance(s) for non-therapeutic purposes, or use of medication for purposes other than those for which it is prescribed. The medical diagnosis of SA is defined by any one of the following four criteria during a 12-month period: (1) failure to fulfill major obligations at work, school, or home; (2) recurrent use in situations in which it is physically hazardous; (3) recurrent substance-related legal problems; (4) continued use despite persistent social or interpersonal problems (197). Substance abuse can lead to substance dependence.

**Acupuncture:** An ancient oriental medical technique where needles are placed at anatomic points along the 12 meridians of the body. Oriental medical theory, passed down for thousands of years, states that vital energy (chi) flows through the body along these 12 meridians. Although current medicine does not fully understand how acupuncture works, we do know from functional MRI studies that acupuncture activates/deactivates particular areas of the brain during needling. In addition, it is known that endorphin (endogenous opioid) levels rise during needling. Clinically, acupuncture has been successfully employed to treat a variety of disorders including opioid addiction (198).

**Acute pain:** The normal, predicted physiological response to a noxious chemical, thermal, or mechanical stimulus and typically is associated with invasive procedures, trauma, and disease. Acute pain is generally time-limited. Duration of acute pain generally coincides with the time frame of normal healing, and serves to protect an injured body segment.

**Addiction:** A primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. Addiction is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction (199).

**Adverse childhood events (ACE):** This refers to childhood abuse (physical, emotional, or sexual), neglect, domestic violence, and household dysfunction. ACE is a significant risk factor for alcohol and drug abuse. There is a linear relationship between amount of ACEs and negative health outcomes (200).

**Biofeedback:** This behavioral therapy method can teach a person to gain awareness and control over physiologic processes like blood pressure, skin temperature, heart rate, and etc. via real-time feedback of said parameters to the person. Biofeedback has been used to treat a wide variety of diseases, including psychiatric disorders such as anxiety, attention-deficit hyperactivity disorder (ADHD), and substance use disorders (SUD) (201).

**Change:** To make or become different. Major life changes, such as overcoming an addiction, often occur in five stages, as follow: (1) pre-contemplation stage is when a person has not yet considered making a change; (2) contemplation stage is when a person thinks of making a change, but doesn't know how, or even if the change is worth making; (3) preparation stage is when a person becomes ready to change and makes change plans; (4) action stage occurs when people carry out their change plans; (5) and finally, the maintenance stage occurs when a person tries to make the change stick over time. Relapses sometimes occur, and can be a normal part of change. A person may relapse several times before permanent change takes hold. Research shows that skipping any one of the change stages often results in failure of change to take hold (202).

**Childhood sexual abuse (CSA):** This is a strong predictor of psychopathologies in adulthood, including a three-fold elevated risk for alcohol and drug dependence (203).

**Chronic pain:** The state in which pain persists beyond the usual course of an acute disease or healing of an injury or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

**Comorbidity:** The presence and effect of two illnesses occurring in the same person simultaneously or sequentially. For example, there is significant psychiatric comorbidity in persons with substance dependence. That is, many individuals who abuse and depend on drugs or alcohol may have an underlying psychiatric condition such as depression, bipolar disorder, post-traumatic stress disorder (PTSD), anxiety disorder, obsessive-compulsive disorder (OCD), etc. Other non-psychiatric comorbidities such as respiratory, cardiac, renal, or hepatic disease, sleep apnea, or seizures are also important in the consideration of chronic opiate therapy (204).

**Conversion:** A person is helped to see their addiction as a disorder which needs treatment. Unfortunately, so many people lose nearly everything in their lives and hit rock bottom before conversion is achieved (205).

**Counter-motivation:** Is resistance against change. The term includes the complex biological, psychological, and social factors involved with resisting a change. When asked about a making a change, a person may display counter-motivation by interrupting, ignoring, arguing, denying, daydreaming, reminiscing, etc. (206).

**Dependence or Physical dependence:** A state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction. The medical diagnosis of

**Substance dependence (SD)** is defined by any three of the following seven criteria during a 12-month period: (1) tolerance; (2) withdrawal; (3) substance often taken in larger amounts or over longer period than intended; (4) persistent desire or unsuccessful efforts to cut down or control use; (5) great deal of time spent in activities necessary to obtain, use, or recover from the substance; (6) important social, occupational, or recreational activities given up or reduced; (7) continued use despite knowledge of having persistent or recurrent physical or psychological problem likely to have been caused or exacerbated by the substance (207).

**Detoxification (Detox) or medically supervised withdrawal:** Gradual reduction, or tapering, of a medication dose over time, under the supervision of a physician, to achieve elimination of tolerance and physical dependence [109]. Detoxification may be aided by medical intervention, or occur naturally via the body's detoxification pathways. Detoxification is one of the first steps in the treatment of addiction (208).

**Discrepancy:** This can refer to the difference between current situation and future goals. A counselor may help a client develop this in order to incite a desire to change (209). For example, a person is currently unemployed, living on the

streets, and using heroin which has caused poor health. This person has wanted children and their own home since childhood, but now sees the discrepancy between current situation and future dreams. Perhaps this person will gain new motivation to change.

**Diversion:** The use of prescription drugs for recreational consumption, i.e. diverting them from their original medical purpose (210). The Federal Controlled Substances Act (CSA) establishes a closed system of distribution for drugs classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Any pharmaceutical which escapes the closed system is said to have been “diverted” and is illegal. Those people who “diverted” the drug are in violation of the law (211). Conversely, drug diversion may also refer to legal programs which educate, rehabilitate, and “divert” first-time drug offenders from jail and their original destructive life course (212).

**Guided Imagery:** This technique uses the imaginative capacity of one’s own mind to create a relaxed state or, alternatively, to overcome some troubling aspect of life. This method of therapy has been used with success as one treatment for chronic pain (213).

**High:** Abused drugs (e.g. alcohol, nicotine, some prescription medications, and opioids) raise dopamine levels in the limbic system faster, higher, and longer than any natural reward (e.g. food and sex), causing a euphoric sensation (214).

**Hypnosis:** A procedure which alters one’s state of consciousness to a mode that is more accepting of suggestion. This procedure is believed to create a way around the typical evaluative, critical, conscious mind and communicate directly with one’s subconscious. Hypnosis has been used for smoking cessation, but with conflicting results (215).

**Lapse:** A brief episode of drug use after a period of abstinence which is usually unexpected, of short duration, has relatively minor consequences, and is marked by a patient’s desire to return to abstinence. A lapse can progress into a full-blown relapse with sustained loss of control (216).

**Maintenance treatment:** Dispensing or administering an opioid medication (e.g. methadone or buprenorphine) at a stable dose over 21 days or more for the treatment of opioid addiction (217).

**Medication-assisted treatment (MAT):** Any treatment of opioid addiction that includes a medication (i.e. methadone, buprenorphine, or naltrexone) and is approved by the FDA for opioid detoxification or maintenance treatment (218)).

**Meditation:** The self-regulation of attention. During mindfulness meditation one must focus their full attention on a designated object of meditation, like one’s breath. This exercise trains the mind and provides a person with relaxation, metacognition, and the revelation of previously subconscious ideas. By focusing the mind, one can work to reduce pain and change the negative mental/emotional states involved with addiction (219).

**Misuse or non-medical use:** Incorporates all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and requirements of good medical practice (220).

**Motivation:** Complex mixture of biological, psychological, and social factors that together drive a person (221).

**Motivational interviewing:** A directive, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence (222). Ambivalence is the conflict of opposing ideas and attitudes which the client must articulate and resolve on his/her own, only guided by the counselor. For example, a client must first ask, “Am I ready to quit?” honestly and then decide within themselves which path to trod. It is the counselor’s duty to lead them to this question, guide the process, and instill within them the confidence to pursue a change.

**Neuroplasticity:** The ability of the nervous system to adjust or compensate to an injury or disease (223). Often neuroplasticity is a good thing, but with persistent pain or chronic drug/alcohol use, these changes can make matters worse, or cause new problems altogether (e.g. psychiatric disorders or opioid induced hyperalgesia).

**Opioid abuse/dependence:** Repeated use of a drug while producing problems in three or more areas over a 12-month period. Areas include tolerance, withdrawal, overdose, and use despite impending adverse consequences. The most commonly abused opioid is oxycodone from diverted prescriptions. Others include hydrocodone, morphine, meperidine, fentanyl, methadone, buprenorphine, butorphanol, tramadol and pentazocine (224).

**Opioid Treatment Program (OTP), Methadone Clinic, or Narcotic Treatment Program:** Any federally certified treatment program which provides supervised assessment and medication-assisted treatment of patients who are addicted to opioids (225).

**Pain:** An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. Pain is a complex experience embracing physical, mental, social, and behavioral processes, compromising the life of many individuals (226).

**Pseudoaddiction:** The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors of pseudoaddiction resolve upon institution of effective analgesic therapy. Addiction and pseudoaddiction can both occur in the same person (227).

**Reciprocal risk factors:** One primary condition puts you at risk for a second condition, but the second condition also can exacerbate symptoms of the first. For example, bipolar disorder puts a person at risk for developing substance abuse or addiction via cyclical mood changes. In return, substance abuse exacerbates a person's bipolar disorder – creating a destructive cycle (228).

**Recovery:** A process of change through which individuals improve health and wellness, live a self-directed life, and strive to reach full potential. Recovery must arise from hope and is person-driven. Recovery occurs via many pathways; is holistic; and must be supported by peers, allies, relationships, and social networks. Recovery is culturally-based and influenced; is supported by addressing trauma; involves individual, family, and community strengths and responsibility. Finally, recovery must be based on respect (229).

**Rehabilitation (Rehab):** Rebuilding a person's life as a whole after addiction or some other traumatic event. This process is complex and may involve a combination of changes in the biological, psychological, and social aspects of a person's life. This is often the most time intensive element of recovery and may take months to years (230).

**Relapse:** A breakdown or setback in a person's attempt to change or modify any target behavior. Relapse may also be defined as an unfolding process in which resumption of substance misuse is the last event in a long series of maladaptive responses to internal or external stressors or stimuli. Relapse may be influenced by many aspects of life including physiologic and environmental factors (231).

**Self-efficacy:** A person's belief that change is possible and that they can accomplish it (232). In general, a person must first believe that they are fully capable before they undertake a change. For example, one must have confidence and know they are strong enough to leave drugs/alcohol. During this process it is important for both counselors and clients to remember that everyone has unused potential and that everyone is capable of change.

**Self-medication:** The use of un-prescribed drugs to treat a medical problem. Self-medication is sometimes used by individuals with mental disorders to ameliorate the discomfort of their disease. However, these patients often become addicted to their medications and thus comorbidity develops (233).

**Tolerance:** A physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect. Or, a reduced effect is observed with a constant dose over time. Tolerance may, or may not, be evident during opioid treatment and does not equate with addiction. Tolerance can occur to an opioid's analgesic effects and to its unwanted side effects, i.e. sedation, and nausea (234). Physiologically, when using a drug like alcohol, nicotine, some prescription medications, or opioids, changes take place in the brain. Over time, these changes down-regulate natural dopamine production and reduce the brain's ability to respond to dopamine. An addict will perceive this relative lack of dopamine in the brain as increased tolerance, and he/she will often counter it with increased drug use (235).

**Trial period:** The period of time when medication or other treatment efficacy is tested to determine whether treatment goals can be met. If goals cannot be met, the trial is discontinued and an alternate treatment may be considered (236).

**Waiver:** Documented authorization from Secretary of Health and Human Services that exempts a qualified physician from rules applied to Opioid Treatment Programs (OTPs) and allows him/her to use buprenorphine for treating addiction in an office-based practice (237).

**Withdrawal:** If drug use is stopped abruptly, a withdrawal syndrome can occur where adaptive body responses, originally present to counter and detoxify the drug, become unopposed and often produce a painful experience for the drug user. Withdrawal is the cardinal sign of physical dependence on a drug (238).

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(Adopted May 2014)

## End-of-life responsibilities and palliative care

### 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 at the end of their lives. Licensees should be knowledgeable regarding effective and compassionate pain relief, and patients and their families should be assured such relief will be provided. 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;
- [may 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 details a 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.

\*\* Taken from the Center to Advance Palliative Care (2012) <http://www.capc.org/building-a-hospital-based-palliative-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)

## Joint Statement on Pain Management in End-of-Life Care

(Adopted by the North Carolina Medical, Nursing, and Pharmacy Boards)

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

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

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

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

With regard to pharmacy practice, North Carolina has no quantity restrictions on dispensing controlled substances including those in Schedule II. This is significant when utilizing the federal rule that allows the partial filling of Schedule II prescriptions for up to 60 days. In these situations it would minimize expenses and unnecessary waste of drugs if the prescriber would note on the prescription that the patient is terminally ill and specify the largest anticipated quantity that could be needed for the next two months. The pharmacist could then dispense smaller quantities of the prescription to meet the patient's needs up to the total quantity authorized. Government-approved labeling for dosage level and frequency can be useful as guidance for patient care. Health professionals may, on occasion, determine that higher levels are justified in specific cases. However, these occasions would be exceptions to general practice and would need to be properly documented to establish informed consent of the patient and family.

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

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

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

- thorough documentation of all aspects of the patient's assessment and care;
- a working diagnosis and therapeutic treatment plan including pharmacologic and non-pharmacologic interventions;

- regular and documented evaluation of response to the interventions and, as appropriate, revisions to the treatment plan;
- evidence of communication among care providers;
- education of the patient and family; and
- a clear understanding by the patient, the family and healthcare team of the treatment goals.

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

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

## Office-based procedures

### Preface

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

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

### General Guidelines

#### The Physician's Professional and Legal Obligation

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

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

#### Exemptions

These guidelines do not apply to Level I procedures.

#### Written Policies and Procedures

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

#### Emergency Procedure and Transfer Protocol

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

All office personnel should be familiar with and capable of carrying out written emergency instructions. The instructions should be followed in the event of an emergency, any untoward anesthetic, medical or surgical complications, or other conditions making hospitalization of a patient necessary. The instructions should include arrangements for immediate contact of emergency medical services when indicated and when advanced cardiac life support is needed. When emergency medical services are not indicated, the instructions should include procedures for timely escort of the patient to the hospital or to an appropriate practitioner.

#### Infection Control

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

#### Performance Improvement

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

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

### **Medical Records and Informed Consent**

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

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

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

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

### **Credentialing of Physicians**

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

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

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

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

### **Accreditation**

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

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

**Patient Selection**

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

**ASA Physical Status Classifications**

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

**Candidates for Level II Procedures**

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

**Candidates for Level III Procedures**

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

**Surgical or Special Procedure Guidelines****Patient Preparation**

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

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

The physician performing the surgical or special procedure also should:

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

**Discharge Criteria**

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

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

**Information to the Patient**

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

1. the procedure performed;
2. information about potential complications;

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

### **Reportable Complications**

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

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

### **Equipment Maintenance**

All anesthesia-related equipment and monitors should be maintained to current operating room standards. All devices should have regular service/maintenance checks at least annually or per manufacturer recommendations.

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

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

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

### **Compliance with Relevant Health Laws**

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

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

### **Patient Rights**

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

### **Enforcement**

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

## **Level II Guidelines**

### **Personnel**

The physician who performs the surgical or special procedure or a health care professional who is present during the intraoperative and postoperative periods should be ACLS certified, and at least one other health care professional should

be BCLS certified. In an office where anesthesia services are provided to infants and children, personnel should be appropriately trained to handle pediatric emergencies (*i.e.*, APLS or PALS certified).

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

### **Surgical or Special Procedure Guidelines**

#### **Intraoperative Care and Monitoring**

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

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

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

#### **Postoperative Care and Monitoring**

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

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

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

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

#### **Equipment and Supplies**

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

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

14. IV solution and IV equipment.

### Level III Guidelines

#### Personnel

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

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

### Surgical or Special Procedure Guidelines

#### Intraoperative Monitoring

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

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

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

#### Postoperative Care and Monitoring

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

Care of the patient may then be transferred to the care of a qualified health care professional in the recovery area. Qualified health care professionals capable of administering medications as required for analgesia, nausea/vomiting, or other indications should monitor the patient postoperatively.

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

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

#### Equipment and Supplies

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

1. full and current crash cart at the location where the anesthetizing is being carried out (the crash cart inventory should include appropriate resuscitative equipment and medications for surgical, procedural or anesthetic complications);

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

## Definitions

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

AAAHHC – the Accreditation Association for Ambulatory Health Care

ABMS – the American Board of Medical Specialties

ACGME – the Accreditation Council for Graduate Medical Education

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

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

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

Anesthesia provider – an anesthesiologist or CRNA.

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

AOA – the American Osteopathic Association

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

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

ASA – the American Society of Anesthesiologists

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

Board – the North Carolina Medical Board.

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

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

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

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

FDA – the Food and Drug Administration.

General anesthesia – a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

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

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

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

Immediately available – within the office.

JCAHO – the Joint Commission for the Accreditation of Health Organizations

Level I procedures – any surgical or special procedures:

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

Level II procedures – any surgical or special procedures:

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

Level III procedures – any surgical or special procedures:

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

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

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

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

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

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

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

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

OSHA – the Occupational Safety and Health Administration.

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

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

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

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

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

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

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

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

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

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

(Adopted September 2011) (Amended January 2003, May 2011) 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 FAQs](#).

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

### **Care of patient undergoing surgery 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 control - health care settings**

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

(1) "Health care organization" means hospital; clinic; physician, dentist, podiatrist, optometrist, or chiropractic office; home health agency; nursing home; local health department; community health center; mental health agency; hospice; ambulatory surgical center; urgent care center; emergency room; or any other health care provider that provides clinical care.

(2) "Invasive procedure" means entry into tissues, cavities, or organs or repair of traumatic injuries. The term includes the use of needles to puncture skin, vaginal and cesarean deliveries, surgery, and dental procedures during which bleeding occurs or the potential for bleeding exists.

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

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

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

(e) In order to prevent transmission of HIV and hepatitis B from health care workers to patients, each health care organization that performs invasive procedures shall implement a written infection control policy. The health care organization shall ensure that health care workers in its employ or who have staff privileges are trained in the principles of infection control and the practices required by the policy; require and monitor compliance with the policy; and update the policy as needed to prevent transmission of HIV and hepatitis B from health care workers to patients. The health care organization shall designate a staff member to direct these activities. The designated staff member in each health care organization shall complete a course in infection control approved by the Department. The course shall address:

(1) Epidemiologic principles of infectious disease;

(2) Principles and practice of asepsis;

(3) Sterilization, disinfection, and sanitation;

(4) Universal blood and body fluid precautions;

(5) Engineering controls to reduce the risk of sharp injuries;

(6) Disposal of sharps; and

(7) Techniques that reduce the risk of sharp injuries to health care workers.

(f) The infection control policy required by this Rule shall address the following components that are necessary to prevent transmission of HIV and hepatitis B from infected health care workers to patients:

(1) Sterilization and disinfection, including a schedule for maintenance and microbiologic monitoring of equipment; the policy shall require documentation of maintenance and monitoring;

(2) Sanitation of rooms and equipment, including cleaning procedures, agents, and schedules;

(3) Accessibility of infection control devices and supplies;

(4) Procedures to be followed in implementing 10A NCAC 41A .0202(4) and .0203(b)(4) when a health care provider or a patient has an exposure to blood or other body fluids of another person in a manner that poses a significant risk of transmission of HIV or hepatitis B.

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

### **10A NCAC 41A .0207: HIV and hepatitis B infected health care workers**

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

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

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

(b) All health care workers who perform surgical or obstetrical procedures or dental procedures and who know themselves to be infected with HIV or hepatitis B shall notify the State Health Director. Health care workers who assist in these procedures in a manner that may result in exposure of patients to their blood and who know themselves to be

infected with HIV or hepatitis B shall also notify the State Health Director. The notification shall be made in writing to the Chief, Communicable Disease Control Branch, 1902 Mail Service Center, Raleigh, NC 27699-1902..

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

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

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

- (1) Restrictions that are necessary to prevent transmission from the infected health care worker to patients;
- (2) Identification of patients that have been exposed to a significant risk of transmission of HIV or hepatitis B; and
- (3) Periodic review of the clinical condition and practice of the infected health care worker.

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

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

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

(i) An infected health care worker who has been evaluated by the State Health Director shall notify the State Health Director prior to a change in practice involving surgical or obstetrical procedures or dental procedures. The infected health care worker shall not make the proposed change without approval from the State Health Director. If the State Health Director makes a determination in accordance with Paragraph (c) of this Rule that there is a significant risk of transmission of HIV or hepatitis B to patients, the State Health Director shall appoint an expert panel in accordance with Paragraph (d) of this Rule. Otherwise, the State Health Director shall notify the health care worker that he or she may make the proposed change in practice.

(j) If practice restrictions are imposed on a licensed health care worker, a copy of the isolation order shall be provided to the appropriate licensure board. The State Health Director shall report violations of the isolation order to the appropriate licensure board. The licensure board shall report to the State Health Director any information about the infected health care worker that may be relevant to the risk of transmission of HIV or hepatitis B to patients.

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

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

## 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:

1. the organization requires satisfactory completion of a training program with training, documentation and clinical requirements similar in scope and complexity to ACGME- or AOA-approved programs, in the specialty or subspecialty field of medicine in which the physician seeks certification. Solely experiential or on-the-job training is not sufficient;
2. 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;
3. the organization requires diplomates to recertify every ten years or less, and the recertification requires, at a minimum, passage of a written examination;
4. the organization prohibits all certification and recertification candidates from attempting more than three times in three years to pass the examination;
5. 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;
6. 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
7. 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)

### **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)

## **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 patient-physician 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)

**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)

### **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)

## **Competence and re-entry to the active and re-entry to the active practice of medicine**

The ability to practice medicine results from a complex interaction of knowledge, physical skills, judgment, and character tempered by experience leading to competence. Maintenance of competence requires a commitment to lifelong learning and the continuous practice of medicine, in whatever field one has chosen. Absence from the active practice of medicine leads to the attenuation of the ability to practice competently.

It is the position of the North Carolina Medical Board, in accord with GS 90-6(a), that practitioners seeking licensure, or reactivation of a North Carolina medical license, who have had an interruption, for whatever reason, in the continuous practice of medicine greater than two (2) years must reestablish, to the Board's satisfaction, their competence to practice medicine safely.

Any such applicant must meet all the requirements for and completion of a regular license application. In addition, full-scale assessments, engagement in formal training programs, supervised practice arrangements, formal testing, or other proofs of competence may be required.

The Board will cooperate with appropriate entities in the development of programs and resources that can be used to fulfill the above requirements, including the issuance, when necessary and appropriate, of a time or location limited and/or restricted license (e.g., residency training license).

It shall be the responsibility of the applicant to develop a reentry program subject to the approval of the Board.

(Adopted July 2006)

## Capital punishment

In *North Carolina Dept. 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.” Consistent with the Supreme Court’s ruling, 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 Opinion 2.06 (printed below) as an accurate statement of the professional ethics of physician participation in executions.

### **Relevant Provisions of AMA Code of Medical Ethics Opinion 2.06**

An individual’s opinion on capital punishment is the personal moral decision of the individual. A physician, as a member of a profession dedicated to preserving life when there is hope of doing so, should not be a participant in a legally authorized execution. Physician participation in execution is defined generally as actions which would fall into one or more of the following categories: (1) an action which would directly cause the death of the condemned; (2) an action which would assist, supervise or contribute to the ability of another individual to directly cause the death of the condemned; (3) an action which could automatically cause an execution to be carried out on a condemned prisoner.

Physician participation in an execution includes, but is not limited to, the following actions: prescribing or administering tranquilizers and other psychotropic agents and medications that are part of the execution procedure; monitoring vital signs on site or remotely (including monitoring electrocardiograms); attending or observing an execution as a physician; and rendering of technical advice regarding execution.

In the case where the method of execution is lethal injection, the following actions by the physician would also constitute physician participation in execution: selecting injection sites; starting intravenous lines as a port for a lethal injection device; prescribing, preparing, administering, or supervising injection drugs or their doses or types; inspecting, testing, or maintaining lethal injection devices; and consulting with or supervising lethal injection personnel.

The following actions do not constitute physician participation in execution: (1) testifying as to medical history and diagnoses or mental state as they relate to competence to stand trial, testifying as to relevant medical evidence during trial, testifying as to medical aspects of aggravating or mitigating circumstances during the penalty phase of a capital case, or testifying as to medical diagnoses as they relate to the legal assessment of competence for execution; (2) certifying death, provided that the condemned has been declared dead by another person; (3) witnessing an execution in a totally nonprofessional capacity; (4) witnessing an execution at the specific voluntary request of the condemned person, provided that the physician observes the execution in a nonprofessional capacity; and (5) relieving the acute suffering of a condemned person while awaiting execution, including providing tranquilizers at the specific voluntary request of the condemned person to help relieve pain or anxiety in anticipation of the execution.

(Adopted January 2007) (Amended July 2009) (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.<sup>1</sup> 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)(Revised November 2015)

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<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 prevention of drug overdoses is consistent with the Board's statutory mission to protect the people of North Carolina. 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.

(Adopted September 2008) (Amended March 2013)

## 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 9.07 entitled “Medical Testimony.” In addition to AMA Ethics Opinion 9.07, 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 9.07 provides:*

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

When a legal claim pertains to a patient the physician has treated, the physician must hold the patient’s medical interests paramount, including the confidentiality of the patient’s health information, unless the physician is authorized or legally compelled to disclose the information.

Physicians who serve as fact witnesses must deliver honest testimony. This requires that they engage in continuous self-examination to ensure that their testimony represents the facts of the case. When treating physicians are called upon to testify in matters that could adversely impact their patients’ medical interests, they should decline to testify unless the patient consents or unless ordered to do so by legally constituted authority. If, as a result of legal proceedings, the patient and the physician are placed in adversarial positions it may be appropriate for a treating physician to transfer the care of the patient to another physician.

When physicians choose to provide expert testimony, they should have recent and substantive experience or knowledge in the area in which they testify, and be committed to evaluating cases objectively and to providing an independent opinion. Their testimony should reflect current scientific thought and standards of care that have gained acceptance among peers in the relevant field. If a medical witness knowingly provides testimony based on a theory not widely accepted in the profession, the witness should characterize the theory as such. Also, testimony pertinent to a standard of care must consider standards that prevailed at the time the event under review occurred.

All physicians must accurately represent their qualifications and must testify honestly. Physician testimony must not be influenced by financial compensation; for example, it is unethical for a physician to accept compensation that is contingent upon the outcome of litigation.

Organized medicine, including state and specialty societies, and medical licensing boards can help maintain high standards for medical witnesses by assessing claims of false or misleading testimony and issuing disciplinary sanctions as appropriate. (II, IV, V, VII) Issued December 2004 based on the report “Medical Testimony,” adopted June 2004.

(Adopted March 2008) (Revised: September 2012)

## **Collaborative care 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. The Accreditation Council for Graduate Medical Education highlights the importance of interpersonal/communication skills and professionalism as two of the six core competencies required for graduation from residency. 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 with physicians, hospital personnel, patients, family members, or others that interferes with patient care. Behaviors such as foul language; rude, loud or offensive comments; and intimidation of staff, patients and family members are commonly recognized as detrimental to patient care. Furthermore, it has become apparent that disruptive behavior is often a marker for concerns that can range from a lack of interpersonal skills to deeper problems, such as depression or substance abuse. As a result, disruptive behavior may reach a threshold such that it constitutes grounds for further inquiry by the Board into the potential underlying causes of such behavior. Behavior by a licensee that is disruptive could be grounds for Board discipline.

The Board distinguishes disruptive behavior from constructive criticism that is offered in a professional manner with the aim of improving patient care. The Board also reminds its licensees of their responsibility not only to patients, but also to themselves. Symptoms of stress, such as exhaustion and depression, can negatively affect a licensee's health and performance. Licensees suffering such symptoms are encouraged to seek the support needed to help them regain their equilibrium.

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 this process when appropriate.

(Adopted January 2010)

## 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 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 potentially useful tool 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 reduced cost of patient care.

The Board cautions, however, that licensees practicing via telemedicine will be held to the same standard of care as licensees employing more traditional in-person medical care. A failure to conform to the appropriate standard of care, whether that care is rendered in-person or via telemedicine, may subject the licensee to potential discipline by this Board. It is the Board’s position that there is not a separate standard of care applicable to telemedicine. Telemedicine providers will be evaluated according to the standard of care applicable to their area of specialty. Additionally, telemedicine providers are expected to adhere to current standards for practice improvement and monitoring of outcomes

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 telemedicine equipment and competent in its operation.

**Evaluations and Examinations**— Licensees using telemedicine technologies to provide care to patients located in North Carolina must provide 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.

Other evaluations may also be considered appropriate if the licensee is at a distance from the patient, but a licensed health care professional is able to provide various physical findings that the licensee needs to complete an adequate assessment. 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.<sup>2</sup>

**Licensee-Patient Relationship**—The Board stresses the importance of proper patient identification in the context of the 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 and should be prepared to inform the patient of the licensee’s name, location and professional credentials. A diagnosis should be established through the use of accepted medical practices, i.e., a patient history, mental status evaluation, physical examination and appropriate diagnostic and laboratory testing. 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 prescribing controlled substances for the treatment of pain by means of telemedicine is not consistent with the stand of care. Licensees prescribing controlled substances by means of telemedicine for other conditions should obey all relevant federal and state laws and are expected to participate in the Controlled Substances Reporting System.<sup>3</sup>

**Medical Records**— The licensee treating a patient via telemedicine must maintain a complete record of the telemedicine patient’s care according to prevailing medical record standards. The medical record serves to document the analysis and plan of an episode of care for future reference. It must reflect an appropriate evaluation of the patient’s presenting symptoms, and relevant components of the electronic professional interaction must be documented as with any other encounter.

The licensee must maintain the record’s confidentiality and disclose the records to the patient 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 record constitute one complete patient record. Licensees

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<sup>2</sup> See also the Board’s Position Statement entitled “Contact with Patients before Prescribing.”

<sup>3</sup> See Ryan Haight Act

practicing via telemedicine will be held to the same standards of professionalism concerning medical records transfer and communication with the primary care provider and medical home as those licensees practicing via traditional means.

**Licensure** — The practice of medicine is deemed to occur in the state in which 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.<sup>4</sup> Licensees need not reside in North Carolina, as long as 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 to 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](http://www.fsmb.org/directory_smb.html).

(Adopted July 2010)

(Revised November 2014)

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<sup>4</sup> N.C. Gen. Stat. § 90-18(c)(11) exempts from the requirement for licensure: “The practice of medicine or surgery by any nonregistered reputable physician or surgeon who comes into this State, either in person or by use of any electronic or other mediums, on an irregular basis, to consult with a resident registered physician or to consult with personnel at a medical school about educational or medical training. This proviso shall not apply to physicians resident in a neighboring state and regularly practicing in this State.”

The Board also notes that the North Carolina General Statutes define the practice of medicine as including, “The performance of any act, within or without this State, described in this subdivision by use of any electronic or other means, including the Internet or telephone.” N.C. Gen. Stat. § 90-1.1(5)

### **Physician scope of practice**

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

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

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

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

(Adopted March 2011)

### **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.
- 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://www.ncmedboard.org/articles/detail/practicing\\_medicine\\_in\\_the\\_facebook\\_age\\_maintaining\\_professionalism\\_online](http://www.ncmedboard.org/articles/detail/practicing_medicine_in_the_facebook_age_maintaining_professionalism_online).

(Adopted March 2013)

## 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.G.S. § 90-21.20(c1).<sup>5</sup> This legal and ethical obligation requires a licensee to recognize the signs, symptoms, and etiology of child maltreatment.<sup>6</sup> Licensees are also encouraged to learn how to refer children for expert medical evaluations of possible maltreatment.

(Adopted September 2014)

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<sup>5</sup> 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 G.S. 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.G.S. § 7B-301(a).

<sup>6</sup> Web-based training on "Recognizing and Responding to Suspicions of Child Maltreatment" is available at <http://www.preventchildabusenc.org/services/trainings-and-professional-development/rrcourse>

## **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 profit-making 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 non-profit 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)