

# **Position Statements North Carolina Medical Board**

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#### 1: Introduction

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

The North Carolina Medical Board's ("Board") 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 licensed in North Carolina. They also are intended to 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 the 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 during a disciplinary hearing whether or not the issues have been the subject of a position statement. The Board intends that the position statements will reflect the Board's 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.

(Adopted: November 1999) (Amended: January 2021)

#### 2.1.1: The Licensee-Patient Relationship

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

#### A. Elements of the Licensee-Patient Relationship

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

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

- There be appropriate professional communication between the licensee and the patient;
- The licensee timely report all significant findings to the patient or the patient's legally designated representative;
- Conflicts of interest be resolved to the benefit of the patient;
- Personal details of the patient's life shared with the licensee are held in confidence;
- The licensee maintain competence, professional knowledge, and skills;
- There is respect for the patient's autonomy;
- The licensee maintains a compassionate and professional demeanor;
- The licensee respect the patient's right to request restrictions on medical information disclosure;
- The licensee be an advocate for appropriate medical care;
- Patient advocacy remains unaltered by the healthcare setting; and
- The licensee 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 licensee-patient relationship, founded on patient trust and fostered by professional communication, patient primacy, confidentiality, competence, patient autonomy, compassion, and appropriate care are foremost considerations of licensees.

#### **B.** Termination of the Licensee-Patient Relationship

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

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

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

(Adopted: July 1995) (Amended: July 1998; January 2000; March 2002; August 2003; September 2006; July 2012; September 2016; January 2021)

#### 2.1: Responsibilities of Licensees & Patients

#### 2.1.2: Departures from or Closings of Medical Practices

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

- Patients are notified in a timely fashion of changes in the practice and given the opportunity to seek other medical care, sufficiently far in advance (at least 30 days), to allow other medical care to be secured. The Board does not have specific rules on which patients should receive this notification or how it should be accomplished, but a reasonable option would be to notify active patients the licensee has seen within the past 1-2 years. Methods of notification which might be considered include, letters to patients, newspaper notices, posting an announcement in public locations in the office, website announcements, front desk flyers, etc. Each medical practice and patient population is unique and the Board would expect the licensee and the group or employer to utilize the most effective means of patient notification for their particular situation.
- Patients clearly understand they have a choice of health care providers and notice to patients of the departing licensee should include an unambiguous statement that patients may choose from whom to receive medical care. It is unethical to take any actions such as withholding information regarding the new practice location of the licensee when requested by a patient. Both the licensee and any relevant practice group or employer are responsible for notifying patients, and no party should interfere in the discharge of this obligation by withholding essential information.
- Patients are told both how to contact licensee(s) remaining in practice, and when specifically requested, how to contact departing licensees.
- Patients are told how to obtain copies of, or transfer, their medical records.

#### Written Policies:

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

- A procedure and timeline that describes how the licensee or practice will notify each patient about (1) a pending practice closure or licensee departure, (2) how medical records are to be accessed, and (3) how future notices of the location of the practice's medical records will be provided.
- How long medical records will be retained and the procedure by which the licensee or practice will dispose of unclaimed medical records.
- How the licensee or practice will respond to requests from patients for copies of or access to their medical records.
- In the event of a licensee's death or incapacity, how the deceased licensee's executor, administrator, personal representative, or survivor will notify patients of the location of their medical records, how patients can access those records, and how and when unclaimed medical records will be destroyed after a specified period of time.
- The procedure by which the licensee or practice will maintain medical record confidentiality and data integrity. Practice transitions are also times when there is increased risk of privacy breaches or inappropriate disclosure. HIPAA and other privacy rules require that patients must be promptly informed about any security breach or unauthorized disclosure describing what information was breached, and what steps patients may take to minimize adverse consequences of inappropriate disclosure of their personal health information.

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

**Additional Resources:** The Board has published "A Physicians Guide to Closing a Practice" to assist licensees with meeting professional obligations.

(Adopted: January 2000) (Amended: August 2003; July 2009; March 2018; January 2021)

#### 2.1.3: The Retired Physician/Licensee

The retirement of a licensee is defined by the 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 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)

#### 2.1.4: Availability of Licensees to Their Patients

It is the position of the 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 or when the licensee is otherwise out of office.

If the licensee is not going to be available after hours or otherwise out of office it is the responsibility of the licensee to ensure that the patient has sufficient information regarding how to secure 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; January 2021)

#### 2.2.1: Sexual Misconduct Involving Patients

The privileges statutorily granted to all licensees by the Board puts them in a position of power in relation to the patient. The patient enters the therapeutic relationship from a position of vulnerability due to illness, suffering, the need to divulge deeply personal information, and to subject themselves to intimate physical examination. This vulnerability is further heightened in light of the patient's trust in the licensee, who has demonstrated the training, knowledge, and character to be granted the privilege and the power to deliver medical care. Due to the nature of their intimate involvement with patients, surrogates<sup>1</sup> are hereinafter included in the term "patient" for the purpose of this policy. It is the position of the Board that sexual misconduct involving a patient or a surrogate by a licensee 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 Physician Sexual Misconduct ("FSMB Guidelines").

For the purposes of this policy, licensee sexual misconduct is understood as behavior that exploits the licensee-patient relationship in a sexual way. Sexual misconduct between a licensee and a patient is never diagnostic or therapeutic. Sexual misconduct may be verbal or physical, can occur in person or virtually, and may include expressions of thoughts and feelings or gestures that are of a sexual nature or that reasonably may be construed by the patient as sexual.

Sexual misconduct occurs along a continuum of escalating severity. This continuum comprises a variety of behaviors, sometimes beginning with "grooming" behaviors which may not seem to constitute sexual misconduct on their own, but are precursors to other, more severe violations such as sexual misconduct involving language, gestures, or physical touching. Grooming behaviors may include gift-giving, special treatment, sharing of personal information, or other acts or expressions that are meant to gain a patient's trust and acquiescence to subsequent abuse. When the patient is a child, adolescent, or teenager, the patient's parents may also be groomed to gauge whether an opportunity for sexual abuse exists. All types of sexual misconduct could constitute a basis for disciplinary action by the Board.

More severe forms of sexual misconduct include sexually inappropriate or improper gestures or language that are seductive, sexually suggestive, disrespectful of patient privacy, or sexually demeaning to a patient. These may not necessarily involve physical contact, but can have the effect of embarrassing, shaming, humiliating, or demeaning the patient. Instances of such sexual misconduct can take place in person, online, by mail, by phone, and through texting. Examples may include, but are not limited to:

<sup>&</sup>lt;sup>1</sup>For the purposes of this policy "surrogate" is defined as spouses or partners, parents, guardians, or others involved in the care of and/or decision-making for the patient.

#### 2: Patient-Licensee Relationships

#### 2.2: Special Issues in Patient-Licensee Relationships

- 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 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 genitals/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, or making comments about potential sexual performance during an examination;
- 5. Using the licensee-patient relationship to solicit a date or romantic relationship;
- 6. Initiation by the licensee of conversation regarding the sexual problems, preferences, or fantasies of the licensee;
- 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.

The severity of sexual misconduct increases when physical contact takes place between a licensee and patient and is explicitly sexual or may be reasonably interpreted as sexual, even if initiated by a patient. Examples of physical sexual misconduct between a licensee and a patient includes, but is not limited to the following:

- 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 licensee or masturbation by the licensee while the patient is present (including in person, online, by phone, or through texting); and
- 7. Offering to provide practice-related services, such as drugs, in exchange for sexual favors.

Sexual misconduct may still occur following the termination of a licensee-patient relationship, especially in relationships that involve a high degree of emotional dependence and vulnerability. Termination of a licensee-patient relationship solely for the purpose of allowing sexual contact to occur is unacceptable and would still constitute sexual misconduct.

Licensees have the legal and ethical duty to report instances of sexual misconduct, instances of potential grooming behaviors, and other serious patient safety issues and events. Early reporting of sexual misconduct will prevent a licensee's sexual misconduct from impacting more patients.

The Board also refers licensees to the Board's Position Statement entitled "<u>Guidelines for</u> <u>Avoiding Misunderstandings During Patient Encounters and Physical Examinations</u>."

(Adopted: May 1991) (Amended: April 2012; March 2016; January 2021; March 2022)

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

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

- Licensees should recognize that misunderstandings regarding boundaries may occur at any time during a patient encounter, but particularly during disclosure of private information by the patient about symptoms, prior personal experiences, or during the physical examination. The licensee should maintain a professional demeanor at all times. While some licensees have adopted a more informal approach to patient interactions, such as use of first names for both patients and the licensee, this may blur boundaries and result in later misunderstandings.
- Sensitivity to patient modesty and dignity must be maintained at all times. The patient should be assured of adequate privacy and should never be asked to disrobe in the presence of the licensee. Examining rooms should be well maintained and equipped with appropriate furniture and supplies for examination and treatment. Gowns, sheets, and/or other appropriate apparel should be made available to the patient.
- Regardless of the patient's gender, a third-party chaperone, possibly a staff member, should be readily available at all times during a physical examination, and it is strongly advised that a third party be present when the licensee performs an examination of the breasts, genitalia, or rectum. It is the licensee's responsibility to have a staff member available at any point during the examination. If no chaperone is available, the patient should be clearly advised of what will occur during the examination and provide verbal informed consent for an unchaperoned examination.
- The licensee should individualize the approach to physical examinations so that each patient's sense of vulnerability, apprehension, fear, and embarrassment are diminished to the extent possible. An explanation of the necessity of a complete physical examination, the components of that examination, and the purpose of disrobing may be necessary in order to minimize the patient's apprehension.
- The licensee and staff should exercise the same degree of professionalism and care when performing diagnostic procedures (e.g., electrocardiograms, electromyograms, endoscopic procedures, and radiological studies, etc.), as well as during surgical procedures and postsurgical follow-up examinations when the patient is in varying stages of consciousness.

#### 2: Patient-Licensee Relationships 2.2: Special Issues in Patient-Licensee Relationships

- Sexual impropriety by the licensee may include behavior, gestures, comments, or expressions that are seductive, sexually suggestive, disrespectful of patient privacy, or sexually demeaning to a patient, and may include, but are not limited to:
  - Neglecting to employ disrobing or draping practices that respect patient privacy or deliberately watching a patient dress or undress.
  - Subjecting a patient to an intimate examination in the presence of students or other persons without the patient's consent.
  - Examination or touching of genitals/genital mucosal areas without the use of gloves.
  - Unprofessional comments made at any time during the encounter about or to the patient, including making sexual comments about a patient's appearance, body, or clothing or offering demeaning observations about the patient or others.
  - Using a licensee-patient encounter to solicit a date or romantic relationship.
  - Conversations or comments regarding the sexual problems, preferences, or fantasies of the licensee.
  - Performing an examination without clinical justification or without explaining to the patient the need for such examination.
  - Requesting details of the patient's sexual history or sexual preferences when not clinically indicated.
- The licensee should also be alert for suggestive or flirtatious behavior or mannerisms on the part of the patient and should not permit a compromising situation to develop.

(Adopted: May 1991) (Amended: May 1993; May 1996; January 2001; February 2001; October 2002; July 2010; November 2017; March 2019; January 2021)

#### 2.2.3: Self-Treatment and Treatment of Family Members

Rules 21 NCAC 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 licensee 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 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; January 2021)

#### 3.1.1: Professional Use of Social Media

The Board recognizes that social media has increasing relevance to professionals and supports its responsible use. However, licensed health care professionals 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 licensees to consider the implications of their online activities including, but not limited to, the following:

- Licensees must understand that the code of conduct that governs their face to face encounters with patients also extends to online activity. As such, licensees interacting with patients online must maintain appropriate boundaries in accordance with professional ethical guidelines, just as they would in any other context.
- Licensees have an absolute obligation to maintain patient privacy and must refrain from posting identifiable patient information online regardless of the practice location or circumstance, i.e. volunteer services or services provided abroad.
- A licensee's publicly available online content directly reflects on his or her professionalism. It is advisable that licensees separate their professional and personal identities online (i.e. 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 profane, 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 Federation of State Medical Boards' policy on "Social Media and Electronic Communications." Further discussion of this issue by the Board's Office of the Medical Director can be found here.

(Adopted: September 2008) (Amended: March 2013; January 2017; March 2021)

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

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

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

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

(Adopted: July 2017) (Amended: March 2021)

## **3.2.1:** MEDICAL RECORDS – Documentation, Electronic Health Records, Access, and Retention

#### Documentation

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

The medical record is a chronological document that:

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

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

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

Licensees are also encouraged to include patient learning needs, barriers to care, and other factors as part of the medical record.

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

• Each page in the medical record contains the patient's name or ID number.

### **3:** Privacy, Confidentiality, & Medical Records **3.2:** Medical Records

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

#### **Electronic Health Records**

The Board recognizes and encourages the trend towards the use of electronic health records ("EHR"). The promise and potential of information technology in health care, particularly the use of EHR presents licensees with distinct challenges. While the Board encourages the adoption and appropriate use of various forms of EHR, there are some unique aspects and problems associated with EHR that have been repeatedly encountered by the Board, some of which are discussed below. This subsection is meant to identify issues which the Board has repeatedly found to be problematic in malpractice and complaint cases coming to the Board's attention. Basic, well-established principles of medical record documentation, as outlined above, apply to all forms of medical record documentation, including EHR.

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

- *EHR Deficiencies*. Licensees must be aware of the idiosyncrasies and weaknesses of the EHR system they are using and adjust their practice accordingly. Licensees are ultimately responsible for the adequacy of their EHR entries and documentation.
- *Responsibility of Licensees*. Licensees remain responsible for clinical decision making. EHR are becoming increasing sophisticated and may provide flags for follow-up care or other clinical decision-making support, such as health maintenance recommendations. While an EHR system may assist in the clinical decision-making process, it is not responsible for decision making. For example, it is not acceptable to blame an EHR because it failed to recommend particular testing. Increasingly elaborate documentation, clinical management, and productivity tools may also result in increased opportunities for errors or

omissions. These errors are a failure of the licensee to assume appropriate responsibility for the care of the patient. In the end, decision-making responsibility rests solely with the licensee; regardless of the information or notices provided by the EHR.

- Use of Templates. The Board cautions against overuse of template content or reliance on EHR software which pre-populates, carries forward, or clones information from one encounter to the next, or from different licensees, without the licensee carefully reviewing and updating all information. Documentation of clinical findings for each patient encounter must accurately and contemporaneously reflect the actual care provided. The use of "copy-and-paste" should only be employed in circumstances when the totality of copied material from prior interactions is pertinent to the current situation.
- Availability of, or Access to, EHR. Licensees must be able to provide patient medical records in a timely manner for various situations, such as consultations, transfer of care to another licensee, or practice closure. The Board has encountered situations where licensees were unable to access their patients' medical records due to fee or other disputes with the EHR vendor. This is particularly true when the medical records are maintained off site (cloud storage). Licensees must understand provisions of their contract with the EHR vendor in this regard. These principles of medical record access apply as well to telemedicine licensees.
- *Breakdown of Patient-Licensee Communication*. Misunderstandings and miscommunications between patients, patient family members, licensed health care professionals, and office staff generate a substantial percentage of complaints received by the Board. Many EHR systems allow direct licensee-patient communication (i.e. "patient portal"). While this form of communication can facilitate communication, such as follow-up of lab or x-ray results or medication refills, they also place a responsibility on the licensee to provide timely responses to legitimate requests from patients for feedback or information.
- *Employed Licensees and Independent Contractors*. The Board recommends all employed licensees/independent contractors review their employment agreements regarding ownership of the EHR. There should be explicit provisions which set forth the rights and duties of the practice and the licensee upon termination of employment, with regards to notification of patients and access to medical records.

#### Access to Medical Records

A licensee's policies and practices relating to medical records under his or her control should be designed to benefit the health and welfare of patients, whether current or past, and should facilitate the transfer of clear and reliable information about a patient's care. Such policies and practices should conform to applicable federal and state laws governing health information. It is the position of the Board that notes made by a licensee in the course of diagnosing and treating patients are primarily for the licensee's use and to promote continuity of care. Patients, however, have a substantial right of access to their medical records and a qualified right to amend their medical records pursuant to HIPAA privacy regulations.

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

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

Licensees may charge a reasonable fee for the preparation and/or the photocopying of medical records, keeping in mind that state law limits fees a licensee can charge for copies of medical records in certain cases, including liability claims for personal injury, social security disability claims, and workers' compensation claims. To assist in avoiding misunderstandings, and for a reasonable fee, the licensee should be willing to review the medical records with the patient at the patient's request. Medical records should not be withheld because an account is overdue or a bill is owed (including charges for copies or summaries of medical records).

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

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

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

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

#### **Retention of Medical Records**

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

Other Considerations and Board Expectations:

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

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

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

(Adopted: July 2018) (Replaced Medical Record Documentation; Access to Medical Records; and Retention of Medical Records) (Amended: March 2021)

#### 4.1.1: Contact with Patients Before Prescribing

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

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

Prescribing for an individual whom the licensee has not met or personally examined may also be suitable when that individual is the partner of a patient whom the licensee is treating for certain publicly reported infectious diseases, including sexually transmitted infections, most commonly gonorrhea and chlamydia. Partner management of patients with these conditions should be consistent with the applicable standard of care and include the following items:

- Signed prescriptions of medication 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.

#### 4: Prescribing

• 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 tollfree telephone prescribing, is inappropriate and unprofessional.

(Adopted: November 1999) (Amended: February 2001; November 2009; May 2013; November 2014; March 2015; July 2015; March 2021)

#### 4.1.2: Writing of Prescriptions

The writing of prescriptions should follow these general guidelines.

- No prescription should be issued for a patient in the absence of a documented and established licensee-patient relationship. A licensee-patient relationship should be based on an appropriate history and physical examination in addition to overall care that is consistent with the standards of acceptable and prevailing medical practice. Limited exceptions for prescribing outside an established licensee-patient relationship are specified in the Board's Position Statement titled "Contact with Patients Before Prescribing."
- Prescriptions written by licensees for their personal or family use should comply with the Board's position statement on "Self-Treatment and Treatment of Family Members." As noted in that position statement and contained in the Board's regulations, it is prohibited for licensees to write prescriptions for controlled substances for themselves, their family members, or persons with whom they are living or in a sexual relationship.
- The practice of pre-signing prescriptions, either written or electronic, is unacceptable.
- It is the responsibility of licensees who prescribe controlled substances to be aware of and fully comply with applicable federal and state laws and regulations, including evolving standards and regulations regarding e-prescribing.
- The prescriber should document each medication prescribed in the patient's medical record.
- Physicians who supervise other providers (physician assistants and nurse practitioners) who prescribe controlled substances must possess a valid DEA registration that includes the same schedule(s) of controlled substances as the supervised health professional.
- Licensees should not write prescriptions for professional colleagues or other coworkers in the absence of a documented and established licensee-patient relationship. In addition, advance practice providers are prohibited from writing prescriptions for controlled substances for supervising physicians pursuant to Rules 21 NCAC 328 .0212 and 32M .0109.
- A frequent source of complaints to the Board regarding prescribing involves miscommunication or misunderstandings between pharmacists and prescribers. It should be recognized that the pharmacist has a corresponding responsibility with the prescriber for assuring the medication is dispensed properly. When appropriate, licensees are encouraged to discuss prescribing issues or problems with the pharmacist.

(Adopted: May 1991) (Amended: May 1996; March 2002; July 2002, July 2012; January 2021)

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

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

In order to provide licensees with guidance that reflects the most current medical and scientific research and recommended practices, the Board previously adopted and endorsed the <u>2016 CDC Guideline for Prescribing Opioids for Chronic Pain</u> ("2016 CDC Guideline") written and maintained by the Center for Disease Control and Prevention ("CDC").

In 2022, the CDC updated its 2016 CDC Guideline. The <u>2022 CDC Clinical Practice</u> <u>Guideline for Prescribing Opioids for Pain</u> ("2022 CDC Guideline") provides additional guidance and emphasizes the following aspects of prescribing opioids for the treatment of pain in the primary care context: (1) providing individualized pain care in the setting of a complete assessment of the risks versus benefit of all available modalities including but not limited to opioids for the management of acute, subacute, and chronic pain; (2) incorporating patient input into the choice of the various modalities chosen to treat a given patient's pain needs via shared decision-making; (3) maximizing multimodal therapies for a given patient's pain care, which may lessen the need for opioid therapy; (4) refraining from abruptly discontinuing or rapidly tapering chronic opioid therapy for those patients already on long-term therapy; and (5) thoroughly documenting the decision-making process behind the initiation, continuation, or discontinuation of opioid therapy for any given patient.

While the 2016 CDC Guideline and the 2022 CDC Guideline do not constitute regulations or necessarily state the standard of care in North Carolina in every context, the Board's believes that these guidelines can provide useful information to licensees related to the appropriate considerations to be made prior to, and during, treatment plans involving opioids. It is the Board's hope that familiarity with the concepts included in the two CDC guidance documents will help licensees provide safe and effective care for their North Carolina patients.

(Adopted: July 2005) (Amended: May 2013; January 2017; September 2023)

#### 5.1.1: 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 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 Licensee's Professional and Legal Obligation

The 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 licensee 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).

#### **Procedure Level Definitions**

Level I procedures – any surgical or special procedures:

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

Level II procedures – any surgical or special procedures:

- 1. That require the administration of local or peripheral nerve block, minor conduction blockade, Bier block, minimal sedation, or conscious sedation; and
- 2. 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:

- 1. That require, or reasonably should require, the use of major conduction blockade, deep sedation/analgesia, or general anesthesia; and
- 2. 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.

#### (Additional definitions are provided at the end of this position statement.)

#### 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 licensee 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 transfer to an emergency department and/or 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 licensed health care professional.

#### **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 complications and 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 Licensees**

A licensee 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 licensee's competence to perform a surgical or special procedure include, without limitation:

- 1. State licensure in North Carolina;
- 2. Procedure specific education, training, experience and successful evaluation appropriate for the patient population being treated (*i.e.*, pediatrics);
- 3. For licensees, 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 licensee'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:
  - Adherence to professional society standards;
  - Credentials approved by a nationally recognized accrediting or credentialing entity; or
  - Didactic course complemented by hands-on, observed experience; training is to be followed by a specified number of cases supervised by a licensed health care professional already competent in the respective procedure, in accordance with professional society standards.

If the licensee 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 licensee 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 licensee who performs the surgical or special procedures.

#### **Patient Selection**

The licensee 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 licensee 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 licensee 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 licensee 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 licensee 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 licensee. The information and data obtained during the course of this evaluation should be documented in the medical record.

The licensee 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**

Licensees 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. Licensee'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 licensee 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.

#### **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 licensee 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 BLS 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 BLS 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 licensee 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 licensee 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 BLS 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 licensee. The licensee 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 licensee or the anesthesia provider should be ACLS certified, and at least one other health care professional should be BLS 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 licensee 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 licensee who performs the surgical or special procedure should evaluate the patient immediately upon completion of the surgery or special procedure and the anesthesia.

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

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

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

# **Equipment and Supplies**

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

- 1. Full and current crash cart at the location where the anesthetizing is being carried out (the crash cart inventory should include appropriate resuscitative equipment and medications for surgical, procedural or anesthetic complications);
- 2. Age-appropriate sized monitors, resuscitative equipment, supplies, and medication in accordance with the scope of the surgical or special procedures and the anesthesia services provided;
- 3. Emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours;
- 4. Electrocardiographic monitor;
- 5. Noninvasive blood pressure monitor;
- 6. Pulse oximeter;
- 7. Continuous suction device;
- 8. Endotracheal tubes, and laryngoscopes;
- 9. Positive pressure ventilation device (*e.g.*, Ambu);
- 10. Reliable source of oxygen;
- 11. Emergency intubation equipment;
- 12. Adequate operating room lighting;
- 13. Appropriate sterilization equipment;
- 14. IV solution and IV equipment;

- 15. Sufficient ampules of dantrolene sodium should be emergently available;
- 16. Esophageal or precordial stethoscope;
- 17. Emergency resuscitation equipment;
- 18. Temperature monitoring device;
- 19. End tidal CO2 monitor (for endotracheal anesthesia); and
- 20. Appropriate operating or procedure table.

# Definitions

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

AAAHC - the Accreditation Association for Ambulatory Health Care

ABMS – the American Board of Medical Specialties

ACGME – the Accreditation Council for Graduate Medical Education

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

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

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

Anesthesia provider – an anesthesiologist or CRNA.

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

AOA – the American Osteopathic Association

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

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

ASA – the American Society of Anesthesiologists

BLS certified – a person who holds a current certification in basic 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 preprocedure 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 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

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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.

(Adopted: January 2003) (Amended: May 2011; May 2015) (Pending Review)

# 5.1.2: Laser Surgery

It is the position of the 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 professional 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 health care professionals 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 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 licensees 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, but are not limited to, the specific types of procedures and equipment used; the anatomical location being treated; the

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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 Board, 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; May 2021)

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

The evaluation, diagnosis, and care of the surgical patient undergoing surgery or other invasive procedure\* is primarily the responsibility of the licensee performing the procedure (e.g. "proceduralist"\*\*). The proceduralist bears responsibility for ensuring the patient undergoes a pre-procedure assessment appropriate to the surgery/procedure. The assessment shall include a review of the patient's history, physical exam, and other data relevant to the procedure. The proceduralist shall have a detailed discussion with each patient regarding the diagnosis and the nature of the surgery/procedure, advising the patient fully of the risks involved. It is also the responsibility of the proceduralist to reevaluate the patient immediately prior to the procedure.

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

\*Invasive procedures are medical acts performed for the purpose of structurally altering the human body by incision or destruction of tissues, including therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transportation of live human tissue. This includes endoscopies, cardiac catheterizations, interventional radiology procedures, and other procedures.

\*\*Proceduralist refers to the licensee performing the procedure.

(Adopted: September 1991) (Amended: March 2001; September 2006; July 2012; May 2021)

# 5.1.4: Telemedicine

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

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 can be a useful practice model that, if employed appropriately, can provide important benefits to patients, including: increased access to health care, expanded utilization of specialty expertise, rapid availability of patient records, and the potential of reduced healthcare costs, increased efficiency, and improved overall healthcare outcomes. The call for ongoing research and formal training in the care models and technologies associated with telemedicine reflects the evolving nature of telemedicine practice.

# Standard of Care

The Board cautions that licensees providing care to North Carolina patients via telemedicine will be held to the same established standard of care as those practicing in traditional in-person medical settings. The Board does not endorse a separate standard of care for telemedicine.

Licensees utilizing telemedicine in the provision of medical services to a patient (whether existing or new) are encouraged to take appropriate steps to establish the licensee-patient relationship, conduct all appropriate evaluations consistent with established evidenced based standards of care for the particular patient presentation, and protect and maintain patient confidentiality. When the standard of care that is ordinarily applied to an in-person encounter cannot be met by virtual means, the use of telemedicine technologies is not appropriate. Licensees, who fail to conform to the North Carolina statewide standard of care, may be subject to discipline by this Board.

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

# Licensure

The Board deems the practice of medicine to occur in the state where the patient is located. Therefore, any provider<sup>2</sup> using telemedicine to provide medical services to patients located in North Carolina should be licensed in North Carolina unless an

<sup>&</sup>lt;sup>2</sup> For the purpose of this position statement, "provider" includes any person legally authorized to provide health care services by means of telemedicine, who is licensed in North Carolina or by a regulatory agency outside of North Carolina.

appropriate exception, such as those listed below, applies. Licensees need not reside in North Carolina if they have a valid, current license with the Board.

There are exceptions in North Carolina to the requirement that a physician, physician assistant, or nurse practitioner possess a North Carolina license prior to providing care for patients located in North Carolina. Those exceptions include, but are not limited to: (1) provider-to-provider consultations across state lines where a North Carolina licensee remains responsible for the care of the North Carolina patient, but an out-of-state provider consults "on an irregular basis" with the North Carolina licensee (N.C. Gen. Stat. § 90-18(c)(11)); and (2) episodic follow-up care in which the patient is temporarily located in North Carolina but has an established relationship with an out-of-state provider, i.e., the patient is attending college or vacationing in North Carolina.

North Carolina licensees intending to practice medicine via telemedicine technology to treat or diagnose patients outside of North Carolina should check with the state licensing board in the state where they intend to provide care. Most states require medical providers to be licensed in the state where the patient is located, and some have enacted limitations on telemedicine practice or require or offer a special registration. A directory of all U.S. medical boards may be accessed at the <u>Federation of State Medical</u> <u>Boards' website</u>.

# Scope of Practice

A licensee who uses telemedicine should ensure that the services provided are consistent with the licensee's scope of practice, including the licensee's education, training, experience, and ability.

# Training of Staff

Staff involved in the telemedicine visit should be trained in the appropriate use of the technology being used to deliver care and competent in its operation. Such training includes applicable federal and state legal requirements of medical/health information privacy, including compliance with Health Insurance Portability and Accountability Act ("HIPAA") and state privacy, confidentiality, security, and medical retention rules. Licensees may supervise and delegate tasks to qualified individuals via telemedicine technologies so long as doing so is permitted by law or established by custom.

# Licensee-Patient Relationship

The Board stresses the importance of proper patient identification prior to any telemedicine encounter. Failure to verify the patient's identity may lead to fraudulent activity or the improper disclosure of confidential patient information. The licensee using telemedicine should verify the identity and location of the patient. Furthermore, the licensee's name, location, and professional credentials should be provided to the patient. Licensees using telemedicine should also ensure the availability for appropriate

follow-up care and maintain a complete medical record that is available to the patient and other treating health care providers.

Although it may be difficult in some circumstances to precisely define the beginning of the licensee-patient relationship, particularly when the licensee and patient are in separate locations, it tends to begin when an individual with a health-related matter seeks care from a licensee. The relationship is clearly established when the licensee agrees to undertake diagnosis and treatment of the patient, and the patient agrees to be treated, whether or not there has been an in-person encounter between the licensee and patient. A licensee-patient relationship may be established via either synchronous or asynchronous telemedicine technologies without any requirement of a prior in-person meeting, so long as the standard of care is met.

# **Evaluations and Examinations**

Licensees using telemedicine technologies to provide care to patients located in North Carolina are encouraged to provide, or rely upon, an appropriate evaluation prior to diagnosing and/or treating the patient. This evaluation need not be in-person if the licensee employs technology sufficient to accurately diagnose and treat the patient in conformity with the applicable standard of care. There are situations, however, (*see* below under Prescribing and the Board's Position Statement "<u>4.1.1. Contact with</u> <u>Patients Before Prescribing</u>") where an initial in-person evaluation is necessary. A diagnosis should be established using accepted medical practices, i.e., a patient history, mental status evaluation, physical examination, and appropriate diagnostic and laboratory testing.

Evaluations may also be considered appropriate if a licensed health care professional is able to facilitate aspects of the patient assessment needed to render reasonable diagnostic possibilities and care plans.

As part of meeting the standard of care, licensees should use digital images, live video, or other modalities as needed to make a diagnosis if the standard of care in-person would have required physical examination. Treatment and consultation recommendations made in a virtual setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in in-person settings. If the standard of care requires an evaluation utilizing additional ancillary diagnostic testing under the standard of care, the licensee is encouraged to complete such diagnostics, arrange for the patient to obtain the needed testing, or refer the patient to another provider.

In those instances when images are being transmitted for diagnostic interpretation purposes, it is incumbent on the licensee to assure that all necessary information is obtained for review. If not, then the diagnosis provided should reflect the incomplete nature of the material and be deemed preliminary until such time as the study can be reviewed in its entirety. Diagnosis, prescribing, or other treatment based solely on static online questionnaires, or those that do not obtain all of the information necessary to meet applicable standards of care, are not acceptable. Licensees practicing telemedicine utilizing questionnaires should have the ability to ask follow-up questions or obtain further history, especially when doing so is required to collect adequate information to appropriately diagnosis or treat.

# **Prescribing**

Licensees are expected to practice in accordance with the Board's Position Statement "<u>4.1.1. Contact with Patients Before Prescribing</u>." The Board expects the proper prescribing and monitoring of controlled substances, emphasizing the importance of appropriate and safe practices. Patient encounters conducted exclusively through telemedicine may not be deemed suitable in specific circumstances, including but not limited to, the treatment of pain. Licensees prescribing medications by means of telemedicine should comply with all relevant federal and state laws and are expected to participate in the Controlled Substances Reporting System.

Prescribing medications via telemedicine, as is the case during in-person care, is at the professional discretion of the licensee. The indication, appropriateness, and safety considerations for each prescription issued during a telemedicine encounter should be evaluated by the licensee in accordance with state and federal laws, as well as current standards of practice, and consequently carry the same professional accountability as prescriptions delivered during an encounter in person. However, where such measures are upheld, and the appropriate clinical consideration is carried out and documented, licensees may exercise their judgment and prescribe medications as part of telemedicine encounters.

# Medical Records

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

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

# **Continuity of Care and Referral for Emergent Situations**

Patients should be able to seek, with relative ease, follow-up care or information from the licensee [or licensee's designee] who conducts an encounter using telemedicine technologies. Licensees solely providing services using telemedicine technologies with no existing licensee-patient relationship prior to the encounter should document the encounter using telemedicine technologies that are easily available to the patient and, subject to the patient's consent, any identified care provider of the patient immediately after the encounter. Licensees have the responsibility to refer patients for in-person follow-up care when a patient's medical issue requires an additional in-person physical exam, diagnostic procedure, ancillary lab, or radiologic test.

If a patient is not an appropriate candidate for care via telemedicine technologies or experiences an emergent situation, complication, or side effects after an encounter using telemedicine technologies, licensees should have a standing plan in place and have the responsibility to refer the patient to appropriate in-person care (e.g., acute care, emergency room, or another provider) to ensure patient safety. It is insufficient for licensees to simply refer all patients to the emergency department; each situation should be evaluated on an individual basis and an appropriate referral should be made based on the severity and urgency of the situation. Licensees have an obligation to support continuity of care for their patients. In cases wherein telemedicine encounter is insufficient, but an emergency does not exist, the provider should be capable of making an appropriate referral to an ambulatory provider within a reasonable geographical approximation to the patient and not rely on emergency or urgent care services alone.

Terminating the medical care of a patient without adequate notice or without making other arrangements for the continued care of the patient may be considered patient abandonment and may result in discipline by the Board. Subsection B: Termination of the Licensee-Patient Relationship of the Board's Position Statement titled "2.1.1: The Licensee-Patient Relationship" is applicable in the context of telemedicine/telehealth provider including the written notice, timeline, and provision of continuity of care in the interim of transfer of care to a new provider.

# **Disclaimers**

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

# Additional Considerations

Licensees may choose to make health-related and non-health-related goods or products available to patients to meet a legitimate patient need in instances where the goods are medically necessary for patients and not immediately or reliably available to patients by

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other means. Licensees who choose to make goods available to patients should be mindful of the inherent power differential that characterizes the licensee-patient relationship and therefore the significant potential for exploitation of patients. The principle of non-exploitation of patients also applies to scenarios involving physicianowned pharmacies located in practice offices. In such instances, licensees should offer patients freedom of choice in filling any prescriptions and allow prescriptions to be filled elsewhere.

A licensee who incorporates artificial intelligence ("AI") tools as part of telemedicine to diagnose or treat a patient in North Carolina should (a) understand that the use of an AI tool and acceptance of suggested diagnosis or related treatment plan is at the discretion of the treating practitioner; and (b) understand the limitations of using an AI tool, including the potential bias against populations that were not adequately represented in original testing of the tool.

(Adopted: July 2010) (Amended: November 2014; March 2019; September 2023; March 2024)

# 5.1.5: Licensee Use of Innovative or New Treatment

The Board recognizes that progress in medical science, advances in patient care, and improved outcomes require exploration of innovative treatment and new technology. While the Board supports licensee use of scientifically valid research and innovation, it is the Board's position that licensees must guard against exaggerating or overpromising benefits of participation in research or use of novel or off-label treatment when there is insufficient data to support claims made for the treatment.

The Board acknowledges there are a wide variety of circumstances which may lead a licensee to recommend new or innovative treatment. For example, there may be different considerations when a conventional treatment has failed and a patient wants to individually undertake off-label or novel use of an existing drug or therapy. Licensees must balance respect for patients' autonomy in seeking treatment options against the need to safeguard patients from the risks of novel, but often unproven, treatment.

Licensees offering innovative or novel treatments should:

- Make treatment decisions in the best interest of the patient and use their knowledge and skill for the patient's benefit. Conflicting interests should be resolved to the benefit of the patient.
- Ensure all information, especially in terms of risks, benefits, and efficacy, is presented in an objective and honest manner. Where information is absent or equivocal this should also be communicated to the patient.
- Ensure the patient clearly understands why the new treatment is recommended, its purpose, and how it is different from current or conventional treatment.
- Refrain from using advertising that contains deceptive, false, or misleading claims.
- Avoid promotional "tokens of legitimacy" which might include patient or celebrity endorsements, marketing using various certifications, awards, or citations of licensee affiliation or membership in academic or professional societies connected with the service or product.
- Understand the relevant clinical issues of the treatment offered and have received sufficient education and training from qualified sources regarding the modality to provide treatment in a competent, safe and effective manner.
- Maintain detailed, accurate documentation of the course of treatment and outcomes that includes adverse events, identified both during and after treatment, and which should be communicated to patients in a forthright and timely fashion. New information which may come to light following treatment should also be communicated to the patient.
- Recognize the licensee retains responsibility for patient care and management when using clinical decision-making support tools such as augmented or artificial intelligence.
- Comply with relevant federal, state, and agency laws and regulations.
- Inform patients that innovative or novel treatments may not be covered by certain third-party insurance plans.

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These guidelines are important in maintaining mutual trust between patient and licensee, protecting patient autonomy, and obtaining meaningful informed consent. The Board's position statement on "<u>The Licensee-Patient Relationship</u>" may also be helpful to licensees as they consider these issues.

(Adopted: January 2020) (Amended: May 2021)

# 6.1.1: 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. North Carolina General Statute § 90-320(a) 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) 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)).

It is the position of the 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 licensee is unable in good conscience to meet the wishes of a patient, 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)

# 6.1.2: Palliative Care and End-of-Life Responsibilities

## **Assuring Patients**

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

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

# **Palliative Care**

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

Palliative care is provided by a specially-trained team of doctors, nurses and other specialists who work together with a patient's other doctors to provide an extra layer of support. Palliative care is based on the needs of the patient, not on the patient's prognosis. It is appropriate at any age and at any stage in a serious illness, and it 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 documents a palliative care diagnosis and details of any pain management plan. (See the Board's position statement on the "Policy for the Use of Opioids for the Treatment of Pain" for an outline of what the Board expects of licensees in the management of pain.) Because the Board is aware of the inherent risks associated with effective symptom relief in such situations, it will not interpret their occurrence as subject to discipline by the Board.

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

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

\*\*\*Taken from the Center to Advance Palliative Care https://www.capc.org/about/palliative-care/

\*\*\*\*Taken from the World Health Organization definition of Palliative Care (2002)

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

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

# (Adopted by the North Carolina Medical Board, North Carolina Board of Nursing, and North Carolina Board of Pharmacy)

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

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

It is the position of all three Boards that patients and their families should be assured of competent, comprehensive palliative care at the end of their lives. Healthcare providers, including physicians, physician assistants, advanced practice registered nurses, nurses, and pharmacists, should be knowledgeable regarding effective and compassionate pain relief, and patients and their families should be assured such relief will be provided.

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

With regard to pharmacy practice, in general North Carolina has no quantity restrictions on dispensing controlled substances—including those in Schedule II. The STOP Act limits initial prescriptions for opioid medications in Schedules II and III to five- and seven-day supplies when prescribed for acute pain or post-operative acute pain, respectively. But those limitations do **not** apply to treatment of chronic pain or pain being treated as a component of hospice or palliative care. Federal law allows partial filling of Schedule III and IV prescriptions for up to six months, and, for terminally ill patients, partial filing of Schedule II prescriptions for up to 60 days. This allows the pharmacist to dispense smaller quantities of the prescription to meet the patient's needs, thereby minimizing patient expenses and unnecessary waste of drugs. The prescriber should note on the prescription that the patient is terminally ill to facilitate these partial fills.

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

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

The nurse (RN or LPN) is often the health professional most involved in assessment of pain and in the on-going management of pain, through implementing the prescribed/ordered pain management plan, evaluating the patient's response to such interventions, and adjusting medication levels based on prescriptions/orders and patient status. Consistent with the licensee's scope of practice, the RN or LPN is accountable for implementing the pain management plan utilizing his/her knowledge base and documented assessment of the patient's needs through the use of designated pain evaluation tools.

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

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

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- Thorough documentation of all aspects of the patient's assessment and care;
- A working diagnosis and therapeutic treatment plan including pharmacologic and non-pharmacologic interventions;
- Regular and documented evaluation of response to the interventions and, as appropriate, revisions to the treatment plan;
- Evidence of communication among care providers;
- Education of the patient and family; and
- A clear understanding by the patient, the family and health care team of the treatment goals.

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

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

# 6.1.4: Clinician Obligation to Complete a Certificate of Death

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

The Board recognizes that clinicians may not be comfortable with uncertainty, however, a clinician should not decline to sign a death certificate simply because the exact anatomic or physiologic cause of death is uncertain. Although <u>N.C. Gen. Stat. § 130A</u> <u>115(c)</u> requires that the practitioner "state the cause of death in *definite and precise* terms" (emphasis added), it is the Board's interpretation of this statute that the licensee should employ appropriate terminology and nomenclature with as much accuracy as is possible; however, it is also recognized by the Board that providing the most complete, definitive, and conclusive cause of death may, under many circumstances, not be possible. Clinicians are not expected or required to establish beyond a doubt the specific cause of death but should exercise their best judgment under the circumstances using available information.

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

Under the law, the Board cannot pursue disciplinary action against clinicians who complete death certificates in good faith and to the best of their ability in accord with the information available — even if that information is limited. The law also grants immunity from civil liability to clinicians completing death certificates in good faith. (N.C. Gen. Stat. § 130A-115(f)) The clinician completing the death certificate is only asked to provide a cause of death "to the best of [his or her] knowledge," not to a medical certainty.

The Board also recognizes that clinicians may believe, for a variety of reasons, they were not "in charge of the patient's care for the illness or condition which resulted in death." This is often because death has occurred weeks or months after the last contact with the patient. The Board encourages clinicians to undertake completion of death certificates for patients (current, recent, or remote) under these circumstances as a professional,

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ethical, civic, and public health responsibility. Failure or refusal to complete a death certificate, when the licensee clearly has a responsibility to do so, could lead the Board to consider disciplinary action.

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

All death certificates must be filed electronically with the Office of Vital Records via the North Carolina Database Application for Vital Events ("NCDAVE") system. NCDAVE is a statewide online system used to electronically register death certificates and eliminates the need for physical transfer of paper certificates. Individuals responsible for completing death certificates who refuse to certify a death certificate via NCDAVE may be subject to administrative fines. To access NCDAVE, please visit: <a href="https://davenc.vitalchek.com/Web/Logon.aspx">https://davenc.vitalchek.com/Web/Logon.aspx</a>

(Adopted: March 2019) (Amended: July 2021; May 2023)

# 7.1.1: Child Maltreatment

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

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

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

Reporting Child Abuse and Neglect in North Carolina (3rd Edition)

# Prevent Child Abuse NC Recognizing & Responding Online Course

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

(Adopted: September 2014) (Amended: November 2019)

# 8.1.1: Physician Practice Drift

When physicians are granted a license by the Board, they are generally given the privilege of practicing the full breadth of medicine and are not limited to a particular specialty. This general medical license allows physicians a certain degree of discretion to expand or shift their practice areas. The Board recognizes that medicine is a dynamic field that, along with individual practices, continues to evolve. Business and financial opportunities, personal lifestyle considerations, and access to care are all reasons that physicians modify their practice.

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

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

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

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

(Adopted: March 2011) (Amended: November 2019; July 2021)

# 8.1.2: The Medical Supervisor-Trainee Relationship

It is the position of the 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. The Board notes, 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, not limited to physical or verbal harassment, sexual harassment, or other forms of intimidation are considered unprofessional conduct and subject to discipline by the Board. However, constructive 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) (Amended: July 2021)

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

It is the position of the Board that 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 Professionals Health Program. Incompetent licensees should be reported to the clinical authority empowered to take appropriate action. Licensees also may report such issues to the Board, and when there is no other institution reasonably able to deal with the problem, this may be the only way of discharging the duty to report.

The duty to act when confronted with an impaired or incompetent colleague is subordinate to a licensee's duty to maintain a patient's confidentiality. In other words, when an impaired or incompetent colleague is also a patient, the licensee should prioritize the duty to preserve the colleague/patient's confidentiality when considering whether to report the colleague/patient.

(Adopted: November 1998) (Amended: May 2010; July 2021)

# 8.3.1: Advertising and Publicity\*

It is the position of the 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, digital/on-line, 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. Licensees should not post false patient testimonials supporting their own promotional aims.

# **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:

#### 8.3: Licensee Promotion & Marketing Practices

- 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 licensees 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 licensee 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 licensees 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; July 2021)

# 8.3.2: Sale of Goods from Licensee's Offices

Inherent in the in-office sale of products is a perceived conflict of interest. On this issue, it is the position of the 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 licensee or staff from the licensee'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; July 2021)

8.4: Licensee Interactions with Government Agencies and Legal Proceedings

# 8.4.1: Unethical Agreements in Complaint Settlements

It is the position of the 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)

8.4: Licensee Interactions with Government Agencies and Legal Proceedings

# 8.4.2: Medical Testimony

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

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

# \* The language of AMA Code of Medical Ethics Opinion 9.7.1 provides:

#### 9.7.1 Medical Testimony

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

Whenever physicians serve as witnesses they must:

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

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

d) Protecting the confidentiality of the patient's health information, unless the physician is authorized or legally compelled to disclose the information.

8.4: Licensee Interactions with Government Agencies and Legal Proceedings

- e) Delivering honest testimony. This requires that they engage in continuous selfexamination to ensure that their testimony represents the facts of the case.
- f) Declining to testify if the matters could adversely affect their patients' medical interests unless the patient consents or unless ordered to do so by legally constituted authority.
- g) Considering transferring the care of the patient to another physician if the legal proceedings result in placing the patient and the physician in adversarial positions.

Physicians who testify as expert witnesses must:

- h) Testify only in areas in which they have appropriate training and recent, substantive experience and knowledge.
- i) Evaluate cases objectively and provide an independent opinion.
- j) Ensure that their testimony:
  - 1) reflects current scientific thought and standards of care that have gained acceptance among peers in the relevant field.
  - 2) appropriately characterizes the theory on which the testimony is based if the theory is not widely accepted in the profession.
  - 3) considers standards that prevailed at the time the event under review occurred when testifying about a standard of care.

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

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

# 9.1.1: Physician Supervision of Other Licensed Health Care Professionals

The physician who provides medical supervision of other licensed healthcare professionals 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 professional 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 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; and
- The supervisee's scope of practice consistent with the supervisee's education, national certification and/or collaborative practice agreement.

The above factors outlining the supervisory relationship should be outlined in a written collaborative practice agreement, supervisory arrangement, protocol, or other written guidelines. Physicians should only supervise another professional for the diagnosis, treatment, and overall care (including procedures) for which the physician has an appropriate level of education, training, experience, and/or certification. Physicians should also be cognizant of maintaining appropriate boundaries with their supervisees, including refraining from requesting medical treatment by the physician's supervisee.<sup>\*</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

### 9: Professional Working Relationships

with a physician to provide the legally required supervision of the physician assistant or nurse practitioner.

\*See also the Board's position statement on "Self-treatment and Treatment of Family Members."

(Adopted: July 2007) (Amended: November 2015; September 2021)

#### 9: Professional Working Relationships

## 9.1.2: Professional Behavior Within the Healthcare Team

The Board recognizes that the manner in which licensees interact with others can significantly impact patient care.

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

Disruptive behavior represents both a verbal and non-verbal style of interaction between licensees, coworkers, patients, family members, or others that interferes with patient care. Behaviors not limited to rude, loud, or offensive comments; sexual harassment or other inappropriate physical contact; and intimidation of staff, patients, and family members are commonly recognized as detrimental to patient care. The Board distinguishes disruptive behavior from: (1) constructive criticism that is offered in a professional manner with the aim of improving patient care; or (2) reasonably direct or blunt communication that may be appropriate to protect the health of a patient in urgent or emergency situations.

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

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

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

(Adopted: January 2010) (Amended: July 2019; September 2021)

# 9.1.3. Licensee Employment

The Board recognizes that the practice of medicine continues to shift from licensees practicing in personally owned practices toward licensees practicing while subject to employment and other contractual relationships. The medical practice of the employed licensee may present unique challenges to maintaining professionalism in the practice of medicine.

In order for licensees to avoid putting themselves in professional situations that may expose them to sanctions by the Board, the Board recommends licensees consider the following when entering a new work environment:

- Understand the organizational structure and ownership of their potential employer.
- Employment agreements are legal documents. Licensees are encouraged to seek their own legal counsel before signing them.
- Be familiar with your employer's policies for healthcare delivery within the practice or healthcare system.
- Recognize that your professional obligation to provide care that conforms to the standards of acceptable and prevailing medical practice, or the ethics of the medical profession, supersedes your employment relationship.
- Patient welfare must take priority in any situation where the interests of licensees' and employers' conflict.

The Board encourages its licensees to review and consider the following when entering into employment relationships.

- 1. Responsibilities to Patients and the Profession
  - a. Patient advocacy is a fundamental element of the patient-licensee relationship that should not be altered by the employer or setting in which licensees practice, or the methods by which they are compensated.
  - b. A licensee's paramount responsibility is to their patients. At the same time, employed licensees occupy a position of significant trust and owe a duty of loyalty to their employer. Having two distinct loyalties can create conflicts of interest that employed licensees should strive to recognize and address.
  - c. When factors outside a licensee's medical judgment (e.g., moral, religious, financial, etc.) influence or limit a licensee's particular treatment or referral options, a licensee is ethically obligated to disclose those factors to the patient. The Board reminds its licensees of the position statement "<u>2.1.1 The Licensee-Patient Relationship</u>," which states that it is unethical for a licensee to allow financial incentives or other interests to adversely affect or influence a licensee's medical judgment or patient care.

#### 9: Professional Working Relationships

- d. Employed licensees should be free to exercise, in their individual capacity, their personal and professional judgment in voting, speaking, and advocating on any manner regarding patient care interests, the profession, healthcare in the community, and the independent exercise of medical judgment.
- e. Licensees working in a supervisory or administrative role who direct individual patient care decisions of other licensees are themselves engaged in the practice of medicine and may be subject to Board scrutiny.
- f. Employed licensees have a responsibility to assure that bills issued for services they provide are accurate and should therefore retain the right to review billing claims as may be necessary to verify that such bills are correct.
- g. Employed licensees should be free to engage in volunteer work outside of, and which does not interfere with, their duties as employees.
- 2. Consideration and Termination of Employment Agreements
  - a. Licensees are encouraged to obtain the advice of legal counsel when negotiating employment agreements. Licensees are encouraged to work with their counsel to review, inquire about, and fully understand, the terms of proposed employment agreements, including, but not limited to, terms addressing:
    - i. The licensee's work duties and other obligations;
    - ii. Compensation, including productivity and incentive compensation, as well as benefits;
    - iii. Restrictions contained in the agreement, including non-compete and nonsolicitation clauses or other restrictions; and
    - iv. The terms of employment and any potential bases for early termination.
  - b. Licensees should be aware of the Board's position statement on the <u>Corporate</u> <u>Practice of Medicine</u> and only accept employment that involves the practice of medicine with lawfully authorized employers.
  - c. Termination of an employment or contractual relationship between a licensee and an entity employing that licensee does not necessarily end the patient-licensee relationship between the employed licensee and persons under his/her care. Whether serving in an employer or employee role, licensees should refer to the Board's position statement "2.1.2: Departures from or Closings of Medical Practices" regarding patient notification and choice, continuity of care, and providing medical records to patients.

#### 9: Professional Working Relationships

d. Actions taken against a licensee's privileges should be reported to the Board consistent with <u>N.C. Gen. Stat. § 90-14.13</u>. Any licensee with reporting responsibilities for the privileging actions contained in N.C. Gen. Stat. § 90-14.13 has the professional ethical responsibility to assure that proper reporting has occurred and may face an inquiry by the Board for the failure to do so.

(Adopted: March 2023)

# 10.1.1: Referral Fees and Fee Splitting

Payment by or to a licensee solely for the referral of a patient is unethical and, in most instances, is inconsistent with state law. 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 licensee-patient relationship. Furthermore, referral fees are prohibited by state law pursuant to N.C. Gen. Stat. § 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:

- 1. A description of the discounted price in comparison to the actual cost of services;
- 2. 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
- 3. 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; September 2021)

# 10.1.2.: 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 licensee is aiding and abetting the corporate practice of medicine. In addition, the Board may seek injunctive relief against lay owners of businesses engaged in the corporate practice of medicine.

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

# **Hospital-Owned Practices**

As mentioned above, the Board recognizes an exception to the prohibition on the corporate practice of medicine for 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 licensed employees have to their patients and allow them to discharge such obligations. For example, it is the position of the Board that licensees 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)