

# MINUTES



**March 16-18, 2016**

**1203 Front Street  
Raleigh, North Carolina**

General Session Minutes of the North Carolina Medical Board Meeting held March 16 - 18, 2016.

The March 2016 meeting of the North Carolina Medical Board was held at the Board's Office, 1203 Front Street, Raleigh, NC 27609. Pascal O. Udekwu, MD, President called the meeting to order. Board members in attendance were: Eleanor E. Greene, MD, President-Elect; Timothy E. Lietz, MD, Secretary/Treasurer; Cheryl L. Walker-McGill, MD, Immediate Past-President; Mr. Michael J. Arnold; Mr. A. Wayne Holloman; Bryant A. Murphy, MD; Debra A. Bolick, MD; Judge Ralph A. Walker; Barbara E. Walker, DO; Venkata R. Jonnalagadda, MD; Ms. Jerri L. Patterson, NP. Board Members absent: None.

### **Presidential Remarks**

Dr. Udekwu reminded the Board members of their duty to avoid conflicts of interest with respect to any matters coming before the Board as required by the State Government Ethics Act. No conflicts were reported.

### **Minutes Approval**

**Motion:** A motion passed to approve the January 20 - 22, 2016 Board Minutes. There was not a Board Hearing in February; therefore there were no minutes for that month.

### **Announcements**

Dr. Pascal Udekwu introduced and administered the oaths to new Board Members, Ms. Jerri L. Patterson and Dr. Venkata R. Jonnalagadda.

Mr. David Henderson announced that at the May Board meeting, there will be a Hearing and Interview training. The New Board Member Orientation will also take place during the May Board meeting.

### **Presentations**

Dr. Donald C. Maharty, Vice President of Medical Education, Cape Fear Valley Health System; Regional Assistant Dean, Campbell University School of Osteopathic Medicine, presented an update on the North Carolina Osteopathic Medical Association.

Dr. Randall Williams, Deputy Secretary of NCDHHS, made a presentation on Opioids overdose related to Hepatitis C cases and CDC Guidelines on prescribing narcotics.

### **NCMB Attorney's Report**

Mr. Thomas W. Mansfield, Chief Legal Officer, gave the Attorney's Report.

A motion passed to close the session pursuant to Section 143-318.11(a) of the North Carolina General Statutes to prevent the disclosure of information that is confidential pursuant to Sections 90-8, 90-14, 90-16, 90-21.22 of the North Carolina General Statutes and not considered a public record

within the meaning of Chapter 132 of the General Statutes and/or to preserve attorney/client privilege.

A motion passed to return to open session.

## **NCMB Committee Reports**

### **EXECUTIVE COMMITTEE REPORT**

Members present were: Pascal O. Udekwu, MD, Chairperson; Cheryl L. Walker-McGill, MD; Eleanor E. Greene, MD; Timothy E. Lietz, MD; and Mr. Michael J. Arnold.

#### Strategic Plan

a. Strategic Goals Update

The Committee reviewed the updated Strategic Goals Tracker.

Committee Recommendation: Accept as information.

Board Action: Accept Committee recommendation. Accept as information.

#### Financial Statements

a. Monthly Accounting

The Committee reviewed the compiled financial statements for December 2015 and January 2016. January is the third month of fiscal year 2016. The Committee also reviewed the final report of actual vs. budget for fiscal year 2015.

Committee Recommendation: Accept the financial statements and 2015 actual vs. budget information as reported.

Board Action: Accept Committee recommendation. Accept the financial statements and 2015 actual vs. budget information as reported.

b. Investment Account Statements

The Committee reviewed the investment statements for January and February 2016.

Committee Recommendation: Accept as information.

Board Action: Accept Committee recommendation. Accept as information.

## Old Business

### a. Draft Controlled Substances CME Requirement Rule

On September 18, 2015, Governor McCrory signed Session Law 2015-241; House Bill 97 into law (State Budget). One provision relates to mandated NCMB CME regarding controlled substance prescribing. The provision will require rule-making to make updates to the CME requirements for applicable licensees.

At the January 2016 meeting, the Board tentatively approved draft rules for the purpose of soliciting feedback. The Committee reviewed feedback regarding the proposed rules including a request that the Board provide free CME to satisfy this requirement.

**Committee Recommendation:** (1) Approve modified version of the draft rules for filing with the Rules Review Commission. (2) Board staff to pursue CME credit for review of the Board's Policy for the Use of Opiates for the Treatment of Pain and for attending a Board presentation on the Board's policy.

**Board Action:** (1) Approve original version of the proposed rules (Appendixes A and B) for filing with the Rules Review Commission. (2) Board staff to pursue CME credit for review of the Board's Policy for the Use of Opiates for the Treatment of Pain and for attending a Board presentation on the Board's policy.

### b. CSRS Reports Advisory Group Recommendation

The Committee reviewed a recommendation from the CSRS Reports Advisory Group which outlines a proposed procedure for processing CSRS reports received by the Board pursuant to Rule 21 NCAC 32Y .0101.

**Committee Recommendation:** Defer to the full Board.

**Board Action:** Approve process recommended by the Advisory Group (Appendix C).

## New Business

### a. Request to Add Credentialing Coordinator Position

Staff recommends the Board approve adding a full-time, permanent Credentialing Coordinator position in the Licensing Section.

**Committee Recommendation:** Defer to the full Board.

**Board Action:** Approve adding a full-time, permanent Credentialing Coordinator position in the Licensing Section.

b. North Carolina Physicians Health Program (NCPHP) Compliance Committee

Staff recommends the Board appoint the Honorable John B. Lewis, Jr., to fill Ms. Shikha Sinha's unexpired term on the NCPHP Compliance Committee.

Committee Recommendation: Defer to the full Board.

Board Action: Appoint the Honorable John B. Lewis, Jr., to fill Ms. Shikha Sinha's unexpired term on the NCPHP Compliance Committee.

A motion passed to close the session pursuant to Section 143-318.11(a) of the North Carolina General Statutes to prevent the disclosure of information that is confidential pursuant to Sections 90-8, 90-14, 90-16, 90-21.22 of the North Carolina General Statutes and not considered a public record within the meaning of Chapter 132 of the General Statutes and/or to preserve attorney/client privilege.

A motion passed to return to open session.

**POLICY COMMITTEE REPORT**

Members Present: Cheryl L. Walker-McGill, MD, Chairperson; Mr. Michael J. Arnold; Mr. A. Wayne Holloman and Ms. Jerri L. Patterson, NP.

Old Business

a. Physician Compounding (Appendix D)

The Committee discussed the Board's resolution as well as the position statement on this topic issued by the Federation of State Medical Boards (FSMB). The Committee inquired about the role of the resolution in light of this new development.

Committee Recommendation: Staff to follow-up with the Federation of State Medical Boards. Move forward with the Board's resolution.

Board Action: Accept Committee recommendation.

b. Office-based procedures (Appendix E)

Staff gave an update regarding a review of the Board's position statement by an outside agency.

Committee Recommendation: Note review of position statement. No changes.

Board Action: Accept Committee recommendation. Note review of position statement. No changes.

c. Corporate practice of medicine (Appendix F)

The Committee favorably reviewed the position statement with its most recent edits.

Committee Recommendation: Approve proposed position statement.

Board Action: Accept Committee recommendation. Approve proposed position statement.

New Business

a. Sexual Exploitation of Patients (Appendix G)

The Committee discussed the development of this position statement. Concerns were raised about whether the position statement was sufficiently explicit regarding various types of communication. The Committee suggested addition of language to this effect.

Committee Recommendation: Accept proposed position statement with new language.

Board Action: Accept Committee recommendation. Accept proposed position statement with new language.

b. Care of the Patient Undergoing Surgery or Other Invasive Procedure (Appendix H)

The Committee reviewed the position statement and did not have suggested changes.

Committee Recommendation: Note review of position statement. No changes.

Board Action: Accept Committee recommendation. Note review of position statement. No changes.

c. CDC Guidelines for Prescribing Opioids for Chronic Pain

Staff highlighted some of the differences between the CDC Guidelines and the Board's guidance document. The Committee discussed the ongoing evolution of appropriate prescribing for chronic pain. It was suggested that the Board position should also encompass the prescribing of benzodiazepines. The Committee requested information regarding the efforts that have been made on a state level throughout the country.

Committee Recommendation: Bring this matter back to the Committee in May 2016, along with the requested information.

Board Action: Accept Committee recommendation. Bring this matter back to the Committee in May 2016, along with the requested information.

d. Position Statement Review Tracking Chart (Appendix I)

The Committee reviewed the Position Statement Review Tracking Chart and confirmed that all position statements are on track to be reviewed at least once every four years as required by the January 2010 Board Action.

Committee Recommendation: Accept as information.

Board Action: Accept Committee recommendation. Accept as information.

## **LICENSE COMMITTEE REPORT**

Members present were: Bryant A. Murphy, MD, Chairperson; Debra A. Bolick, MD; Eleanor E. Greene, MD; Mr. A. Wayne Holloman and Judge Ralph A. Walker.

### Old Business

#### a. Interstate Licensure Compact

Update from FSMB regarding current progress of the Interstate Licensure Compact.

Committee Recommendation: Accept as information. Staff will continue to monitor.

Board Action: Accept Committee recommendation. Accept as information. Staff will continue to monitor.

### New Business

#### a. Key Performance Indicators

Data from October, 2015 – January, 2016.

Committee Recommendation: Accept as information. Staff will continue to monitor.

Board Action: Accept committee recommendation. Accept as information. Staff will continue to monitor.

A motion passed to close the session pursuant to Section 143-318.11(a) of the North Carolina General Statutes to prevent the disclosure of information that is confidential pursuant to Sections 90-8, 90-14, 90-16, 90-21.22 of the North Carolina General Statutes and not considered a public record within the meaning of Chapter 132 of the General Statutes and/or to preserve attorney/client privilege.

The License Committee reviewed four cases. A written report was presented for the Board's review. The Board adopted the Committee's recommendation to approve the written report. The specifics of this report are not included because these actions are not public.

A motion passed to return to open session.

## **LICENSE INTERVIEW REPORT**

A motion passed to close the session pursuant to Section 143-318.11(a) of the North Carolina General Statutes to prevent the disclosure of information that is confidential pursuant to Sections 90-8, 90-14, 90-16, 90-21.22 of the North Carolina General Statutes and not considered a public record within the meaning of Chapter 132 of the General Statutes and/or to preserve attorney/client privilege.

Four licensure interviews were conducted. A written report was presented for the Board's review. The Board adopted the Committee's recommendation to approve the written report. The specifics of this report are not included because these actions are not public information.

A motion passed to return to open session.

## **ALLIED HEALTH COMMITTEE REPORT**

Committee Members present were: Barbara E. Walker, DO, Chair; Venkata R. Jonnalagadda, MD; and Jerri L. Patterson, NP.

Old Business

a. PHYSICIAN ASSISTANTS

No items for discussion.

b. NC EMERGENCY MEDICAL SERVICES

Elizabeth Kanof, MD requests the NCMB consider a change in the statute to allow the Board to recommend a person other than a Board member to the EMS Disciplinary Committee. The appointment statute is administered by the Department of Health and Human Services (DHHS) and any change to the appointment statute would need to be initiated by DHHS.

Committee Recommendation: Follow current statute.

Board Action: Accept Committee recommendation. Follow current statute.

c. ANESTHESIOLOGIST ASSISTANTS

No items for discussion.

d. NURSE PRACTITIONERS

No items for discussion.

e. CLINICAL PHARMACIST PRACTITIONERS

In November 2015, the Allied Health Committee approved amendments to the Clinical Pharmacist Practitioner rule. A public hearing was held on March 14, 2016 at the Board of Pharmacy. No comments were received at the public hearing. The Board of Pharmacy received written comments to the proposed rule change, all of which were supportive. (Appendix J)

Committee Recommendation: Approve the proposed rule for submission to the Rules Review Commission.

Board Action: Accept Committee recommendation. Approve the proposed rule for submission to the Rules Review Commission.

f. PERFUSIONISTS

No items for discussion.

g. POLYSOMNOGRAPHIC TECHNOLOGISTS

No items for discussion.

New Business

a. PHYSICIAN ASSISTANTS

PAAC meeting minutes from March 16, 2016

Committee Recommendation: Accept report as information.

Board Action: Accept Committee recommendation. Accept report as information.

b. NC EMERGENCY MEDICAL SERVICES

No items for discussion.

c. ANESTHESIOLOGIST ASSISTANTS

No items for discussion.

d. NURSE PRACTITIONERS

No items for discussion.

e. CLINICAL PHARMACIST PRACTITIONERS

No items for discussion.

f. PERFUSIONISTS

Minutes of the January, 2016 PAC meeting

Committee Recommendation: Accept the minutes of the January 2015 PAC meeting.

Board Action: Accept Committee recommendation. Accept the minutes of the January 2015 PAC meeting.

g. POLYSOMNOGRAPHIC TECHNOLOGISTS

No items for discussion.

CLOSED SESSION

A motion passed to close the session pursuant to Section 143-318.11(a) of the North Carolina General Statutes to prevent the disclosure of information that is confidential pursuant to Sections 90-8, 90-14, 90-16, 90-21.22 of the North Carolina General Statutes and not considered a public record within the meaning of Chapter 132 of the General Statutes and/or to preserve attorney/client privilege.

a. PHYSICIAN ASSISTANTS

No items for discussion.

b. NC EMERGENCY MEDICAL SERVICES

No items for discussion.

c. ANESTHESIOLOGIST ASSISTANTS

No items for discussion.

d. NURSE PRACTITIONERS

NP Joint Subcommittee Panel will meet next week to discuss Investigations report and will be reported to the Allied Health Committee at the May Board meeting.

e. CLINICAL PHARMACISTS

No items for discussion.

f. PERFUSIONISTS

No items for discussion.

g. POLYSOMNOGRAPHIC TECHNOLOGISTS

No items for discussion.

A motion passed to return to open session.

**PHYSICIAN ASSISTANT ADVISORY COUNCIL (PAAC)**

Members present were: Barbara E. Walker, DO, Chairperson and Venkata R. Jonnalagadda, MD.

Old Business

a. PA Terminology

At the last PAAC meeting, Mr. Katz raised the issue of the Board considering using the term “collaboration” instead of “supervision” when describing the relationship between physician assistant and physician. Mr. Katz reported that AAPA model legislation endorses this change of terminology. Further evaluation of the ramifications of the rule changes will need to occur and be brought back to a future AHC meeting.

b. Record Retention Rule for PAs

Should the Board adopt a rule explicitly requiring a physician assistant to maintain a record of quality assurance meetings for a minimum of three years? See (Appendix K) for Record Retention Rule for PAs.

c. PA Site Visits

Board Investigator Don Pittman discussed current PA compliance audit process. Open discussion to consider whether compliance audits should be performed in person, electronically, or by mail. Discussion confirmed the value of continued compliance audits. Consider a hot link to the site visit form on the website.

d. The Relevancy of QI Language

Consider amending Rule 21 NCAC 32S .0213 to delete the language “and quality improvement measures” from the rule. See (Appendix K) proposed change to Rule 21 NCAC 32S .0213. Marcus Jimison and Katharine Kovacs, PA-C to draft Frequently Asked Question (FAQ) to present at May 2016 AHC meeting, explaining the expectations of the Board regarding QI meeting documentation.

## NEW BUSINESS

### a. AAPA Model Legislation

AAPA model legislation. The issues discussed were: collaboration v. supervision terminology; registration of supervising physicians; removal of language indicating supervising physician is responsible for PA's care; and independent board for physician assistants.

### b. Documentation Issues

Documentation concerns for PAs working part-time or locum positions. Marcus Jimison and Katharine Kovacs, PA-C to draft FAQ to present at May 2016 AHC meeting regarding current rules for part time and locum jobs.

### c. Implications of Relaxed Supervision of Advance Practice Nurses for Physician Assistants.

Thomas P. Colletti, DHSC, MPAS, PA-C presented discussion of the implications of the suggested relaxed supervision requirements for advanced practice nurses.

### d. New CME Requirements

Update on new controlled substance CME requirement. See (Appendix B), proposed rule, 21 NCAC 32S .0216

Committee Recommendation: Accept PAAC report as information.

Board Recommendation: Accept committee recommendations. Accept PAAC report as information.

## **DISCIPLINARY (COMPLAINTS) COMMITTEE REPORT**

Members present were: Barbara E. Walker, DO, Chairperson; Mr. Michael J. Arnold; Eleanor E. Greene, MD; Venkata Jonnalagadda, MD; Timothy E. Lietz, MD and Bryant A. Murphy, MD

A motion passed to close the session pursuant to Section 143-318.11(a) of the North Carolina General Statutes to prevent the disclosure of information that is confidential pursuant to Sections 90-8, 90-14, 90-16, 90-21.22 of the North Carolina General Statutes and not considered a public record within the meaning of Chapter 132 of the General Statutes and/or to preserve attorney/client privilege.

The Disciplinary (Complaints) Committee reported on sixteen complaint cases. A written report was presented for the Board's review. The Board adopted the Committee's recommendation to approve the written report. The specifics of this report are not included because these actions are not public.

A motion passed to return to open session.

## **DISCIPLINARY (MALPRACTICE) COMMITTEE REPORT**

Members present were: Barbara E. Walker, DO Chairperson; Mr. Michael J. Arnold; Eleanor E. Greene, MD; Venkata Jonnalagadda, MD; Timothy E. Lietz, MD; and Bryant A. Murphy, MD

A motion passed to close the session pursuant to Section 143-318.11(a) of the North Carolina General Statutes to prevent the disclosure of information that is confidential pursuant to Sections 90-8, 90-14, 90-16, 90-21.22 of the North Carolina General Statutes and not considered a public record within the meaning of Chapter 132 of the General Statutes and/or to preserve attorney/client privilege.

The Disciplinary (Malpractice) Committee reported on twenty-five cases. A written report was presented for the Board's review. The Board adopted the Committee's recommendation to approve the written report. The specifics of this report are not included because these actions are not public information.

A motion passed to return to open session.

### **DISCIPLINARY (MEDICAL EXAMINER) COMMITTEE REPORT**

Members present were: Barbara E. Walker, DO Chairperson; Mr. Michael J. Arnold; Eleanor E. Greene, MD; Venkata R. Jonnalagadda, MD; Timothy E. Lietz, MD and Bryant A. Murphy, MD

A motion passed to close the session pursuant to Section 143-318.11(a) of the North Carolina General Statutes to prevent the disclosure of information that is confidential pursuant to Sections 90-8, 90-14, 90-16, 90-21.22 of the North Carolina General Statutes and not considered a public record within the meaning of Chapter 132 of the General Statutes and/or to preserve attorney/client privilege.

The Disciplinary (Medical Examiner) Committee reported on one cases. A written report was presented for the Board's review. The Board adopted the Committee's recommendation to approve the written report. The specifics of this report are not included because these actions are not public information.

A motion passed to return to open session.

### **INVESTIGATIVE INTERVIEW REPORT**

A motion passed to close the session pursuant to Section 143-318.11(a) of the North Carolina General Statutes to prevent the disclosure of information that is confidential pursuant to Sections 90-8, 90-14, 90-16, 90-21.22 of the North Carolina General Statutes and not considered a public record within the meaning of Chapter 132 of the General Statutes and/or to preserve attorney/client privilege.

Five investigative interviews were conducted. A written report was presented for the Board's review. The Board adopted the recommendations and approved the written report. The specifics of this report are not included because these actions are not public information.

A motion passed to return to open session.

### **DISCIPLINARY (INVESTIGATIVE) COMMITTEE REPORT**

Members present were: Barbara E. Walker, DO Chairperson; Mr. Michael J. Arnold; Debra A. Bolick, MD; Eleanor E. Greene, MD; Timothy E. Lietz, MD; Bryant A. Murphy, MD

A motion passed to close the session pursuant to Section 143-318.11(a) of the North Carolina General Statutes to prevent the disclosure of information that is confidential pursuant to Sections 90-8, 90-14, 90-16, 90-21.22 of the North Carolina General Statutes and not considered a public record within the meaning of Chapter 132 of the General Statutes and/or to preserve attorney/client privilege.

Forty-four investigative cases were reviewed. A written report was presented for the Board's review. The Board adopted the recommendations and approved the written report. The specifics of this report are not included because these actions are not public information.

A motion passed to return to open session.

### **OUTREACH COMMITTEE**

Members present were: Timothy E. Lietz, MD, Chairperson; Debra A. Bolick, MD; Bryant A. Murphy, MD; Ralph A. Walker, JD, LLB.

Old Business

a. Update on ongoing Outreach activities

The Committee discussed progress in outreach for the year. The Communications Director noted that invitations from hospitals and health systems have increased, and that many more groups and programs have requested talks on responsible opioid prescribing, due to increased activity in that area.

Committee recommendation: Accept as information.

Board action: Accept Committee recommendation. Accept as information.

b. Preview of 2015 Annual Report

The Committee reviewed preliminary copies of the 2015 Annual Report; The Communications Department plans to post the report on NCMB's website by the end of March and publish a limited run of hard copies sometime in April.

Committee recommendation: Accept as information.

Board action: Accept Committee recommendation. Accept as information.

c. Update on President's mini-residency initiative

The Chief Communications Officer gave a brief progress report on plans for a mini-residency program aimed at educating medical students about the role of the Medical Board in health care. NCMB is in communication with the Brody School of Medicine at ECU and the School of Osteopathic Medicine at Campbell University and hopes to develop pilot programs that would draw participants from the ranks of student leaders (third and fourth year medical students). The Board's goal is to demonstrate the value of the concept through the pilot programs, which NCMB would then seek to replicate at the state's other medical schools.

Committee recommendation: Accept as information.

Board action: Accept Committee recommendation. Accept as information.

**ADJOURNMENT**

This meeting was adjourned at 3:00 p.m., March 18, 2016.

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Timothy E. Lietz, MD  
Secretary/Treasurer

**SUBCHAPTER 32R – CONTINUING MEDICAL EDUCATION (CME) REQUIREMENTS****SECTION .0100 – CONTINUING MEDICAL EDUCATION (CME) REQUIREMENTS****21 NCAC 32R .0101 CONTINUING MEDICAL EDUCATION (CME) REQUIRED**

(a) Continuing Medical Education (CME) is defined as education, training and activities to increase knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of healthcare to the public. The purpose of CME is to maintain, develop, or improve the physician's knowledge, skills, professional performance and relationships which physicians use to provide services for their patients, their practice, the public, or the profession.

(b) Each person licensed to practice medicine in the State of North ~~Carolina~~ Carolina, except those holding a residency training license, shall complete at least 60 hours of Category 1 CME relevant to the physician's current or intended specialty or area of practice every three years. Beginning on January 1, 2017, every physician who prescribes controlled substances, except those holding a residency training license, shall take at least three hours of CME, from the required 60 hours of Category 1 CME, that is designed specifically to address controlled substance prescribing practices. The controlled substance prescribing CME shall include instruction on controlled substance prescribing practices, recognizing signs of the abuse or misuse of controlled substances, and controlled substance prescribing for chronic pain management.

(c) The three year period described in Paragraph (b) of this Rule begins on the physician's first birthday following initial licensure.

*History Note: Authority G.S. 90-14(a)(15);2015 Session Law 12F .16(b); G.S. 90-5.1  
Eff. January 1, 2000;  
Amended Eff. \_\_\_\_\_; August 1, 2012; January 1, 2001.*

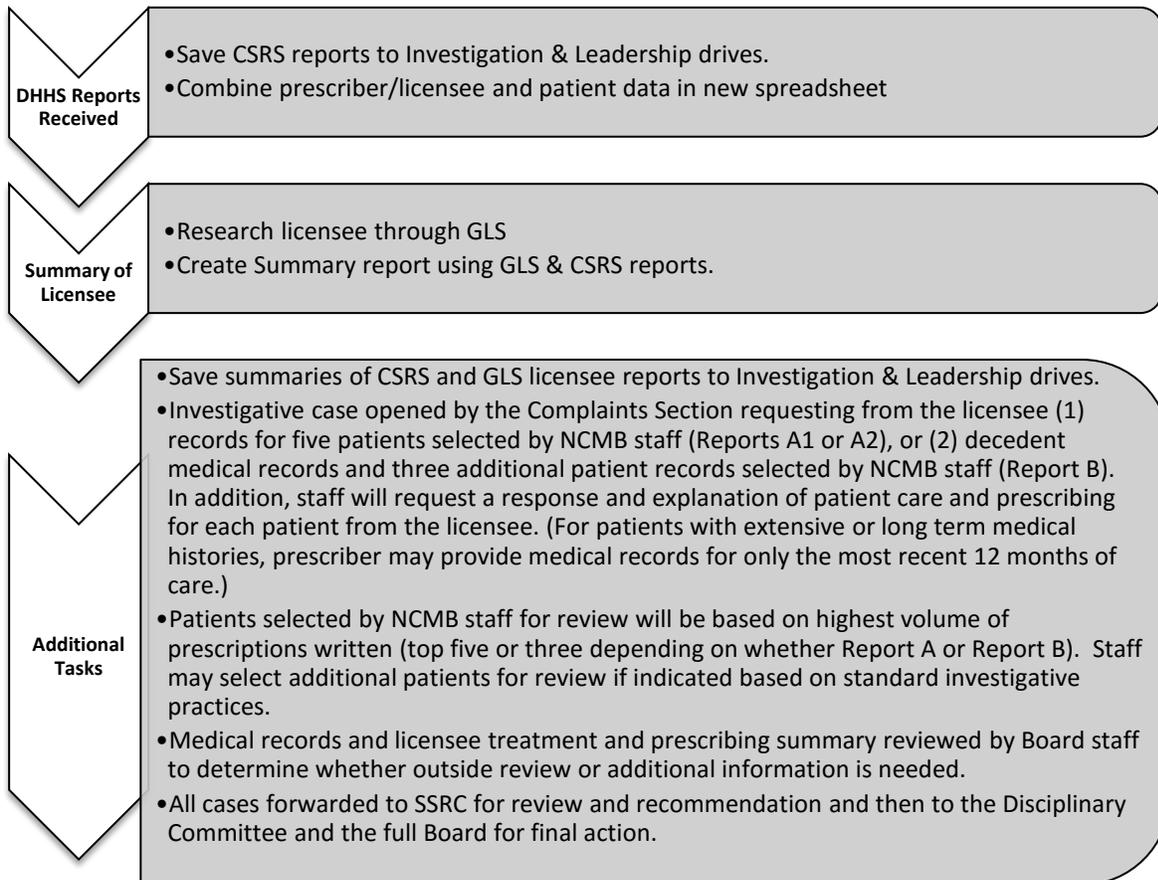
**21 NCAC 32S .0216 CONTINUING MEDICAL EDUCATION**

(a) A physician assistant shall complete at least ~~100 hours of continuing medical education (CME) every two years, at least~~ 50 hours of continuing medical education (CME) every two years. ~~which~~ The CME must be recognized by the National Commission on Certification of Physician Assistants (NCCPA) as Category I CME. A physician assistant shall provide CME documentation for inspection by the board or its agent upon request. The two year period shall run from the physician assistant's birthday, beginning in the year 1999, or the first birthday following initial licensure, whichever occurs later.

(b) Beginning on January 1, 2017, a physician assistant who prescribes controlled substances must complete at least two hours of CME, from the required 50 hours, designed specifically to address controlled substance prescribing practices. The controlled substance prescribing CME, shall include instruction on controlled substance prescribing, recognizing signs of the abuse or misuse of controlled substances, and controlled substance prescribing for chronic pain management.

~~(b)~~(c) A physician assistant who possesses a current certification with the NCCPA shall be deemed in compliance with the requirement of Paragraph (a) of this Rule. The physician assistant must attest on his or her annual renewal that he or she is currently certified by the NCCPA. Physician assistants who attest that they possess a current certificate with the NCCPA shall not be exempt from the controlled substance prescribing CME requirement of Paragraph (b) of this Rule and must complete the required two hours of controlled substance CME unless such CME is a component part of their certification activity.

*History Note: Authority G.S. 90-5.1(a)(3); 90-5.1(a)(10); 90-9.3; 90-18(c)(13); 90-18.1; 2015 Session Law 12F.16(b); G.S. 90-5.1  
Eff. September 1, 2009;  
Amended Eff. \_\_\_\_\_; May 1, 2015; November 1, 2010.*



**Federation of State Medical Boards  
House of Delegates Meeting  
April \_\_, 2016**

**Subject: Task Force to Study the Need for State Board Regulation of Physician Compounding**

**Introduced by: North Carolina Medical Board**

**Considered/Approved: January 2016**

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**Whereas,** In 2012, a meningitis outbreak resulted from contaminated steroid injections produced at the New England Compounding Center (“NECC”) in Massachusetts, a compounding pharmacy.

**Whereas,** In the aftermath of the NECC incident, pharmacy boards around the country increased the level of inspection and regulation of such compounding pharmacies.

**Whereas,** Historically, physicians have also compounded medications for the use of their patients.

Therefore, be it hereby

**Resolved,** That the Federation of State Medical Boards (FSMB) will establish a task force to review: (1) current federal regulations; (2) the degree to which physicians are currently compounding medicines; and (3) current state laws governing physician compounding.

**Resolved,** That the FSMB task force will work with the Food and Drug Administration and National Association of Boards of Pharmacy to evaluate the current regulatory environment pertaining to physician compounding.

**Resolved,** That, the FSMB task force will develop recommendations for those states that permit physician compounding.

**CURRENT POSITION STATEMENT:****Office-based procedures****Preface**

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

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

**General Guidelines****The Physician's Professional and Legal Obligation**

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

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

**Exemptions**

These guidelines do not apply to Level I procedures.

**Written Policies and Procedures**

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

**Emergency Procedure and Transfer Protocol**

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

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

### **Infection Control**

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

### **Performance Improvement**

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

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

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

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

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

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

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

### **Credentialing of Physicians**

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

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

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

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

### **Accreditation**

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

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

### **Patient Selection**

The physician who performs the surgical or special procedure should evaluate the condition of the patient and the potential risks associated with the proposed treatment plan. The physician also is responsible for determining that the patient has an adequate support system to provide for

necessary follow-up care. Patients with pre-existing medical problems or other conditions, who are at undue risk for complications, should be referred to an appropriate specialist for preoperative consultation.

### **ASA Physical Status Classifications**

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

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

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

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

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

## **Surgical or Special Procedure Guidelines**

### **Patient Preparation**

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

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

The physician performing the surgical or special procedure also should:

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

### **Discharge Criteria**

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

1. confirmation of stable vital signs;
2. stable oxygen saturation levels;
3. return to pre-procedure mental status;

4. adequate pain control;
5. minimal bleeding, nausea and vomiting;
6. resolving neural blockade, resolution of the neuraxial blockade; and
7. eligible to be discharged in the company of a competent adult.

### **Information to the Patient**

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

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

### **Reportable Complications**

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

Records of reportable complications should be in writing and should include:

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

### **Equipment Maintenance**

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

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

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

## **Compliance with Relevant Health Laws**

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

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

## **Patient Rights**

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

## **Enforcement**

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

## **Level II Guidelines**

### **Personnel**

The physician who performs the surgical or special procedure or a health care professional who is present during the intraoperative and postoperative periods should be ACLS certified, and at least one other health care professional should be BCLS certified. In an office where anesthesia services are provided to infants and children, personnel should be appropriately trained to handle pediatric emergencies (*i.e.*, APLS or PALS certified).

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

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

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

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

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

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

### **Postoperative Care and Monitoring**

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

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

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

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

### **Equipment and Supplies**

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

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

### **Level III Guidelines**

#### **Personnel**

Anesthesia should be administered by an anesthesiologist or a CRNA supervised by a physician. The physician who performs the surgical or special procedure should not administer the anesthesia. The anesthesia provider should not be otherwise involved in the surgical or special procedure. The physician or the anesthesia provider should be ACLS certified, and at least one other health care professional should be BCLS certified. In an office where anesthesia services are provided to infants and children, personnel should be appropriately trained to handle pediatric emergencies (*i.e.*, APLS or PALS certified).

## **Surgical or Special Procedure Guidelines**

### **Intraoperative Monitoring**

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

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

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

### **Postoperative Care and Monitoring**

The physician who performs the surgical or special procedure should evaluate the patient immediately upon completion of the surgery or special procedure and the anesthesia. Care of the patient may then be transferred to the care of a qualified health care professional in the recovery area. Qualified health care professionals capable of administering medications as required for analgesia, nausea/vomiting, or other indications should monitor the patient postoperatively.

Recovery from a Level III procedure should be monitored by an ACLS certified (PALS or APLS certified when appropriate) health care professional using appropriate criteria for the level of anesthesia. At least one health care professional who is ACLS certified should be immediately

available during postoperative monitoring and until the patient meets discharge criteria. Each patient should meet discharge criteria prior to leaving the operating or recovery area.

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

### **Equipment and Supplies**

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

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

### **definitions**

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

AAAHHC – the Accreditation Association for Ambulatory Health Care

ABMS – the American Board of Medical Specialties

ACGME – the Accreditation Council for Graduate Medical Education

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

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

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

Anesthesia provider – an anesthesiologist or CRNA.

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

AOA – the American Osteopathic Association

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

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

ASA – the American Society of Anesthesiologists

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

Board – the North Carolina Medical Board.

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

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

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

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

FDA – the Food and Drug Administration.

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

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

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

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

Immediately available – within the office.

JCAHO – the Joint Commission for the Accreditation of Health Organizations

Level I procedures – any surgical or special procedures:

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

Level II procedures – any surgical or special procedures:

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

Level III procedures – any surgical or special procedures:

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

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

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

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

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

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

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

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

OSHA – the Occupational Safety and Health Administration.

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

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

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

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

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

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

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

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

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

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

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

## PROPOSED POSITION STATEMENT:

**Corporate practice of medicine**

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

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

Hospital-owned practices

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

(Adopted March 2016)

## PROPOSED POSITION STATEMENT:

**Sexual Exploitation of Patients**

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

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

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

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

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

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

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

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

(Adopted May 19991)(Amended April 2012; March 2016)

## CURRENT POSITION STATEMENT:

**Care of the patient undergoing surgical or other invasive procedure\***

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

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

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

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

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

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

| <b>POSITION STATEMENT</b>  | <b>ADOPTED</b> | <b>SCHEDULED FOR REVIEW</b> | <b>LAST REVISION/ REVIEWED/ ADOPTED</b> | <b>REVISION/ REVIEWED</b> | <b>REVISION/ REVIEWED</b> | <b>REVISION/ REVIEWED</b> | <b>REVISION/ REVIEWED</b> |
|--|----------------|-----------------------------|---|---------------------------|---------------------------|---------------------------|---------------------------|
| Office-Based Procedures  | Sep-00         |                             | Mar-16                                  | Jan-03                    |                           |                           |                           |
| Sexual Exploitation of Patients                                    | Jul-93         | Mar-16                      | May-12                                  | Nov-11                    | Jul-06                    | Oct-03                    | Jan-01                    |
| Care of the Patient Undergoing Surgery or Other Invasive Procedure | May-91         | Mar-16                      | May-12                                  | Sep-06                    | Jan-01                    | Apr-96                    |                           |
| The Physician-Patient Relationship                                 | Sep-91         |                             | Jul-12                                  | Sep-06                    | Mar-01                    |                           |                           |
| The Retired Physician  | Jul-95         |                             | Jul-12                                  | Sep-06                    | Aug-03                    | Mar-02                    | Jan-00                    |
| Medical Testimony  | Jan-97         |                             | Jul-12                                  | Sep-06                    |                           |                           |                           |
| Advance Directives and Patient Autonomy                            | Mar-08         |                             | Sep-12                                  | Mar-08                    |                           |                           |                           |
| End-of-Life Responsibilities and Palliative Care                   | Jul-93         |                             | Nov-12                                  | Mar-08                    | May-96                    |                           |                           |
| Drug Overdose Prevention   | Oct-99         |                             | Jan-13                                  | Mar-08                    | May-07                    |                           |                           |
| Professional Use of Social Media                                   | Sep-08         |                             | Mar-13                                  | Sep-08                    |                           |                           |                           |
| The Treatment of Obesity   | Mar-13         |                             | Mar-13                                  |                           |                           |                           |                           |
| Contact With Patients Before Prescribing                           | Oct-87         |                             | May-13                                  | Nov-10                    | Jan-05                    | Mar-96                    |                           |
| Medical Record Documentation                                       | Nov-99         |                             | May-13                                  | Jul-10                    | Feb-01                    |                           |                           |
| Retention of Medical Records                                       | May-94         |                             | May-13                                  | May-09                    | May-96                    |                           |                           |
| Capital Punishment   | May-98         |                             | Jul-13                                  | May-09                    |                           |                           |                           |
| Professional   | Jan-07         |                             | Jul-13                                  | Jul-09                    |                           |                           |                           |

|   |        |  |         |        |        |        |        |
|---|--------|--|---------|--------|--------|--------|--------|
| Obligations pertaining to incompetence, impairment, and unethical conduct of healthcare providers |        |  |         |        |        |        |        |
| Unethical Agreements in Complaint Settlements   | Nov-98 |  | Sept-13 | Mar-10 | Nov-98 |        |        |
| Guidelines for Avoiding Misunderstandings During Physical Examinations                            | Nov-93 |  | Sept-13 | Mar-10 | May-96 |        |        |
| Departures from or Closings of Medical  | May-91 |  | Jan-14  | Jul-10 | Oct-02 | Feb-01 | Jan-01 |
| Policy for the Use of Controlled Substances for the Treatment of Pain                             | Jan-00 |  | May-13  | Jul-09 | Aug-03 |        |        |
| Access to Physician Records   | Sep-96 |  | May-14  | Jan-13 | Sep-08 | Jul-05 |        |
| Medical Supervisor-Trainee Relationship   | Nov-93 |  | May-14  | Sep-10 | Aug-03 | Mar-02 | Sep-97 |
| Advertising and Publicity   | Apr-04 |  | Jul-14  | Nov-10 | Apr-04 |        |        |
| Telemedicine  | Nov-99 |  | Aug-14  | Nov-10 | Sep-05 | Mar-01 |        |
| Medical, Nursing, Pharmacy Boards: Joint Statement on Pain Management in End-of-Life Care         | May-10 |  | Nov-14  | May-10 |        |        |        |
| Writing of Prescriptions  | Oct-99 |  | Nov-14  | Jan-11 | Oct-99 |        |        |
| HIV/HBV Infected Health Care Workers  | May-91 |  | Jan-15  | Mar-11 | Mar-05 | Jul-02 | Mar-02 |
| Laser Surgery   | Nov-92 |  | Mar-15  | Jan-11 | Jan-05 | May-96 |        |
| Sale of Goods From Physician Offices  | Jul-99 |  | Mar-15  | Jul-05 | Jul-05 | Aug-02 | Mar-02 |
| Competence and  | Mar-01 |  | Mar-15  | May-11 | Mar-06 |        |        |

|  |        |        |        |        |         |        |        |
|--|--------|--------|--------|--------|---------|--------|--------|
| Reentry to the Active Practice of Medicine   |        |        |        |        |         |        |        |
| Prescribing Controlled Substances for Other Than Valid Medical or Therapeutic Purposes, with Particular Reference to Substances or Preparations with Anabolic Properties | Jul-06 |        | May-15 | Jul-06 | May-15  |        |        |
| Referral Fees and Fee Splitting  | Jul-07 |        | Sep-12 | Jul-07 | Sept-15 |        |        |
| Physician Supervision of Other Licensed Health Care Practitioners  | Jul-07 |        | Nov-15 |        |         |        |        |
| Self- Treatment and Treatment of Family Members and Others With Whom Significant Emotional Relationships Exist   | Nov-93 |        | Nov-15 | Jul-06 | May-96  |        |        |
| Availability of Physicians to Their Patients   | May-91 | Jan-16 | Mar-12 | Sep-05 | Mar-02  | May-00 | May 96 |

21 NCAC 32T .0101 is proposed to be amended as follows:

## 21 NCAC 32T .0101 CLINICAL PHARMACIST PRACTITIONER

(a) Definitions as used in the Rule:

- (1) "Medical Board" means the North Carolina Medical Board.
- (2) "Pharmacy Board" means the North Carolina Board of Pharmacy.
- (3) "Joint Subcommittee" means the subcommittee composed of four members of the Pharmacy Board and four members of the Medical Board to whom responsibility is given by G.S. 90-6(c) to develop rules to govern the provision of drug therapy management by the Clinical Pharmacist Practitioner in North Carolina.
- (4) "Clinical Pharmacist Practitioner or CPP" means a licensed pharmacist who is approved to provide drug therapy management under the direction of, or under the supervision of a licensed physician who has provided written instructions for a patient and disease specific drug therapy which may include ordering, changing, substituting therapies or ordering tests. Only a pharmacist approved by the Pharmacy Board and the Medical Board may legally identify himself as a CPP.
- (5) "Supervising Physician" means a licensed physician who, by signing the CPP agreement, is held accountable for the on-going supervision and evaluation of the drug therapy management performed by the CPP as defined in ~~the physician, patient, pharmacist and disease specific~~ written CPP agreement.
- (6) "Primary Supervising Physician" means the licensed physician who shall provide on-going supervision, collaboration, consultation, and evaluation of the drug therapy management performed by the CPP as defined in the written CPP agreement.
- (7) "Back-up Supervising Physician" means a licensed physician who shall provide supervision, collaboration, consultation, and evaluation of the drug therapy management performed by the CPP as defined in the written CPP agreement when the Primary Supervising Physician is not available.
- ~~(6)~~(8) "Approval" means authorization by the Medical Board and the Pharmacy Board for a pharmacist to practice as a CPP in accordance with this Rule.
- ~~(7)~~(9) "Continuing Education or CE" is defined as courses or materials which have been approved for credit by the American Council on Pharmaceutical Education.
- ~~(8)~~(10) "Clinical Experience approved by the Boards" means work in a pharmacy practice setting which includes experience consistent with the following components as listed in Parts (b)(2)(A), (B), (C), (D), (E), (H), (I), (J), (N), (O), and (P) of this Rule. Clinical experience requirements must be met only through activities separate from the certificate programs referred to in Parts (b)(1)(B) of this Rule.

(b) CPP application for approval.

- (1) The requirements for application for CPP approval include that the pharmacist:
  - (A) has an unrestricted and current license to practice as a pharmacist in North Carolina;
  - (B) meets one of the following qualifications:
    - (i) has earned Certification from the Board of Pharmaceutical Specialties, is a Certified Geriatric Pharmacist as certified by the Commission for Certification in Geriatric Pharmacy, or has completed an American

Society of Health System Pharmacists (ASHP) accredited residency program, which includes two years of clinical experience approved by the Boards;

- (ii) has successfully completed the course of study and holds the academic degree of Doctor of Pharmacy and has three years of clinical experience approved by the Boards and has completed a North Carolina Center for Pharmaceutical Care (NCCPC) or American Council on Pharmaceutical Education (ACPE) approved certificate program in the area of practice covered by the CPP agreement; or
  - (iii) has successfully completed the course of study and holds the academic degree of Bachelor of Science in Pharmacy and has five years of clinical experience approved by the Boards and has completed two NCCPC or ACPE approved certificate programs with at least one program in the area of practice covered by the CPP agreement;
- (C) submits the required application and the fee to the ~~Medical~~ Pharmacy Board;
  - (D) submits any information deemed necessary by the ~~Medical~~ Pharmacy Board in order to evaluate the application; and
  - (E) has a signed supervising physician agreement.

If for any reason a CPP discontinues working in the approved physician arrangement, the clinical pharmacist practitioner shall notify ~~both Boards~~ the Pharmacy Board in writing within ten days and the CPP's approval shall automatically terminate or be placed on an inactive status until such time as a new application is approved in accordance with this Subchapter.

- (2) All certificate programs referred to in Subpart (b)(1)(B)(i) of this Rule must contain a core curriculum including the following components:
- (A) communicating with healthcare professionals and patients regarding drug therapy, wellness, and health promotion;
  - (B) designing, implementing, monitoring, evaluating, and modifying or recommending modifications in drug therapy to insure effective, safe, and economical patient care;
  - (C) identifying, assessing and solving medication-related problems and providing a clinical judgment as to the continuing effectiveness of individualized therapeutic plans and intended therapeutic outcomes;
  - (D) conducting physical assessments, evaluating patient problems, ordering and monitoring medications and laboratory tests;
  - (E) referring patients to other health professionals as appropriate;
  - (F) administering medications;
  - (G) monitoring patients and patient populations regarding the purposes, uses, effects and pharmacoeconomics of their medication and related therapy;
  - (H) counseling patients regarding the purposes, uses, and effects of their medication and related therapy;
  - (I) integrating relevant diet, nutritional and non-drug therapy with pharmaceutical care;
  - (J) recommending, counseling, and monitoring patient use of non-prescription drugs, herbal remedies and alternative medicine practices;

- (K) ordering of and educating patients regarding proper usage of devices, and durable medical equipment;
  - (L) providing emergency first care;
  - (M) retrieving, evaluating, utilizing, and managing data and professional resources;
  - (N) using clinical data to optimize therapeutic drug regimens;
  - (O) collaborating with other health professionals;
  - (P) documenting interventions and evaluating pharmaceutical care outcomes;
  - (Q) integrating pharmacy practice within healthcare environments;
  - (R) integrating national standards for the quality of healthcare; and
  - (S) conducting outcomes and other research.
- (3) The completed application for approval to practice as a CPP shall be reviewed by the Medical Board upon verification of a full and unrestricted license to practice as a pharmacist in North Carolina.
- (A) The application shall be approved and at the time of approval the Medical Board shall issue a number which shall be printed on each prescription written by the CPP; or
  - (B) the application shall be denied; or
  - (C) the application shall be approved with restrictions.
- (c) Annual Renewal.
- (1) Each CPP shall register annually on or before December 31 ~~the anniversary of his or her birth date~~ by:
- (A) verifying a current Pharmacist license;
  - (B) submitting the renewal fee as specified in Subparagraph (j)(2) of this Rule;
  - (C) completing the Medical Pharmacy Board's renewal form; and
  - (D) reporting continuing education credits as required by subsection (d) of this Rule. ~~specified by the Medical Board.~~
- (2) If the CPP has not renewed within ~~30~~ 60 days of December 31, ~~the anniversary of the CPP's birth date~~, the approval to practice as a CPP shall lapse.
- (d) Continuing Education.
- (1) Each CPP shall earn 35 hours of practice relevant CE each year approved by the Pharmacy Board.
- (2) Documentation of these hours shall be kept at the CPP practice site and made available for inspection by agents of the Medical Board or Pharmacy Board.
- (e) ~~The~~ A supervising physician who has a signed agreement with the CPP shall be readily available for consultation with the CPP; and shall review ~~and countersign~~ each order written by the CPP. ~~CPP within seven days.~~
- (f) The written CPP agreement shall:
- (1) be approved and signed by ~~both~~ the Primary Supervising Physician, and Back-Up Supervising Physician ~~supervising physician~~ and the CPP ~~CPP~~, and a copy shall be maintained in each practice site for inspection by agents of either Board upon request;
  - (2) be specific in regards to the physician, the pharmacist, the patient and the disease;
  - (3) specify the predetermined drug therapy which shall include the diagnosis and product selection by the patient's physician; any modifications which may be permitted, dosage forms, dosage schedules and tests which may be ordered;

- (4) prohibit the substitution of a chemically dissimilar drug product by the CPP for the product prescribed by the physician without first obtaining written consent of the physician;
  - (5) include a pre-determined plan for emergency services;
  - (6) for the first six months of the CPP agreement, include a plan and schedule for monthly meetings to discuss practice-relevant clinic issues and quality improvement measures weekly quality control, review and countersignature of all orders written by the CPP in a face-to-face conference between the physician Primary Supervising Physician and CPP, and thereafter include a plan and schedule for meetings between the Primary Supervising Physician and CPP at least every six months to discuss practice-relevant clinical issues and quality improvement measures. Documentation of the meetings between the CPP and the Primary Supervising Physician shall: CPP;
    - (A) identify clinical issues discussed and actions taken;
    - (B) be signed and dated by those who attended; and
    - (C) be retained by both the CPP and Primary Supervising Physician and be available for review by members or agents of either Board for five calendar years;
  - (7) require that the patient be notified of the collaborative relationship; and
  - (8) be terminated when patient care is transferred to another physician and new orders shall be written by the succeeding physician.
  - (g) The supervising physician of the CPP shall:
    - (1) be fully licensed with the Medical Board and engaged in clinical practice;
    - (2) not be serving in a postgraduate medical training program;
    - (3) be approved in accordance with this Subchapter before the CPP supervision occurs; and
    - (4) supervise no more than three pharmacists.
  - (h) The CPP shall wear a nametag spelling out the words "Clinical Pharmacist Practitioner".
  - (i) The CPP may be censured or reprimanded or the CPP's approval may be restricted, suspended, revoked, annulled, denied or terminated by the Medical Board or the Pharmacy Board and the pharmacist may be censured or reprimanded or the pharmacist's license may be restricted, suspended, revoked, annulled, denied, or terminated by the Pharmacy Board, in accordance with provisions of G.S. 150B if either Board finds one or more of the following:
    - (1) the CPP has held himself or herself out or permitted another to represent the CPP as a licensed physician;
    - (2) the CPP has engaged or attempted to engage in the provision of drug therapy management other than at the direction of, or under the supervision of, a physician licensed and approved by the Medical Board to be that CPP's supervising physician;
    - (3) the CPP has performed or attempted to provide medical management outside the approved drug therapy agreement or for which the CPP is not qualified by education and training to perform;
    - (4) The CPP commits any act prohibited by any provision of G.S. 90-85.38 as determined by the Pharmacy Board or G.S. 90-14(a)(1), (a)(3) through (a)(14) and (c) as determined by the Medical Board; or
    - (5) the CPP has failed to comply with any of the provisions of this Rule.
- Any modification of treatment for financial gain on the part of the supervising physician or CPP shall be grounds for denial of Board approval of the agreement.
- (j) Fees:

- (1) An application fee of one hundred dollars (\$100.00) shall be paid at the time of initial application for approval and each subsequent application for approval to practice.
- (2) The fee for annual renewal of approval, due at the time of annual renewal pursuant to subsection (c) of this Rule, ~~on the CPP's anniversary of birth date~~ is fifty dollars (\$50.00).
- (3) No portion of any fee in this Rule is refundable.

*History Note* Authority G.S. 90-6(c); 90-18(c)3a; 90-18.4;  
Eff. April 1, 2001;  
Amended Eff. July 1, 2016; March 1, 2007; October 1, 2001.

**21 NCAC 32S .0213 PHYSICIAN SUPERVISION OF PHYSICIAN ASSISTANTS**

- (a) A physician wishing to serve as a primary supervising physician shall exercise supervision of the physician assistant in accordance with rules adopted by the Board.
- (b) A physician assistant may perform medical acts, tasks, or functions only under the supervision of a physician. Supervision shall be continuous but, except as otherwise provided in the rules of this Subchapter, shall not be construed as requiring the physical presence of the supervising physician at the time and place that the services are rendered.
- (c) Each team of physician(s) and physician assistant(s) shall ensure:
- (1) the physician assistant's scope of practice is identified;
  - (2) delegation of medical tasks is appropriate to the skills of the supervising physician(s) as well as the physician assistant's level of competence;
  - (3) the relationship of, and access to, each supervising physician is defined; and
  - (4) a process for evaluation of the physician assistant's performance is established.
- (d) Each supervising physician and physician assistant shall sign a statement, as defined in Rule .0201(9) of this Subchapter, that describes the supervisory arrangements in all settings. The physician assistant shall maintain written prescribing instructions at each site. This statement shall be kept on file at all practice sites, and shall be available upon request by the Board.
- (e) A primary supervising physician and a physician assistant in a new practice arrangement shall meet monthly for the first six months to discuss practice relevant clinical issues. ~~and quality improvement measures.~~ Thereafter, the primary supervising physician and the physician assistant shall meet at least once every six months. A written record of these meetings shall be signed and dated by both the supervising physician and the physician assistant, and shall be available upon request by the Board, and shall be available for review by members or agents of the Board for five (or three?) calendar years and be retained by both the physician assistant and primary supervising physician. The written record shall include a description of the relevant clinical issues discussed. ~~and the quality improvement measures taken.~~

*History Note: Authority G.S. 90-9.3; 90-18(c)(13); 90-18.1;  
 Eff. September 1, 2009;  
 Amended Eff. May 1, 2015.*