MINUTES

NORTH CAROLINA MEDICAL BOARD

January 20-21, 2016

1203 Front Street
Raleigh, North Carolina

General Session Minutes of the North Carolina Medical Board Meeting held January 20-21, 2016.

The January 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 Arnold; Ms. H. Diane Meelheim, FNP-BC; Mr. A. Wayne Holloman; Bryant A. Murphy, MD; Debra Bolick, MD; Judge Ralph A. Walker and Barbara E. Walker, DO. Board Members absent: Subhash C. Gumber, MD.

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.

Minute Approval

Motion: A motion passed to approve the November 18-20, 2015 Board Minutes and the December 10-11, 2015 Hearing Minutes.

Announcements

Dr. Lietz announced that Dr. Walker-McGill is a candidate for the Federation of State Medical Boards (FSMB) Board of Directors. The election will occur at the FSMB Annual Meeting in April. Dr. Udekwu reminded the Board members that although the NCMB is a member of the FSMB, the NCMB will continue to evaluate FSMB actions and recommendations in the context of the NCMB's responsibility to the people of North Carolina.

Dr. Udekwu announced that the Governor reappointed Dr. Greene for another term on the Board.

Mr. Henderson announced that applications for the nurse practitioner and physician assistant seats were due to the Review Panel on December 22nd. The Review Panel will meet on January 30th to conduct interviews.

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.

A motion passed to direct Thomas W. Mansfield, Chief Legal Officer, to write on behalf of the Board to Jesse Cavenar, Jr., MD, with regard to his recent correspondence. Mr. Mansfield will inform Dr. Cavenar of the following:

- In the event Dr. Cavenar would like to file a complaint against a licensee of the Board, he must use the Board's online complaint process;
- The Board will investigate such a complaint if Dr. Cavenar provides identifying information and the allegations in the complaint have not been previously investigated;
- All communications from Dr. Cavenar regarding any other concerns, comments or questions he wishes to present to the Board shall be addressed to the Board's Chief Legal Officer; and
- Such communications regarding other concerns will be reviewed to determine whether those issues have been investigated previously.

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 Strategic Goals Tracker update will be discussed during the Chief Executive Officer's "State of the Organization" presentation on Thursday, January 21, 2016. Staff recommended that this agenda item be deferred until that time.

Committee Recommendation: Defer the Strategic Goals Tracker update until Thursday, January 21, 2016.

Board Action: The following are approved: the final report for the 2015 goals; the revised language for the 2016 goals; and the proposed activities, outcomes and measures for the 2016 goals.

Financial Statements

a. Monthly Accounting

The Committee reviewed the compiled financial statements for November 2015. November is the first month of fiscal year 2016.

Committee Recommendation: Accept the financial statements as reported.

Board Action: Accept Committee Recommendation. Accept the financial statements as reported.

b. Investment Account Statements

The Committee reviewed the investment statements for November and December 2015.

Committee Recommendation: Accept as information.

Board Action: Accept Committee Recommendation. Accept as information.

c. Year-End Financial Statement Audit (Koonce, Wooten & Haywood, LLP)

Mr. Chris Duffus, CPA and Mr. Joshua Anderson, CPA, with the firm Koonce, Wooten & Haywood, LLP, presented the audited financial statements for the fiscal year ending October 31, 2015. Messrs. Duffus and Anderson verified that the statements have been presented fairly and in accordance with generally accepted accounting principles. An unmodified opinion has been made in the report.

Staff was excused from the room in order to afford the Executive Committee an opportunity to ask questions and/or discuss any concerns directly with the auditors.

Committee Recommendation: Accept the audit report as presented.

Board Action: Accept Committee Recommendation. Accept the audit report as presented.

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.

Staff drafted proposed changes to the CME rule for consideration by the Board as follows: For physicians who prescribe controlled substances, at least three hours of the Category 1 CME required in a three-year cycle shall be controlled substances CME. For physician assistants who prescribe controlled substances, at least two hours of the Category 1 CME required in a two-year cycle shall be controlled substances CME. Copies of the rules with proposed changes are attached as (Appendix A).

Committee Recommendation: Approve draft rules for dissemination to interested parties via the website, Forum and other means. Collect feedback and report back to the Board in March 2016.

Board Action: Accept Committee Recommendation. Approve draft rules for dissemination to interested parties via the website, Forum and other means. Collect feedback and report back to the Board in March 2016.

POLICY COMMITTEE REPORT

Members Present: Cheryl L. Walker-McGill, MD, Chairperson; Mr. Michael J. Arnold; H. Diane Meelheim, FNP-BC and Mr. Wayne Holloman.

Old Business

a. Physician Compounding (Appendix B)

The Board has been approached by the FSMB about the issue of physician compounding. Discussions between staff and the FSMB have resulted in a recommendation by staff that the Board create a resolution to have the FSMB form a task force to study the regulatory environment as it relates to physician compounding. A proposed resolution was provided to the Committee.

Committee Recommendation: Approve submission of draft resolution to the FSMB.

Board Action: Accept Committee recommendation. Approve submission of draft resolution to the FSMB.

b. Office-based procedures

Staff gave an update regarding retaining an outside agency to review the Board's position statement on office-based procedures.

Committee Recommendation: Table discussion until March 2016 Board meeting.

Board Action: Accept Committee recommendation. Table discussion until March 2016 Board meeting.

New Business

a. Corporate practice of medicine (Appendix C)

Staff shared a proposed corporate practice of medicine position statement and explained its genesis. The Committee suggested providing a hyperlink to the statutory reference.

Committee Recommendation: Allow Legal Department to make suggested changes and bring back to the Committee in March 2016.

Board Action: Accept Committee recommendation. Allow Legal Department to make suggested changes and bring back to the Committee in March 2016.

b. Physician longevity and wellness (Appendixes D and E)

Staff suggested a new category of documents should be created to differentiate the disciplinary nature of position statements from the guidance and advice nature of both the Longevity in Practice statement and the Physician Wellness Engagement and Resiliency statement. It was also suggested that these types of statements are more consistent with the mission of the Outreach Committee and would, perhaps, best be overseen by that committee. An update on the Longevity Workgroup was also provided. The workgroup determined that its goals had been accomplished with the placement of this statement in the Outreach Committee and its work is now concluded.

Committee Recommendation: Create new category of advisory statements to include the Longevity in Practice and Physician Wellness Engagement and Resiliency statements. Refer these statements to the Outreach Committee.

Board Action: Accept Committee recommendation. Create new category of advisory statements to include the Longevity in Practice and Physician Wellness Engagement and Resiliency statements. Refer these statements to the Outreach Committee.

c. Availability of licensees to their patients

The Committee queried whether there were any suggested changes or issues. There were none at this time.

Committee Recommendation: Accept position statement in its current form and note review by the Board.

Board Action: Accept Committee recommendation. Accept position statement in its current form and note review by the Board.

d. Telemedicine

Dr. Hafner-Fogarty mailed a letter to the Board President requesting changes to the Telemedicine position statement.

The Committee reviewed the suggestions made in the letter. It was acknowledged that the term “virtual medicine” may, in fact, be more appropriate down the road. However, this issue was discussed at the national level prior to the Board’s adoption of the position statement and it was determined that telemedicine was the most widely accepted term at this time. The Committee also briefly discussed the suggestion regarding adaptive interviews and determined that the suggestion was not appropriate at this time.

Committee Recommendation: Accept letter as information and thank Dr. Hafner-Fogarty for her submission.

Board Action: Accept Committee recommendation. Accept letter as information and thank Dr. Hafner-Fogarty for her submission.

e. Position Statement Review Tracking Chart (Appendix F)

The Policy 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 Murphy, MD, Chairperson; Debra Bolick, MD; Eleanor Greene, MD; Mr. A. Wayne Holloman, Judge Ralph Walker

New Business

a. Reentry

During the November 2015 Board meeting, the Board asked the License Committee to review the reentry diagram and the potential delay when requiring all Path 3 applicants to appear for a split board license interview. The specific issue for consideration is whether the interview requirement can be made discretionary in the Board's judgement based on the individual facts of each application. The concern is that imposing a mandatory requirement for all Path 3 reentry applicants is causing unnecessary delay in some applications.

Committee Recommendation: Change the mandatory split board licensure requirement in Path 3 to a discretionary one as in Path 2.

Board Action: Accept the Committee recommendation. Change the mandatory split board licensure requirement in Path 3 to a discretionary one as in Path 2.

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 nine 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: H. Diane Meelheim, FNP-BC, Chairperson; Barbara E. Walker, DO

Old Business

1. NURSE PRACTITIONERS

   Rules for Approval (Appendix G)

The Committee considered proposed rule changes to 21 NCAC 32M.0117 (reporting criteria). On September 16, 2015, the Board approved the Allied Health Committee's recommendation to approve the attached proposed rule, which allows the NC Board of Nursing to receive certain information obtained in the NC Controlled Substances Reporting System pursuant to NCGS 90-113.74. The proposed rule was published in the NC Register. A public hearing was held on January 14, 2016. No one attended the hearing. One comment was received. If approved by the Rules Review commission, the proposed effective date is April 1, 2016.

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.

New Business

1. PHYSICIAN ASSISTANTS

   No items for discussion.

2. PERFUSIONISTS

Minutes of the November, 2015 PAC meeting

Committee Recommendation: Accept the minutes of the November 2015 Perfusionist Advisory Committee (PAC) meeting.

Board Action: Accept Committee recommendation. Accept the minutes of the November 2015 Perfusionist Advisory Committee (PAC) meeting.

3. CLINICAL PHARMACIST PRACTITIONERS

No items for discussion.

4. NC EMERGENCY MEDICAL SERVICES (EMS)

EMS Requests for Scope of Practice Changes

The NC Medical Board EMS Advisory Group met on November 10, 2015. Dr. Tripp Winslow, Office of Emergency Medical Services ("OEMS") Medical Director, was present and discussed his report. The Advisory Group requests that the Board approve the following changes to the EMS scope of practice:

1. Allow Basic Life Support(BLS)]personnel to utilize continuous capnography monitoring;
2. Allow BLS personnel to place gastric tubes through blind insertion airway devices – no medications of fluids may be administered through the gastric tube;
3. Anti-viral medications should be included for paramedics. These are needed for inter-facility, because they sometimes have to be given for inter-facility transports. OEMS would like blanket approval for anti-viral medications.

Committee Recommendation: Accept the proposed changes.

Board Action: Accept Committee recommendation. Accept the proposed changes.

5. ANESTHESIOLOGIST ASSISTANTS

No items for discussion.

6. NURSE PRACTITIONERS

No items for discussion.

7. POLYSOMNOGRAPHIC TECHNOLOGISTS

No items for discussion.

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 Allied Health Committee reviewed two Physician Assistant cases. 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 (COMPLAINTS) COMMITTEE REPORT

Members present were: Barbara E. Walker, DO, Chairperson; Mr. Michael J. Arnold; Eleanor E. Greene, MD; Timothy E. Lietz, MD; H. Diane Meelheim, FNP 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 twenty-one 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; Timothy E. Lietz, MD; H. Diane Meelheim, FNP 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 thirty-nine 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; Timothy E. Lietz, MD; H. Diane Meelheim, FNP 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 two 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; H. Diane Meelheim, FNP; 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 plans for outreach this year. Last year residency programs were a priority. This year, staff will focus on hospital/health system opportunities. Staff have approached NC Hospital Association for assistance getting the word out to member institutions. Staff are also working with the major malpractice carriers in the state to determine whether NCMB can partner with them to reach licensee insureds. The staff is also working to identify opportunities to speak to patient/consumer groups. If Board Members are active in any community groups (Rotary Club, Ruritans, etc.) and can provide the Communications with a name and contact information, staff will follow up and try to schedule a talk.

Committee recommendation: Accept as information only.

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

b. Update on mini-profile of Board Members

Staff shared a mock-up of the planned Q & A article series featuring individual Board Members. The first Q & A article, featuring Dr. Udekwu, is planned for the Spring 2016 issue of the Forum. The Committee noted that staff should schedule future mini profiles based on Board Member term expiration dates to ensure Board Members are featured before their terms expire.

Committee recommendation: Staff should proceed with plans to photograph several Board Members at the March 2016 Board Meeting and send questions for completion to the next two Board Members to be featured.

Board action: Accept Committee recommendation. Staff should proceed with plans to photograph several Board Members at the March 2016 Board Meeting and send questions for completion to the next two Board Members to be featured.

New Business:

a. Implementation of Longevity in Practice Workgroup recommendations

The Committee discussed the Longevity in Practice Workgroup's work to date. The Workgroup will prepare a summary of the Roundtable discussion notes for posting on the NCMB website. The Workgroup has not identified useful resources at this time but will continue to research this. The Committee discussed what content would be appropriate on Outreach slides and noted that the Board should be careful in how it communicates its interest in Longevity in Practice, recognizing this is a sensitive issue.

Committee recommendation: The Workgroup and staff should continue to search for useful resources related to Longevity in Practice; Staff should create several Outreach slides on the topic for consideration by the Committee.

Board action: Accept Committee recommendation. The Workgroup and staff should continue to search for useful resources related to Longevity in Practice; Staff should create several Outreach slides on the topic for consideration by the Committee.

b. President's mini-internship program

The Chief Communications Officer summarized planning to date for this new initiative and said the Committee will be kept advised as planning progresses.

Committee recommendation: Accept as information only.

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

c. 2015 NCMB Annual Report

Discussion of program overview highlights to be included in report.

The Communications Director outlined plans for production of the 2015 NCMB agency annual report. The Committee discussed several 2015 accomplishments and suggested some additional items, such as the creation by statute of a 13th Board seat reserved for a physician assistant member.

Committee recommendation: The Communication Department should proceed with Annual Report; Production of the report will begin in February and the report is scheduled for publication by March 31.

ADJOURNMENT

This meeting was adjourned at 6:00 p.m., January 21, 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.

Resolution 16-__

Federation of State Medical Boards
House of Delegates Meeting
April 30, 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**

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.

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.

<u>Hospital-owned practices</u>

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.

Longevity in Practice

As the Board's licensees advance in their practices and careers, new issues and concerns, as well as opportunities, may develop over time. It is the aim of the Board to protect the public by providing guidance and resources to its licensees so that they may surmount any relevant hurdles and take advantage of the opportunities that their experience may provide.

Licensees of the Board have an obligation to their patients and themselves to ensure that their health is not an obstacle to providing safe, effective care. Licensees also have an ethical obligation to address issues of impairment or incompetence that they identify in their colleagues.

Although individuals are affected by age differently, the reality is that there is a general association between the aging process and cognitive and physical decline. The Board notes that other healthcare related tools such as wisdom, compassion, and management of stress may improve with age.

Because there is no certain age at which a licensee will experience physical or cognitive decline, the Board encourages its licensees to undergo appropriate examinations and assessments if they experience symptoms that might forecast potential physical or cognitive impairment. In some instances, such assessments can identify ways in which a licensee can undergo remediation to ensure that patient care is not compromised.

Licensees may also decide to make other modifications to their practice if they determine that they have experienced some decline in their clinical ability. Such modifications might include stopping or limiting more complex procedural work, narrowing the scope of one's practice, allotting more time to each patient, or cutting back work hours.

In some instances, the licensee may ultimately decide that the appropriate step is to retire from the active practice of medicine. The Board believes that even as licensees transition out of clinical practice, they can be a vital resource to the patients of North Carolina either by serving in leadership positions, as mentors, or through appropriate volunteer opportunities.

Physician wellness, engagement and resiliency

It is the position of the North Carolina Medical Board that its licensees have a professional obligation to take care of themselves. The role of the Board has always been "for the benefit and protection of the people of North Carolina." Data shows that there is a growing trend of burnout among physicians and health care professionals. When licensees are burned out, the people of North Carolina are at risk. Stress and burnout can have detrimental effects on a licensee that can lead to depression, addiction, or suicide. For patients, this may lead to substandard care or even lack of care.

Burnout can develop over time and the signs can be subtle or overt. The Board encourages its licensees to continuously evaluate themselves for signs of burnout throughout their career. In addition, if these signs of burnout come to the attention of a licensee in another physician, then he or she should consider intervening. Signs and symptoms of burnout include, but are not limited to:

- Physical, mental, and emotional exhaustion
- Depersonalization and cynicism
- Self-doubt
- Inability to concentrate, focus or remember
- Decreased appetite
- Sleep disturbance
- Lethargy
- Frequent headaches, dizziness, muscle aches and pains
- Loss of motivation, ideals and hope
- Depression or thoughts of suicide
- Withdrawal from people and responsibilities
- Disengagement and detachment
- Addictions to food, drugs, alcohol or other addictive behaviors
- Increased irritability
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For a comprehensive assessment, consider taking the Maslach Burnout Inventory assessment.

In addition to recognizing the signs of burnout, the Board encourages its licensees to take preventative steps to reduce the risk of burnout. Contributing factors to burnout can include circumstances at home, illness, personal loss, finances, or other significant changes. However, work environment is generally the leading contribution to professional burnout. Licensees should be attentive to burnout inducing workplace conditions such overscheduling and patient overload, reduced time with patients, increased paperwork, lack of professional support, working extended hours without breaks for eating and sleeping, and other administrative pressures. There are a number of ways to alter these conditions:

- Becoming more involved with administrative decision making
- Delegating work to others
- Asking for help or if able, hiring help
- Setting limits and learning to say no

- Altering priorities
- Leaving work at work and not bringing it home
- Stop trying to please everyone
- Talking with colleagues and mentors
- Spending free time with loved ones
- Taking regular time off
- Volunteering for a worthy cause
- Relaxing and meditating
- Exercising regularly
- Eating Healthy
- Getting enough sleep
- Making regular appointments with your primary health care provider

The Board recommends seeking a professional opinion since assessing oneself is always difficult. Simply asking for help will not lead to an adverse Board action. Licensees may contact the North Carolina Physicians Health Program and its support will remain anonymous as long as licensees are deemed safe to practice and there is no risk of harm to the public. Throughout their career, licensees should be mindful of the risk of burnout. Avoiding contributing factors and detecting the signs and symptoms early can reduce this risk. In addition, licensees should promote their own well-being, engage in their work in a meaningful way, and practice resiliency – the ability to withstand stress and grow stronger over time.

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POSITION STATEMENT	ADOPTED	SCHEDULED FOR REVIEW	LAST REVISED/ REVIEWED/ ADOPTED	REVISED/ REVIEWED	REVISED/ REVIEWED	REVISED/ REVIEWED	REVISED/ REVIEWED
Office-Based Procedures	Sep-00	May-15	May-11	Jan-03			
Availability of Physicians to Their Patients	May-91	Jan-16	Mar-12	Sep-05	Mar-02	May-00	May 96
Sexual Exploitation of Patients	Jul-93		May-12	Nov-11	Jul-06	Oct-03	Jan-01
Care of the Patient Undergoing Surgery or Other Invasive Procedure	May-91		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 Obligations pertaining to incompetence, impairment, and unethical conduct of healthcare providers	Jan-07		Jul-13	Jul-09			
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 Reentry to the Active Practice of Medicine	Mar-01		Mar-15	May-11	Mar-06		
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		

21 NCAC 32M .0117 is proposed for adoption as follows:

21 NCAC 32M .0117 REPORTING CRITERIA

(a) The Department of Health and Human Services ("Department") may report to the North Carolina Board of Nursing ("Board of Nursing") information regarding the prescribing practices of those nurse practitioners ("prescribers") whose prescribing:

(1) falls within the top one percent of those prescribing 100 milligrams of morphine equivalents ("MME") per patient per day; or

(2) falls within the top one percent of those prescribing 100 MME's per patient per day in combination with any benzodiazepine and who are within the top one percent of all controlled substance prescribers by volume.

(b) In addition, the Department may report to the Board information regarding prescribers who have had two or more patient deaths in the preceding twelve months due to opioid poisoning.

(c) The Department may submit these reports to the Board upon request and may include the information described in G.S. 90-113.73(b).

(d) The reports and communications between the Department and the Board shall remain confidential pursuant to G.S. 90-16 and G.S. 90-113.74.

History Note: Authority G.S. 90-113.74;
Eff. May 1, 2015.