General Session Minutes of the North Carolina Medical Board Meeting held May 18-20, 2011.

The North Carolina Medical Board met May 18-20, 2011, at its office located at 1203 Front Street, Raleigh, NC. Janice E. Huff, MD, President, called the meeting to order. Board members in attendance were: Donald E. Jablonski, DO, Past President; Ralph C. Loomis, MD, President-Elect; William A. Walker, MD, Secretary/Treasurer; Ms. Pamela Blizzard; Thomas R. Hill, MD; Ms. Thelma Lennon; Peggy R. Robinson, PA-C; Paul S. Camnitz, MD; Karen R. Gerancher, MD and Eleanor E. Greene, MD. Absent was John B. Lewis, Jr., LLB.

Presidential Remarks

Dr. Huff commenced the meeting by reading from the State Government Ethics Act, “Ethics awareness and conflict of interest reminder.” No conflicts were reported.

Minute Approval

Motion: A motion passed to approve the March 16, 2011 Board Minutes and the April 14, 2011 Hearing Minutes.

Announcements

1. Mr. Curt Ellis, Director of Investigations, recognized Mr. Jerry Weaver as a new Investigator with the NCMB.

2. Mr. David Henderson, Executive Director, recognized Mr. Thom Mansfield on his ten-year anniversary at the NCMB.

EXECUTIVE COMMITTEE REPORT

The Executive Committee of the North Carolina Medical Board was called to order at 1:00 pm, Thursday May 19, 2011, at the offices of the Board. Members present were: Janice E. Huff, MD, Chair; Ralph C. Loomis, MD, William A. Walker, MD, Pamela L. Blizzard and Donald E. Jablonski, DO. Also present were R. David Henderson (Executive Director), Hari Gupta (Director of Operations) and Peter T. Celentano, CPA (Comptroller).

1) Financial Statements

a) Monthly Accounting March 2011

The Committee reviewed the March 2011 compiled financial statements. March is the fifth month of fiscal year 2011.

Committee Recommendation: Accept the financial statements as reported.

Board Action: The Board accepted the Committee recommendation.
b) Investment Account Statements

The Committee reviewed the April and March 2011 investment account statements.

Committee Recommendation: Accept the investment account statements as reported.

Board Action: The Board accepted the Committee recommendation.

2) Old Business

a) Investment Advisor Update

The Committee met with our new investment advisors from Fifth Third Bank who updated the Committee on the transfer of assets from Sterling Capital Management and reviewed a draft of the proposed Investment Policy Statement.

Committee Recommendation: Accept the Investment Policy Statement as drafted.

Board Action: The Board accepted the Committee recommendation.

3) New Business

a) Legislative Update

The Committee reviewed the legislative update provided by the Board’s Legislative Liaison.

Committee Recommendation: Accept the report as submitted.

Board Action: The Board accepted the Committee recommendation.

The Committee adjourned at 3:05 pm.

The Committee reconvened at 7:30 am, Friday May 20, 2011.

2) Old Business

b) Closure Letters

At the March 2011 meeting, the Board voted to add the following language to closure letters:

"In the future, information related to the above referenced investigation should be disclosed to applicable licensing authorities and credentialing agencies. You may use a photocopy of this letter in your response to such inquiries."

Since that time, the Board has received suggested changes to this language.
Committee Recommendation: Insert the following language in all closure letters, including “Accept as Information” cases:

“The North Carolina Medical Board considers this to have been an investigation. Under certain circumstances, other credentialing, regulatory, or licensing boards may require that you report this investigation. If so, a photocopy of this letter may be used for that purpose.”

Board Action: The Board accepted the Committee recommendation.

3) New Business

b) Amicus Brief - NC State Board of Dental Examiners v. FTC

The NC Board of Dental Examiners has asked the NC Medical Board to join three other NC health care licensing boards in support of the Dental Board’s case against the FTC.

Committee Recommendation: Staff is authorized to expend up to $3,500 to hire an attorney to prepare and file an amicus brief in support of the NC Board of Dental Examiners.

Board Action: The Board accepted the Committee recommendation.

c) Biannual Meetings with the Executive Director

The Committee would like to meet with the Executive Director twice a year to provide an opportunity to discuss any medical regulatory issues.

Committee Recommendation: Executive Director to meet with the Board each year during the May and November Board meetings.

Board Action: The Board accepted the Committee recommendation.

d) Letter from Public Citizen

The Committee discussed a letter from Public Citizen dated March 14, 2011, regarding the Board’s receipt and handling of hospital change in staff privileges reports and the response to that letter dated May 18, 2011.

Committee Recommendation: Accept as information. No further action necessary.

Board Action: The Board accepted the Committee recommendation.
1. Old Business
   a. Position Statement Review
      i. – Office Based Procedures (APPENDIX A)

   Issue: In November 2009, the Board approved the Policy Committee’s recommendation to review Position Statements at least once every four years. A review schedule has been formulated for the Committee’s consideration.

   9/2010 Committee Recommendation: Table this issue to allow comments from the full Board to be received. All comments will be considered at the November Committee meeting.

   9/2010 Board Action: Adopt the Committee recommendation

   11/2010 Committee Recommendation: Table this issue. Request input from standard distribution list, as well as, plastic surgeon speciality, dermatology speciality, OBGYN speciality, GI speciality, and insurance companies.


   1/2011 Committee Discussion: The Committee discussed comments received from various parties. The Committee agreed that the position statement is lengthy, but included important and useful information. The Committee instructed the staff to inquire about the inclusion of language addressing “expenses of accreditation.” The Committee also suggested that language may be added to better explain what the Board views as “reasonable proximity.”

   1/2011 Committee Recommendation: Table issue until the March 2011 meeting. Legal will wordsmith the position statement to incorporate suggested changes and attempt to reorganize the position statement to make it more accessible.

   1/2011 Board Action: Adopt Committee recommendation.

   3/2011 Committee Discussion: The Committee reviewed the current position statement with new formatting that the staff felt would make it easier to negotiate its content. The staff reported that the language addressing “expenses of accreditation” was considered fundamental at the time of the position statement’s creation. The Committee made suggestions regarding the formatting of the preface section. It was suggested that “reasonable proximity” might be 30 minutes. The staff recommended adding “reasonable proximity” to the definition section. Additionally, it was suggested that the definition section be renamed Definitions and Acronyms.

   3/2011 Committee Recommendation: Remain tabled until a draft encompassing the suggested changes could be prepared. The proposed position statement will be
submitted to the Policy Committee prior to the May Board meeting.


5/2011 Committee Discussion: The position statement was presented to the Committee with the suggested changes from the March meeting.

5/2011 Committee Recommendation: Present to the full Board for approval as amended.

5/2011 Board Action: Adopt the Committee recommendation.

ii. Self- Treatment and Treatment of Family Members and Others with Whom Significant Emotional Relationships Exist  (APPENDIX B)

Issue: In November 2009, the Board approved the Policy Committee’s recommendation to review Position Statements at least once every four years. A review schedule has been formulated for the Committee’s consideration.

3/2011 Committee Discussion: Mr. Brosius suggested that the Board may need to establish some bright lines, because the current position statement leaves room for some treatments that the Board may deem unethical depending on physician interpretation. Dr. Loomis suggested that he preferred a hardline approach and would recommend eliminating minor treatment of illness. He indicated that the Board’s interest is for the patients to receive the best care. Dr. Greene agreed that eliminating treatment of minor illness would remove any room for confusion, but also felt we should leave the ability to treat during an emergency in the position statement. Dr. Camnitz indicated that he did not like the vagueness of the position statement and would prefer it be more specific regarding over-the-counter medications and prescription medications, possibly indicating specific schedules that would be restricted. The Committee further discussed chronic versus acute. It was also recommended that “physician” should be replaced with “licensee” to be consistent with edits made in previous position statement reviews.

3/2011 Committee Recommendation: Table issue for the Legal Department to incorporate the recommendations from the Committee discussion.


This Position Statement has now been assigned to a Task Force specifically analyzing the issue and headed by Dr. Loomis.

5/2011 Committee Discussion: Dr. Loomis reported that the Task Force was scheduled to meet in June 2011. Dr. Kirby stated that the AMA has a statement regarding treatment of professional peers and suggested that something similar be included in our position statement.

5/2011 Committee Recommendation: Table issue until Task Force report is presented to the Committee. Dr. Kirby is to provide the AMA position prior to the Task Force meeting.
5/2011 Board Action: Accept Committee recommendation

2. New Business:
   a. Position Statement Review (APPENDIX C)

   1/2010 Committee Recommendation: (Loomis/Camnitz) Adopt a 4 year review schedule as presented. All reviews will be offered to the full Board for input. Additionally all reviews will be documented and will be reported to the full Board, even if no changes are made.

   1/2010 Board Action: Adopt the recommendation of the Policy Committee.

   i. Prescribing Legend or Controlled Substances for Other Than Valid Medical or Therapeutic Purposes, with Particular Reference to Substances or Preparations with Anabolic Properties (APPENDIX D)

   5/2011 Committee Discussion: Dr. Loomis has concerns about the last paragraph in the General Section. He inquired about why and when this paragraph was added. Dr. Loomis stated that if there was no good reason for it to exist, the Committee might consider removing it. Dr. Greene and Dr. Camnitz both offered alternative wording, instead of removing the paragraph in question. The Committee discussed the definition of legend drugs.

   5/2011 Committee Recommendation: Table issue to provide staff an opportunity to research the origin of the paragraph in question. Additionally, add a description of legend drugs to the position statement.

   5/2011 Board Action: Accept Committee recommendation

   ii. Sale of Goods from Physician Offices (APPENDIX E)

   5/2011 Committee Discussion: The Committee reviewed the position statement. Dr. Kirby remarked that currently Medicare has regulations regarding notification to patients of other places where products/services can be obtained.

   5/2011 Committee Recommendation: Accept position statement as present. No changes are necessary.

   5/2011 Board Action: Accept Committee recommendation

b. Writing of Prescriptions (APPENDIX F)

   Issue: See inquiry below.

   David,
   I've received a question from a practice manager lately about the Medical Board’s Position on e-prescribing of controlled substances. I believe that in the past the NCMB
has not favored this practice. Can you tell me if I’m correct and if there is any plan to revisit this policy in the near future? Thanks so much!

Amy Whited

5/2011 Committee Discussion: The current position statement was modified at the March 2011 meeting of the Medical Board. The Committee discussed e-prescribing and its increased use in practices. The Committee does not recommend any changes to the current position statement.

5/2011 Committee Recommendation: Mr. Brosius to notify Ms. Whited that the Board recognizes that e-prescribing is appropriate and may be the way of the future.

5/2011 Board Action: Accept Committee Recommendation

3. Additional Business:
   a. Review of Position Statements

   5/2011 Committee Discussion: Mr. Brosius discussed the current process for reviewing position statements. It was determined that the Committee could review one position statement per Committee meeting and maintain the 4 year schedule set forth in January 2010.

   5/2011 Committee Recommendation: Approve the review of one position statement per Committee meeting.

   5/2011 Board Action: Accept Committee recommendation

b. Amended Position Statements

   5/2011 Committee Discussion: The Committee discussed the best way to notify the Board’s licensees when a position statement has been amended. Dr. Camnitz and Dr. Greene recommended that the amended position statements be highlighted in the Forum and on the Board’s website.

   5/2011 Committee Recommendation: Ms. Fisher will review the options and present her findings at the July Policy Committee.

   5/2011 Board Action: Accept Committee recommendation
CONTINUED COMPETENCE COMMITTEE REPORT
The Continued Competence Committee of the North Carolina Medical Board was called to order at 8:00 am Thursday May 19, 2011, at the office of the Medical Board. Members present were: Paul S. Camnitz, MD, Chair; Peggy R. Robinson, PA-C; and Eleanor E. Greene, MD. Also present were: Ralph C. Loomis, MD; Thomas R. Hill, MD; Karen R. Gerancher, MD; Donald E. Jablonski, DO; William A. Walker, MD; Janice E. Huff, MD; Scott Kirby, MD; David Henderson and Maureen Bedell.

1. Old Business
   a. There was no old business to discuss.

2. New Business
   a. Maintenance of Licensure Program. The Committee reviewed the options regarding the NCMB participating in the Federation of State Medical Boards (FSMB) Maintenance of Licensure (MOL) Pilot Project. A discussion followed.

   Committee Recommendations: (1) Postpone participation in the pilot project at this time, (2) Meet with interested parties (e.g., the medical societies/associations and the Area Health Education Centers) to discuss MOL, (3) Consider convening a task force to study this issue, (4) Conduct a financial analysis to determine the cost to licensees and the Board, and (5) obtain demographic information to determine how many licensees will be affected by a MOL program.

   Board Action: The Board accepted the Committee recommendations.

   b. CME Rules. Proposed changes to the CME Rules were deferred to a later date.

LICENSE COMMITTEE REPORT
The License Committee of the North Carolina Medical Board was called to order at 3:00 p.m., May 18, 2011, at the office of the Medical Board. Members present were: Thomas Hill, MD, Chair, Donald Jablonski, DO, Karen Gerancher, MD, Eleanor Greene, MD and Paul Camnitz, MD. Mr. John Lewis was absent. Also present were: Scott Kirby, MD, Thom Mansfield, Patrick Balestrieri, Carren Mackiewicz, Josh Albert, Nancy Hemphill, Joy Cooke, Michelle Allen, Mary Rogers and Lisa Hackney

Open Session

Old Business

1. Guidelines for Reporting Withdrawal and Denial of Applications to NPDB, HIPDB and FSMB

   Issue: There has been discussion regarding exactly what license application “withdrawals and denials” should be reported to FSMB, NPDB and HIPDB. We have contacted all three entities and recently received guidance and direction regarding the reporting issues. See bookmarked copy of Mr. Balestrieri’s January 4, 2011 memorandum outlining the reporting guidelines.
Committee Recommendation: Continue discussion at May meeting following FSMB discussion at the Annual Meeting. Patrick to provide update.

3/2011 Board Action: Table until May meeting.

5/20/22 Update – FSMB House of Delegates referred this issue back to the Board of Directors (for further study and report back in 2012) as it was still vague and confusing.

Committee Recommendation: Continue handling withdrawals on a case by case basis as it has been done in the past until further study is done.

Board Action: Continue handling withdrawals on a case by case basis as it has been done in the past until further study is done.

2. Proposed changes to RTL rule 21 NCAC 32B. 1402 (limiting number of attempts)

Issue: To be consistent with the rule changes already made to the full license application, the following modifications need to be made to the RTL rule:

- Replace (3) with proposed (3) re: immigration status. NCMB does not need to do this because the GME offices are already doing it.
- Replace (4) with proposed (4) re: medical school certification form.
- Edit (11) limiting the number of attempts for passing USMLE 1&2 or COMLEX 1&2 to 3.

21 NCAC 32B .1402 APPLICATION FOR RESIDENT’S TRAINING LICENSE

(a) In order to obtain a Resident's Training License, an applicant shall:

(1) submit a completed application, attesting under oath that the information on the application is true and complete, and authorizing the release to the Board of all information pertaining to the application;
(2) submit documentation of a legal name change, if applicable;
(3) supply a certified copy of applicant’s birth certificate if the applicant was born in the United States or a certified copy of a valid and unexpired US passport. If the applicant does not possess proof of U.S. citizenship, the applicant must provide information about applicant's immigration and work status which the Board will use to verify applicant's ability to work lawfully in the United States;
(4) submit a recent photograph, at least two inches by two inches, affixed to the Board's Medical Education Certification form. The dean or other official of the applicant's medical school shall certify this as a true likeness of the applicant, and that the applicant has completed at least 130 weeks of medical education. The applicant's date of graduation from medical school shall be written in the designated space, and the school seal shall be stamped over the photograph;
(5) submit a recent photograph, at least two inches by two inches, affixed to the oath, and attested by a notary public;
(6) submit proof on the Board’s Medical Education Certification form that the applicant has completed at least 130 weeks of medical education. The applicant’s date of graduation from medical school shall be written in the designated space, and the school seal shall be stamped on the form; the dean or other official of the applicant’s medical school shall sign the form verifying the information.
(7) If the graduate of a medical school other than those approved by LCME, AOA, COCA or CACMS, shall furnish an original ECFMG certification status report of a currently valid
certification of the ECFMG. The ECFMG certification status report requirement shall be waived if:

(A) the applicant has passed the ECFMG examination and successfully completed an approved Fifth Pathway program (original ECFMG score transcript from the ECFMG required); or
(B) the applicant has been licensed in another state on the basis of a written examination before the establishment of the ECFMG in 1958;

(6) submit an appointment letter from the program director of the GME program or his appointed agent verifying the applicant's appointment and commencement date;

(7) provide two original references from persons with no family or martial relationship to the applicant. These references must be:
   (A) from physicians who have observed the applicant's work in a clinical setting;
   (B) on forms supplied by the Board;
   (C) dated within six months of the application; and
   (D) bearing the original signature of the writer;

(8) submit two completed fingerprint record cards supplied by the Board;

(9) submit a signed consent form allowing a search of local, state, and national files for any criminal record;

(10) pay a non-refundable fee pursuant to G.S. 90-13.1(b), plus the cost of a criminal background check;

(11) provide proof that the applicant has taken and passed:
   (a) the COMLEX Level 1 and both components of COMLEX Level 2 (cognitive evaluation and performance evaluation); or
   (b) the USMLE Step 1 and both components of the USMLE Step 2 (Clinical Knowledge and Clinical Skills);

(12) upon request, supply any additional information the Board deems necessary to evaluate the applicant's competence and character.

   (b) An applicant may be required to appear in person for an interview with the Board or its agent to evaluate the applicant's competence and character.

Committee Recommendation: Accept following changes to the RTL rule:

1. Replace (3) with proposed (3) re: immigration status. NCMB does not need to do this because the GME offices are already doing it.

2. Replace (4) with proposed (4) re: medical school certification form.

3. Edit (11) limiting the number of attempts for passing USMLE 1&2 or COMLEX 1&2 to 3.

3/2011 Board Action:

1. Replace (3) with proposed (3) re: immigration status. NCMB does not need to do this because the GME offices are already doing it.

2. Replace (4) with proposed (4) re: medical school certification form.

3. Table decision regarding limit USMLE 1&2 and COMLEX 1&2 to 3 attempts until additional information is obtained from the GME office, USMLE and the Deans of the Medical Schools regarding how this rule would impact them.

5/2011 Update: Awaiting feedback from stakeholders

Committee Recommendation: Table for discussion at July 2011 meeting.

Board Action: Table for discussion at July 2011 meeting.
3. Update on application wording regarding pre-populated fields in the on-line application

Issue: There was discussion during the September Board meeting about new applications being “pre-populated” with information from old applications with regard to misdemeanors, felonies, malpractice, privileges and regulatory Board actions. This affects licensees who have previously been licensed by NCMB; applicants who applied in the past and were denied, expired or withdrew. The general consensus of staff was to not pre-populate this information. However, because the data for LI (License Information) page, applications and renewals is stored in one place a majority of the information is pre-populated. The instructions for these pages are currently being reviewed for necessary modification. Also, pre-populating this information has been one of the things applicants have requested through our survey.

November 2010 Board Action: Have staff provide an update at the January meeting regarding the status of changing the instructions.

1/2011 Update: Staff meeting has been scheduled to update instructions. Update will be provided at Licensing Committee meeting.

1/20/11 Board Action: Task to Hari to implement. Provide updated information to licensing committee at May meeting.

5/2011 Update: Staff reported that a decision has been made on what language will be used as well as a procedure for the applicant to update any pre-populated information. These changes have been submitted to Operations to implement.

Committee Recommendation: Accept as information.

Board Action: Accept as information

New Business:

1. License Interviews for Reentry Candidates

Issue: Previously the Board voted that all applicants for licensure who met the criteria for a reentry agreement be required to meet with a member of the Board prior to licensure. The reason was to make sure the applicant understands what is expected of them and the importance of adhering to the conditions of the reentry agreement. It has been recommended that the Board revisit this policy to determine whether the policy should be adjusted.

Committee Recommendation: Continue requiring one-on-one licensing interviews for reentry candidates and confirm they and mentor understand the expectations outlined in the agreement as well as the entire reentry process.

Board Action: Continue requiring one-on-one licensing interviews for reentry candidates and confirm they and mentor understand the expectations outlined in the agreement as well as the entire reentry process.
2. Medical School Faculty Limited License Fee

Issue: The Board’s action at the March meeting to amend the rule immediately going back to the $150.00 application fee for Medical School Faculty Limited Licenses was not a viable option and was recirculated via email to Board Members on March 28th for another vote.

Dear Board Members:

This is a continuation of our discussion about the Medical School Faculty Limited License fee situation. As it stands, our rule has been approved by the Rules Review Commission with a fee of $350 per application. The rule is in limbo, and we need to take action to make it go into effect. We have spoken extensively with rulemaking staff about this, and it appears that our options are limited.

1. The Board can eliminate the application fee entirely by amending the existing rule. That would take 4-5 months.

2. The Board can lower the fee from $350 to $150 by amending our rule. We would need to send a request for consultation about the fee to the Joint Legislative Commission on Governmental Operations (“Gov Ops”).

3. The simplest thing is to send Gov Ops our request for consultation on the rule as approved (at the $350 level). No legislators have been assigned to the Gov Ops Commission. The “request for consultation” must be sent to an email box. The staff at the Office of Administrative Hearings says that she has never known Gov Ops to convene during the legislative session. Basically, 90 days pass and agencies’ requests for fee changes become effective.

Committee Recommendation: Ratify the vote taken March 28th via email which was unanimous to send the RRC-approved rule to the Joint Legislative Operations Committee for “request for consultation” on the fee change. The rule, as approved, increased the fee to $350 per application. The email to “Gov Ops” was sent on 3/31/2011. If Gov Ops does not meet, then the rule will become effective 90 days later, or roughly June 30.

Board Action: Ratify the vote taken March 28th via email which was unanimous to send the RRC-approved rule to the Joint Legislative Operations Committee for “request for consultation” on the fee change. The rule, as approved, increased the fee to $350 per application. The email to “Gov Ops” was sent on 3/31/2011. If Gov Ops does not meet, then the rule will become effective 90 days later, or roughly June 30.

3. Clarification of “clinical practice” required for Expedited License requirement

21 NCAC 32B .2001 (b)(6)

Issue: In order to qualify for an expedited license, the rule requires in part that the applicant be in active clinical practice for the past two years prior to licensure. Specifically, the applicant must provide proof of clinical practice for an average of 20 hours or more per week during this two year period.
Committee Recommendation: Allow graduate medical training as acceptable clinical practice. Add statement to the application that applicants may be required to submit proof of the 20 hours of clinical work.

Board Action: Allow graduate medical training as acceptable clinical practice. Add statement to the application that applicants may be required to submit proof of the 20 hours of clinical work.

4. Interventional Radiology in an Ambulatory Setting

Issue: Dr. Hill wishes to bring the Committee members and staff up to date on a corporation—an outpatient center for vascular access and other invasive procedures. It is not a typical ambulatory setting, where multiple physicians and proceduralists do a variety of procedures. It is a single-specialty center. Dr. Hill also wants to share concerns regarding the concept of a “single-specialty center for procedures”.

Committee Recommendation: Accept as information. Mr. Balestrieri was requested to obtain web site information on the corporation for the License Committee report on Friday.

Board Action: Accept as information.

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.

Six licensure cases were discussed. 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.

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 PA/EMS

The Allied Health Committee of the North Carolina Medical Board was called to order at 1:00 p.m., Wednesday, May 18, 2011 at the office of the Medical Board.

Committee Members present were: Peggy Robinson, PA-C, Chairperson, William Walker, MD, and Pamela Blizzard. Also present were: Marcus Jimison, Lori King, CPCS, Quanta Williams, Jane Paige, Katharine Kovacs, PA, Marc Katz, PA, Carren Mackiewicz and Robert Kyle, MD.

Committee Members absent: None.

1. Old business. PAs with Five or More Primary Supervising Physicians.

Issue: Update on the status of PAs with five or more primary supervising physicians and audits on these PAs. M. Jimison to discuss.

Committee Recommendation:

M. Jimison provided an update. PAs with five or more primary supervising physicians will be incorporated into the audits each year starting in 2012. An article about the compliance review program will be included in the next issue of the Forum. L. King informed the committee that the 2010 results of compliance reviews were in the April issue of the Forum and that the Investigations Department recently sent out a letter requesting active PAs with no current Intent to Practice on file with the Board to complete an Intent to Practice Form if they are actively practicing. This same letter also advised the PAs to inactivate any primary supervising physician with whom they are no longer working. Staff to add FAQ about compliance reviews to the website. Accept as information.

Board Action:

M. Jimison provided an update. PAs with five or more primary supervising physicians will be incorporated into the audits each year starting in 2012. An article about the compliance review program will be included in the next issue of the Forum. L. King informed the committee that the 2010 results of compliance reviews were in the April issue of the Forum and that the Investigations Department recently sent out a letter requesting active PAs with no current Intent to Practice on file with the Board to complete an Intent to Practice Form if they are actively practicing. This same letter also advised the PAs to inactivate any primary supervising physician with whom they are no longer working. Staff to add FAQ about compliance reviews to the website. Accept as information.

Open Session NC Emergency Medical Services

1. None.

Committee Adjourned: 2:20 p.m.

The next regular meeting of the Allied Health Committee Meeting is tentatively set for the July, 2011 Board Meeting.
Allied Health Committee Report – May 2011 – Closed Session

As a result of the Board’s 2009 Retreat, the Board should proceed with extreme caution with applicants who (1) have a history of substance abuse plus a family history of substance abuse, multiple relapses and/or coexisting psychiatric illness, and (2) have a history of quality of care concerns including multiple malpractice payments.

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.

One licensee application was reviewed. 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 LP/AA/CPP

The Allied Health Committee of the North Carolina Medical Board was called to order at 1:00 pm, May 18, 2011 at the office of the North Carolina Medical Board. Members present were: Peggy Robinson, PA-C, Chair; William Walker, MD; and Pamela Blizzard. Also present were Marcus Jimison, Jane Paige, Lori King, Katharine Kovacs, and Carren Mackiewicz, and Quanta Williams.

1. Open Session Anesthesiologist Assistants  
   a. No items for discussion

2. Open Session Nurse Practitioners  
   a. No items for discussion

3. Open Session Clinical Pharmacist Practitioners  
   a. No Items for discussion

4. Open Session Perfusionists  
   a. Open session portion of the minutes of the March PAC meeting.  
      i. The open session minutes of the March PAC meeting have been sent to the Committee members for review.

      Committee Recommendation: Accept as information

      Board Action: Accept as information

   b. Interview for PAC Vacancy
i. The AHC interviewed Dr. Robert Kyle for the opening on the Perfusionist Advisory Committee. Dr. Kyle is a Clinical Associate Professor at UNC Chapel Hill. He is the section chief of cardiothoracic surgery in the Department of Anesthesiology.

He has an appreciation for the perfusionist’s role & would like to be appointed to the PAC because of the insight that he feels he can offer.

Committee Recommendation: Appoint Dr. Kyle to the PAC conditioned on the Board not receiving any additional applications before the May 31, 2011 deadline. If any other letters of interest are received before the May 31 deadline, the Chair will consider the application(s) and, in her discretion, determine whether the Committee should interview the applicant(s).

Board Action: Appoint Dr. Kyle to the PAC conditioned on the Board not receiving any additional applications before the May 31, 2011 deadline. If any other letters of interest are received before the May 31 deadline, the Chair will consider the application(s) and, in her discretion, determine whether the Committee should interview the applicant(s).

5. Open Session Polysomnography
   a. No items for discussion

NURSE PRACTITIONER JOINT SUBCOMMITTEE

The Nurse Practitioner Joint Subcommittee (NPJS) was called to order at 3:08 pm May 19, 2011 at the office of the NC Board of Nursing. Members present were: Nancy Bruton-Maree, RN, Chair (NCBON); Peggy Robinson, PA-C (NCMB); Mary Ann Fuchs, RN (NCBON); Dan Hudgins (NCBON); William Walker, MD (NCMB); and Pamela Blizzard (NCMB). Also present were: Donna Mooney (NCBON); Julie George (NCBON); Marcus Jimison (NCMB); Anna (NCBON); David Kalbacker (NCBON); Katharine Kovacs (NCMB); Paulette Young (NCBON); and Quanta Williams (NCMB).

1. Approval of minutes of January 2011 meeting
   a. Motion: To approve the minutes of the January meeting. Passed.
2. Additions to agenda
   a. None
3. Old Business
   a. Change to NP Interview Policy
      i. Ms. Fuchs requested to amend #1 to say “the Board of Nursing or the Medical Board”

      Motion: To approve the changes with the amendment to #1. Passed.
b. Compliance Review Protocol
   i. FYI only

4. New Business
   a. Report of any disciplinary actions, including Consent Agreements, taken by either Board since the last meeting
      i. The Board of Nursing reported 15 public actions taken against a nurse practitioner since the last meeting.
      ii. The Medical Board didn’t report any public actions taken against a nurse practitioner since the last meeting.

5. Other Business
   a. NPJS Materials
      i. Ms. Robinson requested that the information for NPJS meetings be sent in time enough to be included on the NCMS Board Meeting Book. Ms. George will look into this.

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.

Twelve licensee approvals were reviewed. 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.

REVIEW (COMPLAINT) COMMITTEE REPORT
Paul Camnitz, MD, Chair; Peggy R. Robinson, PA-C; John B. Lewis

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 Review (Complaint) Committee reported on twenty 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 (COMPLAINTS) COMMITTEE REPORT
William Walker, MD, Chair; Dr. Thomas R. Hill, MD; Pamela Blizzard; Karen R. Gerancher, MD; Eleanor E. Greene, 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 ten 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
William Walker, MD, Chair; Dr. Thomas R. Hill, MD; Pamela Blizzard; Karen R. Gerancher, MD; Eleanor E. Greene, 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 42 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
William Walker, MD, Chair; Dr. Thomas R. Hill, MD; Pamela Blizzard; Karen R. Gerancher, MD; Eleanor E. Greene, 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 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.
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.

Twenty-one informal 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
William Walker, MD, Chair; Dr. Thomas R. Hill, MD; Pamela Blizzard; Karen R. Gerancher, MD; Eleanor E. Greene, 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 (Investigative) Committee reported on 39 investigative 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.

REVIEW (INVESTIGATIVE) COMMITTEE REPORT
Paul Camnitz, MD, Chair; Peggy R. Robinson, PA-C; John B. Lewis

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 Review (Investigative) Committee reported on 45 investigative 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.
NORTH CAROLINA PHYSICIANS HEALTH PROGRAM (NCPHP) COMMITTEE REPORT
Thelma Lennon, Chair; Janice Huff, MD; Ralph C. Loomis, 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 Board reviewed 43 cases involving participants in the NC Physicians Health Program. The Board adopted the committee’s recommendation to approve the written report. The specifics of this report are not included as these actions are not public information.

A motion passed to return to open session.

RETREAT COMMITTEE

The Retreat Committee of the North Carolina Medical Board was called to order at 1:00pm Wednesday May 18, 2011, at the office of the Medical Board. Members present were: Karen R. Gerancher, MD, Chair; Janice E. Huff, MD; Ms. Thelma Lennon and Thomas R. Hill, MD. Also present were: David Henderson, Christina Apperson and Maureen Bedell.

1. Old Business
   a. Approval of Minutes
      The minutes of the March 2011 meeting were approved.
   b. Retreat Location
      A meeting room at the Renaissance Hotel has been reserved.
   c. Potential Speakers/Topics
      The committee discussed the following possible retreat topics: (1) maintenance of licensure; (2) current litigation before the FTC challenging the North Carolina Dental Board’s authority to regulate the practice of dentistry (and its impact on the NCMB); (3) telemedicine; (4) evaluation of Board processes, which has the potential to include the results of a voluntary audit conducted of the NCMB by the AIM Assessment Project if time permits; (5) legislative update and education on the processes of the NC General Assembly; and (6) on-site assessments of licensees.

      Committee Recommendation: Defer to the full Board.

      Board Action: The Board agreed on the following Retreat topics: FTC, telehealth, AIMAP, legislative update and professional competency assessments.

2. New Business
   a. Dinner
      Christina Apperson has graciously agreed to host the Board dinner at her home Friday evening.
   b. Other
      There was no other business.
ADJOURNMENT
This meeting was adjourned at 1:10 P.M. May 20, 2011.

_____________________________________________________
William A. Walker, MD
Secretary/Treasurer
APPENDIX A

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 by a national medical specialty board that is recognized by the ABMS 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.

¹ See N.C. Gen. Stat. § 131E-145 et seq.
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 CO2 monitor (for endotracheal anesthesia); and
20. appropriate operating or procedure table.

Definitions and Acronyms

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

AAAHC – the Accreditation Association for Ambulatory Health Care

ABMS – the American Board of Medical Specialties

ACGME – the Accreditation Council for Graduate Medical Education

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

Advanced cardiac life support certified – a licensee that has successfully completed and recertified periodically an advanced cardiac life support course offered by a recognized accrediting organization appropriate to the licensee’s field of practice. For example, for those licensees treating adult patients, training in ACLS is appropriate; for those treating children, training in PALS or APLS is appropriate.
Ambulatory surgical facility – a facility licensed under Article 6, Part D of Chapter 131E of the North Carolina General Statutes or if the facility is located outside North Carolina, under that jurisdiction’s relevant facility licensure laws.

Anesthesia provider – an anesthesiologist or CRNA.

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

AOA – the American Osteopathic Association

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

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

ASA – the American Society of Anesthesiologists

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

Board – the North Carolina Medical Board.

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

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

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

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

Self-treatment and treatment of family members and others with whom significant emotional relationships exist*

It is the position of the North Carolina Medical Board that, except for minor illnesses and emergencies, physicians should not treat, medically or surgically, or prescribe for themselves, their family members, or others with whom they have significant emotional relationships. The Board strongly believes that such treatment and prescribing practices are inappropriate and may result in less than optimal care being provided. A variety of factors, including personal feelings and attitudes that will inevitably affect judgment, will compromise the objectivity of the physician and make the delivery of sound medical care problematic in such situations, while real patient autonomy and informed consent may be sacrificed.

When a minor illness or emergency requires self-treatment or treatment of a family member or other person with whom the physician has a significant emotional relationship, the physician must prepare and keep a proper written record of that treatment, including but not limited to prescriptions written and the medical indications for them. Record keeping is too frequently neglected when physicians manage such cases.

The Board expects physicians to delegate the medical and surgical care of themselves, their families, and those with whom they have significant emotional relationships to one or more of their colleagues in order to ensure appropriate and objective care is provided and to avoid misunderstandings related to their prescribing practices.

*This position statement was formerly titled, "Treatment of and Prescribing for Family Members."

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APPENDIX D

Prescribing legend or controlled substances for other than validated medical or therapeutic purposes, with particular reference to substance or preparations with anabolic properties

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

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

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

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

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

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

Sale of goods from physician offices

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

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

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

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

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

(Adopted March 2001) (Amended March 2006)
Writing of Prescriptions

It is the position of the North Carolina Medical Board that prescriptions should be written in ink or indelible pencil or typewritten or electronically printed and should be signed by the practitioner at the time of issuance. Prescriptions that are handwritten should indicate the quantity in both numbers AND words, e.g., 30 (thirty). Such prescriptions must not be written on pre-signed prescription blanks.

Each prescription for a DEA controlled substance (2, 2N, 3, 3N, 4, and 5) should be written on a separate prescription blank. Multiple medications may appear on a single prescription blank only when none are DEA-controlled.

No prescriptions should be issued for a patient in the absence of a documented physician-patient relationship.

No prescription should be issued by a practitioner for his or her personal use. (See Position Statement entitled “Self-Treatment and Treatment of Family Members and Others with Whom Significant Emotional Relationships Exist.”)

The practice of pre-signing prescriptions is unacceptable to the Board.

It is the responsibility of those who prescribe controlled substances to fully comply with applicable federal and state laws and regulations. Links to these laws and regulations may be found on the Board’s Web site (www.ncmedboard.org).

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May 18-20, 2011
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Clinical Pharmacist Practitioners

Kaczmorski, Scott Adam
Nuzum, Donald Scott
Sauls, Amy Denise
Anesthesiologist Assistant, Perfusionist & Provisional Perfusionist Licenses
May 2011

Perfusionists:
Heath, Michele Marie
Gall, Chandra Janelle (Provisional license converted to Full)

Provisional Perfusionists:
Hawk, Ryan Charles

Anesthesiologist Assistants:
None
Initial PA Applicants Licensed 03/01/11 – 04/30/11

**PA-Cs**

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Name

Thams, Julie Ann 03/03/2011
Toussaint, Ramona Marie 03/02/2011
Treloar, Alan Francis 04/25/2011
Troutman, Emily 03/22/2011
Tuschl, Christina Marie 03/10/2011
Walter, Sharon Hooper 03/10/2011
Witt, Chris William 03/22/2011
Womble, Mary Hamlin 04/13/2011

PA-Cs Reactivations/Reinstatements/Re-Entries

Name

Baio, Debra Lynn 04/19/2011
Lamm, Greyard Robert 03/29/2011
Saxon, Donald Paul 04/27/2011
Urban, Julia Irene 03/14/2011
Walker, Sarah Cavanagh 04/11/2011