BOARD MEETING MINUTES

September 15 - 17, 2021

3127 Smoketree Court
Raleigh, North Carolina

General Session Minutes of the North Carolina Medical Board (NCMB) Meeting held September 15 - 17, 2021.

The September 15 - 17, 2021 meeting of the North Carolina Medical Board was held at 3127 Smoketree Court, Raleigh, NC 27604, and video conference. Venkata R. Jonnalagadda, President, called the meeting to order. Board members in attendance were: John W. Rusher, MD, President-Elect; Michaux R. Kilpatrick, MD; Secretary/Treasurer; Shawn P. Parker, JD; Varnell D. McDonald-Fletcher, PA-C; Christine M. Khandelwal, DO; Jerri L. Patterson, NP; W. Howard Hall, MD; Joshua D. Malcolm, JD; Damian F. McHugh, MD; Devdutta G. Sangvai, MD, Mr. William M. Brawley and Anuradha Rao-Patel, MD

PRESIDENTIAL REMARKS

Dr. Venkata R. Jonnalagadda 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. Reported conflicts were included within individual committee reports.

Dr. Venkata R. Jonnalagadda congratulated Dr. Christine Khandelwal on her re-appointment to the NC Medical Board for another term, November 2021 – October 2024.

Dr. Jonnalagadda recognized new staff and staff anniversary milestones

PRESENTATIONS

Dr. Jonnalagadda introduced Philip Brown, MD, President, North Carolina Medical Society (NCMS) who gave a presentation on the NCMS.

NORTH CAROLINA PHYSICIAN HEALTH PROGRAM REPORTS (NCPHP)

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, and 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.

Dr. Jordan gave the PHP Compliance Committee report. The specifics of this report are not included because the information contained in the report is confidential and non-public.

A motion passed to return to open session.

NCMB ATTORNEY'S REPORT

Mr. Brian L. Blankenship, Deputy General Counsel and Mr. Thomas W. Mansfield, Chief Legal Officer, gave the Attorney's Report on Friday, September 17th, 2021.

Mr. Blankenship and Mr. Mansfield updated the Board on the schedule of upcoming hearings, hearing assignments and rule activity of the Board.

A motion passed to close the session pursuant to N.C. Gen Stat. §143-318.11(a) 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 public records within the meaning of Chapter 132 of the General Statutes and/or to preserve attorney/client privilege.

Information regarding outside litigation matters and statistical information regarding work performed by the Board's Legal Department since the last Attorney's Report was presented.

A motion was passed to return to open session.

Legislative and Government Relations Update

On Friday, September 17th, 2021, the Board's Legislative Liaison, Mr. Thomas W. Mansfield, and Board Attorney Elizabeth Meredith provided a legislative update to the Board.

The Board accepted the report as information.

Strategic Priorities Report

There are three goals for 2021.

The first goal is: "Continue and enhance other outreach efforts to build on recent success and stakeholder appreciation." This goal is completed.

The next goal is Goal 3a: "Build a foundation for a data analytics program to support data-informed regulation and focused licensee education." The Board has hired Blaze Advisors to help it develop a data intelligence strategy. Staff will meet with the Blaze Project Manager for a "thought leadership session" on September 28 to solicit ideas and priorities and to socialize key concepts and foundations. Blaze estimates this process will be completed in 6 – 8 weeks.

The final goal is Goal #4a/b: "Engage stakeholders and influencers by positioning NCMB as a trusted subject matter expert." Having identified the vaccination effort and the Interstate Medical Licensure Compact as two topics the Board is uniquely qualified to assist with, staff is now implementing communication plans related to those activities. For example, staff is working with the State Health Director and DHHS to help support the vaccine rollout and to try and better understand vaccine hesitancy.

Work will continue on the remaining goals through the end of the calendar year. Staff will provide an update in November and a final report in January.

NCMB COMMITTEE REPORTS

Executive Committee Report

Members present via video/teleconference were: Venkata R. Jonnalagadda, MD, Chairperson; John W. Rusher, MD; Michaux R. Kilpatrick, MD; Varnell McDonald-Fletcher, PA-C, and Shawn P. Parker, JD.

Financial Update

a. Year-To-Date Financials

   The Committee reviewed the following financial reports through July 31, 2021: Balance Sheet, Profit & Loss versus Budget, and the Profit & Loss Comparison.

   Committee Recommendation: Accept the financial information as reported.

   Board Action: Accept Committee recommendation. Accept the financial information as reported.

b. Investment Account

   The Committee reviewed the investment statements for July and August 2021.

   Committee Recommendation: Accept the investment statements as reported.

   Board Action: Accept Committee recommendation. Accept the investment statements as reported.

c. Proposed FY2022 Budget

   The Committee reviewed the proposed budget for fiscal year 2022. The new fiscal year begins November 1, 2021.

   Committee Recommendation: Approve the proposed fiscal year 2022 budget.

   Board Action: Accept Committee recommendation. Accept the proposed fiscal year 2022 budget.

New Business:

a. NCMB Appointments Update

The Governor has made the following appointments for terms beginning November 1, 2021, and ending October 31, 2024:

- Malinda Privette, MD, to replace Venkata R. Jonnalagadda, MD (physician seat)
- Christine Khandelwal, DO, to serve a second term (doctor of osteopathic medicine or a full-time faculty member of one of the medical schools in North Carolina who utilizes integrative medicine in that person's clinical practice seat)
- Miguel Pineiro, PA-C, to replace Varnell D. McDonald-Fletcher, PA-C (physician assistant seat)
- Sharona Johnson, FNP-BC, to replace Jerry L. Patterson, NP (nurse practitioner seat)

On August 31, 2021, the Legislature, upon recommendation of the President Pro Tempore, reappointed Mr. Parker to a term beginning November 1, 2021, and expiring October 31, 2024.

Committee Recommendation: Accept as Information.

Board Action: Accept Committee recommendation. Accept as information.

b. CEO Annual Performance Evaluation

A motion passed to go into closed session pursuant to Section 143-318.11(a) of the North Carolina General Statutes to consider the qualifications, competence, performance, character, fitness, conditions of appointment, or conditions of initial employment of an individual public officer or employee or prospective public officer or employee.

As per Article V, Section 2 of the NCMB Bylaws, the Executive Committee met with Mr. Henderson to conduct the annual CEO performance review.

A motion passed to return to open session

Policy Committee Report

Members present were: Christine M. Khandelwal, DO, Chairperson; Mr. William M. Brawley; Damian F. McHugh, MD; Devdutta G. Sangvai, MD; and Anuradha Rao-Patel, MD

Old Business:

a. Position Statements Review Workgroup

The Committee and staff reviewed the revisions and comments made by Board Members and staff for Position Statement 5.1.1 (Office-Based Procedures), section 9 (Professional Working Relationships), and section 10 (Fees & Charges) of the draft

compendium. The Committee agreed to accept the non-substantive and stylistic revisions throughout. The Committee and staff then reviewed each comment or substantive change and determined whether to accept those revisions and/or make additional revisions. The accepted changes and pending revisions are incorporated in the attached, redline version. (Appendix A)

Staff were instructed to update all remaining position statements on the website and finalize and publish the full compendium.

Committee Recommendation:
1. Accept approved changes to section 9 (Professional Working Relationships) and section 10 (Fees & Charges) and update the individual position statements on the website to reflect those changes.
2. Accept approved changes to Position Statement 5.1.1 (Office-Based Procedures) and update the individual position statement on the website to reflect those changes. Table consideration of changes to Candidates for Level II or Level III Procedures sections until the November Policy Committee meeting.
3. Staff shall finalize and publish the full compendium.

Board Action: Accept Committee recommendation.

Licensing Committee Report

Members present were: Varnell D. McDonald-Fletcher, PA-C, Chairperson; Jerri L. Patterson, NP; W. Howard Hall, MD and Joshua D. Malcolm. Members absent were: Devdutta G. Sangvai, 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, and 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 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.

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, and 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 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.

Advanced Practice Providers and Allied Health Committee Report

Members present were: Jerri L. Patterson, NP, Chairperson; Anuradha Rao-Patel, MD; Varnell McDonald-Fletcher, PA-C and William M. Brawley

Old Business:

a. Proposed Rule Change regarding Physician Assistant Postgraduate Programs – 21 NCAC 32S .0213 – Melissa Ricker, PA-C and Cragin Green, PA-C; Emily Adams, Executive Director, North Carolina Academy of Physician Assistants; and Marcus Jimison, Senior Board Attorney.

   Committee Recommendation: Approve amendment as written.

   Board Action: Accept Committee recommendation. Accepted recommendation to approve amendment as written.

New Business:

a. Review of current Physician Assistant Waivers, Orders, and FAQs as a result of the Covid-19 pandemic. – M. Jimison.

   Committee Recommendation: Accept as information.

   Board Action: Accept Committee recommendation. Accepted as information.

b. Perfusionist Advisory Committee – Reappointment of members with expiring terms – M. Jimison.

   Committee Recommendation: Approve reappointment of PAC members with expiring terms, Greg Griffin and Sally Paul.

   Board Action: Accept Committee recommendation. Accepted reappointment of PAC members with expiring terms, Greg Griffin and Sally Paul.

Disciplinary (Malpractice) Committee Report

Members present were: Shawn P. Parker, JD, Chairperson; W. Howard Hall, MD; Christine M. Khandelwal, DO; Joshua D. Malcolm, JD; Damian F. McHugh, MD; Jerri L. Patterson, NP and Devdutta G. Sangvai, 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, and 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 reviewed 31 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 (Investigative) Committee Report

Members present were: Shawn P. Parker, JD, Chairperson; W. Howard Hall, MD; Christine M. Khandelwal, DO; Joshua D. Malcolm, JD; Damian F. McHugh, MD; Jerri L. Patterson, NP and Devdutta G. Sangvai, 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, and 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 reviewed 46 investigative cases. 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 (Complaints) Committee Report

Members present were: Shawn P. Parker, JD, Chairperson; W. Howard Hall, MD; Christine M. Khandelwal, DO; Joshua D. Malcolm, JD; Damian F. McHugh, MD; Jerri L. Patterson, NP; and Devdutta G. Sangvai, 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, and 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 reviewed 20 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 (Compliance) Committee Report

Members present were: Shawn P. Parker, JD, Chairperson; W. Howard Hall, MD; Christine M. Khandelwal, DO; Joshua D. Malcolm, JD; Damian F. McHugh, MD; Jerri L. Patterson, NP and Devdutta G. Sangvai, 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, and 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 (Compliance) Committee reviewed 10 investigative cases. 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.

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, and 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.

Nine 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.

Diversity and Inclusion Workgroup Report

Members present were: John W. Rusher, MD, Chair; and Michaux R. Kilpatrick, MD.

Old Business:

a. Education/Training Update

At the January 2021 meeting, the Board voted to hold a diversity, equity, and inclusion training session each year and to schedule the 2021 training during the May Board meeting. The Racial Equity Institute provided their "Groundwater" training to Board members and staff Wednesday, May 19. Later this year, staff will begin planning for next year's training, tentatively scheduled for May 2022.

Workgroup Recommendation: Accept as information.

Board Action: Accept Workgroup recommendation. Accept as information.

b. Implicit Bias

i. Internal/NCMB.

Staff Workgroup Report/Recommendations – unconscious bias in the license application process.

The Strategic Goal Workgroup on Unconscious Bias in Licensing studied the application and renewal processes, including the questions asked on those forms, and three years of board actions from the Licensing Committee. The purpose of this study was to (1) determine whether there was evidence of unconscious bias in the licensing or renewal process, and (2) if so, what actions should be taken to reduce or eliminate unconscious bias.

A review of board actions revealed:

- A very small percentage of applicants are denied or asked to withdraw their application each year
- For some of these applicants, there was no information regarding race or ethnicity
- Almost all applicants who appeared for a split board licensing interview were granted a license of some type
- No real discernable patterns regarding race or ethnicity were detected. The only possible pattern related to gender: 12 denials or requests to withdraw were for male applicants; three for female applicants.

Workgroup recommendations:

1. No changes to application and renewal forms or to application and renewal processes at this time.
2. At the beginning of 2023, consider doing a deeper statistical analysis of licensing decisions (denials, licenses issued with public actions, licenses issued with private actions, reentry agreements, requests for split board interviews, etc.) regarding race, gender, national origin, and ethnicity for the purpose of detecting any discernible patterns or disparate outcomes.

Board Action: Accept Workgroup recommendations:

1. No changes to application and renewal forms or to application and renewal processes at this time.
2. At the beginning of 2023, consider doing a deeper statistical analysis of licensing decisions (denials, licenses issued with public actions, licenses issued with private actions, reentry agreements, requests for split board interviews, etc.) regarding race, gender, national origin, and ethnicity for the purpose of detecting any discernible patterns or disparate outcomes.

II. Staff Workgroup Report/recommendations – unconscious bias in the investigative process.

The Strategic Goal Workgroup on Unconscious Bias in Reports of Investigation (ROIs) studied Field Investigation Reports, Complaints Cases and Malpractice Cases. The purpose of this study was to (1) determine whether there was evidence of unconscious bias in the investigative process, and (2) if so, what actions should be taken to reduce or eliminate unconscious bias.

A review of those cases revealed:

- Date of Birth and Social Security Account Numbers are already masked (with audit ability) in ThoughtSpan, the Board's database program
- The use of gender-neutral pronouns makes reading of the ROIs challenging based on the nature of some allegations
- Current processes create multiple reviewers of each case for checks and balances. This includes the initial openings of Field Investigations, ROI approval, Senior Staff Review Committee, and the Board extraction process
- All Complaints Section cases have an additional review by the Office of Medical Director
- Malpractice payment amounts and malpractice case summaries prepared by third parties could create bias in the review and decision-making process

Workgroup recommendations:

1. Modify the investigative process to redact the malpractice payment information and to note when malpractice summaries are written by third

parties in Complaints Section cases prior to Legal, OMD, Senior Staff and Board Review.
2. Continue to identify cases in Senior Staff Review Committee and Disciplinary Committee by case number and refrain from utilizing the licensee's name when possible.
3. At the beginning of 2023, consider conducting an analysis of review of the current masked data for anomalies within ThoughtSpan.
4. Conduct annual training specific of unconscious bias awareness to staff and Board members as approved by the Board January 2021.

Board Action: Accept Workgroup recommendations.

1. Modify the investigative process to redact the malpractice payment information and to note when malpractice summaries are written by third parties in Complaints Section cases prior to Legal, OMD, Senior Staff and Board Review.
2. Continue to identify cases in Senior Staff Review Committee and Disciplinary Committee by case number and refrain from utilizing the licensee's name when possible.
3. At the beginning of 2023, consider conducting an analysis of review of the current masked data for anomalies within ThoughtSpan.
4. Conduct annual training specific of unconscious bias awareness to staff and Board members as approved by the Board January 2021.

iii. External/Licensees

Update - changes to CME rules to make it clear that cultural competency CME is practice relevant.

At the July Board meeting, the Board adopted proposed changes to the physician and physician assistant rules to make it clear that cultural competency and implicit bias training CME are practice relevant. Those rules have been filed with the Rules Review Commission. Next steps:

Public Hearing/End of Comment Period: 11.15.2021
Submit for final approval by NCMB: 11.2021 meeting
Deadline to submit to Rules Review Commission: 11.22.2021
Rules Review Commission Meeting: 12.16.2021
Effective Date: 01.01.2022

Workgroup recommendation: Accept as information.

Board Action: Accept Workgroup recommendation. Accept as information.

c. Update Regarding the Board's Support of the State Health Improvement Plan (SHIP).

In March, the Workgroup identified seven health indicators from the Healthy 2030 Report that were relevant to the NCMB's statutory powers and duty. The relevant health indicators include increasing access to care and supporting licensees' efforts to address healthy behaviors with their patients, including drug overdose deaths, tobacco use, excessive drinking, sugar-sweetened beverage consumption, HIV diagnosis rates, and teen birth rates. At the July Board meeting, the NC Institute of Medicine gave an overview of the Healthy NC 2030 Report and shared the State Health Improvement Plan (SHIP). The Workgroup asked staff to review the "What Works?" action items from the SHIP as it relates to the above health indicators.

The Workgroup discussed the seven SHIP recommendations that are aligned with its statutory duty to educate licensees to ensure ongoing competency and improve a licensee's practice.

Workgroup recommendation: For FY22, focus on the following three indicators: Drug Overdose Deaths (Indicator #10), Tobacco Use (Indicator #11), and Primary Care Workforce (Indicator #17). Staff to connect with appropriate officials at the Department of Public Health regarding next steps.

Board Action: Accept Workgroup recommendation. For FY22, focus on the following three indicators: Drug Overdose Deaths (Indicator #10), Tobacco Use (Indicator #11), and Primary Care Workforce (Indicator #17). Staff to connect with appropriate officials at the Department of Public Health regarding next steps.

d. Update Regarding the FSMB's Workgroup on Diversity, Equity, and Inclusion (DEI) in Medical Regulation.

Earlier this year, FSMB Chair Dr. Ken Simons appointed Dr. Kilpatrick to the FSMB's Workgroup on Diversity, Equity, and Inclusion in Medical Regulation (DEI Workgroup). The charge of the DEI Workgroup is to identify best practices for state medical boards to mitigate and eliminate systemic inequities in medical regulation and patient care.

Dr. Kilpatrick reported the DEI Workgroup drafted 16 DEI questions that were included in the FSMB's 7th Annual State Medical Board Survey which was sent to all state medical boards on September 9. The responses to these questions will help identify state medical board best practices.

Workgroup recommendation: Staff to circulate the 16 DEI questions to Workgroup members for feedback.

Board Action: Accept Workgroup recommendation. Staff to circulate the 16 DEI questions to Workgroup members for feedback.

New Business:

a. Upcoming Meetings/Webinars

The 2021 NCIOM Virtual Annual Meeting will be held Wednesday, October 20, 2021 from 9:00 AM to 1:00 PM and will explore the behavioral health goals identified by Healthy NC 2030. With a focus on community resilience and equity, the Annual Meeting will feature expert speakers in topics including substance use and overdose, access to behavioral health services, suicide prevention, and adverse childhood experiences.

In addition, the Federation of State Medical Boards will host a "Trends in the U.S. Physician Workforce" webinar Monday, September 20 from 2 to 3 p.m. EST. This virtual education program will address how COVID-19 has exacerbated our nation's doctor shortage, unveiling many of the pressures and challenges physicians face daily. Physician stress and burnout, increased use of telehealth visits and other financial pressures have caused many physicians to rethink their careers.

Board members and staff are encouraged to attend these programs.

Workgroup recommendation: Accept as information.

Board Action: Accept Workgroup recommendation. Accept as information.

Outreach Committee Report

Members present were: Damian F. McHugh, MD, Chairperson; Joshua D. Malcolm, JD; Shawn P. Parker, JD and William M. Brawley

Old Business:

a. Update on presentations
    i. Public and professional presentations
    ii. Regulatory Immersion Series events

The Communication Director and Chief Communications Officer gave a brief update on professional and public outreach efforts. Since July, NCMB has presented its Regulatory Immersion Series (RImS) program at Campbell University's PA program and at East Carolina University's PA program. RImS presentations are scheduled in November for the Campbell University's School of Osteopathic Medicine, the University of North Carolina – Chapel Hill PA program and the High Point University PA program. It was noted that, due to the prevalence of the Delta variant of COVID-19 and surging cases statewide, some in person presentations have either been converted to virtual, postponed or cancelled. On the public outreach front, NCMB set a record with a Facebook live presentation to NC Asian Americans Together, which

attracted an audience of about 1,900! Thanks to NCMB Complaint Director Shikha Sinha for presenting and to Michelle Yanik in Communications for identifying the opportunity.

Committee recommendation: Accept as information.

Board action: Accept committee recommendation. Accept as information.

b. Abuse and Mistreatment Research
    i. Update on convening stakeholders on developing a licensee child maltreatment resource center; communication tools

    NCMB's Chief Medical Officer presented an update on her work to date to assess interest among stakeholders in developing a statewide resource center and communication tools to assist licensees with carrying out the obligation of reporting suspected child abuse and neglect. The CMO indicated that the stakeholders she has discussed the idea with see merit in the idea and are interested in further exploring the possibilities. She noted the importance of working with state officials to avoid duplication of efforts and to take advantage of existing resources.

Committee recommendation: Accept as information.

Board action: Accept committee recommendation. Accept as information.

New Business:

a. NC DAVE Electronic Death Registry System

The Committee received a report on the state's plans to fully implement its new online electronic death registration system. NCMB staff recently attended a meeting hosted by Rep. James Boles that included representatives from NC Vital Records and funeral professionals. As of Jan. 1, NC Vital Records wants all death certificates to be submitted electronically using the new system, which has been implemented statewide on a pilot basis over the past year. NC Vital Records has noted that only a small percentage of clinicians who certify deaths have registered for the system. NCMB has included information on the electronic death registration system in its newsletter twice in the past year and is interested in supporting the state's efforts to raise awareness of the new process for registering deaths and to increase registration with the new system.

Committee recommendation: Direct the Communications Department to explore strategies to raise awareness of and increase registration with the new electronic death registry system.

Board action: Accept committee recommendation. Direct the Communications Department to explore strategies to raise awareness of and increase registration with the new electronic death registry system.

b. MedBoard Matters Podcast
    i. Year in review
    ii. Looking forward

The MedBoard Matters podcast marks its one year anniversary this month. The Communications Director reported to the Committee that the Communications Department plans to continue producing the monthly podcast. Feedback on the podcast has been universally positive and staff feel comfortable integrating production into their day-to-day workflow. While the first year's focus was on developing a distinct voice and mastering production, the next year NCMB will explore ways to grow its audience, both by asking listeners to share the podcast with friends and colleagues and other means. The Communications Coordinator provided information on the top five podcast episodes, as well as data about the the podcast's reach. MedBoard Matters has listeners in 12 countries. The vast majority (97 percent) of listeners are in the US, with most in North Carolina.

Committee recommendation: Accept as information.

Board action: Accept committee recommendation. Accept as information.

Wellness and Burnout Workgroup

Members present were: Christine M Khandelwal DO, Chairperson; Damian F. McHugh, MD; and W. Howard Hall, MD

Old Business:

a. Use of Health Information

    Legal staff gave a brief overview of the use of health information in investigative and disciplinary matters as it relates to the Board's statutory authority. The Workgroup commented on keeping the information in mind at future meetings.

    Workgroup Recommendation: Accept as Information.

    Board Recommendation: Accept Workgroup Recommendation. Accept as Information.

b. Data Endorsing Treatment and Relapse Inquiry /North Carolina Professionals Health Program (NCPHP) Tracking Internal Metrics

    The Chief Medical Officer along with Dr. Joe Jordan, NCPHP CEO, presented

reference data endorsing the five-year standard for inquiries related to past history of drug, substance and alcohol use. Data shows relapse and treatment success after five years of abstinence. NCPHP's internal metrics mirror these studies. The Workgroup inquired as to whether the Board's data also mirrored NCPHP's metrics, and it was noted that it was reflected.

Workgroup Recommendation: Retain the scope of application questions to five years. Accept as information.

Board Recommendation: Accept Workgroup Recommendation. Retain the scope of application questions to five years. Accept as information.

New Business:

a. Communications Plan for the Workgroup

The Communications Director presented a basic Communications Plan to reflect the Workgroup's priorities and requested guidance on a draft wellness statement related to the importance of licensee's health. The Workgroup noted the draft was a good starting point and should consider incorporating the Quadruple Aim.

Workgroup Recommendation: Table discussion on draft statement for November.

Board Recommendation: Accept Workgroup Recommendation. Table discussion on draft statement for November.

b. Systems Factors Impacting Burnout

Dr. Clark Gaither, NCPHP Medical Director, presented on systems factors impacting burnout and the importance of healthcare organizations supporting and ensuring health and wellness of healthcare professionals. He commends the National Academy of Medicine's work in this area.

c. WBW Future Direction

Dr. Hall requested that as the Workgroup moves forward, it consider its role as stewards of the Board to encourage meaningful changes where possible, working in partnership with NCPHP to highlight systems causes for burnout. The Workgroup should look for lessons and directions from others, such as graduate medical education programs and the Accreditation Council for Graduate Medical Education (ACGME). The Workgroup should also consider the moral responsibility administrative licensees may have on mitigating burnout.

Workgroup Recommendation: Staff to identify and invite outside presenters on the systems related to issues of wellness and burnout.

Board Recommendation: Accept Workgroup Recommendation. Staff to identify and invite outside presenters on systems related to issues of wellness and burnout.

ADJOURNMENT

The Medical Board adjourned at 12:25 p.m. on Friday, September 17, 2021.

The next meeting of the Medical Board is scheduled for November 17 - 19, 2021.

Michaux R. Kilpatrick, MD; Secretary/Treasure

Position Statements
North Carolina Medical Board

Table of Contents

5.1.1: Office-Based Procedures

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

This Position Statement is in the form of guidelines designed to assure patient safety and identify the criteria by which the Board will assess the conduct of 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 Licensee's Professional and Legal Obligation
The Board has adopted the guidelines contained in this Position Statement in order to assure patients have access to safe, high quality office-based surgical and special procedures. The guidelines further assure that a licensee with appropriate qualifications takes responsibility for the supervision of all aspects of the perioperative surgical, procedural and anesthesia care delivered in the office setting, including compliance with all aspects of these guidelines.

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

Procedure Level Definitions
Level I procedures – any surgical or special procedures:

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.

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

Exemptions
These guidelines do not apply to Level I procedures.

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

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

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

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

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

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

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

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

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

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

Credentialing of Licensees

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

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

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

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

Accreditation

After one year of operation following the adoption of these guidelines, any licensee who performs Level II or Level III procedures in an office should be able to demonstrate, upon request by the Board, substantial compliance with these guidelines, or should obtain

accreditation of the office setting by an approved accreditation agency or organization. The approved accreditation agency or organization should submit, upon request by the Board, a summary report for the office accredited by that agency.

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

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

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

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

Candidates for Level III Procedures
Patients with an ASA physical status classification I, II, or , III may be acceptable candidates for Level III procedures if deemed so by a licensee qualified to assess the specific disability and its impact on anesthesia and surgical or procedural risks and the optimal setting for the procedure..

Surgical or Special Procedure Guidelines

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

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

The licensee performing the surgical or special procedure also should:

1. ensure that an appropriate pre-anesthetic examination and evaluation is performed proximate to the procedure;
2. prescribe the anesthetic, unless the anesthesia is administered by an anesthesiologist in which case the anesthesiologist may prescribe the anesthetic;
3. ensure that qualified health care professionals participate;

4. remain physically present during the intraoperative period and be immediately available for diagnosis, treatment, and management of anesthesia-related complications or emergencies; and
5. ensure the provision of indicated post-anesthesia care.

Discharge Criteria

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

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

Information to the Patient

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

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

Reportable Complications

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

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

Equipment Maintenance

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

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

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

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

Nothing in this position statement affects the scope of activities subject to or exempted from the North Carolina health care facility licensure laws.(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 licensee who performs the surgical or special procedure or a health care professional who is present during the intraoperative and postoperative periods should be ACLS certified, and at least one other health care professional should be BLS certified. In an office where anesthesia services are provided to infants and children, personnel should be appropriately trained to handle pediatric emergencies (*i.e.*, APLS or PALS certified).

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

Surgical or Special Procedure Guidelines

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

- direct observation of the patient and, to the extent practicable, observation of the patient's responses to verbal commands;
- pulse oximetry should be performed continuously (an alternative method of measuring oxygen saturation may be substituted for pulse oximetry if the method has been demonstrated to have at least equivalent clinical effectiveness);

- an electrocardiogram monitor should be used continuously on the patient;
- the patient's blood pressure, pulse rate, and respirations should be measured and recorded at least every five minutes; and
- the body temperature of a pediatric patient should be measured continuously.

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

Postoperative Care and Monitoring
The licensee who performs the surgical or special procedure should evaluate the patient immediately upon completion of the surgery or special procedure and the anesthesia.

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

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

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

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

1. Full and current crash cart at the location where the anesthetizing is being carried out. (the crash cart inventory should include appropriate resuscitative equipment and medications for surgical, procedural or anesthetic complications);
2. age-appropriate sized monitors, resuscitative equipment, supplies, and medication in accordance with the scope of the surgical or special procedures and the anesthesia services provided;
3. emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours;
4. electrocardiographic monitor;
5. noninvasive blood pressure monitor;
6. pulse oximeter;
7. continuous suction device;
8. endotracheal tubes, laryngoscopes;
9. positive pressure ventilation device (e.g., Ambu);
10. reliable source of oxygen;
11. emergency intubation equipment;
12. adequate operating room lighting;
13. appropriate sterilization equipment; and
14. IV solution and IV equipment.
15.

Level III Guidelines

Personnel

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

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

Surgical or Special Procedure Guidelines

Intraoperative Monitoring

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

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

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

Postoperative Care and Monitoring

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

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

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

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

Equipment and Supplies

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

1. full and current crash cart at the location where the anesthetizing is being carried out (the crash cart inventory should include appropriate resuscitative equipment and medications for surgical, procedural or anesthetic complications);
2. age-appropriate sized monitors, resuscitative equipment, supplies, and medication in accordance with the scope of the surgical or special procedures and the anesthesia services provided;
3. emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours;
4. electrocardiographic monitor;
5. noninvasive blood pressure monitor;
6. pulse oximeter;
7. continuous suction device;
8. endotracheal tubes, and laryngoscopes;
9. positive pressure ventilation device (*e.g.*, Ambu);
10. reliable source of oxygen;
11. emergency intubation equipment;
12. adequate operating room lighting;
13. appropriate sterilization equipment;
14. IV solution and IV equipment;
15. sufficient ampules of dantrolene sodium should be emergently available;
16. esophageal or precordial stethoscope;
17. emergency resuscitation equipment;
18. temperature monitoring device;
19. end tidal CO2 monitor (for endotracheal anesthesia); and
20. appropriate operating or procedure table.

Definitions

AAAASF – the American Association for the Accreditation of Ambulatory Surgery Facilities.
AAAHC – the Accreditation Association for Ambulatory Health Care
ABMS – the American Board of Medical Specialties
ACGME – the Accreditation Council for Graduate Medical Education
ACLS certified – a person who holds a current "ACLS Provider" credential certifying that they have successfully completed the national cognitive and skills evaluations in accordance with the curriculum of the American Heart Association for the Advanced Cardiovascular Life Support Program.
Advanced cardiac life support certified – a licensee that has successfully completed and recertified periodically an advanced cardiac life support course offered by a recognized

accrediting organization appropriate to the licensee's field of practice. For example, for those licensees treating adult patients, training in ACLS is appropriate; for those treating children, training in PALS or APLS is appropriate.
Ambulatory surgical facility – a facility licensed under Article 6, Part D of Chapter 131E of the North Carolina General Statutes or if the facility is located outside North Carolina, under that jurisdiction's relevant facility licensure laws.
Anesthesia provider – an anesthesiologist or CRNA.
Anesthesiologist – a physician who has successfully completed a residency program in anesthesiology approved by the ACGME or AOA, or who is currently a diplomate of either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982.
AOA – the American Osteopathic Association
APLS certified – a person who holds a current certification in advanced pediatric life support from a program approved by the American Heart Association.
Approved accrediting agency or organization – a nationally recognized accrediting agency (*e.g.*, AAAASF; AAAHC, JCAHO, and HFAP) including any agency approved by the Board.
ASA – the American Society of Anesthesiologists
BLS certified – a person who holds a current certification in basic life support from a program approved by the American Heart Association.
Board – the North Carolina Medical Board.
Conscious sedation – the administration of a drug or drugs in order to induce that state of consciousness in a patient which allows the patient to tolerate unpleasant medical procedures without losing defensive reflexes, adequate cardio-respiratory function and the ability to respond purposefully to verbal command or to tactile stimulation if verbal response is not possible as, for example, in the case of a small child or deaf person. Conscious sedation does not include an oral dose of pain medication or minimal pre-procedure tranquilization such as the administration of a pre-procedure oral dose of a benzodiazepine designed to calm the patient. "Conscious sedation" should be synonymous with the term "sedation/analgesia" as used by the American Society of Anesthesiologists.
Credentialed – a physician that has been granted, and continues to maintain, the privilege by a hospital or ambulatory surgical facility licensed in the jurisdiction in which it is located to provide specified services, such as surgical or special procedures or the administration of one or more types of anesthetic agents or procedures, or can show documentation of adequate training and experience.
CRNA – a registered nurse who is authorized by the North Carolina Board of Nursing to perform nurse anesthesia activities.
Deep sedation/analgesia – the administration of a drug or drugs which produces depression of consciousness during which patients cannot be easily aroused but can respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
FDA – the Food and Drug Administration.
General anesthesia – a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.
Health care professional – any office staff member who is licensed or certified by a recognized professional or health care organization.
HFAP – the Health Facilities Accreditation Program, a division of the AOA.

Hospital – a facility licensed under Article 5, Part A of Chapter 131E of the North Carolina General Statutes or if the facility is located outside North Carolina, under that jurisdiction's relevant facility licensure laws.
Immediately available – within the office.
JCAHO – the Joint Commission for the Accreditation of Health Organizations

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.

(Adopted January 2003) (Amended May 2011; May 2015)

9.1.1: Physician Supervision of Other Licensed Health Care Professionals

The physician who provides medical supervision of other licensed healthcare professionals is expected to provide adequate oversight. The physician must always maintain the ultimate responsibility to assure that high quality care is provided to every patient. In discharging that responsibility, the physician should exercise the appropriate amount of supervision over a licensed healthcare professional which will ensure the maintenance of quality medical care and patient safety in accord with existing state and federal law and the rules and regulations of the Board. What constitutes an "appropriate amount of supervision" will depend on a variety of factors. Those factors include, but are not limited to:

- The number of supervisees under a physician's supervision
- The geographical distance between the supervising physician and the supervisee
- The supervisee's practice setting
- The medical specialty of the supervising physician and the supervisee
- The level of training of the supervisee
- The experience of the supervisee
- The frequency, quality, and type of ongoing education of the supervisee
- The amount of time the supervising physician and the supervisee have worked together
-
- The supervisee's scope of practice consistent with the supervisee's education, national certification and/or collaborative practice agreement

The above factors outlining the supervisory relationship should be outlined in a written collaborative practice agreement, supervisory arrangement, protocol, or other written guidelines. Physicians should only supervise another professional for the diagnosis, treatment, and overall care (including procedures) for which the physician has an appropriate level of education, training, experience, and/or certification. Physicians should also be cognizant of maintaining appropriate boundaries with their supervisees, including refraining from requesting medical treatment by the physician's supervisee.[1] Physician assistants and nurse practitioners are specifically prohibited from prescribing controlled substances for the use of their supervising physicians.

Practices owned solely by physician assistants or nurse practitioners may not hire or contract with physicians to practice medicine on behalf of the physician assistant or nurse practitioner owned

[1] See also the Board's position statement on "Self-treatment and Treatment of Family Members."

practice. The physician assistant or nurse practitioner may contract with a physician to provide the legally required supervision of the physician assistant or nurse practitioner.

(Adopted July 2007) (Amended November 2015)

9.1.2: Professional Behavior Within the Healthcare Team

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

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

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

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

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

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

(Adopted January 2010) (Amended July 2019)

10.1.1: Referral Fees and Fee Splitting

Payment by or to a licensee solely for the referral of a patient is unethical and, in most instances, is inconsistent with state law. A licensee may not accept payment of any kind, in any form, from any source, such as a pharmaceutical company or pharmacist, an optical company, or the manufacturer of medical appliances and devices, for prescribing or referring a patient to said source. In each case, the payment violates the requirement to deal honestly with patients and colleagues. The patient relies upon the advice of the licensee on matters of referral. All referrals and prescriptions must be based on the skill and quality of the licensee to whom the patient has been referred or the quality and efficacy of the drug or product prescribed.

It is unethical for licensees to offer financial incentives or other valuable considerations to patients in exchange for recruitment of other patients. Such incentives can distort the information that patients provide to potential patients, thus distorting the expectations of potential patients and compromising the trust that is the foundation of the licensee-patient relationship. Furthermore, referral fees are prohibited by state law pursuant to N.C. Gen. Stat. § 90-401. Violation of this law may result in disciplinary action by the Board.

Except in instances permitted by law (N.C. Gen. Stat. § 55B-14(c)), it is the position of the Board that a licensee cannot share revenue on a percentage basis with a non-licensee. To do so is fee splitting and is grounds for disciplinary action.

Voucher Advertising
It is the Board's position that, so long as certain conditions are followed, advertising involving the utilization of vouchers does not constitute unethical fee-splitting or a prohibited solicitation or referral fee under North Carolina law. Those conditions include: (1) ensuring that the negotiated fee between the voucher advertising company and the licensee represents reasonable compensation for the cost of advertising; and (2) incorporating the following terms and conditions in a clear and conspicuous manner in all advertisements:

(a) A description of the discounted price in comparison to the actual cost of services;

(b) A disclosure that all patients may not be eligible for the advertised medical service and that decisions about medical care should not be made in haste. Determinations regarding the medical indications for individual patients will be made on an individual basis by applying accepted and prevailing standards of medical practice; and

(c) A disclosure to prospective patients that, if it is later decided that the patient is not a candidate for the previously purchased medical service, the patient's purchase price will be refunded in its entirety. If the patient does not claim the service, then the patient's purchase price must still be refunded in its entirety. In the event that the voucher advertising company does not refund the purchase price in its entirety, it will be the sole obligation of the licensee to refund the entire purchase price.

(Adopted November 1993) (Amended May 1996; July 2006; January 2013)

10.1.2.: Corporate Practice of Medicine

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

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

Hospital-owned practices

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

(Adopted March 2016)