VIRGINIA BOARD OF MEDICINE FULL BOARD MINUTES

PUBLIC COMMENT

Dr. Ransone began the morning by calling to order a public meeting for the purpose of taking comment on the Board of Medicine's proposed revisions subsequent to the periodic review of its regulations, 18VAC85-20-22 et seq. As there was no comment, Dr. Ransone thanked all in attendance and closed the meeting at 8:50 a.m.

CALL TO ORDER:	Dr. Ransone then called the meeting of the Full Board to order.
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ROLL CALL:

MEMBERS PRESENT:	Karen Ransone, MD, President Claudette Dalton, MD, Vice-President Stuart Mackler, MD, Secretary/Treasurer Deeni Bassam, MD Sandra Anderson Bell, MD Randy Clements, DPM William Epstein, MD Stephen Heretick, JD Valerie Hoffman, DC Gopinath Jadhav, MD Jane Maddux Juan Montero, MD Jane Piness, MD Wayne Reynolds, DO Michael Signer, Ph.D., JD
MEMBERS ABSENT:	Jennifer Lee, MD Roderick Mathews, JD
STAFF PRESENT:	William L. Harp, MD, Executive Director Jennifer Deschenes, JD, Deputy Executive Director, Discipline Barbara Matusiak, MD, Medical Review Coordinator Ola Powers, Deputy Executive Director, Licensing Colanthia Morton Opher, Operations Manager Amy Marschean, Assistant Attorney General
OTHERS PRESENT:	William A. Hazel, MD, Secretary of Health and Human Resources Mike Jurgensen, MSV

Tammie Smith, Richmond Times-Dispatch Jerry Canaan, MSV Matt Benedetti, VSPS Terry Schulte, VAFP Lewis Ladocsi, MD, VSPS Victoria Vastine, MD, VSPS Isaac Wornom, MD, VSPS Paul Rein, DO Jesus Lizarzaburu, MD, VAFP

EMERGENCY EGRESS PROCEDURES

Dr. Dalton read the emergency egress procedures for Conference Room 2.

MOMENT OF SILENCE

Dr. Ransone asked that all observe a moment of silence for Board members and their recently lost loved ones.

WILLIAM A. HAZEL, MD---SECRETARY OF HEALTH AND HUMAN RESOURCES

Dr. Hazel addressed the Board and thanked the members for their work and dedication. He gave an extemporaneous address regarding health care in our nation and in the Commonwealth. He said that in the long run the challenge we face is how can we serve the public when the old ways of providing care are no longer getting the job done, and may even have become an impediment to providing health care services to our citizens? He pointed out that by 2014, there will be 32 million more individuals in our nation that will need the services of a healthcare professional. As a profession, do physicians want to be to American medicine what the unions have been to automobile industry in Detroit? The challenge of meeting the healthcare needs of our citizens will require that the old work rules change. He believes that all in healthcare must find a way to transform our roles to support a coordinated delivery system that provides more care and better care, taking advantage of state of the art technology and processes. Dr. Hazel fielded a few questions from the Board.

APPROVAL OF THE OCTOBER 28, 2010 MINUTES

Dr. Mackler moved to accept the minutes of October 28, 2010. The motion was seconded and carried unanimously.

ADOPTION OF AGENDA

Dr. Dalton moved to adopt the agenda as presented. The motion was seconded and carried unanimously.

PUBLIC COMMENT ON AGENDA ITEMS

Isaac Wornom, MD – spoke in favor of the recommendation being proposed by the Ad Hoc Committee on Office-Based Surgery.

Victoria Vastine, MD – spoke in favor of the recommendation being proposed by the Ad Hoc Committee on Office-Based Surgery.

Paul Rein, DO – spoke in favor of the recommendation being proposed by the Ad Hoc Committee on Office-Based Surgery.

Lewis Ladocsi, MD – spoke in favor of the recommendation being proposed by the Ad Hoc Committee on Office-Based Surgery.

Jesus Lizarzaburu, MD – spoke against the recommendation of the Ad Hoc Committee on Office-Based Surgery. He stated that VAFP believes the current disciplinary system effectively deals with office-based surgical issues, but believes strongly that physicians should disclose to patients their credentials and preparation to perform procedures. Dr. Lizarzaburu brought the Board's attention to a consent form (page 200 in agenda packet) previously presented to the Ad Hoc committee as an effective way to further empower and protect the public.

During the course of public comment, some Board members chose to ask questions of the speakers. Issues included the validity of the data regarding morbidity and mortality, adverse incidents by specialty, and opinions on the Arizona and Florida approaches to office-based procedures. In the discussion of morbidity, patient harm and mortality, Dr. Mackler asked about mortality in Virginia with office-based procedures. Board staff was able to respond with 3 deaths in the last decade related to plastic/cosmetic surgery. An anesthesiologist in attendance said he knew of 8 deaths with office-based procedures just in his geographic area; he said 6 were related to plastic surgery.

As the public comment period concluded, Dr. Ransone called for a 15-minute recess.

The business meeting of the Full Board resumed at 10:54 a.m.

NEW BUSINESS

DHP DIRECTOR'S REPORT

Agency Operating Efficiency Measures

Dr. Harp gave regrets for Dr. Reynolds-Cane and Mr. Owens who had to be elsewhere. He then informed the Board of the innovative measures that the DHP Executive Leadership Team has developed for the agency to operate more efficiently and support the Governor in his efforts to deal with a tight budget.

Lyme Disease Task Force

Dr. Harp informed the Board that Dr. Ransone has been asked to assist the Lyme Disease Task Force. The Task Force will be exploring diagnosis, prevention, public education, and medical treatment of the disease. Dr. Ransone holds a Master's in infectious disease.

REPORT OF OFFICERS AND EXECUTIVE DIRECTOR

PRESIDENT'S REPORT

There was no report.

VICE-PRESIDENT'S REPORT

There was no report.

SECRETARY-TREASURER'S REPORT

There was no report.

EXECUTIVE DIRECTOR'S REPORT

• Revenue and Expenditures Report

Dr. Harp advised that the most recent report indicates that the Board is well within budget.

HPMP Statistics

This report was provided for information only. Medicine currently has 110 licensees enrolled in the Health Practitioners' Monitoring Program.

• MD Vacancy in 6th district

Dr. Harp informed the Board that Dr. Mann has moved to the eastern part of the state and is no longer eligible to occupy the 6th district seat. The Board is awaiting a new appointment.

• Advisory Board on Polysomnographic Technology

Dr. Harp said that the Board of Medicine's newest advisory board met on February 4, 2011 and stated that he looks forward to working with the Advisory Board members as they develop the regulations for their profession.

FSMB Items

Dr. Harp advised the Board that Dr. Dalton has been nominated for the Federation of State Medical Boards' Board of Directors. Dr. Dalton said she has some stiff competition and asked the members' support in her run for this office.

In addition, Dr. Reynolds has volunteered to do committee work at FSMB.

Also, anyone interested in attending the FSMB's annual meeting should contact Ms. Morton-Opher.

COMMITTEE AND ADVISORY BOARD MINUTES

Dr. Bell moved to accept the Committee, Ad Hoc Committee, Work Group and Advisory Board minutes en bloc. The motion was seconded and carried unanimously.

OTHER REPORTS

Assistant Attorney General

Ms. Marschean gave an update on two legal matters involving the Board.

Board of Health Professions

No report.

Podiatry Report

No report.

Chiropractic Report

No report.

NEW BUSINESS

Regulatory Actions

Chart of Regulatory Actions

This report was provided for information only. No action was required.

Legislative Actions

Adoption of Proposed Regulations regarding supervision and practice agreements of physician assistants.

Mr. Heretick moved to adopt the amendments to the regulations governing the practice of physician assistants. The motion was seconded and carried.

Adoption of Notice of Intended Regulatory Actions (NOIRA) for Polysomnography

Dr. Piness moved to adopt the NOIRA for promulgation of regulations for polysomnography in response to the mandate in Chapter 838 of the 2010 General Assembly. The motion was seconded and carried.

Recommendation from the Ad Hoc on Office-Based Surgery Committee

Dr. Dalton began the discussion by expressing her concern that regulations were in place for office-based anesthesia but no regulations exist for the person that performs the surgical procedure. She said that having the patient bear the responsibility of understanding: 1) the possible complications that may be encountered during and after a procedure, 2) the practitioner's preparation, expertise and skill, 3) the role of any other personnel that might be involved, and 4) having the procedure done in an office versus a regulated hospital is unreasonable. She believes the current data is meaningless, and we tend not to see as many problems because we don't have the "Hollywood types or snow bunnies". She is uncomfortable with weekend courses and thinks at a minimum the Board should recommend that a committee be formed to look at the possibility of regulations and review the available data. The motion was seconded and carried. Dr. Ransone called for discussion.

Dr. Hoffman asked for clarification on the charge of the Ad Hoc Committee.

Dr. Harp referred to the additional handouts provided at the outset of the meeting that included the initial agenda of the Ad Hoc Committee noting the history of the issue and the charge. Dr. Harp pointed out that although other stakeholders were at the table, the issue has primarily been focused on the plastic/cosmetic surgery procedures and providers. The recommendation of the Ad Hoc Committee was discussed at the Legislative Committee meeting held January 21, 2011. The Legislative Committee

determined that the matter should be forwarded to the Board for further discussion and recommendation.

Dr. Mackler, chair of the Ad Hoc Committee, thanked all for their involvement to date in this issue. However, he said the motion on the table would be a step backward and offered an amendment. Dr. Mackler requested that the motion be amended to authorize the formation of a committee to develop a guidance document on office-based procedures.

Dr. Bassam then posed a question to the Board. Is there a need to do something more than what we're already doing? And if so, the Board should offer direction for the Ad Hoc Committee on what form would that action should be. Are we suggesting a guidance document or regulations? Are we, as a Board, going to dictate who can do what in an office, or are we going to approach this from the position of requiring a more well-defined informational process for patients to aid in the decision of what and by whom they wish to have done to their own bodies?

Dr. Piness stated that her concern is how this will affect other specialties. Should regulating cosmetic procedures be our focus or is there a greater need to enforce reporting?

Dr. Jadhav questioned whether this issue concerns just office-based procedures and surgeries, or anything that a practitioner can perform in his office under his specialty.

In response, Dr. Ransone referred to the Florida regulations in the Board packet on page 196 as a reasonable definition of an office-based procedure and the minimal qualifications for the practitioner.

Dr. Mackler spoke to the numerous letters received from the plastic surgery community that indicate there are numerous cases with unfavorable outcomes that are not being reported to the Board. He recalled that there were two physicians that performed cosmetic procedures resulting in adverse outcomes that the Board had disciplined in the last 14 months. One involved a bad scar on the upper extremity and the second resulted in excessive abdominal skin after liposuction. Both procedures were done by physicians not trained in plastic surgery.

Dr. Randy Clements brought to the Board's attention an article in the agenda packet from *Plastic Surgery Practice* that suggested 80% of all cosmetic surgery is performed by other than trained plastic surgeons. The statistics quoted in the article did not appear to support the assumption that cosmetic procedures performed by non-plastic surgeons placed patients at greater risk.

Ms. Deschenes reminded the Board and all in attendance that 54.1-2909 A(4) requires that any evidence that indicates a reasonable probability that a person licensed under this chapter is or may be professionally incompetent; has engaged in intentional or

negligent conduct that causes or is likely to cause injury to a patient or patients; has engaged in unprofessional conduct; or may be mentally or physically unable to engage safely in the practice of his profession be reported to the board within 30 days of this realization.

Dr. Bassam reiterated that he believes there is a need for the Board to do something further to address all the issues being discussed. He believes there are two things good government does: 1) prevent a person from committing violent act on another person, and 2) protect the consumer from fraud.

Dr. Bassam stated his concern that some practitioners may misrepresent their level of expertise to the public, and in doing so, would be committing fraud upon the consumer. He believes good government should prevent that from happening. He rejects the idea that individuals do not have the capacity to make informed decisions about what happens to their own bodies. The question becomes how is the consumer empowered to make the best informed decision.

After additional debate, Dr. Jadhav called for the question. The vote to call the question failed. Discussion continued.

Dr. Dalton amended her initial motion to move that the Board accept the motion from the Ad Hoc Committee that a guidance document on office-based surgical procedures be developed for use during the promulgation of proposed regulations to protect patients from the threat of inadequately trained providers who offer cosmetic and other surgical services in outpatient settings. The motion was seconded. Dr. Ransone opened the floor for discussion.

Mr. Heretick said that bad facts make bad law. The motion proposes to create a guidance document; however, he has not heard evidence that confirms that inadequately trained physicians have created widespread harm that would affect the population across the board. Is the exception or the anomaly driving this request for regulation? If you want to minimize the risk, the proper action must be taken. The problem appears to be that we know there are bad outcomes that are not being reported to the Board. If a patient or a practitioner is aware of a bad outcome and wants to remain quiet about it, the Board has no way of dealing with the situation. The Board cannot effectively regulate ethics and standards of practice unless reports/complaints are received. Office-based surgical regulations, if written, would need to take into account that the Board of Medicine issues a general license to practice medicine and would need to be universal, practical and enforceable. Mr. Heretick requested that this matter be remanded back to the Ad Hoc Committee and asked that the scope be more clearly defined in order to move forward in a constructive way.

Dr. Harp informed the members that the Virginia Department of Health and Virginia Health Information (VHI) are working together in the collection of data on outpatient procedures. The numbers have not been analyzed as yet, but preliminary review would appear to indicate that there are not a lot of adverse outcomes or complications being reported.

Dr. Piness stated that two areas of concern were brought to her attention in regards to reporting: 1) anonymity cannot be guaranteed, and 2) reporting could be a HIPPA violation if the patient does not give explicit permission.

Mr. Signer said that there are three major questions: 1) is there enough data to support any changes? 2) does this affect just plastic surgery or all specialties? and 3) what are the regulatory options? If the Board can come to an agreement on the specifics, then the Ad Hoc Committee can bring what's missing back to the table.

Dr. Bassam asked Dr. Dalton to withdraw her motion and for the Board to vote on whether or not there is a need to do something beyond what is presently in law and regulation. Dr. Dalton respectfully declined.

Dr. Ransone restated the original recommendation from the Ad Hoc Committee as captured in Dr. Dalton's motion. The motion failed 15 to 1.

Dr. Bassam moved that the Board consider the need to promulgate regulations for officebased procedures beyond what we already have. The motion was seconded. The floor was opened for discussion. After a brief discussion, the motion failed.

Mr. Heretick then moved that this subject be remanded back to the Ad Hoc Committee for more definition on the nature and scope of any limitations on licensees performing procedures in office-based settings. The motion was seconded. The floor was opened for discussion. There being none, the motion carried.

Licensing Report

Ms. Powers provided a verbal report on the current status of the licensing section. She advised that as of February 16th, the Board has 54,476 licensees. Ms. Powers also acknowledged the addition of the newest and 8th advisory board, the Advisory Board on Polysomnographic Technology.

Discipline Report

Ms. Deschenes introduced Ms. Dawn Alexander as the new compliance specialist at the Board of Medicine.

Ms. Deschenes asked the Board's consideration in expanding delegation to staff under 54.1-2409 to allow for closure of Priority A and B cases on practitioners who passed away before the disciplinary process could be completed.

Dr. Jadhav moved that delegation be granted for the above process. The motion was

seconded and carried unanimously.

Ms. Deschenes let the Board members know that the next Full Board meeting, June 23-25th promises to be challenging with a full docket of business and hearings. Some formal hearings will be held in May to help relieve the docket in June.

Appointment of the Nominating Committee

Dr. Ransone appointed three volunteers, Dr. Piness, Ms. Maddux, and Mr. Heretick, to serve as the 2011 Nominating Committee. The Committee will present a slate of officers for approval at the June 23rd meeting.

Credentials Committee Recommendation

The Board was provided with the Credentials Committee's recommendation in the matter heard on February 16, 2011.

On a motion made by Mr. Heretick and duly seconded, the Board voted unanimously to accept the Recommendation of the Credentials Committee.

Announcements

Staff reminded the Board of their hearing assignments for the remainder of the day.

Adjournment: With no other business to conduct, the meeting adjourned at 12:33 p.m.

Next scheduled meeting: June 23, 2011

Karen Ransone, M.D. President, Chair William L. Harp, M.D. Executive Director

Colanthia M. Opher Recording Secretary