

**VIRGINIA BOARD OF MEDICINE
Ad Hoc Committee on Office-Based Surgery**

Tuesday, January 11, 2011

Department of Health Professions

Richmond, VA

CALL TO ORDER: The meeting convened at 10:14 a.m.

MEMBERS PRESENT: Stuart Mackler, MD, Chair
John Alspaugh, MD, alternate
Jeffrey Frost, DPM, alternate
Lewis Ladocsi, MD
Mitchell Miller, MD
Julia Konderding Padget, MD
Barklie Zimmerman, MD

MEMBERS ABSENT: Stephen Bendheim, MD
Arnold Beresh, DPM
Thomas Clifford, MD
Patrick Clougherty, MD
Gopinath Jadhav, MD
John Pitman, MD

STAFF PRESENT: William L. Harp, MD, Executive Director
Ola Powers, Deputy Executive Director, Licensing
Colanthia Morton Opher, Operations Manager
Elaine Yeatts, DHP Senior Policy Analyst

OTHERS PRESENT: Karah Gunther, HDJN
Terry Schulte, VAFP
Roger Emory, MD
Saied Asfa, MD
Enrique Silberblatt, MD
Carol Wray, MD
Michael Jurgensen, MSV
Michael Goodman, JD
Kristi VanderLaan, JD

ROLL CALL

EMERGENCY EGRESS INSTRUCTIONS

Dr. Mackler provided the Emergency Egress procedures.

REQUEST FROM DR. LADOC SI TO SEAT AN ALTERNATE TO DR. PITMAN

At roll call, a quorum was not declared. The Committee members voted to allow Dr. Alspaugh and Dr. Frost to serve as alternates for their societies in the absence of the appointed members.

APPROVAL OF THE MINUTES FROM NOVEMBER 4, 2010

Dr. Miller requested the following amendments:

Page 2 – Adoption of the Agenda

Dr. ~~Mitchell~~ Miller moved to approve the expanded agenda as presented.

Page 4 – REVIEW OF THE ROUNDTABLE LIST OF CONCERNS

Dr. Miller's corrected language: "He spoke to the credentialing process that exists in hospitals. He also suggested that there should be a process to ensure transparency for patients contemplating undergoing a procedure in regards to the procedure itself, best practices, and the qualifications of the physicians offering such services."

Page 2—REVIEW OF THE ROUNDTABLE LIST OF CONCERNS

Dr. Ladocsi requested the addition of "As an example other than plastic surgery, he mentioned that outpatient endovascular treatment of uterine fibroids was being done by an untrained provider in Midlothian. He said there are complicated and potentially fatal procedures being performed by less than qualified practitioners, and that the Board of Medicine was not in the best position to gather the data to define the breadth of the problem. He thinks this problem extends way beyond the cosmetic realm, and now may be the time to head off a serious dilemma and protect the public. He said that whatever steps are taken, the process should seek to avoid any unintended consequences to those practicing safely and competently within their areas of expertise

After brief discussion, Dr. Zimmerman moved to approve the minutes with the above amendments. The motion was seconded and carried.

ADOPTION OF THE AGENDA

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

PUBLIC COMMENT ON AGENDA ITEMS

After introduction of the public in attendance and prior to the Committee hearing comment, Dr. Harp gave a brief overview of the Board's reporting requirements under Section 54.1-2909 of the Code of Virginia and its legal authority to address substandard care.

Roger Emory, MD, plastic surgeon from Abingdon, spoke in favor of the Board developing a scheme for greater oversight of office-based procedures such as “smart liposuction” that is being performed by unqualified and/or non-ABMS practitioners. Dr. Emory said he would like to see an agreement between the office –based practitioner and a hospital-based practitioner for transfer of care in an emergency situation. He opined that a week or weekend training program was not sufficient for some of the office-based procedures that are currently being performed. He said that the ABMS has well-established standards for training, and that North Carolina has adopted standards to protect the public.

Saied Asfa, MD, plastic surgeon from Harrisonburg, spoke in favor of regulations to limit the procedures that can be performed in the office setting. Such a document could also address guidelines for patient care. He suggested that the Board consider Florida’s model of regulation.

Enrique Silberblatt, MD, plastic surgeon from Roanoke, spoke in favor of regulating office-based procedures. Dr. Silberblatt said his major concern is patient safety and especially transfer of care in an emergency situation. He suggested that the hospital credentialing process be used to assess new procedures and practitioners that should be granted privileges to perform them. Formalizing this requirement would enhance patient safety. He informed the Committee that there is a nonsurgical practitioner that not only performs office-based liposuction, but also conducts training at which the participants earn CAT I CME for their attendance.

Carol Wray, MD, plastic surgeon from Salem, spoke in favor of regulating office-based procedures. Dr. Wray agrees that patient safety is foremost. She also voiced her concern about misleading advertisements.

NEW BUSINESS

REVIEW OF THE MINUTES FROM NOVEMBER 4, 2010

This was considered accomplished during the approval of the minutes.

FURTHER DATA/CONCERNS

Dr. Ladocsi stated to the Committee that, on behalf of the Virginia Society of Plastic Surgeons, he wanted to convey that they consider the issue of outpatient surgery by untrained providers to be a patient safety issue only, and that their concerns do not extend to quality of results, economics or turf issues. Their concern is with the types of surgeries being done in offices by less than qualified practitioners.

Related to the concept of hospital credentialing for all providers of surgical services, Dr. Miller said that he is aware that hospitals have wrestled with how to address practitioners who don’t apply for or don’t want hospital privileges. How are they to be handled in any credentialing process? He questioned how far should this be taken; if the emergency room

practitioner defaults to the practice of urgent care is that something the Board needs to step in and regulate? The concern is how to determine who is adequately trained to do what. Should all physicians be strictly limited to their specialty?

Dr. Ladocsi responded by saying that VSPS supports the definition of proper surgical training as defined by the American Boards of Medical Specialties. Further, if this certified training is required to provide surgical care in hospitals, it should also be the standard to provide care in the outpatient setting.

The Committee acknowledged that there may be multiple standards for similar procedures. Although ABMS may address the standards in any specialty, there are numerous examples of procedures that cross specialty lines.

Dr. Harp posed two questions to the members of the Committee. First, what should be the minimum training for the general practitioner in order to perform certain procedures? And secondly, of what procedures were the Committee members aware that were problematic in their specialties?

Dr. Miller noted that he is aware of vein and cosmetic procedures being performed in spa settings, but is unaware of physicians strongly venturing outside their areas of expertise. Dr. Zimmerman indicated he is aware of physicians offering cosmetic vein treatment. He commented that he learned these procedures in a 2-day course, but added that he is competent to handle any complications.

Dr. Foster said that he was not aware of any such circumstances; however his practice has clear delineation in the law by anatomical location. Dr. Miller informed the Committee that just recently a DPM wanted to be the first to do total ankle replacement. Privileges were granted, and the outcome was good.

Dr. Padget stated that dermatology is not routinely performed in hospital settings, and she is not aware of any cases that would give rise to concern; however, the diagnosis of pigmented lesions that may turn out to be melanoma is on the national radar. There is no data to support any significant complications or deaths.

Dr. Miller referred to the letter submitted by the Virginia Academy of Family Physicians and stated that their society hasn't been overwhelmed by the scope of the problem. From their position, the proposal for regulation of office-based procedures is untimely and unnecessarily burdensome. He stated that patient safety and choice could be enhanced with a properly constructed consent form. Additionally he said, if there are fair and reasonable standards that don't encumber the scope of practice of a prudent practitioner outside the standards of their board, they should be taken into consideration. However, if we require all practitioners to be credentialed in a hospital, it will leave out a lot of good practitioners. VAFP is not against the concept of regulating office-based procedures, if there is a fair and equitable way to do so. However, VAFP does believe the disciplinary process currently in place at the Board of Medicine is adequate to deal with the few problematic incidences of office-based surgery.

Dr. Ladocsi respectfully noted that VSPS maintains that the Board of Medicine's disciplinary process is inadequate to deal with the increasing numbers of untrained providers performing outpatient cosmetic surgery.

The Committee then turned its attention to an article regarding major and lethal complications of liposuction, the review of 72 cases in Germany between 1998 and 2002. Dr. Harp said that this article supports that there can be real problems. By the same token, another article, "Office Surgery Incidents: What Seven Years of Florida Data Show Us" concludes that requiring specialty board certification or hospital privileges would not alter the potential for patient harm, as this group of physicians was responsible for its proportion of bad outcomes.

Dr. Harp briefly reviewed the short cosmetic workshops being offered by the American Academy of Cosmetic Family Medicine, noting that in order for CME to be offered, the quality of the course and the qualifications of the instructor would have to meet the requirements of CME outlined by the American Medical Association.

Dr. Harp then referred to the Executive Summary of the North Carolina Medical Board's Special Committee on Practice Drift Public Meeting from October 13, 2010, and specifically the statement regarding Physician Scope of Practice. The statement's first sentence advises that it is intended to guide physicians who undertake to perform new procedures, use new technologies, or migrate into areas of practice for which they have not received formal graduate medical education. Dr. Harp reiterated that the same type of guidance document in Virginia can be used to inform its practitioners and the public and generally describe what acceptable standard of care is. Dr. Harp stated that a NCMB position statement does not carry the weight of law.

Dr. Ladocsi disagreed with the reported weight of North Carolina's position statement. As a matter of clarity, Board staff will follow up and report its findings.

Dr. Harp asked the Committee to review the Arizona Medical Board's Scope of Practice Guidelines and its information on how to choose a physician for cosmetic or plastic surgery, complete with a checklist and a follow up questionnaire.

After an in-depth discussion, Dr. Ladocsi moved that the Ad Hoc Committee on Office-Based Surgery express to the Board of Medicine its conclusion that patients in Virginia are currently at risk of injury from untrained providers who offer cosmetic and other surgical services in outpatient settings. The motion was seconded.

After discussion, the motion was amended as follows: the Ad Hoc Committee on Office-Based Surgery expresses to the Board of Medicine its conclusion that patients in Virginia are ~~currently~~ at potential risk of injury from ~~untrained~~ inadequately trained providers who offer cosmetic and other surgical services in outpatient settings. The motion was seconded and carried 5 in favor with Dr. Ladocsi opposed.

The Committee then discussed the next steps to be taken in the process.

Dr. Miller asked the Committee to consider a guidance document that would be a "high

road” statement about medical training necessary for any procedures to be undertaken. Although it would not have the weight of law or regulations, it would help the practitioner is “on the fence” to choose the right path with patient safety in mind.

Dr. Miller and Dr. Zimmerman noted that a process should be in place that provides better transparency and disclosure regarding a physician’s training and/or board certification in order for patients to best select a practitioner.

Ms. Yeatts agreed that the use of a guidance document would help to inform the practitioner and the public on what the Board considers to be an acceptable standard of practice for office-based surgery. It could also serve as a stopgap measure while the Board considered and/or promulgated regulations. She reminded the Committee that regulations could take up to two years from inception to conclusion, so the advantage of a guidance document would be that it informs the licensees of the board’s stance on these matters.

Dr. Ladocsi restated that, from his stand point, a guidance document is not worth the paper it’s written on, and is a waste of time. He suggested that the Board consider regulations that would legally bind practitioners to the standard of practice in the interest of patient care and safety. He stated that Section 54.1-2912.1 is inadequate to cover the issues before the Committee.

Dr. Ladocsi asked the Board to consider making regulatory changes to protect the patient without interfering with the practice of qualified practitioners. He pointed out that the Board currently regulates office-based anesthesia, therefore acknowledging that untrained providers of anesthesia are potentially dangerous to patients and should be prohibited from providing care. Likewise, untrained providers of surgical procedures should be prohibited from providing care.

Dr. Miller moved that a guidance document be developed to address office –based surgical procedures. The motion was seconded. After discussion, the vote was 3 in favor; 4 opposed. The motion did not carry.

After further discussion, Dr. Miller’s motion was amended to recommend to the Board of Medicine that a guidance document be created to be used during the development of regulations to address office-based surgery. The motion was seconded and carried with 1 opposed.

Dr. Ladocsi asked that the following criteria be considered when making “good” regulatory changes:

- Protect the public
- Not interfere with the provision of healthcare
- Be simple, clear, and easy to enforce
- Avoid excessive burden on the BOM staff

With that, Dr. Ladocsi moved that the Ad Hoc Committee recommend the Board of Medicine make regulatory changes to protect patients from the threat of untrained providers who offer cosmetic and other surgical services in outpatient settings.

Dr. Zimmerman amended the language to be a recommendation to the Board of Medicine that a guidance document on office-based surgical procedures be created for use during the development of proposed regulations to protect patients from the threat of inadequately trained providers who offer cosmetic and other surgical services in outpatient settings. The amended motion was seconded and carried 6 in favor and Dr. Miller abstaining.

For any future meetings of the Ad Hoc Committee, the composition should include Dr. Alspaugh, Dr. Frost, an additional member from the family practice specialty and a representative from AAOCFM.

Next meeting – TBA

Adjournment – With no other business to conduct, the Ad Hoc Committee meeting adjourned at 1:45 p.m.

Stuart Mackler, MD, Chair

William L. Harp, M.D.
Executive Director

Colanthia M. Opher
Recording Secretary