

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

Thursday, November 4, 2010

Department of Health Professions

Richmond, VA

CALL TO ORDER: The meeting was called to order by Dr. Stuart Mackler at 10:13 a.m.

ROLL CALL

MEMBERS PRESENT: Stuart Mackler, MD, Chair
Thomas Clifford, MD
Patrick Clougherty, MD
Lewis Ladocsi, MD
Jesus Lizarzaburu, MD-alternate
Mitchell Miller, MD
Nathan Rabhan, MD-voting alternate
Scott Vantre, DPM-voting alternate

MEMBERS ABSENT: Gopinath Jadhav, MD
Julia Konerding Padgett, MD
Arnold Beresh, DPM
Stephen Bendheim, MD
Barklie Zimmerman, MD

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

OTHERS PRESENT: Tyler Cox, HDJN
Ralston King, VOS
Aimee Perron Siebert, Emergency Physicians
Mike Jurgensen, MSV
Matt Benedetti, MB&A/VASPS

EMERGENCY EGRESS INSTRUCTIONS

Dr. Mackler provided the Emergency Egress procedures.

ADOPTION OF THE AGENDA

Dr. Mackler noted there was an expanded version of the agenda and distributed it at the top of the meeting. Dr. Mitchell moved to approve the expanded agenda as presented. The motion was seconded and carried unanimously.

PUBLIC COMMENT ON AGENDA ITEMS

Dr. Mackler recognized the public present and invited them to introduce themselves.

There was no public comment.

REVIEW OF THE ROUNDTABLE LIST OF CONCERNS

Dr. Mackler briefly reviewed the list of concerns that came out of the July 13, 2010 meeting and opened the floor for discussion.

Dr. Ladosci began by stating that 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.

Dr. Harp addressed Dr. Ladosci's concern about the Board's lack of data. He explained that the reporting requirements for practitioners and the malpractice carriers should capture paid claims information. He said the loopholes regarding the reporting of private settlements and corporate settlements had been closed, and all settlements and judgments must be reported regardless of the dollar amount. Only paid claims greater than \$10,000 will count in the tally of three or more claims within the last 10 years that would require a physician to undergo a competency assessment pursuant to Section 54.1-2912.3,

Looking at available data, Dr. Harp reported that the total number of surgery-related National Practitioner Data Bank (NPDB) reports for 2006 was 3,218. Review of NPDB's statistics shows that the number of Virginia's medical malpractice payments has been on the decline as follows:

- 2002 – 221
- 2003 – 203
- 2004 – 188
- 2005 – 167
- 2006 – 163

---DRAFT UNAPPROVED---

Dr. Harp informed the Committee that several years ago the Virginia Department of Health began work with Virginia Health Information (VHI) for the collection of statistics on outpatient procedures. The procedural groups for reporting were identified as follows:

- Colonoscopy
- Laparoscopy and Laparoscopic Surgery (including laparoscopy, laparoscopy/hysteroscopy, laparoscopic cholecystectomy, laparoscopic hernia repair)
- Surgery of the breast (including repair and reconstruction)
- Hernia Repair
- Liposuction
- Facial Surgery (including facelift, blepharoplasty, and laser resurfacing)
- Knee arthroscopy

He said this is an active pilot project and estimates that VHI receives approximately 500,000 reports annually. Complications and adverse outcomes can be reported in this data. He noted that the collection of data is ongoing, but it has yet to be studied.

At the Department of Health Professions (DHP), he reported that over the last five years, the Enforcement Division has received approximately 450 surgically-related complaints for an average of approximately 90 per year. Anecdotally, the vast majority of these complaints were likely related to inpatient surgical procedures.

Dr. Harp added that an internal search on the Board's 9100 Notices and Orders produced approximately 10 hits that appeared to relate to outpatient surgical procedures. The specialties associated with the complaints have been:

- Ob-Gyn
- Dermatology
- Otolaryngology
- Urology
- Ophthalmology
- Family Practice
- General Surgery
- Plastic Surgery
- Psychiatry

The procedures identified in the complaints have included:

- Liposuction
- Face Lift
- Panniculectomy
- Colonoscopy
- Penile Enlargement
- Therapeutic Abortion
- Failure to Order Pathology on a Specimen

---DRAFT UNAPPROVED---

- Aiding and Abetting Unlicensed Practice
- Failure to Maintain Sterile Instruments

Dr. Harp reported to the Committee that there are approximately 27,500 terminations of pregnancy in the Commonwealth annually. Anecdotally, the Board of Medicine may receive one complaint every year or two.

Dr. Harp added that the cost of initial certification by the Joint Commission as an ambulatory surgery center is approximately \$7,000 with a 3-year cycle of renewal cost of approximately \$5,000.

Dr. Clougherty reported to the Committee that, with little effort, he was able to Google several practitioners that offer procedures apparently not within their usual practice and outside their specialty, giving him concern for the safety of the public in such circumstances. The Committee members agreed that the advertising issues involved in such circumstances may go beyond the authority of the Board of Medicine and may need address "at another level."

Dr. Miller commented that the parameters of medical care have changed significantly, with procedures being provided on an outpatient basis more commonly than years ago. He spoke to the peer review that exists in hospitals and indicated that some method of peer review should be considered for doctors performing procedures in their offices. He also suggested that there should be transparency for patients contemplating undergoing a procedure in regards to the procedure itself, best practices, and the qualifications of the physicians offering such procedures.

Dr. Lizarzaburu opined that having the Board of Medicine promulgate regulations for all licensees in response to a limited number of elective procedures is untimely and would be unnecessarily burdensome. He suggested that concerns about a patient's choice of practitioner could be addressed by the use of a consent form. He stated that modifying regulations for 30,000+ licensees to address a narrow problem should be carefully considered.

Ms. Yeatts suggested that the development of a guidance document could provide some parameters and direction regarding office-based surgery procedures and in the process, address a number of the stated concerns. She advised that the document would not carry the weight of the law or regulation and could not be the sole reason to find a violation through the disciplinary process. The Committee did not see this as the preferred option.

The Committee then considered the previous comments from Dr. Clougherty and Dr. Ladocsi, as well as the written comments from Dr. Zimmerman. It also reviewed the North Carolina Medical Board's (NCMB) position statement on office-based procedures and Tennessee's general rules and regulations governing office-based surgery.

---DRAFT UNAPPROVED---

Dr. Clougherty moved to accept Dr. Ladocsi's recommendation of promulgating regulations similar to the NCMB's position statement with a minor language change. The motion was not seconded.

Dr. Rabhan suggested language that the Committee acknowledge that there may be a potential problem in the realm of office-based procedures, and it was suggested that a meeting be held in January to continue to work towards a recommendation for presentation to the Full Board at its February 17, 2011 meeting. Also added was an amendment that any regulations promulgated should include minimum qualifications for the providers of procedures. The motion and amendments were then carried.

Staff will send out an e-mail advising of the next meeting date.

With no other business to conduct, the meeting adjourned at 12:20 p.m.

Stuart Mackler, MD, Chair

William L. Harp, M.D.
Executive Director

Colanthia M. Opher
Recording Secretary