MEDICAL BOARD OF CALIFORNIA
Executive Office

MEMBERS OF THE COMMITTEE
Mary Lynn Moran, M.D., Chair
Janet Salomonson, M.D.
Gerrie Schipske, R.N.P., J.D.
Jack Bruner, M.D.
Beth Grivett, P.A.
Suzanne Kilmer, M.D.
Victor Narurkar, M.D.
James Newman, M.D.
Paul Phinney, M.D.
Harrison Robbins, M.D.

ADVISORY COMMITTEE ON PHYSICIAN RESPONSIBILITY IN THE SUPERVISION OF AFFILIATED HEALTH CARE PROFESSIONALS

Action may be taken on any item listed on the agenda.

April 29, 2010

Sheraton Gateway Los Angeles
Gateway Ballroom
6101 West Century Blvd.
Los Angeles, CA 90045
310-642-1111

AGENDA

2:15 p.m. – 3:30 p.m.
(or until the conclusion of business)

ALL TIMES ARE APPROXIMATE AND SUBJECT TO CHANGE
If a quorum of the Board is present, members of the Board who are not members of the Committee may attend only as observers.

1. Call to Order / Roll Call

2. Public Comment on Items not on the Agenda
Note: The Board may not discuss or take action on any matter raised during this public comment section, except to decide whether to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7(a)]

3. Approval of Minutes from the January 28, 2010 meeting

4. Discussion on SB 1150 (Negrete McLeod) – Ms. Whitney

5. Discussion and Consideration of Work Statement Defining the Goals and Work of the Committee and Timelines– Dr. Moran

The mission of the Medical Board of California is to protect healthcare consumers through the proper licensing and regulation of physicians and surgeons and certain allied healthcare professions and through the vigorous, objective enforcement of the Medical Practice Act, and to promote access to quality medical care through the Board's licensing and regulatory functions.

6. Consideration of Recommendation to Defer Committee Action on Certified Registered Nurse Anesthetists Supervision Issue Until Litigation is Resolved – Ms. Cordray

7. Agenda Items for July 29-30, 2010 Meeting in Sacramento, CA

8. Adjournment

Meetings of the Medical Board of California are open to the public except when specifically noticed otherwise in accordance with the Open Meetings Act. The audience will be given appropriate opportunities to comment on any issue presented in open session before the Board, but the President may apportion available time among those who wish to speak.

****

For additional information call (916) 263-2389.

NOTICE: The meeting is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Cheryl Thompson at (916) 263-2389 or CThompson@dca.ca.gov or send a written request to Ms. Thompson. Providing your request at least five (5) business days before the meeting will help ensure availability of the requested accommodation.

STATE AND CONSUMER SERVICES AGENCY - *Department of Consumer Affairs* Arnold Schwarzenegger, *Governor*

MEDICAL BOARD OF CALIFORNIA
Executive Office

Advisory Committee on Physician Responsibility in the Supervision of Affiliated Health Care Professionals

Embassy Suites, San Francisco Airport
150 Anza Boulevard
Burlingame, CA

January 28, 2010

MINUTES

Members of the Committee:
Mary Lynn Moran, M.D.
Janet Salomonson, M.D.
Gerrie Schipske, R.N.P., J.D.(absent)

Staff of Committee:
Janie Cordray

Audience:
Barb Johnston, Executive Director
Linda Whitney, Chief of Licensing
Renee Threadgill, Chief of Enforcement
Kevin Schunke, Manager, Licensing
Jack Bruner, M.D., California Society of Plastic Surgeons
Yvonne Choong, California Medical Association
Beth Grivett, P.A. California Academy of Physician Assistants
Tim Madden, Randlett and Associates

Those in attendance by telephone:
Harrison Robbins, M.D., California Academy of Cosmetic Surgeons
Robert Shumway, M.D. California Academy of Cosmetic Surgeons
John Valencia, Wilke, Fleury, Hoffelt, Gould & Birney, LLP

Agenda Items 1 & 2: Call to order & Introductions of Advisory Committee Members and Guests – Dr. Moran

Dr. Moran called the meeting to order at approximately 3:00 p.m. Dr. Janet Salomonson was present, but Ms. Schipske was unable to attend due to an emergency.

Dr. Moran introduced Dr. Jack Bruner, representing the California Society of Plastic Surgeons, and Beth Grivet, Physician Assistant, representing the California Academy of Physician Assistants.

DRAFT

Dr. Moran then asked for those in attendance by telephone to identify themselves. Those who responded were: Mr. John Valencia, of Wilke, Fleury, Hoffelt, Gold & Birney, Drs. Robert Shumway and Harrison Robins, representing the California Academy of Cosmetic Surgeons.

Agenda Item 3: Overview of the Mission and Goals of the Advisory Committee – Dr. Moran and Ms. Whitney

Dr. Moran explained that the advisory committee was established to examine physician supervision and availability for affiliated healing arts staff pursuant to a request made by Senator Negrete McLeod. The Committee will first study the current environment, including current, real world practice, as well as current laws and regulations, and look for solutions for any deficiencies in patient protection.

In developing the mission of this advisory committee, Dr. Moran asked that the committee members provide ideas and suggestions. She asked that they send any questions, suggestions or materials to Janie Cordray, who will be staffing the committee meetings, by February 15. She explained that due to limited time, there would be little substantial discussion on any subject at the meeting. The Committee would formally articulate and adopt its mission and goals at the next meeting.

Agenda Item 4: Nominees for Membership – Dr. Moran

Ms. Whitney handed out a revised listing of the nominees to participate on the advisory committee with the board members. Dr. Moran explained that they had tried to be inclusive and include those physicians and organizations who have shown an interest in past Board activities in this subject.

Dr. Moran asked for nominees not on the listing provided. Dr. Shumway asked if Dr. Harrison Robins could be included in the committee membership, who would represent the California Academy of Cosmetic Surgeons. Dr. Moran agreed.

Dr. Moran asked for a motion to accept the following list to recommend those individuals to the full board for appointment to the advisory committee. Once appointed by the full board, staff will coordinate with each of the nominees regarding travel reimbursements and the state requirements. There was a motion made and it passed.

Dr. Moran announced that the following would be proposed to the Board to serve on the Advisory Committee:

Jack Bruner, representing California Society of Plastic Surgeons
Beth Grivett, P.A. California Academy of Physician Assistants
Suzanne Kilmer, M.D., American Society for Dermatologic Surgery
Victor Narukar, M.D. California Society of Dermatology & Dermatologic Surgery
James Newman, M.D., California Society of Facial Plastic Surgery
Paul Phinney, M.D., California Medical Association
Harrison Robbins, M.D., California Academy of Cosmetic Surgeons

Agenda Item 5: Legislative History: Ms. Cordray

Ms. Cordray explained that most of the people in attendance or on the phone had been working with the Board on issues of cosmetic medical practices since the mid 1990s when the Board entered the arena of regulating outpatient surgery. Since then, the Board has been working on many issues, the most recent, issues surrounding laser and IPL use.

In 2007, in order to comply with SB 1423 (Figueroa), the Board held three public forums with the Board of Registered Nursing on the safety of lasers and IPLs in cosmetic settings. What was learned at the forums would likely serve as the foundation for the work of the advisory committee.

Ms. Cordray directed the members' attention to the written materials that summarized the previous work of the Board. Due to time limits, she did not provide a thorough history of the Board's work. In summary, however, the Board concluded at the end of the public forums that the problems, including those of supervision, were not a result of a lack of laws and regulations, but a lack of enforcement.

In 2008 and 2009, a number of bills were introduced relating to cosmetic surgery and medical spas. Most were not successful.

- AB 2398 (Nakanishi; 2008): The bill was sponsored by the American Society for Dermatological Surgery, and sought to improve patient safety by making it tougher for corporate entities to practice medicine illegally in California. (This practice is illegal under current law, but it is often difficult to prove that physicians "knowingly" broke the law.) It would have authorized the revocation of the license of a physician who practices medicine with a business organization that offers to provide, or provides, outpatient elective cosmetic procedures, knowing that it is owned or operated in violation of the prohibition against the corporate practice of medicine. This bill failed to reach the floor.

- AB 252 (Carter; 2009): Initially, the bill was essentially a reintroduction of the 2008 Nakanishi bill (AB 2398). Again, this bill was sponsored by the American Society for Dermatological Surgery, and addressed violations of the corporate practice of medicine in the cosmetic medicine industry. It specified that non-physician entities owning cosmetic medicine practices providing medical treatments (laser hair removal, laser resurfacing, Botox and filler injections) were in violation of the corporate practice prohibition of B&P Code Section 2400. The bill would have made a violation of the corporate practice bar a felony for the artificial (non-medically owned) entities, and grounds for license revocation for physicians who knowingly worked or contracted with these entities. While the bill was successful in the Legislature, it was vetoed by the Governor.

- SB 674 (Negrete McLeod; 2009): Covered a variety of subjects, including advertising, outpatient setting accreditation, the wearing of name tags, and public information. The most relevant to the Committee's discussions was the portion of the bill that addressed the supervision of laser and IPL device procedures. Specifically, it would have required the Board to adopt regulations regarding the appropriate level of physician availability for facilities using lasers or IPLs. While the bill was identified as an "author sponsored" bill, it was supported by the American Society of Dermatologic Surgery, the California Society of Dermatology and Dermatologic Surgery, the California Medical Association, and the California Society of Plastic Surgeons. Again, this bill was successful in the Legislature, but was vetoed by the Governor.

Ms. Cordray explained that while SB 674 (Negrete McLeod) was vetoed, under its current authority, the Board may examine the issues surrounding physician supervision and physicians' availability to those supervised. The Medical Board has regulatory authority over physicians, while the Nursing Board has regulatory authority over nurses. For that reason, the Committee will need to focus on physician responsibility.

Following the vetoing of SB 674, its author, Senator Negrete McLeod wrote to the Board. She asked that the Board consider conducting a review of the issues surrounding physician supervision and availability. She noted that no legislation was needed for the Board to conduct such a review. The establishment of the Advisory Committee is partially a response to the Senator's request.

Ms. Cordray explained that the Board may not legislate, but it has considerable authority to promulgate regulations. It further has the authority to enforce the law through actions against its licensees.

Agenda Item 6: Discussion of the work to be accomplished, as well as expectations and time lines of outcomes or products of the Committee's work – Dr. Moran

Dr. Moran said that the Committee will focus on the issue of physician availability per the Senator's request, but will work hard to not lose sight of the broader issues related to physician availability in other settings and the issue of supervision that may not have been addressed by current law, regulations, or enforcement.

Dr. Moran continued to explain that the expectations of the Committee would be to focus on patient protection through physician responsibility. While the Medical Board has jurisdiction over its physicians, the Nursing Board is the entity that has authority over nursing. For that reason, the Committee will focus on physician responsibility, and the law's expectations that relate to the responsibilities of doctors to provide quality care.

She said that it was the hope that the Committee would gather sufficient information to enable a consensus in order to make recommendations to the full Board. The recommendations may be to promulgate regulations, establish greater enforcement of the laws and regulations, or seek legislation to create safeguards by closing existing loopholes, or a combination of all three.

Dr. Moran explained that the Committee will take the time needed to do the work, but practically speaking, if legislation is sought, the committee must conclude its work in this calendar year so that it may be introduced in 2011. Similarly, if regulations are to be promulgated, the Committee's work should be concluded by the end of the year so that the rulemaking process could begin in 2011.

Agenda Item 7: 2010 meeting dates – Dr. Moran

Dr. Moran explained that the next meeting dates should be chosen, and a calendar was in the members' informational packet.

Dr. Moran explained that if meeting as a committee for only an hour, meetings may be scheduled to coincide with regularly scheduled board meetings. If it is determined that more time is needed for discussion and input from the public, such as a meeting of 3-4 hours, then the meeting should be

scheduled for another time. They could also consider meeting on a Wednesday afternoon prior to a regularly scheduled board meeting.

The next board meetings are:

- 4/29-30 in Los Angeles
- 7/29-30 in Sacramento (but that meeting is held in a consumer protection seminar week, thus Tuesday and Wednesday afternoon are already booked.)
- November 3-4 in Long Beach (which is a Wednesday/Thursday. If furloughs are discontinued the Committee could meet on Friday or Tuesday.)

Dr. Moran asked every member in attendance and on the telephone to check their calendars, and directed staff to e-mail everyone in the next week to determine the next meeting date.

Agenda Item 8: Public Comment on items not on the agenda
There were no comments from the public.

Agenda Item 9: Adjournment
Dr. Moran adjourned the meeting at approximately 3:30 p.m.

DRAFT

Medical Board of California Advisory Committee on Physician Responsibility in the Supervision of Affiliated Health Care Professionals

DATE: April 12, 2010
SUBJECT: SB 1150 (Negrete McLeod)
STAFF: Linda Whitney

As discussed at the January 28, 2010 meeting, the Advisory Committee was established, in part, as a result of a request by Senator Negrete McLeod. Since then, the Senator has introduced legislation that, if passed, would mandate the work now being done by the Committee and Medical Board.

The bill covers a number of subjects. The element of the legislation most relevant to the committee is attached.

SENATE BILL No. 1150

Introduced by Senator Negrete McLeod

February 18, 2010

An act to amend Sections 651 and 2023.5 of, and to add Section 2027.5 to, the Business and Professions Code, and to amend Sections 1248, 1248.15, 1248.2, 1248.25, 1248.35, 1248.5, 1248.55, and 1279 of the Health and Safety Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 1150, as introduced, Negrete McLeod. Healing arts.

(1) Existing law provides for the licensure and regulation of various healing arts practitioners and requires certain of those practitioners to use particular designations following their names in specified instances. Existing law provides that it is unlawful for healing arts licensees to disseminate or cause to be disseminated any form of public communication, as defined, containing a false, fraudulent, misleading, or deceptive statement, claim, or image to induce the rendering of services or the furnishing of products relating to a professional practice or business for which he or she is licensed. Existing law authorizes advertising by these healing arts licensees to include certain general information. A violation of these provisions is a misdemeanor.

This bill would require certain healing arts licensees to include in advertisements, as defined, certain words or designations following their names indicating the particular educational degree they hold or healing art they practice, as specified. By changing the definition of a crime, this bill would impose a state-mandated local program.

(2) Existing law requires the Medical Board of California, in conjunction with the Board of Registered Nursing, and in consultation with the Physician Assistant Committee and professionals in the field, to review issues and problems relating to the use of laser or intense light

pulse devices for elective cosmetic procedures by their respective licensees.

This bill would require the board to adopt regulations by January 1, 2012, regarding the appropriate level of physician availability needed within clinics or other settings using certain laser or intense pulse light devices for elective cosmetic procedures.

see pages 13-14

(3) Existing law requires the Medical Board of California to post on the Internet specified information regarding licensed physicians and surgeons.

This bill would require the board to post on its Internet Web site an easy-to-understand factsheet to educate the public about cosmetic surgery and procedures, as specified.

(4) Existing law requires the Medical Board of California, as successor to the Division of Licensing of the Medical Board of California, to adopt standards for accreditation of outpatient settings, as defined, and, in approving accreditation agencies to perform this accreditation, to ensure that the certification program shall, at a minimum, include standards for specified aspects of the settings' operations. Existing law makes a willful violation of these and other provisions relating to outpatient settings a crime.

This bill would include, among those specified aspects, the submission for approval by an accreditation agency at the time of accreditation, a detailed plan, standardized procedures, and protocols to be followed in the event of serious complications or side effects from surgery. The bill would also modify the definition of "outpatient setting" to include facilities that offer in vitro fertilization, as defined. By changing the definition of a crime, this bill would impose a state-mandated local program.

Existing law also requires the Medical Board of California to obtain and maintain a list of all accredited, certified, and licensed outpatient settings, and to notify the public, upon inquiry, whether a setting is accredited, certified, or licensed, or whether the setting's accreditation, certification, or license has been revoked.

This bill would require the board, absent inquiry, to notify the public whether a setting is accredited, certified, or licensed, or the setting's accreditation, certification, or license has been revoked, suspended, or placed on probation, or the setting has received a reprimand by the accreditation agency.

Existing law requires accreditation of an outpatient setting to be denied if the setting does not meet specified standards. Existing law authorizes

by regulation, unreasonably prevent truthful, nondeceptive price or otherwise lawful forms of advertising of services or commodities, by either outright prohibition or imposition of onerous disclosure requirements. However, any member of a board or committee acting in good faith in the adoption or enforcement of any regulation shall be deemed to be acting as an agent of the state.

~~(j)~~

(k) The Attorney General shall commence legal proceedings in the appropriate forum to enjoin advertisements disseminated or about to be disseminated in violation of this section and seek other appropriate relief to enforce this section. Notwithstanding any other provision of law, the costs of enforcing this section to the respective licensing boards or committees may be awarded against any licensee found to be in violation of any provision of this section. This shall not diminish the power of district attorneys, county counsels, or city attorneys pursuant to existing law to seek appropriate relief.

~~(k)~~

(l) A physician and surgeon or doctor of podiatric medicine licensed pursuant to Chapter 5 (commencing with Section 2000) by the Medical Board of California who knowingly and intentionally violates this section may be cited and assessed an administrative fine not to exceed ten thousand dollars ($10,000) per event. Section 125.9 shall govern the issuance of this citation and fine except that the fine limitations prescribed in paragraph (3) of subdivision (b) of Section 125.9 shall not apply to a fine under this subdivision.

SEC. 2. Section 2023.5 of the Business and Professions Code is amended to read:

2023.5. (a) The board, in conjunction with the Board of Registered Nursing, and in consultation with the Physician Assistant Committee and professionals in the field, shall review issues and problems surrounding the use of laser or intense light pulse devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants. The review shall include, but need not be limited to, all of the following:

(1) The appropriate level of physician supervision needed.

(2) The appropriate level of training to ensure competency.

(3) Guidelines for standardized procedures and protocols that address, at a minimum, all of the following:

(A) Patient selection.

(B) Patient education, instruction, and informed consent.

(C) Use of topical agents.

(D) Procedures to be followed in the event of complications or side effects from the treatment.

(E) Procedures governing emergency and urgent care situations.

(b) On or before January 1, 2009, the board and the Board of Registered Nursing shall promulgate regulations to implement changes determined to be necessary with regard to the use of laser or intense pulse light devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants.

(c) On or before January 1, 2012, the board shall adopt regulations regarding the appropriate level of physician availability needed within clinics or other settings using laser or intense pulse light devices for elective cosmetic procedures. However, these regulations shall not apply to laser or intense pulse light devices approved by the federal Food and Drug Administration for over-the-counter use by a health care practitioner or by an unlicensed person on himself or herself.

(d) Nothing in this section shall be construed to modify the prohibition against the unlicensed practice of medicine.

new

SEC. 3. Section 2027.5 is added to the Business and Professions Code, to read:

2027.5. The board shall post on its Internet Web site an easy-to-understand factsheet to educate the public about cosmetic surgery and procedures, including their risks. Included with the factsheet shall be a comprehensive list of questions for patients to ask their physician and surgeon regarding cosmetic surgery.

SEC. 4. Section 1248 of the Health and Safety Code is amended to read:

1248. For purposes of this chapter, the following definitions shall apply:

(a) "Division" means the *Medical Board of California. All references in this chapter to the division, the* Division of Licensing of the Medical Board of California*, or the Division of Medical Quality shall be deemed to refer to the Medical Board of California pursuant to Section 2002 of the Business and Professions Code.*

Medical Board of California Advisory Committee on Physician Responsibility in the Supervision of Affiliated Health Care Professionals

DATE: April 12, 2010
SUBJECT: Work statement defining goals and work of Committee, and timeline
STAFF: Janie Cordray

The following draft work statement is provided to the members for discussion. Staff would ask members to consider the goals of the Committee, and adopt a statement to articulate the work to be performed. In addition, it would be helpful to establish a timeline for the work to be accomplished, as well as possible meeting dates.

DRAFT WORK STATEMENT:

The Advisory Committee was established to study the responsibility of physicians in the supervision of allied health professionals delegated to perform procedures. The committee will seek to address:

- Delegation of procedures: under what circumstances is it appropriate to delegate their performance?
- Assessment of skill before delegation: what is the physician's responsibility to assess the skill level of the allied health professional prior to the procedure's performance?
- Availability and accessibility of physicians supervising (location, electronic communication, telemedicine, etc.).
- Delegation of decision-making authority: is it appropriate to delegate to non-physician practitioners the selection of patients and procedures, and, if so, under what circumstances?
- Evaluation of performance through non-direct supervision: what is necessary for the evaluation of practitioners' performance, ability, skill, judgment, etc.?
- Physician's responsibility in emergencies: what should be required for emergency plans and protocols?
- Informed consent: what should be required for delegated procedures, and, is it appropriate for allied health professionals to provide informed consent to patients?
- Advertising: what is required by law, and what common practices may be misleading?

The Committee will study the above issues to ascertain what actions should be taken to ensure responsible supervision. The goal of the Committee is to determine what regulatory, legislative, or enforcement actions need to be taken to ensure patient safety.

The above will be discussed at the April 29th meeting of the Committee. In the meantime, if you have any questions or suggestions, feel free to contact me at 916-263-2389, or by e-mail at janie.cordray@mbc.ca.gov.

Example: Priorities/Goals/Work & Timelines:

Priority	Subject/Goal	Work:	Personnel/Participants	Meeting Activities & Dates:
1	Availability of physician supervisor to ensure patient safety	Identify what must be required to ensure patient safety, including location of supervisor, the use of telemedicine or electronic communication. Determine if what is required for patient safety should be addressed in: 1) regulations; 2) legislation; 3) enforcement, or; 4) educational activities.	Janie Cordray, staff DCA Legal Counsels representing Medical Board and Nursing Boards. Representative of appropriate specialty societies and professional associations.	July 28, 2010 (4 hours): First meeting of Committee on this subject. Committee presented with current laws and regulations and presentations are made by relevant stakeholders and participants. Discussion and identification of minimum standards. November 3, 2010 (1hour): Staff presents options and recommendations on what is needed to address the minimum standards identified and Committee deliberates. After deliberations, if a consensus is reached, Committee adopts a recommendation that will be presented to the full Board. November 4, 2010: Committee's recommendation is presented to the full Board.
2	The physician's assessment of allied staff's skill to perform delegated tasks to ensure sufficient ability for safe performance.	Identify what must be required of physicians to evaluate staff's skill and ability to perform delegated procedures. Determine the minimum requirements for evaluation before delegation. Determine if what is required for patient safety should be addressed in: 1) regulations; 2) legislation; 3) enforcement, or; 4) educational activities.	Candis Cohen, staff DCA Legal Counsel and DAG Representatives of malpractice carriers Representatives of appropriate specialty societies and professional associations.	November 3, 2010 (1 hour): Committee is presented with current laws, regulations, and enforcement activities, and hears comments or presentations by relevant stakeholders and participants. Discussion and identification of minimum standards. February 15, 2011 (2 hours): Staff presents options and recommendations on what is needed to address the minimum standards identified and Committee deliberates. After deliberations, if a consensus is reached, Committee adopts a recommendation that will be presented to the full Board. February 28, 2011: Committee's recommendation is presented to the full Board.
3				
4				
5				