

## MEDICAL BOARD OF CALIFORNIA Executive Office



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

Medical Board of California Hearing Room 2005 Evergreen Street Sacramento, CA 95815

June 23, 2010

### **MINUTES**

#### **Members of the Committee Present:**

Mary Lynn Moran, M.D., Chair Jack Bruner, M.D. Beth Grivett, P.A. Paul Phinney, M.D. Harrison Robbins, M.D.

#### Members of the Committee Absent:

Janet Salomonson, M.D. Gerrie Schipske, R.N.P., J.D. Suzanne Kilmer, M.D. James Newman, M.D.

## Audience:

Lydia Bauruer
Yvonne Choong, California Medical Association
Candis Cohen, MBC Information Officer
Janie Cordray, MBC Research Director, Staff to the Committee
Frank Cuny, California Citizens for Health Freedom
Norman Davis, Attorney
Bryce Docherty, The Docherty Group
Jennifer Hatfield, Capitol Health Services
Kurt Heppler, DCA Legal Counsel to the Committee
James Kojian, M.D.
Christina Lee, California Medical Association
Ross Locke, MBC Business Services Office
Tim Madden, California Society of Plastic Surgeons
Kathleen McCallum
Rosielyn Pulmano, Senate Business, Professions & Economic Development

Veronica Ramirez, California Medical Association
Amara Sheikh, Farzana Sheikh, M.D.
Rehan Sheikh, Farzana Sheikh, M.D.
Lilly Spitz, Planned Parenthood
Jonathan Sykes, M.D., President-Elect, American Academy of Facial Plastic and Reconstructive Surgery
John P. Toth, M.D., California Citizens for Health Freedom
John Valencia, Wilke, Fleury et al.
Chris Valine, MBC Public Information Analyst
Kay Weinkam, Board of Registered Nursing
Linda Whitney, MBC Executive Director

## Agenda Item 1 Call to order

Dr. Moran called the meeting to order at 11:05 a.m.

## Agenda Item 2 Roll call

Members present and absent are reflected above.

## Agenda Item 4 Approval of minutes of April 29, 2010 meeting

It was moved (Bruner) and seconded (Phinney) that the minutes of the committee's April 29, 2010 meeting be approved; the motion was adopted unanimously.

### Agenda Item 3 Public comment on items not on the agenda

Frank Cuny, executive director, California Citizens for Health Freedom, asked if a patient is seeing a doctor as well as an alternative practitioner, and the patient wants advice from the physician, can the physician comment? He asked for a mechanism for a cooperative relationship so that the physician is not considered to be supervising the alternative practitioner, but the physician may communicate about the patient's care. He suggested the committee might want to consider this issue in the future.

Louise Timmer, immediate past president, American Nursing Association of California, brought complaint information to the committee's attention, and Ms. Cordray said the Board would open a complaint on the matter.

## Agenda Item 5 Presentation regarding current laws and regulations relating to supervision and delegation of procedures to non-physicians

Ms. Cordray announced that she is retiring as of this date, and that Candis Cohen would be staffing the committee. Questions and comments regarding future meetings should be directed to her.

She noted that the Board began its work in this area in 1997 with its Committee on Plastic and Cosmetic Surgery, following cases involving deaths after liposuction. The Board published a formal opinion regarding the use of lasers that raised the ire of laser companies and some physicians, who thought anyone should be able to use them. The laws and

regulations are the same as in 1998. She also mentioned the forums in 2007 and 2008 with the Medical Board and the Board of Registered Nursing that confirmed that almost all of the concerns people had about safety already are covered by laws and regulations that need to be enforced. The forums confirmed violations of corporate practice laws, payments for referrals and fee-splitting, advertising-statute violations, and in some cases, a total absence of physician supervision. She concluded that many of these problems are already illegal and that we do not need new legislation nor regulation, just enforcement.

Dr. Moran thanked Ms. Cordray for all of her work. She then brought to the attention of the committee Business and Professions Code sections 2242(a) and 4022, dealing with prescribing without an appropriate prior exam and medical indication, and noted that current law allows for delegation of prescriptive authority to physician assistants and nurse practitioners, and not RNs. She cited these as among many of the laws that make some of the current practices outside the standard of care.

Ms. Cordray noted for the record that the reason nurses were not specifically invited to speak at this meeting is that the committee's purpose is to look at physician responsibility and the Medical Board has no jurisdiction over nurses. Physician assistants are involved in today's meeting because the Physician Assistant Committee is under the jurisdiction of the Medical Board.

Dr. Bruner asked if any new laws are necessary, and Ms. Cordray replied that aggressive advertising and marketing have been a constant problem, e.g. use of terms "satisfaction guaranteed" or "as low as." She suggested sanctions for advertising violations might be put on the committee's agenda at some point. Also fee-splitting in her experience is a problem. She suggested greater enforcement in these areas.

Dr. Moran called for public comment.

James Kojian, M.D. said that he has been very active in this area for many years, and trains nurses in California. He brought a complaint to the committee's attention; Ms. Cordray agreed to discuss it with him. Regarding med spas and physician supervision, he said the most important point is injector competence, regardless of who the practitioner is. He has seen incompetence in nurses in this area due to a lack of "up-front injector training." Also there are no laws as to who can certify whom. He proposed physicians be the only persons allowed to train nurses on the use of injectors, and over an eight-hour period, and proposed a required, written certification "Botox exam."

Norman Davis, health care attorney, spoke about seven points he thought should be considered by the committee. They dealt with why the issues of delegation and scope of practice are being considered solely regarding the cosmetic and aesthetic field of medicine; what real collaborative efforts besides the forums have been taken between the Medical Board and the Board of Registered Nursing per Business and Professions Code section 2023; if additional regulations are necessary, should they not be applicable in all practice settings if new standards are adopted, are all physicians willing and able to comply, and what agencies will regulate this; what about corporate practice issues; is this discussion really a turf war among professionals wanting to reduce competition among those performing minor aesthetic procedures outside the office setting; and over the past several years, the Medical Board's enforcement program has tended to mix and match issues such as scope of practice, unlicensed activity, aiding and abetting the unlicensed practice of medicine, violation of the corporate practice of medicine and the risk of patient harm.

Missey McCallum, Northern California Aesthetic Nurses Association, agreed that training guidelines would be desirable because nurses in the aesthetic field want it. She said she feared "incrementalism," nurses being able

to perform certain functions but not others without a physician being present, and believes new guidelines in the aesthetic area are not necessary. If there are limits on what nurses can do without physicians being present, especially in this time of physician shortages, it would unduly limit nurses' established scope of practice. Advertising is a concern and should be regulated.

## Agenda Item 6 Update on the status of SB 1150 (Negrete McLeod), and other issues of importance to the Senate Business and Professions Committee

Jennifer Simoes, Medical Board chief of legislation, noted that this advisory committee had been established at the request of Senator Negrete McLeod. SB 1150, introduced this year by Senator McLeod, would impose various requirements related to health care practitioner advertising, cosmetic surgery, outpatient settings and accreditation, and the Medical Board has a support position. She introduced Rosielyn Pulmano of the Senate Business and Professions Committee.

Ms. Pulmano noted that SB 1150 has a provision that requires the Medical Board, on or before January 1, 2012 to adopt regulations regarding the appropriate level of physician availability needed in settings using lasers or intense pulse light devices. This part of the bill was introduced to address roving physicians or physicians who enter into contracts with med spas to serve as a medical director in name only and are never available, even in emergencies. Senator McLeod believes physicians who sign up with med spas or have ownership interests should be available for consultation and should have oversight responsibilities and direct patient contact. Senator McLeod also would like the committee to look at the issue of physicians assuring that allied health professionals are trained and competent to promote patient safety.

Dr. Moran noted per Business and Professions section 2264, a physician may not order a treatment or drugs without an appropriate prior medical exam, unless specifically delegated and defined in the protocol with a nurse practitioner and a physician's assistant. A physician must do an appropriate exam.

#### Agenda Item 7

Presentations by organizations regarding under what circumstances is it appropriate to delegate the performance of procedures; and is it legal or appropriate to delegate to non-physicians the selection of patients and procedures and, if so, under what circumstance?

Abel Torres, M.D., American Society of Dermatologic Surgery, addressed the issue of under what circumstances it is appropriate to delegate cosmetic procedures. He said that the criteria should be that the delegating physician is properly trained in all of the procedures that he/she delegates. That delegating decision should be qualified by residency training, and/or preceptorship, and/or appropriate course work. The physician should have an extensive understanding of continuous medicine and surgery and the anatomy involved, the indications for the procedures, and the pre-and post-operative care involved in the treatment. Delegation should be done to certified or licensed allied health professionals where the physician is physically present on site, immediately available, and able to respond promptly to any questions or problems while the procedure is being performed. The physician also should perform a good faith exam prior to the procedure, and a medical record should be kept. The allied health professional to whom the procedure is delegated should possess a knowledge of continuous medicine, document the training in the procedure, the indications for the procedure, and the preand post-operative care. Additionally, the Medical Practice Act authorizes physicians to diagnose mental and physical conditions and to use drugs on human beings, to sever or penetrate tissue, to choose the treatment to be done, to use other methods of treatment. The treating of cosmetic conditions is medical care. Only after a physician makes these diagnoses and an order or delegation of services agreement may physicians assistants,

medical assistants, or nurses proceed. Aftercare is important too, as patients' conditions change. Should it be legal or appropriate to delegate to non-physicians the selection of patients and procedures? No, there have been too many adverse outcomes in such instances.

Jonathan Sykes, M.D., California Society of Facial Plastic Surgery, American Academy of Facial Plastic Surgery, said everyone in the room wants honesty to the public, qualified, trained practitioners doing the work so patient safety is optimized, and "we want to obey the laws." Or, "if the laws are bad, we want them changed." Since the practice of medicine by physicians is regulated by the Medical Board and what nurses may do is regulated by the Board of Registered Nursing, those two boards should get together and talk about who should do what and how they should do it. He spoke about what is "direct supervision," mentioning an issue of the Medical Board's newsletter dated August 2007 that said it could not be a designated doctor who signed the charts once a month but didn't have true supervision. He and his societies agree, but the Medical Board and the Board of Registered Nursing may interpret this differently. "Training" is not defined. He also sees no correlation between marketing and quality of care. Some people over-market, and the Medical Board should have mechanisms in place to handle that. He views funding for enforcement as a major issue, and thinks a plan should be made for better enforcement.

Tim Madden, California Society of Plastic Surgeons, said delegation of performance of procedures is relatively clear, as described by Dr. Torres. As to what procedures can be delegated and when that is appropriate, that comes down to the level of training and education of the person delegated to. The training and education of physicians themselves is important. Many physicians doing the delegating are not trained and do not understand the procedures they are delegating to mid-level practitioners. Often the mid-level practitioners do not have the training, either, although the ultimate responsibility is with the physician. As to the delegation to non-physicians the selection of patients and procedures, it is the responsibility of the physician to meet with the patients, do an examination, and determine what procedures should be done.

Dr. Moran said the state of California issues a general license, and physicians legally may practice any form of medicine, but as far as delegating, especially with physician assistants and nurse practitioners, the delegation should be in the field that the physician normally practices. The question becomes should there be some legislation about delegation of procedures and what the requirements of the delegating physician should be?

Ms. Cordray said this would always be a moving target, but when taken out of the cosmetic arena and put in some other specialty, she noted that procedures and devices change, and that practices in some specialties vary by location in the state. To be a competent supervisor, one must be competent in the area of medicine that one is delegating procedures. Department of Consumer Affairs' Legal Counsel Kurt Heppler asked that this discussion be held until all the presentations had been heard. Ms. Cordray asked if the Board would have the regulatory authority to promulgate a regulation to define what was needed as far as specialty as in a physician assistant regulation. Mr. Heppler said he would have to research that question. Ms. Cordray suggested at the committee's next meeting Legislative Counsel be asked to opine of the Board's regulatory authority; to tell the committee what it may already do and what would require legislation.

Dr. Phinney had a question for Mr. Madden: Given that new procedures continually develop and new practitioners may or may not be trained in the new procedures, he deduced from Mr. Madden's remarks that what a mid-level practitioner would be authorized to do would depend on the training of the individual at that time and may change over time in different situations. Mr. Madden said yes, so as medicine advances physicians are expected to keep up with it. Dr. Phinney asked further if what a mid-level practitioner does changes, e.g., if his/her supervising physician were on vacation and the substituting physician were not trained

in the same area, and Mr. Madden agreed, the substituting physician could not delegate and could not be the supervising physician.

Dr. Sykes noted that one reason aesthetic medicine has such problems is that it is done largely outside of hospitals and other credentialing facilities. He is personally aware of many physicians who are supervising in this area and just lending their licenses, with no expertise in aesthetic medicine.

Beth Grivett, physician assistant who handles legislative affairs for the California Academy of Physician Assistants and is a member of the committee, said that by law PAs must have a delegation of services agreement to practice in California, and "physician availability" is defined in that agreement for that practice, but does require physician availability at all times, including on request of the patient or the PA. An emergency backup plan is required, and the agreement defines procedures and protocols specific to the practice. Any physician in California can supervise a PA as long as he/she is in good standing with the Medical Board. PAs are an agent of the supervising physician, and PA orders are treated by regulation as if they were given by the physician. Supervising physicians may supervise up to four PAs at a time in the state. PAs only may perform duties customary to that office, and those the physician deems the PA competent to perform. The physician must be available on site or by telecommunication. There is a minimum of 5 percent chart co-signature and review. Chart co-signature must occur within seven days if a Schedule 2 drug is ordered. PAs' most common training is in a PA program, with respect to a procedure in which the PA is untrained, if a physician is physically present and supervising that procedure until the PA is competent, California law considers that adequate training. Physicians cannot delegate to PAs the supervision of medical assistants. The only exception is legislatively designated clinics. PAs can perform good faith examinations, develop a differential diagnosis and treatment plan, and delegate procedures to other allied health care professionals, including nurses. PAs also are trained in the selection of patients for specific procedures. PAs may obtain informed consent, but may not perform procedures if a patient is under general anesthesia.

Harrison Robbins, M.D., committee member and representing the California Academy of Cosmetic Surgeons, said everything he had wanted to say was said well by Drs. Torres and Sykes, and he agreed with them. He disagreed, however, with Ms. Cordray to the extent that the committee could compare and make decisions with all of medicine. Patients make decisions, hopefully after informed consent by physicians. To determine the answers to questions posed at this meeting, physicians and nurses must communicate and work together. He said aesthetic medicine may not legally be practiced in med spas.

Dr. Kojian said the terms "delegation" and "supervision" had been used numerous times, but he reiterated that the key issue is injector competence. The State of California should define that and keep it at a very high standard for all injectors.

Dr. Moran noted during this meeting, there had been a few specific mentions of violations of the Medical Practice Act, indicated that a Medical Board investigator was present in the room with complaint forms, and encouraged those who had such information to provide it to the Board.

### Agenda Item 8 Discussion of the presentations and consideration of the Committee's next steps

Dr. Moran thanked everyone for their input, noting it was extremely valuable and helpful. Supervision is a hotbutton issue, underlying that is the lack of enforcement of existing laws. If existing laws were better enforced, that would eliminate a lot of the problems in this area. She asked for a discussion of ways to enhance enforcement, noting that would take a meeting of its own. She asked staff to look into definitions of supervision

of non-physicians by physicians that exist in other states, although she did not want to take up that issue at the committee's next meeting. She wanted to start with enforcement of current laws with an introduction of possible supervision ideas, if there is time at the next meeting. At the meeting after the next one the committee will tackle the very sticky issue of supervision.

Tricia Hunter, American Nurses Association, California, said under standardized procedures there are nine steps required for collaboration among a physician, a nurse, and the health facility they work in that define education, emergency procedure, recertification – all are clearly defined. She said she believed we have sufficient laws that just are not being enforced. The law is clear on when nurses take an order that they cannot take broad orders; orders must be very patient-specific. The Board of Registered Nursing is also clear on this and supportive about how delegation works and she saw no conflict in how that board interprets most of the laws that this committee has discussed. She encouraged collaboration.

Dr. Moran asked about Business and Professions Code section 2725, the Nursing Practice Act, and said the committee would review that for the next meeting, and Ms. Hunter noted it has very clear guidelines and both agreed that being aware of the relevant nursing laws would be helpful.

John Valencia, Wilke, Fleury et al. for the American Society for Dermatologic Surgery, agreed with Ms. Hunter that this is a question of enforcement of clear guidelines for nurses and physicians. He recommended that the committee invite the California District Attorneys Association and the Municipal City Attorneys Association that represents city attorneys because all have consumer protection divisions and would be good partners in educating the committee regarding their case-assessment process. Other law enforcement officers like Jan Scully, Sacramento County district attorney, have experience in enforcing this body of law.

Mr. Heppler asked Dr. Moran to confirm that she is directing that a subsequent meeting include having a presentation of the Board's enforcement on this issue; that staff do a review of availability and supervision in other states; and that the city law enforcement agencies described above be invited to make a presentation as they see fit. Ms. Cordray suggested that Dr. Moran meet with Ms. Cohen and work on a calendar of such future plans. Dr. Moran agreed. Mr. Heppler offered to research and recommend to the committee at its next meeting what regulations they may need as a result of their findings to date.

Dr. Bruner asked if enforcing the Medical Practice Act were difficult due to budgetary restraints and if the Board could be as effective as it would like while current budget problems prevail. Medical Board Executive Director Linda Whitney said the Administration and the Legislature had just approved the Consumer Protection Enforcement Initiative, which will put more emphasis on the review of complaints and the "up front" part of the enforcement process, so our investigators will be more available to review complaints. She also mentioned the Board's Operation Safe Medicine (OSM) and that the Board is requesting that its functions be extended beyond the two- year pilot. One of the activities OSM is interested in is unlicensed activity, and also corporate practice issues. She said she hoped the extension of OSM would be approved this fiscal year.

## Agenda Item 9 Future agenda items and meeting dates

Mr. Heppler asked Dr. Moran to ask if there were any objections from the committee in proceeding in the direction set forth, or any other issues the members would like to have placed on the agenda. She noted that no date had yet been set for the committee's next meeting.

## Agenda Item 10 Adjournment

Dr. Moran adjourned the meeting at 1 p.m.