STATE AND CONSUMER SERVICES AGENCY - *Department of Consumer Affairs* EDMUND G. BROWN JR, *Governor*

MEDICAL BOARD OF CALIFORNIA
Executive Office

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

May 5, 2011

Sheraton Gateway
Salon F
6101 West Century Boulevard
Los Angeles, CA 90045
310-642-1111

MINUTES

Agenda Item 1: Call to order - Dr. Moran
Dr. Moran called the meeting to order at approximately 2:00 p.m.

Agenda Item 2: Roll call
Roll was taken and a quorum was present.

Members of the Committee Present
Mary Lynn Moran, M.D., Chair
Jack Bruner, M.D.
Beth Grivett, P.A.
Suzanne Kilmer, M.D.
Paul Phinney, M.D.
Harrison Robbins, M.D.
Janet Salomonson, M.D.
Gerrie Schipske, R.N.P., J.D.

Members of the Committee Absent
Christopher Barnard, M.D.
James Newman, M.D.

Staff of Committee:
Jennifer Simoes, Chief of Legislation

Medical Board Staff:
Kurt Heppler
Anita Scuri

Linda Whitney

(This list only identifies those who signed in at the meeting; staff was not available to record the names of persons in attendance)

Audience
Melanie Balestra, NP, California Association of Nurse Practitioners
Yvonne Choong, California Medical Association
Julie D'Angelo Fellmeth, Center for Law in the Public Interest
Norman Davis, Esq.
Joseph Furman, Furman Healthcare Law
Tricia Hunter, American Nurses Association California
Paula Johnson-Rood, RN, Aesthetic Accreditation Committee
Will Kirby, M.D.
James Kojian, M.D.
Jake Laban, JLL Solutions, Inc.
Kathleen McCallum, NCANA
Constance Rock, California Association of Midwives
Reham Sheikh, Member of the Public
Thomas Simerson, M.D.
Lilly Spitz, Planned Parenthood Affiliates
Hermine Warren, American Academy of Medical Esthetic Professionals

(This list only identifies those who signed in at the meeting; staff was not available to record the names of persons in attendance)

Agenda Item 3: Public Comment on Items Not on the Agenda.
None

Agenda Item 4: Approval of Committee meeting minutes of January 27, 2011 – Dr. Moran
Patricia Hunter, American Nurses Association of California commented there is a statement in the minutes on page 14 that a registered nurse cannot use standardized procedure, and that is inaccurate. She clarified registered nurses do work under standardized procedures very often in hospitals.

Dr. Moran stated that subject is being discussed today.

Mr. Heppler noted there are two edits on page 11 of the minutes, where it states, ". . . the unlicensed activity of medicine," and he suggested this be changed to the unlicensed "practice" of medicine. Also, on page 11 it states ". . . the board does not license to specialty," and Mr. Heppler suggested this be changed to the board does not license "by" specialty.

A motion was made to approve the minutes as amended; motion was seconded and carried.

Agenda Item 5: Update on AB 583 (Hayashi) Implementation – Ms. Simoes
Ms. Simoes stated this bill passed and was signed into law in 2010. She explained AB 583 requires a health care practitioner to communicate to a patient, in writing, at the patient's initial office visit or in a prominent display in an area visible to patients, the following information: name and license number, the highest level of academic degree, and board certification. She noted the information on this bill was included in the January 2012 Newsletter. She stated the Board received many calls from physicians who were confused as to whether this was a separate requirement to the Notice to Consumers or the same requirement. California Medical Association (CMA) received many similar calls. The Board clarified the requirements in a Newsletter article, explaining these were separate requirements. She explained the notices could be posted separately, or they could both be posted together on one notice. She stated there are fewer calls since the clarification article.

Dr. Moran asked if this type of notice should be present in a medi spa.

Ms. Simoes stated it should be located anywhere a physician practices. She also stated each notice must be provided in the required font size, but both notices could be provided in one notice, in the larger of the two font sizes.

Agenda Item 6: Corporate Practice of Medicine Overview – Mr. Lee, Deputy Attorney General
Russell Lee identified himself as a deputy attorney general from the Oakland Office of the Attorney General. He explained his office is special because it is the smallest office statewide and consists of only one person – himself. He stated, in his review of materials the committee has reviewed in the past, he realizes the Board has already covered the subject of the corporate practice of medicine in some depth. He stated his syllabus is provided in the Board packet.

Mr. Lee explained California prohibits any person from practicing medicine without a valid license, and the prohibition also applies, with limited exceptions, to corporate entities and other artificial entities that have no specific rights, privileges, or powers under the Medical Practice Act. He noted the bar to the corporate practice of medicine is designed to protect the public from possible abuses, stemming from commercial exploitation of the practice of medicine. It is designed to ensure that healthcare delivery is provided by a physician, and that the implications of those medical decisions ensure the ethical obligation to place the patient's interest above and beyond any other interests, and that the physician is subject to the full enforcement powers of the Medical Board of California. Corporations, with limited exceptions, may not engage in the practice of medicine, and they may not directly or indirectly employ a physician, whether they use the term physician or independent contractor, the courts have said it is not legal in California.

Mr. Lee explained the corporate practice of medicine bar has been interpreted broadly to encompass, not only what you would consider to be direct medical decisions, but also business and administrative decisions in a practice that has medical implications. For example, if you were to purchase a piece of radiological equipment, business considerations could enter in that decision, as to the cost, gross billing, space, and employee needs. There are also many medical considerations involved in that decision involving the type of apparatus, the scope of practice, and the skill level of the operator. He continued that when any medical judgment is involved, it cannot be made by a corporation. A corporate practice violates public policy when it exercises control over decisions normally made by doctors, including decisions about location of the practice, improvements, furnishings, fixtures, inventory, supplies, and design specifications. He stated all of these may impact the

quality of the practice of medical care.

Mr. Lee talked about the entities called "management service organizations." He explained these are corporations or entities that ostensibly charge a fee to select, schedule, secure, and pay for medical services on behalf of a physician. Some of these management services organizations are actually engaging in the unlawful corporate practice of medicine. He said a physician who acts as a medical director of a lay-owned business is usually aiding and abetting the unlicensed practice of medicine. He referred to a precedential decision in a case against Joseph Basile, M.D., which he included in his packet.

Mr. Lee explained a physician can be aiding and abetting the unlicensed practice of medicine when he or she works as an employee or as an independent contractor for a medical clinic that is owned or operated by an unlicensed person. He stated there have been several exceptions through the years, and he has listed them in his syllabus. He explained a physician and certain licensees can form medical corporations under the Mosconi Knox Professional Corporations Act. These physicians and other licensees are permitted to form a professional medical corporation and may practice medicine and employ physicians. There are several restrictions with respect to this act. All of the shareholders must be licensed in certain fields, and the majority of the shares must be owned by licensed physicians. There are also restrictions as to who can be a corporate director, shareholder, and so forth. Although they allow the formation of a corporation and the practice by a corporation, they are designed to make sure physicians run the show and nobody else. The Health Maintenance Organizations (HMOs) are another exception to the corporate practice of medicine. They are allowed to make a profit, and the legislators cut a wide exception for HMOs in the Knox Keene Healthcare Service Plan Act of 1975. He stated there are several other exceptions to the corporate practice of medicine – charitable institutions, foundations, clinics, non-profit corporations, and narcotic treatment programs.

Mr. Lee continued to explain, as prosecutors and in assisting investigators, they have come across several indications that denote whether a practice is actually an unlicensed corporate practice. They basically want to know who is making the decisions. Is it the physician on behalf of the patients, or is it the corporation making decisions for the physician on behalf of the patients? A contract designating the type and quality of medical facilities, equipment, and supplies to be provided, without input from the physician, is the corporate practice of medicine. The hiring and firing of clerical, administrative, and medical staff, if controlled by a corporation is the unlawful corporate practice of medicine. The setting of a doctor's compensation, based on a flat percentage of gross or net receipts is an indication the doctor is merely an employee. The doctor's medical decision making and authority is often subordinated through contractual terms by the language of the contract. Lending a doctor's medical license, DEA license, or prescription pad to the corporation employees to write prescriptions, without the doctor's knowledge or approval, are all indications of corporate practice. He stated these are some of the many factors they look at when investigating and prosecuting these cases.

Mr. Lee went on to talk about some types of cases encountered in the field that are not in his syllabus. He stated that corporate unlicensed practice cases scale them from one to ten or easy to hard. The easy case is when the unlicensed corporation or unlicensed individual hires unlicensed personnel to perform medical services. These cases are easy because there is no doctor involved at all, and they can go ahead and prosecute the case. He explained the case can be referred to the district attorney. This is seen with Operation Safe Medicine. This is an easy case, because all that is needed is an expert to say this is the practice of medicine and the district attorney to argue under the statute.

Mr. Lee continued that a more complex case is an unlicensed California corporation hiring a licensed physician as an employee or "independent contractor" to provide medical services. Even more complex, is when an unlicensed California corporation engages a physician in a "Management Services Agreement," where it states on its face that the physician will form a professional medical corporation in his or her own name and take out an FNP from the Medical Board under his or her authority. The Management Services Agreements are never a public record and often difficult to trace because they come in many different versions, depending on which state the corporation is operating in. The most complex cases are when the unlicensed corporation is a mega corporation that is out of state or sometimes out of the country. Mr. Lee explained it is very time consuming to discern all the parties involved and the nature of the corporate structure. In addition to disciplining doctors, corporations are also investigated because corporations can hire another doctor and open up another set of clinics. The first thing the investigation does is identify the paper compliance or non-compliance – is it a properly formed corporation, is it a professional corporation, and is there an FNP? The investigators check the county license to see and if it is consistent with what was said in the papers filed with the state. The next step of the investigation is to document the corporate structure - is ownership out of state or out of country? This is difficult because it is necessary to track down the Articles of Incorporation and the permits taken out in another state. Interviews are also conducted with the clinic staff because it is necessary to establish exactly how these corporations are functioning on the ground. The number of interviews can be quite extensive, because the med spa may have 20 or 30 locations throughout California.

Mr. Lee stated the next step is to locate patients, to establish if there was a doctor-patient relationship and if medicine was practiced in that facility. The physicians must also be interviewed to find out what type of management agreement are they operating under. Mr. Lee summarized some of the general categories of enforcement options that currently exist with respect to these cases. In some cases, they civil penalties, restitution, and cost recovery can be sought. Disciplinary action can also be taken against the doctor who is operating in these clinics. The Board also has citation and fine authority and the Board's Operation Safe Medicine Unit investigates and refers cases for criminal prosecution

Mr. Lee covered some of the problems in the enforcement of these corporate unlicensed cases from the attorney general and investigator perspectives. He explained the cases are very big, sometimes too big, with multiple locations requiring a special assignment of investigators statewide or at least a couple of investigators that have to travel statewide frequently. Oftentimes, these corporate entities are located out of state, as are the corporate medical directors and other personnel. In addition, the investigation of these cases is not a priority in existing law, which sets forth the priority of cases for investigation and prosecution purposes, and corporate unlicensed practice is not among those. He continued to explain the out of state corporate entities can file for bankruptcy in another state, causing prosecutorial problems here. The corporate entities are very well funded, especially if it is a large conglomerate, with multiple law firms defending them in various states. The result of this is litigation that, even if started in Superior Court, could last for years.

Mr. Lee continued that in terms of possible solutions, it appears the threat of these large civil penalties is an effective deterrent to illegal corporate practice. Civil penalties are not generally dischargeable in a bankruptcy, and can follow an individual as a judgment for a long time. Currently, there is no real cost effective way of obtaining any civil penalties against a licensed or unlicensed individual practicing or aiding and abetting the corporate practice of medicine, other than through the involved litigation in Superior Court. Ideally, the Board

should have the authority to under the Medical Practice Act, through an administrative proceeding, rather than having to litigate for months or years in the Superior Courts. At this time, California physicians who unlawfully practice the corporate practice of medicine are only subject to fines currently in the range of $2,500 to $5,000 per investigation. An investigation can involve hundreds of hours of investigative time and attorney time. Larger penalties could get the attention of these corporations without years of litigation in the Superior Court.

Dr. Moran thanked Mr. Lee for his information and stated Mr. Lee's information was very helpful.

More questions were asked regarding the complexity of the cases; Mr. Lee summed up the answers by saying that a tremendous amount of evidence has to be collected and sometimes it is like hitting a moving target. He stated legislative action would be needed to authorize the Board to impose much larger civil penalties.

Mr. Heppler clarified that a fine that can be assessed by the Medical Board is different than a civil penalty that is compensable to a district attorney bringing the action. One puts the power to fine and collect the fee to the Board. He added that a statute change would be necessary.

Mr. Lee reiterated that litigation in Superior Court is long and drawn out, and it is the judge's decision whether to impose a penalty or an injunction. If it is handled as an administrative action by the Medical Board, fines would be imposed based on an investigation. A statute that allows us to impose heavier fines of $100,000 or $500,000 would require new legislation, patterned after the 805 statute, which allows both Superior Court and administrative law action to impose those fines.

Dr. Moran asked if there was any public comment.

Mr. Norm Davis, from the Law Office of Norm Davis, asked why we cannot identify and expand the regulations to be able to articulate when a corporation is in violation of this doctrine, applying those standards, and nail those corporations. He noted instead, we tend to go after the doctors who, in many cases, innocently get sucked into these situations and are accused of aiding and abetting the unlicensed practice of medicine. He asked why the attorney general's office couldn't recommend legislation that would help standardize the identifying of these culprits and go after them with criminal prosecution so they could be closed down more effectively, rather than going mainly after the doctors.

Mr. Lee responded that those mechanisms exist. The problem is the unlicensed people are often from out of state or out of the country, and it is difficult to identify them even though they should be investigated so they can be enjoined and fined.

Ms. Scuri explained the Medical Board only has jurisdiction over certain aspects of this whole process. The Board cannot require unlicensed individuals to get a license for something they are not legally authorized to do in the first place. The Board becomes aware of them when somebody complains, through their advertisements, and other ways. It is against the law to hold yourself out as *able* to practice medicine or *to* practice medicine – it is a two-pronged prohibition. If anybody has the right to open their business, there is an assumption they are acting in compliance with the law. If the physicians did not readily jump at the opportunity to become the medical directors of these entities, which is illegal, there probably would be fewer of them. The Board does not have the resources to investigate all these entities. The Board's focus is supposed to be on those who are

practicing medicine with a license and whether they meet the qualifications. The Board does have some responsibility for unlicensed practice but, again, it is a criminal violation and sometimes that is more difficult to address because the services of local law enforcement and the district attorney's office must be utilized.

A committee member asked if SB 100 addresses some of the questions or concerns heard this afternoon.

Mr. Heppler stated it is his understanding SB 100 is directed at outpatient surgery centers, the accreditation process, the accreditation agencies, and increased jurisdiction by the Board on those actual facilities.

Mr. Sheikh, a member the audience, asked if a patient has a prescription from his physician and the insurance company denies the prescription, is that the unlicensed practice of medicine and asked if the Medical Board has authority to do take action.

Mr. Heppler explained the Medical Board does not have jurisdiction over a managed or other health care plan. That falls with the Department of Managed Health Care or Department of Insurance.

Agenda Item 7: Report on Other States' Definitions of "Medical Spa" – Mr. Heppler and Dr. Moran
Mr. Heppler stated there was a suggestion at the last meeting to look to other states and jurisdictions to see if they had tackled the task of defining a medical spa. A query was placed on the Federation of State Medical Boards Exec Net, which is a bulletin board of state boards that license physicians and surgeons. Of the eight responses received, Iowa adopted a regulation included in the agenda packet regarding medical spas. Oklahoma adopted guidelines, which are on pages 34 and 35 of the agenda packet. The other states either did not address the issue or did not respond. He stated, as far as California law is concerned, there really is no prospective enforceability of a guideline, unless it is adopted in regulation.

Dr. Bruner stated he has been looking into this for quite awhile and found extensive information from Florida and Massachusetts. The information deals with the scope of practice and many issues on medical spas that this committee is dealing with right now, as far as supervision, etc. Florida, he believed, went as far as to say the only time a physician can open a medical spa and practice esthetic medicine is when the physician is board certified in dermatology and plastic surgery.

Ms. Scuri stated generally the standard of practice is set by the community itself, unless the Legislature decides to set in law. In other words, it may not be within the Board's authority to actually accept the standard of practice in regulation. A statute change might be the direction to go if the Board wishes to do so.

Agenda Item 8 – Review of Proposed "Bill of Rights" for Medical Spa patients – Dr. Moran
Dr. Moran stated this information was provided by Dr. Jim Newman who is not here today. Dr. Newman represents the California Society of Facial Plastic Surgeons. She stated there is a proposal coming from that organization for a draft bill of rights for any perspective patient being seen in a medi spa, outside of a physician's physical office location. This would be provided to patients. She read the proposed Bill of Rights to the audience.

Mr. Heppler commented to the extent this comes from a medical society or group, they can adopt this as something they wish to inform the public about; however, the Medical Board would not adopt these without

statutory authority and then not without the regulatory process. He suggested the guidelines could be put into a newsletter article, but he is not comfortable adopting a bill of rights without sufficient statutory authority and regulatory promulgation.

Dr. Moran noted in point three there is statutory authority for the good faith medical exam required by law; however, the portion that designates what subspecialties can perform certain procedures is clearly not required in our state. She clarified that this document is not representative of the Medical Board. It is representative of a particular group that has suggested this for patient protection.

A committee member asked what the committee is going to do with this document.

Dr. Moran stated this was added to the agenda as something to look at in terms of guidelines that would be, in some cases, ideal. She stated there are other things in the document that are not sustainable or even ideal. She stated this agenda item is not an action item; it is more a point of discussion.

Mr. Heppler suggested the Medical Board report it in their newsletter that this specific association or trade profession adopted this, and it could fit in well as a discussion piece.

Dr. Moran stated it is reflective, to a certain degree, of previous publications in our newsletter that pointed out some of these points that are clearly standard of care and in statute. This is just a written reflection from one person's point of view to a rewriting of that.

Ms. Scuri stated the Board has an education committee and some of this could be presented to the education committee as to whether there is value for a brochure, specific to that kind of a setting that elaborates the points that are actually already in law.

Dr. Moran stated this is something we have discussed doing, both a patient education campaign, as well as educating physicians who are violating the law, perhaps without knowing it.

A committee member asked for clarification of the name of the organization.

Dr. Moran stated Dr. Newman submitted the document, but she did not know if it was on behalf of the California Society of Facial Plastic Surgeons. She clarified that it came out of the California Society of Facial Plastic Surgery, but Dr. Newman does not claim that in his submission.

A member of the committee reported, in 2004 there was a joint effort by the American Society of Plastic Surgeons and the American Society for Aesthetic Plastic Surgeons to put together a similar document, but they did not carry it to any state legislature bodies, because of what we already described. There are a lot of good ideas in this, and I think these are things we all agree should take place.

Hermine Warren, California chair of the American Association of Medical Esthetic Nurses, a division of the American Academy of Medical Esthetic Professionals (AAMEP), noted there are four disciplines of advance practice nurses in California; nurse anesthetist, nurse specialist, nurse practitioner, and nurse midwife. She stated she feels it is very critical when adopting these statutes or policies describing esthetic practice, they

encompass all of the nurse practitioners and specialists who can do extended scope of practice. Ms. Warren stated she is a trainer for Medicis, the maker of Restylane, Perlane, and Dysport. Part of her role is to train plastic surgeons, dermatologists, physician assistants, nurse practitioners, and registered nurses in the art of understanding on-label usage of neurotoxins and also derma fillers. Ms. Warren stated she found it interesting that if the experts are only plastic surgeons, facial plastic surgeons, ocular surgeons, and dermatologists, why is it that advanced practice registered nurses are teaching them and are not acknowledged for it.

Melanie Balestra, California Nurse Practitioner Association, stated she works with physicians, nurse practitioners, and registered nurses in esthetics, and she thinks one of the biggest problems is there is no set criteria; everybody has a different certification. She stated she believes one certification would be helpful, whereas a patient would know the person has passed a test, done the clinical, and has experience. She stated she does not think it is just plastic surgeons or dermatologists who can do this. She said there are also registered nurses and advanced practice nurses who are very qualified to do this. She distributed some handouts of the Pearson Report, a yearly report done for nurse practitioners, purposely to see which states have independent practice, which states have collaborative practice, and which states need to have a written contract.

Thomas Simerson, M.D., introduced himself and stated he wanted to comment on the bill of rights; specifically, that he objected to paragraph three, second sentence. Dr. Simerson stated he practiced internal medicine for 17 years, and is board certified. He commented that he worked full time in the emergency room and for nine years has practiced mostly full time esthetic medicine. He stated there are many who are qualified, and he feels he is as qualified as any of the people listed for those activities and able to handle the complications. He continued that he has probably handled more first and second degree burns than the people listed on this statement.

Agenda Item 9: Review of Board of Nursing Standardized Procedure Regulations – Ms. Scuri.
Ms. Scuri noted pages 39 through 41 in the packet are the law and the regulations governing standardized procedures. She stated this law was originally enacted back in the 1970s, and section 2725 is the foundation for this. It provides specifically for overlapping functions between medicine and nursing. She said it does have a definition of the practice of nursing and it allows, via the mechanism of standardized procedures, for overlap. She explained the Legislature specifically intended to recognize the existence of overlapping functions between physicians and registered nurses and to permit additional sharing of functions within organized health care systems that provide for collaboration between physicians and registered nurses. She noted the policies and the foundation for the standardized procedures were required to be done through regulations, and those regulations were required to be subjected to a regulation from the Medical Board.

She stated the Medical Board adopted a regulation, which is on page 40 of the packet and it simply says that you are required to comply with the regulations adopted by the Board of Registered Nursing (BRN). She added that on the top of page 40 in the packet, the last section added to the law provides that no state agency, other than the BRN, can define or interpret the practice of nursing for those who are licensed as nurses or develop standardized procedures or protocols, unless they are authorized to do so.

The BRN has set out the contents of what must be included in standardized procedure guidelines, located in section 1474, which is on page 41 of the packet. She noted they are required to be in writing, dated and signed by the organized health care system personnel authorized to approve those standardized procedures, they must include a description of the methods used to develop the standardized procedures, improve the standardized

procedures, or any revision of the standardized procedures. She added they must state what the standardized procedure functions registered nurses may perform are and under what circumstances, and they must state any specific requirements that are to be followed by registered nurses in performing particular standardized procedure functions. She noted the reference throughout this regulation to the term "registered nurses." She explained it is because the BRN gives only one real license. An individual must be a registered nurse in order to gain any advanced practice standing or to be a nurse practitioner, so the underlying law relates to the basic level of licensure, which is the registered nurse. Everybody, whether they are a nurse practitioner or not, who is licensed by the BRN, is a registered nurse.

She also commented that the standardized procedure guidelines are also required to include a method for initial and continuing evaluation of the competence of those registered nurses authorized to perform the standardized procedure functions. She stated she believes this committee has discussed the need for such an evaluation, and it is included as a component of the standardized procedure guidelines. It is a requirement of the BRN guidelines that standardized procedure guidelines must include that kind of initial evaluation and reevaluation. Ms. Scuri stated that the guidelines must specify the scope of supervision required for performance of standardized procedure functions whether, for example, immediate supervision is required. There has to be some specification within the standardized procedure guidelines themselves, as to what the appropriate level of supervision is for the particular function that is being delegated. Those guidelines also have to set forth any specialized circumstances under which the registered nurse is to immediately communicate with a patient's physician concerning the patient's condition, which was another concern of the committee. It is already required to be included in the standardized procedure guidelines, and it must state the limitations on settings, if any, in which standardized procedure functions may be performed. The guidelines must specify the patient record keeping requirements and provide for a method of periodic review of the standardized procedures. She stated she is not familiar with how the BRN actually enforces this particular provision. However, the standardized procedure guidelines are required to include a large number of things about which the committee has expressed concern.

Ms. Balestra wanted to qualify that she was indicating that nurses are all required to operate under standardized procedures, but in reference to what the committee is talking about, when physicians delegate what would normally be in the scope of medical practice, those usually are reserved for advance practice nurses. She stated it is not a standardized procedure that anyone can do, but the difficulty is there is no difference in the Nurse Practice Act. "I cannot hold myself out as an RNP, unless I am certified and have a separate certification from the BRN. However, I am operating under the same standardized procedure outline that is in here." She stated what has occurred particularly in this realm of medical practice is the belief that it must mean all RNs can do this if we a standardized procedure is written. In reality, the advanced practice nurses know better. Because of their training, you would not do certain things you are not qualified to do. Unfortunately, RNs are getting bombarded with advertisements to do things that only physicians, advanced practice nurses, or a physician's assistant should be doing. This is the dilemma because the Nurse Practice Act is so different from other states in terms of differentiating between an RN and an advanced practice nurse, so this is kind of a gray area.

Ms. Scuri stated that there is still a responsibility on the part of physicians who are participating in this situation where a nurse is going to act under standardized procedure guidelines. There is still a responsibility on the part of the physician to ensure that person does have the appropriate training and is qualified. Enforcement is always the key and, unless something bad has happened, it does not get called to anyone's attention that there

are deviations from these requirements that do exist.

Ms. Balestra stated that her own dermatologist told her since she is being trained by a nurse practitioner, she can do some of the esthetics parts of the practice. She stated she thinks this is occurring more frequently than this Board may want to acknowledge. She commented this seems to be very common, and it has built up an industry that has a momentum, which has gotten ahead of any regulation or law that both this state and other states have been able to deal with.

James Kojian, a physician who has owned and operated a medical spa in Orange County for the past seven years, stated he is not board certified in either dermatology or plastic surgery. He stated he does not believe most residency programs in plastic surgery and dermatology have the curriculum that discusses neurotoxins and dermal fillers outside of what is available to other physicians. He said he discussed the inconsistencies of the nurse training and the requirements for nurse training a year ago in front of the Board. He stated he presented three exams he had written; Botox, derma fillers, and laser hair removal. He stated there needs to be a standard of training competency for a nurse or nurse practitioner to be able to execute these procedures. He stated there is currently no legislation to determine who should teach the class, how long it should be, how many patients do you have to practice on, or do you have to pass an exam. He stated he did not understand how, with a concern for public safety, there are no standards that exist. He asked if the Medical Board has done anything in this regard.

Kathleen McCallum, speaking for the nurses in her group in Northern California, added they are very comfortable with the mandated training and competence, which is so important for patient safety. She commented on restrictions the former legislation presented and said the issue was not a fine issue, it was an issue that a physician had to be present at all times when these things were being done. She remarked she has been a nurse for 30 years, and has followed doctor's orders and standardized procedures in many settings. She stated she wants to see the competence and training, but does not want to limit the role of nurses and the scope of what they are able to do under the guidelines of the BRN that have already been determined and legislated.

Dr. Moran explained the Board does not have the authority to regulate nurses and what they can do.

Mr. Davis stated he had the opportunity to sit in on the drafting of SB 1423, the 2006 Figueroa bill that was originally designed to prevent esthetic cosmetic procedures that would create patient injuries. He stated, after a lot of debate, the final version of the bill indicated the Medical Board and the BRN would collaborate to promulgate regulations. He stated this should be a combined effort with the Medical Board and the BRN to establish the points covered in SB 1423, as to what the level of physician supervision is needed for laser, intense pulse light devices, and esthetic injections, and the level of training appropriate to ensure competency. He noted that was the goal in 2006; three forums were held, and they were significant in terms of community input. He stated the conclusions were summarized in a meeting and now in 2011, the Board is still attempting work on that effort, with the advisory committee focusing on those issues of training and the level of supervision required. He stated that is a goal, but wanted to say what has happened in the meantime. He noted discussions among the agencies have promulgated unofficial regulations that have been used against doctors and nurses. He added that nurses and doctors need to have the standard articulated, promulgated by the combined BRN and Medical Board to be put into statute, to be defined, that will protect the public and will be articulated and known to doctors and nurses.

Paula Johnson Rood, RN, works for Merz Aesthetics as a clinical trainer for Radius. She is also the owner of Aesthetic Accreditation Agency and the president of the Northern California Esthetic Nurses Association. She commented she agrees about the need for training in esthetics. She started speaking as a trainer for Radius, they do follow very strict guidelines and playbooks on the procedures of injecting and assessing these offices and the need for going back and reassessing, so she knows there is research on how to facilitate better training. She stated in order to hone down on the medical spa setting, it needs to be looked at across the board for all offices. She continued that as she is out there, probably in 50 different offices in the last year, and she sees good med spas, bad med spas, good derms, good plastics, bad plastics, and she thinks there is a real need across the board to get standardized care for patient safety.

Tricia Hunter, American Nurses Association California, stated she served on the BRN for eight years and then had the opportunity to serve in the State Assembly. She said standardized procedures do have limitations. She stated she cannot start her own practice and use standardized procedures; although a nurse practitioner can start her own practice and use standardized procedures. She explained a registered nurse has to be in a licensed clinic, facility, or doctor's office, etc., to use standardized procedures. Additionally when a statute is passed that limits the practice of nursing, i.e., furnishing and dispensing for nurse practitioners, then she, as a registered nurse, can no longer use a standardized procedure to furnish or dispense medications. She stated a registered nurse cannot give Botox under a standardized procedure, but she can with a doctor's order. Additionally, she can no longer deliver a baby under a standardized procedure, although for many years she could. There is now a scope of practice for a nurse midwife that describes delivering a baby. A standardized procedure cannot be written for anything in any setting.

Dr. Moran explained the difficulty is many of these nurses are not working in licensed facilities. They may have something written up, but they are not supposed to be doing procedures in an unlicensed facility. They are not supposed to be prescribing or dispensing, because there are no doctor's orders. They are working in a commercial business, and this is what has come to the attention and concern of the Board.

Ms. Rood stated that the purpose of her license is to protect the public, and she has a responsibility to know the Nursing Practice Act. A lack of understanding of licensing laws is not a defense. She continued to say standardized procedures have a name on them, they are not for a facility; they are for the person whose name is on the standardized procedure. She stated the laws defining standard procedure, practice, supervision, and training are good, and they are supposed to be reviewed yearly. She stated the problem is enforcing them rather than creating a new law.

A member of the audience who is in the esthetic arena agreed there are many things people are doing because they are not aware of the law. She stated it all gets back to education whether it is a physician, a nurse practitioner, or a registered nurse. There needs to be standards for patient care and safety. There needs to be a program that we can stand behind and be educated in a uniform way, and then patients will be getting quality care.

Dr. Salomonson stated she is an M.D. who employs registered nurses and nurse practitioners and she has a tremendous respect for allied health professionals. She agrees there needs to be better training, but it is difficult to define and then get an organization to take it on. She stated she did not think it is the Medical Board's job to

certify or train. The Medical Board needs to figure out how to do this together and make it work. This is why we need to develop guidelines and a way to implement them. There should be some sort of financial penalty so corporations care. She said she applauds the committee's efforts so far in working together and trying to accomplish this.

A member of the audience suggested the training information is out there, and the Board could approve a course when they are doing the definition of a medical spa, or incorporate a course and an exam that needs to be completed. The PAC does that for their controlled substances course, and physician assistants can also obtain a limited license for radiology.

Mr. Heppler explained that the genesis for the controlled substance course was a change in law, mandating what the PAC can do. The Board can approve a course and course provider with Continuing Medical Education, but any requirement to administer a certain product would require a statutory mandate. He remarked that Ms. Simoes will talk about the definition of access and availability, which will be covered a little in SB 100. The common theme is a legislative change the Board would implement by regulation, so we would fill the gaps in the statute, but there is little authority to tackle something of this magnitude without legislative intervention.

Dr. Moran said the Board issues a general license to practice medicine in this state, and does not require a doctor be board certified in what they do, there is no way to require individuals to pass this test. She stated there will never be the ability to pass that kind of legislation. She suggested we focus on the laws that exist and then try to identify the need for legislation. For example, as Mr. Lee mentioned earlier, creating the disincentive to practice bad medicine and making the fees high enough that people, whatever their situation, are not inclined to do it. She added, we should make the effort to educate people as to what the existing laws are.

Dr. Phinney commented that Dr. Moran alluded that licenses are plenary. He agreed but he would not attempt to do general surgery; because he is a general pediatrician and that would not be smart. He stated he has relied on non-physician practitioners to upgrade his skills and to help him become competent in doing additional or new things he wants to learn. He stated this is his responsibility as a physician to make sure he is capable of doing a high quality procedure with a patient. He additionally commented just because an advanced practice nurse or registered nurse has learned a lot about an esthetic procedure and is capable of training physicians to expand their skills in that area does not mean they are then capable of treating a patient by themselves who may be a diabetic on blood thinners, or whatever. Complications of a procedure within a certain realm can be handled, but getting into expansions of scope, under the topic of adequate supervision, is an area that is fraught with danger and, he cautioned this group about going too far in that direction.

Dr. Moran commented on another issue not yet raised, which is the maintenance of licensure. Physicians who obtained their license in California could have been trained 50 years ago, and we do not have any way of ensuring ongoing competence, other than CME. She stated the committee should try to focus on a single area and narrow it down and focus on obvious gaps in legislation and educating physicians, by reminding them of their responsibilities. She suggested the committee look at educating patients and physicians.

Agenda Item 10 Research on Definition of "Availability" – Ms. Simoes

Ms. Simoes talked about the considerable discussion at the last meeting regarding the definition of availability. She stated she did some research to see what she could find out about availability. She stated the basic

definition of being available means present or ready for immediate use, accessible, attainable, qualified or willing to do something or to assume a responsibility and present in such chemical or physical form as to be usable.

She talked to the CMA who issued a report, FO2OH, from the board of trustees in July 2009. She said the CMA adopted some Medicare definitions. Medicare has a sliding scale of definitions for supervision:
1) *General Supervision,* which basically means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the non physician personnel who actually perform the diagnostic procedure or treatment, and maintenance of the necessary equipment and supplies are the continuing responsibility of the physician;
2) *Direct Supervision*, which is required for most outpatient settings for Medicare. In 2009, the definition of direct supervision in the office means the physician must be present in the office suite or surgical site and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean the physician must be present in the room where the procedure is performed. They must be in the office suite or surgical suite; and
3) *Personal Supervision*, which means the physician must be in attendance in the room during the performance of the procedure.
She commented CMA also made some other recommendations to continue to educate their members about the legal requirements concerning mid level providers and encourage its membership to appropriately read the standardized protocols for mid level practitioners at regular intervals, as necessary to ensure they reflect the practice needs of the physician and address issues of patient safety.

Ms. Simoes continued to say that in 2011 the Center for Medicare and Medicaid Services (CMS) did have some updates to their definition of direct supervision. They clarified and refined rules relating to physician supervision of hospital outpatient services. For those hospital outpatient services, CMS, which is the federal government, currently requires direct supervision for most outpatient therapeutic services in hospital outpatient departments. The definition was revised in 2011 and now requires the physician be immediately available, interruptible, and able to furnish assistance and direction throughout the performance of the procedure. The difference is it no longer requires the physician be present in the office or surgical suite. There is no reference to a particular physical boundary and a location, but they still have to be immediately available.

Ms. Simoes also found that in 2008, proposed state legislation included language on this issue for a very brief time. She stated that the language gives us a good example of something this could look like, but the language was stricken because it was too prescriptive. The language says that any physician and surgeon, who delegates a performance or administration of any elective cosmetic medical procedure or treatment to a registered nurse shall, pursuant to the requirements of this article, perform an initial, good faith and appropriate prior examination of the patient for whom the treatment has been delegated. Direct supervision is not required upon delegation to a nurse practitioner, physician assistant, or registered nurse. In all circumstances, upon request to the patient, the delegating physician and surgeon shall afford the patient direct supervision of the procedure or treatment. Direct supervision shall mean the physician and surgeon must be onsite and available for immediate consultation at the time of performance or administration of the procedure or treatment.

She continued to say that the only reference she could find in the legislation on location from the site was " In no event may a physician and surgeon delegate the performance or administration of elective cosmetic medical procedures or treatments to more than four separately addressed locations under his or her supervision, one of which shall be his or her primary practice location. These sites shall be located within a radius no greater than that which may be reached within 60 minutes from the physician and surgeon's primary practice location. A delegating physician and surgeon shall be available to attend to emergent patient circumstances within a reasonable time, not to exceed 24 hours from the onset of those circumstances." She said since then there has been no other legislation that she is aware of, or that others she contacted are aware of, that have set forth these requirements. She reiterated this language was too prescriptive. She said that her research indicated that guidelines are moving away from being too specific on the requirements. She also pointed out it is important to note that if SB 100 moves forward as it is now and is signed by the Governor, the Board will be required to adopt, on or before January 1, 2013, 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.

Dr. Moran thanked the committee for taking time out from their practices to be there and the public members for taking time out from business and life to speak at this meeting. She stated the meeting has been very informative, and she learned a lot about what the laws really are. She stated all her questions have been answered regarding the topic and suggested the committee move forward with some action items of the things the committee feels they can do.

Agenda Item 11 Discussion of Next Meeting Agenda and Possible Dates – Dr. Moran
Dr. Moran recommended at the next meeting to look at where the legislative gaps are and where they can make some constructive recommendations for new legislation, noting Mr. Lee's recommendation of civil penalties. She suggested one agenda item would be identifying the need for new legislation and strategizing what the committee would try to advocate for in terms of change. The second agenda item would be to create both a patient education effort, as well as a physician education effort, in terms of the existing laws. She suggested looking at the review of what has been determined from these sessions and create an eloquent material, as done in previous newsletters, develop something more refined and specific, or do general outreach for information we want to communicate to our licensees and to the public about what they should be looking for when considering treatments. She also agreed with a committee member that including the nursing board concerning education is a good idea.

A member of the public commented he would like to see an effort promoted for collaboration between the BRN and the Medical Board to expand the educational outreach to all those it really affects; doctors, nurses, and advanced practice nurses.

Ms. Schipske suggested there be a licensure requirement and definition of a medical spa, because most consumers think a medical spa has been approved and is okay. Since the Board issues FNPs, it might be appropriate for the Board to issue an FNP when a physician is holding himself or herself out to be a medical spa owner.

Dr. Moran stated part of our educational effort would be to summarize all the things we spent time talking about to be included in our statement to physicians. For example, if you do not have an FNP for this medi spa you are working with, whether you are there or not, whether it is in another state, you are in violation and could be

disciplined. She stated a goal for our next agenda could be to put out such a notice.

Ms. Schipske asked if the Board could move towards some definition of what constitutes a medical spa. Ms. Schipske remarked any time you put the word " medical" in front of something, there is an inference that it is a different type of operation than it is, and it is misleading to the public.

Dr. Moran commented it would require legislation to legally define a medical spa, and we should include that discussion about legislation at our next meeting.

Agenda Item 11
There being no further business, the meeting was adjourned at approximately 4:20 p.m.

STATE AND CONSUMER SERVICES AGENCY - *Department of Consumer Affairs* EDMUND G. BROWN JR, *Governor*

MEDICAL BOARD OF CALIFORNIA
Executive Office

MEMORANDUM

DATE	April 9, 2012
TO	Committee on Physician Supervisory Responsibilities
FROM	Jennifer Simoes, Chief of Legislation
SUBJECT	**SB 100 (Price, Chapter 645, Statutes of 2011)**

ISSUE

SB 100 (Price, Chapter 645, Statutes of 2011) was signed into law by the Governor. One of the provisions included in SB 100 requires the Medical Board of California (Board) to adopt regulations, as follows:

On or before January 1, 2013, 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.

The Board has decided that the Committee on Physician Supervisory Responsibilities is the appropriate committee to assist in obtaining professional and stakeholder input, which is needed to draft the required required regulatory language.

BACKGROUND

At the last meeting of this Committee, the various definitions of "Availability", from the California Medical Association, the Centers for Medicare and Medicaid Services, and past legislation, were discussed. Some of this information can be used as a starting point for drafting the regulatory language required regarding the appropriate level of physician availability in clinics or other settings using laser or intense pulsed light devices.

Availability Definitions (Presented at the last Committee Meeting)

Definition of "Available":

- Present or ready for immediate use
- Accessible, obtainable
- Qualified or willing to do something or to assume a responsibility
- Present in such chemical or physical form as to be usable

Federal Government – Center for Medicare and Medicaid Services (CMS)

CMS has clarified and refined Medicare rules relating to physician supervision of hospital outpatient services over the last couple of years. CMS currently requires direct supervision for most outpatient therapeutic services in hospital outpatient departments. The definition for direct supervision was revised in 2011 and now requires that the physician be immediately available, interruptible, and able to furnish assistance and direction throughout the performance of the procedure. It no longer requires that the physician be present in the office or surgical suite and there is no reference to a particular physical boundary in the definition.

California Medical Association (CMA) Report F-02-08 to the CMA Board of Trustees, July 30, 2009

CMA made the following recommendation in its report regarding supervision:

Recommendation #1: That CMA support addition to current and future California regulations/legislation affecting physician supervision, the Medicare definitions for sliding scale of supervision, with the addition of "treatment" under the general supervision definition, as provided below:

- General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the non-physician personnel who actually perform the diagnostic procedure or treatment and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

- Direct supervision in the office setting means the physician must be present in the office suite or surgical suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

- Personal supervision means a physician must be in attendance in the room during the performance of the procedure.

Previous Legislation

In 2008, AB 2398 (Nakanishi) proposed to add the following to the Business and Professions Code (as amended 4/22/08):

In no event may a physician and surgeon delegate the performance or administration of elective cosmetic medical procedures or treatments to more than four separately addressed locations under his or her supervision, one of which shall be his or her primary practice location. These sites shall be located within a radius no greater than that which may be reached within 60 minutes from the physician and surgeon's primary practice location. A delegating physician and surgeon shall be available to attend to emergent patient circumstances within a reasonable time, not to exceed 24 hours from the onset of those circumstances.

Lasers and Intense Pulsed Light Therapy Background (from dermnetnz.org)

"Laser" is an acronym: **l**ight **a**mplification by the **s**timulated **e**mission of **r**adiation. Lasers are sources of high intensity light that can be accurately focused into small spots with very high energy. The light is produced within an optical cavity containing a medium, which may be a gas, liquid , or solid. The process involves excitation of the molecules of the laser medium, which results in the release of a photon of light as it returns to a stable state. Each medium produces a specific wavelength of light, which may be within the visible spectrum. The aim is to destroy the target cells and not to harm the surrounding tissue. Short pulses reduce the amount that the damaged cells heat up, thereby reducing thermal injury that could result in scarring. Automated scanners aim to reduce the chance of overlapping treatment areas. The wavelength peaks of the laser light, pulse durations and how the target skin tissue absorbs this, determine the clinical applications of the laser types.

Intense pulsed light (IPL) or flashlamp therapy is a non-ablative treatment that uses high intensity pulses of visible light to improve the appearance of the various skin problems. IPL systems work on the same principles as lasers in that light energy is absorbed into particular target cells with colour (chromophores) in the skin. The light energy is converted to heat energy, which causes damage to the specific target area. IPL systems are different from lasers in that they deliver many wavelengths (or colours) in each pulse of light instead of just one wavelength. Most IPL systems use filters to refine the energy output for the treatment of certain areas. This enhances penetration without using excessive energy levels and enables targetting of specific chromophores (these are skin components that absorb light). IPL therapy is considered a non-ablative resurfacing technique, which means that it targets the lower layers of skin (dermis) without affecting the top layers of skin (epidermis).

QUESTIONS FOR THE COMMITTEE

Staff has developed a decision tree of questions to help the committee focus on particular issue areas related to availability. The responses will help to shape the regulatory language:

1. Does this committee believe that a physician should be physically present in the room at all times in a clinic or other setting using laser or IPLs? Does a physician need to be physically present at the location when a laser or IPL is used? If this committee believes a physician needs to be physically present in the room or at the location, no further discussion is needed, if not, see question number 2.

2. Should the regulations require the physician to be immediately available for certain procedures? If so, should those procedures be listed in the regulatory language and what's defined as immediate (time, distance, technology, backup)?

3. Should the definition of "immediately available" allow for the physician to use current technologies (video conferencing, skyping, etc.) to meet this requirement?

4. Are there certain procedures where the physician should be physically present in the room or at the location or immediately physically available (immediately needs to be defined differently if physical presence is required)? If so, should those procedures be listed in the regulatory language?

5. For those procedures that do not require immediate availability, should the regulatory language include a geographical or chronological radius in which the physician should be available? An example of this was included in the proposed AB 2398 (Nakanishi, 2008), as follows: " These sites shall be located within a radius no greater than that which may be reached within 60 minutes from the physician and surgeon's primary practice location. A delegating physician and surgeon shall be available to attend to emergent patient circumstances within a reasonable time, not to exceed 24 hours from the onset of those circumstances.

6. If a physician cannot meet the criteria, what is allowable for back up? Does the physician need a backup plan? What circumstances require the need for a backup plan?