MEDICAL BOARD OF CALIFORNIA

COMMITTEE ON PHYSICIAN SUPERVISORY RESPONSIBILITIES AGENDA

MEMBERS OF THE COMMITTEE
Gerrie Schipske, R.N.P., J.D, Chair
Michael Bishop, M.D.
Janet Salomonson, M.D.
Christopher Barnard, M.D.
Jack Bruner, M.D.
Beth Grivett, P.A.
Suzanne Kilmer, M.D.
James Newman, M.D.
Paul Phinney, M.D.
Harrison Robbins, M.D.

Courtyard by Marriott
Golden A & B
1782 Tribute Rd.
Sacramento, CA 95815
(916) 929-7900 (directions only)

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

While the Board intends to webcast this meeting, it may not be possible to webcast the entire open meeting due to limitations on resources.

Thursday, July 19, 2012
4:00 p.m. – 5:30 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 Committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7(a)]

3. Approval of Minutes from the May 5, 2011 Meeting

4. Approval of Minutes from the April 11, 2012 Meeting

5. Discussion and Possible Recommendation of Draft Regulatory Proposals Regarding the "Appropriate Level of Physician Availability Needed Within Clinics or Other Settings Using Laser or Intense Pulse Light Devices for Elective Cosmetic Procedures" - Required By SB 100 (Price, Chapter 645, Statutes of 2011) – Mr. Heppler and Ms. Simoes

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. Discussion of Future Agenda Items and Possible Dates and Locations

7. Adjournment

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 Tim Einer at (916)263-2389 or email tim.einer@mbc.ca.gov or send a written request to Mr. Einer at the Medical Board of California, 2005 Evergreen Street, Suite 1200, Sacramento, CA 95815. Providing your request at least five (5) business days before the meeting will help ensure availability of the requested accommodation.
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.***

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

MEDICAL BOARD OF CALIFORNIA

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

Sheraton Gateway
Salon F
6101 West Century Boulevard
Los Angeles, CA 90045

May 5, 2011

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)

DRAFT

(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, 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.

DRAFT

MEDICAL BOARD OF CALIFORNIA

COMMITTEE ON PHYSICIAN SUPERVISORY RESPONSIBILITIES

Parks, Recreation & Marine Administration Building
Large Conference Room
2760 N. Studebaker
Long Beach, CA 90815

April 11, 2012

MINUTES

Due to timing for invited guests to provide their presentations, the agenda items below are listed in the order they were presented.

Agenda Item 1 Call to Order
Ms. Schipske called the meeting to order on April 11, 2012 at 3:50 p.m.

Agenda Item 2 Roll Call
A quorum was not present and notice had been sent to interested parties.

Members Present:
Gerrie Schipske, R.N.P., J.D., Chair
Michael Bishop, M.D.
Janet Salomonson, M.D.
Christopher Barnard, M.D.
Jack Bruner, M.D.

Members Absent:
Beth Grivett, P.A.
Suzanne Kilmer, M.D.
James Newman, M.D.
Paul Phinney, M.D.
Harrison Robbins, M.D.

Staff of Committee:
Jennifer Simoes, Chief of Legislation

Staff Present:
Kurt Heppler, Staff Counsel
Linda Whitney, Executive Director

Members of the Audience:
Casey Bahr, Torch Institute
Julie Clause, R.N.

DRAFT

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Norman C. Davis, Esq., Law Office of Norman Davis
Joseph P. Furman, Furman Healthcare Law
Kathy Jakary, R.N.
James Kojian, M.D.
Michael Lum, D.O.
Robert Miller, P.A.
Cynthia A. Moore, R.N.
Hermine Warren, American Association of Esthetic Professionals
Barbara Yaroslavsky, Board President

Agenda Item 3 Approval of Minutes of May 5, 2011 Meeting
Since there was not a quorum, the Minutes will be approved at the next meeting.

Agenda Item 4 Public Comment on Items not on the Agenda
No public comment was given.

Agenda Item 5 Discussion of Conceptual Proposals Regarding the "Appropriate Level of Physician Availability Needed Within Clinics and Other Settings Using Laser or Intense Pulse Light Devices for Elective Cosmetic Procedures" – Required by SB 100 (Price, Chapter 645, Statutes of 2011)

Ms. Schipske stated there was a handout that includes definitions previously discussed, background information on laser and intense pulse light (IPL) therapy, and the decision tree of questions to help this Committee focus on issues related to availability. Ms. Schipske explained SB 100 was signed into law by the governor last year, and became effective January 1, 2012. One of the provisions requires the Medical Board to adopt regulations on or before January 1, 2013 on the issue of physician availability, specifically regarding the appropriate level of physician availability needed within clinics or other settings using laser or IPL devices for elective cosmetic procedures. The regulations do not apply to FDA approved devices sold over the counter for self-use. Ms. Schipske stated the responses from this Committee meeting will help shape the regulatory language that is presented to the full Board. Ms. Schipske turned the meeting over to Ms. Simoes and Mr. Heppler.

Ms. Simoes presented question #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 IPL devices? Does a physician need to be physically present at the location when a laser or IPL device 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.

There was a concern voiced regarding the term "other settings," and the Board knowing where they are located for enforcement purposes.

Dr. Bruner stated there needs to be a definition of "other settings". The Board needs to know the setting is a licensed or accredited setting, and a clinic is a generic term. If licensed healthcare professionals are performing these procedures, this is the practice of medicine and, as such, a physician is generally responsible. If this is the case, then existing laws and regulations already exist. Dr. Bruner questioned what the Committee was looking to change.

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Dr. Salomonson stated the issue of possibly requiring a notice, as to training in the facility, has been previously raised. She stated she is not quite sure what is being required of physicians if there is not a definition of "other settings."

Dr. Barnard wanted to clarify that all lasers are not the same. There is a wide spectrum, and there are different safety profiles associated with different types of lasers. The other concern is whether anesthesia is being used and whether a proper diagnosis been made.

Dr. Bishop stated he is not sure who is actually allowed to do these procedures. He also stated any medical procedure should be done in a clinic, and there should be different criteria if sedation is involved. He continued that if some lasers are more dangerous, a different level of supervision is needed. He also stated the definition of "other settings" needs to be clarified and the level of supervision needed to provide safety for the patient needed to be established.

Mr. Heppler remarked there is recent regulation/legislation on the anesthesia aspect, but not necessarily directed at elective cosmetic procedures. Existing law requires procedures done using general anesthesia to be performed in a hospital or accredited outpatient surgery center. The level of anesthesia determines the setting. The Board has adopted a precedential decision (Joseph F. Basile, M.D.) stating, "If it penetrates the skin, then it is the practice of medicine."

Ms. Schipske commented the focus should be on the type of procedure rather than the setting. The type of procedure would trigger who could do it, under what conditions, and the in what setting.

Mr. Heppler asked if the requirements change depending on the procedure. He asked the members of the Committee if it was their opinion a physician has to be onsite? He also questioned if onsite meant in the room and would the availability vary depending on what the procedure was.

A Committee member summarized that if a licensed physician is supervising a registered nurse, nurse practitioner, or other healthcare practitioner, within their scope of practice, the healthcare practitioner is allowed to perform the procedure. The physician is responsible for that healthcare practitioner and to make sure the healthcare practitioner is licensed, trained, and has the skills to do the procedure. The physician is responsible for examining the patient, establishing the consent for the procedure and the consent for another healthcare practitioner to perform that procedure. A physician does not always have to be present in the room or looking over the shoulder of that licensed healthcare professional for them to do the procedure. The physician does not have to be present for the actual procedure.

Ms. Schipske stated that nurse practitioners practice independently. Under standardized medical protocols, the physician does not have to be present and does not have to supervise. This has spilled over into the cosmetic area, and if the Committee focuses only on this particular type of practice, it will run up against the reality of what is happening in other settings, where nurse practitioners practice independently. Physician assistants practice somewhat independently as well, but they are more directed by the physician in some settings. A good faith examination can be performed by a nurse practitioner or a physician assistant under standardized protocols, without the presence of a physician. Nurse practitioners can perform laser treatment under standardized protocols.

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Ms. Schipske was asked who sets up the standardized protocols and she responded it is a combination of medicine, nursing, and administration, and the protocols must be updated frequently.

Hermine Warren with the American Association of Medical Esthetic Professionals stated she is also an advanced practice nurse. She explained that Ms. Miyato attended the last Committee meeting and discussed the protocols nursing can follow. With standardized protocols in place, nurses can now perform procedures that were not previously allowed. Ms. Warren stated the major topic is what does availability mean? Ms. Warren explained a number of years ago the Institute of Medicine in conjunction with the Robert Wood Foundation came up with nursing initiatives. One of the first initiatives was that nurses should be allowed to practice to the highest extent of their education. Currently, Arizona allows nurse's aides to do laser procedures. Nurses are trained to do laser procedures in the same fashion as physicians are trained because there is no generalized board certified laser program. American Society for Laser Medicine and Surgery (ALMS) allows a physician or registered nurse to get a certification to do this training. There is no different level of training. Ms. Warren continued that most laser adverse effects happen within 48 hours – not at the time of treatment. It seems disruptive to the flow of good medical practice to have a physician present when there is nothing to avert, especially with a 25% physician shortage.

Dr. Salomonson stated she had a misconception of what working under the protocols are if they are not tied to a physician.

Ms. Schipske stated that is part of protocols to indicate the level of training to do a particular procedure and how an emergency or complication will be handled – who will be called. There is a specific protocol on whether a physician is called or a paramedic.

Dr. Bishop stated it is difficult for him to envision a physician who would feel comfortable getting called on an elective procedure when he was not part of the decision-making in the beginning. As a responsible physician, you want to know your patient and if you are responsible for that patient.

Ms. Schipske stated this is the law and actually, the patient is the nurse practitioner's patient. The patient is not necessarily the physician's patient. Some patients who come through some of the clinic settings never see a physician. They are completely taken care of by a mid-level practitioner.

Dr. Bishop stated this is not about what training you have, because anybody can be appropriately trained with a laser within a reasonable expectation. The question is whether the person performing the procedure can deal with the anticipated consequences and complications. If they cannot, there needs to be somebody who can. Dr. Bishop stated he thinks the Committee is trying to decide what is that responsibility and how can it be done. Another question is whether EMT response is adequate. If so, then the Committee might consider that a physician does not need to be there. Also, the point about the diagnosis is crucial. If this patient has never seen a physician, and the practitioner is using a laser on a malignant melanoma that has now metastasized to the brain, this is problematic. The availability is strongly related to the potential complications and how they are handled.

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Ms. Warren commented to Dr. Bishop that it is important to separate out the difference between a medical diagnosis versus an esthetic procedure. An IPL treatment is not usually for ablating a melanoma.

Dr. Bishop responded that they would not know it is a melanoma when they were ablating it.

Dr. Barnard stated this is the main thing he runs into in his practice. He has patients who have had melanomas treated by practitioners with IPL devices or other lasers, and the individuals had no idea what they were treating. The backup is not trained in dermatology or they could be 100 miles away. A proper diagnosis is a real concern.

In response it was stated that having good protocols and procedures addresses that concern. Melanoma is one of the key things misdiagnosed for many people, whether it is a physician or a registered nurse. Anyone can make an error. That is why there are protocols to follow.

Dr. Bishop commented that his original question as to who is allowed to do IPL procedures was never answered.

Ms. Warren stated it is a registered nurse and above.

Ms. Schipske noted because of the money involved in this particular industry, there has to be a standard that is very clear. A physician who associates himself or herself with someone who has no basic training as a nurse should not be doing these kind of procedures.

Dr. Barnard asked if the healthcare professional has to be licensed.

Mr. Heppler stated the Medical Board cannot determine what nurses do. This is strictly the purview of the Board of Registered Nursin. A physician and surgeon can do this procedure, but a licensed esthetician cannot. A physician assistant who has a delegated services agreement can do it as well.

Dr. Barnard stated this is the practice of medicine and asked if this Committee believes a physician should be physically present at all times?

A member of the Committee stated there is not any disagreement that a physician does not necessarily have to be present at all times when lasers and IPL devices are used.

Dr. Salomonson asked who authors the delegation of services agreement and the standardized procedures.

Mr. Heppler explained a delegation of services agreement is executed between the physician and the physician assistant and standardized procedures are worked out in conjunction with the nurse practitioner and the physician and, if they work in a clinic setting, administration is also involved.

Ms. Schipske stated this is still tied in with the physician, but that physician is not necessarily the person who will interact with the nurse after that point. The physician is the consultant on the

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standardization for the protocols; and, the nurse still has to function under a medical doctor. If a medical doctor is not present, nurses are supposed to follow protocols, and if something happens outside the range of that protocol, nurses are supposed to call the physician.

Dr. Bruner stated, although it is not part of the Committee today, a medical spa or medi spa is the practice of medicine, but the state of California does not recognize it that way. If the Committee would look at this issue too, it would solve a lot of problems. If a medi spa is the practice of medicine, the California regulations would need to be followed. There are people who are untrained doing these procedures. He recommended the Board enforce the current laws in this area. When the word "medi" is used on a signboard, the public, who the Board is trying to protect, think of it as the practice of medicine.

Ms. Schipske commented that is an excellent point and, because this Board issues Fictitious Name Permits (FNP), that is one way to keep track of physicians who practice under another name.

Dr. Bishop also stated if a medi spa is providing laser hair removal, IPL, injections, or any other medical procedure, they would be required to have that name registered with the Medical Board. Thus, they would have to have a physician apply for an FNP. They would be practicing medicine, and thus they would be a medical office by definition. A clinic has a definition under the Health and Safety Code. A facility has a definition, and a medical office has another definition. So the medi spa is a medical office or a clinic.

Dr. Salomonson brought up the requirement of posting the Notice to Consumers.

Mr. Heppler stated if we assume there is the penetration of skin, that invokes the practice of medicine and the notice requirement for the physician would be required.

Ms. Schipske clarified that a Notice to Consumers, indicating the Medical Board of California is the regulatory body and including the Board's phone number, must be posted wherever a physician practices.

Dr. Bishop asked if Ms. Schipske wanted to open up a medical clinic and had written protocols with a physician, including how they would respond if something went wrong, and the patient wanted to report to the Medical Board and seek civil penalty, would the physician who participated in that creation of those protocols be liable as well?

Mr. Heppler replied that he could not answer the question as it is a fact-specific inquiry and it would depend on the fact pattern. Generally speaking, from a legal perspective, the Board does not intrude on the actions of the Board of Registered Nursing. Whenever a complaint is filed against a physician, there is fact-finding and an investigation conducted. Mr. Heppler is locked out from that procedure within the Medical Board because he is the transactional attorney. If the physician really did not have too much involvement, as far as administrative discipline, it would be difficult to meet the Board's clear and convincing standard. Mr. Heppler could not comment on the civil liability issue.

Ms. Schipske added that an NP has to have their own malpractice coverage and they are sued separately.

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Dr. Bishop stated that he has great faith in nurses and NPs and has tremendous respect for their skills. The option should be there if the patient would like to see a doctor.

A member of the audience commented on the Notice to Consumers. She said she has never seen that kind of notice for the patients.

Dr. Salomonson advised that it is a relatively new regulation and based upon this comment the Board needs to do more to educate physicians. Dr. Salomonson will relay this information to the Board's Public Information Officer.

A member of the audience commented that he is a physician, and he has been working in the realm of esthetic medicine for the past ten years. He said he does these procedures and does deal with adverse effects. He stated that whether the entities be medi spas or medical spas or practices, in the State of California there are corporate practice of medicine issues. No matter what it is called, the physician has to take ownership. A physician is ultimately responsible. The term "MediSpa" is a trademark owned by Dr. Katz. Anyone who uses that gets a letter from their lawyer. "MediSpa" is not technically a medical spa.

Joseph Furman, who represents physicians in Medical Board matters, spoke to the Committee. He said, in terms of physicians and nurses and other allied health practitioners who want to be in compliance, it is a very complicated and evolving area and is very fact specific. Some very qualified nurse practitioners who are working with very qualified plastic surgeons are apprehensive of getting into this area because of some of these terms that need to be defined. Of particular concern is whether a physician needs to be physically present.

Ms. Schipske said the Committee has to stress, that some of the physicians raised that it would be very dependent upon the diagnosis or the type of procedures that are being performed so to say outright "no" would not necessarily be where the Committee is going.

Mr. Furman asked if a list could be created by a responsible group that would list those procedures that would require a physician's presence immediately. The Committee advised this leads to Question 2.

Ms. Simoes presented Question 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 should "immediate" be defined either as time, distance, technology, through a back-up plan, etc.?

Mr. Heppler said "availability," pertains to proximity, geography, time, technology (Skype), etc.

Ms. Schipske stated, that is consistent with other practices of medicine as well. To single out one practice and make definitions of very specific procedures and distance runs the risk that you are getting into areas at the expense of other practices.

Mr. Heppler said it is a different standard of care issue.

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A member of the audience said he thinks any standard should be applied universally across the board. A procedure is a procedure – wherever it is performed and whoever does it. If it is dangerous, it requires more immediate availability and should be consistent across practices.

Ms. Schipske reminded everyone this Committee is only focusing on SB 100.

The audience member also agreed that the standard should be consistent with the other practices. Whatever exists out there for other practices should be applied evenly here as well.

Norman Davis thanked members for addressing that issue. He thinks any medical procedure should have the same standard if it runs a risk of life or death, or serious injury. He stated these procedures should have more attention and the doctor should be more available. He stated he did not think people were dying from being injected with Botox or by having lasers used on them. So, any standard does have to apply across the board, and what this Committee is doing under SB 100 should be applicable to other practices. The Committee should look at the broader setting, because it has been almost ignored in the earlier discussions.

Dr. Barnard said the one caveat is anesthesia. Lasers and other procedures can require anesthesia and deaths related to cosmetic procedures are generally related to the anesthesia – not so much the direct light.

A member of the audience agreed and stated that the levels of consciousness are a different way of approaching the arena. He believe that all the laser procedures that are performed by nurses specifically, not advanced practice nurses, are not administering levels of anesthesia that would be deleterious to the patient.

Ms. Warren informed the audience that Arizona nurse's aids and other allied health professionals are doing lasers. With respect to the Board, he believed it needs to have its eyes open and look at patient safety. There is no uniformity across the board anywhere. Every place you go, there is a different way of looking at it. He stated it is important to go back to the biggest thing that came out of many of the meetings - the good faith examination. If a good faith examination is performed, a nurse, a nurse practitioner, or a PA should be able to be in a room without a physician, because that patient is cleared for the procedure. It just seems ludicrous to be having somebody there with their mentor if the person has been approved and is technically not contraindicated for whatever the procedure might be. If a good faith examination is used, that frees up a lot of the other things the Committee is addressing within the scope of the meeting.

An audience member said her reason for coming to the meeting is because she is a certified laser instructor and has trained with three national laser companies. She has traveled all around the country and is amazed at the variance of who is able to do what. She has seen physicians' offices, both dermatologists and plastic surgeons, who have medical assistants running their lasers, which should not be happening. This brings up so many openings, and the focus should be on education and level of training.

Ms. Schipske replied, in standardized protocols part of the protocol indicates the training that is necessary to be able to perform that particular procedure. In a clinic setting or in a hospital it is very detailed as to what someone who is performing that procedure has to have for training to do the procedure. The tools are there, they are being ignored in many sites. That would be for any

type of practice in the medical area, it is not just cosmetics. The Board has the regulations, it is just a matter of how they are applied and also making sure there is an educational program.

An audience member said the same mechanisms that can be used for telemedicine, basically, Tele-CME for education, for making it uniform across the country – not just California – to educate and to have a level that is clear, examinations, practical's, and let everyone adopt these standards that the standards are 100% clear for physician supervision, and coordination, and screening. It can be monitored remotely, the standards are important.

Another person stated, this Committee or an ad hoc Committee should get together and say, "What are the procedures that are especially risky, and what sort of standards should apply to those.?" If any sedation is being used, the practitioner has no idea what that patient is going to do. The Committee needs to understand which procedures are dangerous and what adjunctive measures are used during those procedures are dangerous and apply standards to those.

Ms. Schipske said the Board has been directed by the Legislature through SB 100 and the focus got placed on cosmetics. It may be perhaps that the Legislature did not understand this is applicable to every area in medicine.

Mr. Heppler said the emerging precept is that the Committee is not going to single out elective cosmetic procedures as anything different and have two standards of care, but that the Committee wants one uniform sentence.

Ms. Schipske responded that she thinks if the Committee approaches it from that stand, it will not be necessary to make a list of what is safe and not. In the Medical Practice Act and the Nurse Practice Act, it is very clear that there are regulations and safety mechanisms that should be applied across the board.

Mr. Heppler said it takes a medical expert to evaluate standards of care, which can be a battle of the experts. The only difference for standard of care is the Legislature inserts one and says here is the standard of care. This would resonate well with the simple fact that standard of care is community standard of law that evolves over time and the Committee not single one out.

Ms. Schipske asked, if the Committee has consensus or were there, any more comments on Question 2?

Dr. Salomonson said what should be emphasized is that local anesthesia, certainly injectable, but also topical, can be lethal as well. To avoid just altering consciousness, and certainly to know the point of conscious sedation, is a very slippery slope. There have been lethal amounts of lidocaine, so local anesthetic is no guarantee.

Ms. Simoes said the rest of these questions dig in deeper to Question 2. Question 3 is should the definition of immediately available allow for the physician to use current technologies, for instance, video conferencing, Skyping, and other kinds of technology out there, to be available to meet the requirement?

Dr. Bishop noted that the Board's statement says telemedicine is acceptable if the doctor that is receiving the information is a California licensed physician. Unfortunately, it has been

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nationally used for years, and California has adopted the policy that is equivalent to being in the room. He added the Committee might want to tighten that standard by having a nurse or other practitioner available at the transmitting end rather than Skyping from home.

Ms. Simoes stated the question is, can telehealth be used to meet the immediately available requirement?

Dr. Barnard stated he was the medical director of telemedicine at Stanford for three years and also for the whole national region of the Veteran's Administration. He is still involved in telemedicine. He has used it for internal medicine, primary care, and internal medicine, as well as neurology. Dr. Barnard stated that it works beautifully, and he was also involved in teleneurology, teleradiology, and pediatric echos. It clearly is wonderful for diagnosis, for supervising a procedure and doing tele-present surgery for procedures. It can be done, and it is a very appropriate mechanism for providing care in a uniform way across the country.

It was suggested to look at telemedicine in relation to the penal system. In 2009-2010, there was over 13.1 million dollars saved in telemedicine examinations, and there would be no way they would be able to enforce that kind of medical care for the inmates if they did not have a situation that really was effective and worked. So this is also outside of the realm of esthetics, but showing it is well accepted. At that time, Governor Schwarzenegger had signed off on it as a valid method of being able to provide quality care.

Ms. Simoes presented Question 4: Are there certain procedures where the physician should be physically present in the room or at the location or immediately available? And, if so, should those procedures by listed?

Ms. Schipske said, again without singling out one particular focus area in medicine, the Committee would have to have something to apply across the board. Something that is a dangerous procedure that needs the physician present should be a universal standard and not singled out.

Ms. Schipske warned that she would have concerns ir a regulatory body got into specifics in terms of dictating certain procedures that have to have a certain level of response or not, because it takes away from the judgment of the physician or the practitioner or the facility because of where they are located and the available resources. The Committee needs to be very cautious that this Board is not practicing medicine by dictating or getting the Legislature to dictate that specific procedures have to have specific types of responses.

Mr. Heppler advised that a lot of the standards of care are not legislatively driven, because there is a recognition that the profession evolves, with a few exceptions. The standards of care are such that if you did something dangerous it would not make any difference if it was a cosmetic procedure or an invasive procedure. A dangerous act is a dangerous act. If the Board were to say the official backup plan is call 9-1-1; that might be dangerous.

Someone stated this question should be, "Are there certain laser and IPL procedures where the physicians should be physically present"? Are there any laser and IPL procedures where a physician absolutely should be present?

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Ms. Schipske shared that the court just came out with a finding about the nurse anesthetist, where they supported Governor Schwarzenegger that a physician does not have to be present. She stated in some cases, anesthesia is much more dangerous than any laser therapy. She said this is judicial precedent now coming about that there is latitude of what a practitioner who is appropriately trained can do, and that if we now specify the lasers, we may run afoul of where the courts are already heading in that direction.

Dr. Bishop commented, as an anesthesiologist, he believes it is a grossly misguided, inappropriate, and extremely dangerous thing the court did.

Dr. Salomonson said she had to weigh in on the anesthesia issue too, because her interpretation of the ability to get a Medicare exception was that the Medical Board was supposed to render at least an opinion with respect to that. And, the Medical Board was never given an opportunity to render an opinion.

Someone stated that since the Committee is talking about IPL and lasers, to no forget there are modalities within the realm of esthetics that are outside of that – like radio frequency or infrared, and these companies are saying a nurse can use this. The main thing is the ultimate responsibility that whoever is in charge is not practicing beyond their scope of knowledge.

Another person asked what are some of the complications that occur with IPL and laser treatments and does a physician need to be right there. In addition, the individuals asked how many doctors are available for laser hair removal.

Someone stated it is important for the Committee to think the core competencies of what it is doing. This individual stated the questions are: What constitutes a person doing these procedures, whether they are a physician, a PA, an NP, or an RN? What is the required level of competency? Is it a weekend class? Is it a week class? Is it five procedures with a physician, 10 procedures, or 20 procedures? Is it constant supervision for perpetuity?

This individual added that there is no level of education and that is key. There was a study done by the plastic surgical nurses, where a qualitative study questionnaire was sent out to 1,000 plastic surgical nurses asking, "Is there any level of core competency; is there anything that you do that there is a regime for?" The majority of the nurses said they did things different ways in different practices. It was not that everybody had the exact same way they approached their clinical practice.

A member asked if Question 4 should be rephrased to look at the procedures or the levels of those instruments and the training of the individual who will be using the instrument, and then should the physician be available at certain levels of use?

Ms. Schipske replied thatgshe again would raise the question - –does the Board do this for any other area of specialty?

The members all stated that it didn't

Ms. Schipske stated the Committee needs to apply the same standards that the Board has for the other areas. She stated part of the education is for the Board to go back to the Legislature to

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educate then that there is a Medical Practice Act and a Nurse Practice Act, and that there are regulations in place and that is what needs to be focused on - not singling out one or two procedures. The Committee is talking about lasers, but there are a lot of other things that could cause substantial harm that are used and are just not being addressed.

Ms. Whitney replied that training may be the appropriate thing to do. Not training in the use of lasers, but training to assure that the staff is appropriately skilled in specific procedures. This could be clarified in regulation. The Committee could make recommendations on what physicians are expected to do in terms of the oversight of training of those individuals that are in the office or a clinic, for those that have delegated service agreements or standardized procedures.

Mr. Heppler said the Legislature has given the Board pretty specific direction as far as the regulatory approach. If any regulation alters, impairs, or enlarges the scope of statutes, it is void. Mr. Heppler respectfully suggested that there is nothing wrong with saying no different standard of care, but if regulations enlarge the statute to go beyond the statutory boundaries, the Board may have some difficulty.

Ms. Schipske replied that this goes back to the premise that if, in fact, a physician is affiliated with an office, he or she should have an FNP, the Board should have them on record so the Board can enforce the law. She added that if there was a requirement that if a person is holding himself out as doing medical procedures, they have to have a FNP from the Board so people have somewhere to trace this back to, thus protecting the public.

Mr. Heppler said the FNP really serves that purpose. The purpose of an FNP is so the interested consumer can find out the physicians associated with the location.

Ms. Schipske said she did not think, as a Board, it has been made clear to physicians who have gone out and set up these businesses, that they are, in fact, still under the purview of the Medical Board and, as such, if the Board does enforcement in this area, it would start to weed out some of the people who have set up a corporation such as this.

Dr. Kojian said he has his own med spa in Garden Grove and is involved with other ones. He has brought up this issue of training with this Committee in the past three or four years. He asked what the requirements are for a nurse who is an ER nurse or an ICU nurse who wants to do esthetics now, and what is the threshold of training that needs to be met by that nurse to have that nurse capable and responsible in doing procedures in a medical spa? Medical procedures are done in a medical corporation. Medical corporations cannot be owned by a carpenter, they have to be under the auspices of a physician. Individuals who go outside of that law are illegally practicing and are subject to the enforcement. When he was advocating in the past for physicians or very advanced practitioners to train nurses, to take eight-hour classes and require a test after the end of the training, and very high parameters for training nurses, the response was in California the law states that you can perform brain surgery without being board certified in neurosurgery. Dr. Kojian questioned why the lowest standard of the law is being used to make the standard. What is the law regarding the competency and training of a physician or nurse in order execute these procedures?

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Mr. Heppler replied that it is a good question. The Medical Board has a universal license, so if an individual is licensed as a physician, he or she could essentially do anything under the guise of medicine. It is a standard of care issue technically. In some regards California relies on hospitals and their credentialing as sort of a policing mechanism therein. If a complaint was filed and an accusation followed it would get down to the battle of the experts as far as establishing the standard of care. He said that would have to be another fact specific inquiry.

Ms. Schipske said the BRN can answer questions related to any specific requirements for nurses. It is the same thing as a physician in terms of, once you have a license, then you can practice in any area that you want. It is up to the person to get the additional training, and the Board should not be directing what training is necessary.

Dr. Salomonson said, at this point in time, the administration of Botox and fillers is an integral part of plastic surgery residency. It is always a problem when new procedures come along. For example, for general surgeons, many were not trained in laparoscopic cholecystectomy, so should they forever be barred from doing it? No, they have to find a mechanism for training, and it is a dilemma on how they then upgrade to that level. At this point in time, lasers and Botox are an absolute core part of the curriculum for plastic surgery.

Dr. Bishop recommended the following language: "Any procedure which has significant likelihood as determined by the community standard of care of serious and immediate complication that may result in loss of life or limb must require continuous, immediate presence of the physician, and all other procedures must be performed in a facility that has a specific Board-approved action plan in place to address any unanticipated immediate, serious complication and all other delayed complications." He believes this statement addresses all of the issues.

A member said it sounds like the Committee is trying to find what the standard of care is but that is not its role. It needs to say this is the standard of care that has been developed by the body that is appropriate to develop it, and the Committee is going to hold everyone liable/accountable to that standard regardless of what the individual's degree is, and that the person has to have had appropriate training that has been documented, and under proper supervision through that documentation process.

Ms. Schipske said that the question might be, what is adequate training, and she does not know that anyone could define what adequate training would be. This Board does not define what adequate training is. When the Board takes disciplinary action against a physician, it is based on experts, but the Board does not define or specify what training must be received and hold that standard to physicians. The Committee would have to make that recommendation back to the Board.

Someone stated the law just says the Board shall adopt regulations regarding appropriate level of physician availability, not training and not anything else. In this regard, the Committee should limit itsself to that. They added thatwhat Dr. Bishop said addresses the law sufficiently.

Ms. Schipske said the difficulty is that the Committee, in its previous meetings has tried to come up with parameters related to availability, but if it says that someone has to be available, and they

are not competent, then there are questions raised about who can really do these procedures. The Committee can just say someone has to be available, but that is not necessarily correct.

An audience member stated the Committee was on the right track as far as training, if it could be articulated from the BRN and the Medical Board what constitutes adequate training. If the BRN requires training that would apply across the board related to what a nurse has to have to be adequately trained to pick lines and for life-saving techniques in a hospital. There are standards for that in a hospital, but not in medical offices. Maybe that is where the thrust of the action has to be. Maybe the BRN has to be more involved in this practice along the way.

Ms. Schipske said the BRN has been very actively involved, and they have issued letters to nurses regarding this whole issue about lasers and, again, just with the instruction that they should be appropriately trained, but no regulatory body sets what that training would be. She believes it would interfere with the practice of medicine and nursing, because it would be a regulatory body defining what they feel is adequate training. Ms. Schipske said she is licensed as an attorney, and she can practice any type of law. She cannot say she is a specialist in something, unless she has become a specialist, but she can practice in any area of law. The State Bar does not designate what constitutes sufficient training other than once you have come from an accredited school and you have your license, that is considered to be appropriate training. Consumer agencies are limited on what they can really direct.

Dr. Salomonson said this is not the first time the Legislature has put the Board in a position, such as in the case of the midwives, where the Legislature has said to the licensed midwives that they must have a physician to supervise them, but all malpractice carriers prohibit an OB/GYN from providing supervision. It is an inherent, unfulfillable requirement. The Board may have another mandate that may be very difficult to fulfill to protect the public; yet, the Board cannot mandate what the training is, because it typically relies on board certifications and the Board cannot require that. It is true that as the Board adjudicates a case, it does not matter what the training is, but what the physician did and whatever that community standard is.

Someone said this gets back to probably the worst thing a governmental, regulatory body could hear which is that there may not be a regulatory solution for this – it may be a free market solution, not unlike the one with OB/GYNs not being able to get malpractice insurance to supervise midwives. It would be odd if th Committee were to recommend to the Medical Board to designate special levels of training only for laser treatments when there are plenty of registered nurses, nurse practitioners, and physician assistants that are working at medical offices all over the state. It is an odd situation and goes back to being primarily political in nature. Unfortunately, the Medical Board has shown a bias in terms of its medical experts feeling that, unless somebody who is the supervising physician is also board certified as a dermatologist or plastic surgeon, he had no business being in a supervisory capacity to begin with.

Ms. Schipske said she thinks one solution that the Board can do is be more aggressive in its education and public outreach to the consumer. An informed consumer would probably request to see a physician for a good faith examination, if the consumer was educated about why they needed to do that. The Board needs to focus on education; it is not just about physicians, but about the consumer. Somehow, that needs to get back to the Legislature that this Board needs resources, so it is able to do that kind of education. An informed consumer would not tolerate some of the situations that everyone is concerned about. Ms. Schipske said she hoped that part

of the feedback to the Board and the Legislature is that the Board really needs to focus on education and perhaps the Board can develop some kind of literature that can be made available to the consumer expressing what questions the consumer should ask or should be concerned about. Consumers do not realize in many respects that these are medical procedures – they think it is a salon.

Ms. Schipske recommended a joint effort between the Medical Board and the Board of Registered Nursing to do a public education campaign that really does educate the consumer, explains the different roles, and explains that these are medical procedures and most of the time there is no problem, but a small percentage of the time there can be and they do need to make sure they have adequate access to somebody who can really take care of that problem.

Someone responded the Board, has done a fantastic job in terms of educating consumers. There are newsletters that were written as far back as 2009 which addressed these subjects. All physicians know that under the Moscone Knox-Keene Act, any medical corporation needs to be primarily owned by a physician. In addition, most physicians do know they are required to post a notice regarding how to contact the Medical Board if the public has a complaint about service rendered at that setting. These are all ways to go back and chase after the physician in charge. The bigger question for physicians who are in charge is where do they need to be when they are in charge. Can they be in San Francisco when somebody is having a procedure done in San Ramon? Can they be in Newport Beach when somebody is having a procedure done in Irvine? Those are the kinds of questions that need.

Mr. Heppler said he felt the Committee had finished with Question #4.

Ms. Schipske said she did not want to neglect how the Board might focus on the educational component. She teaches healthcare law at Cal State Long Beach and she had her students look at the Board's Web site and their assessment was that it is very good for the physician, but they are consumers and they could not navigate the site or know where to find the information. She hopes to be able to go through the Web site and find out where to get information and what is needed, particularly in multiple languages. Ms. Schipske met with a Vietnamese commander in Garden Grove, and they were concerned that they have physicians that they would like to report, but they do not feel they have a venue that they can do it because it is English-speaking people who answer the phone and you have to hunt on the Web site.

Someone replied their hope is that information on Botox and other information be available on the Web site and it is easy to find.

Ms. Schipske agreed that in consumers' use of the Internet, they look for a constant through the state regulatory agency. We need to make sure articles on laser and Botox are available. Staff agreed to check on where the articles are located or if they were removed. And, they will take this conversation back to the Board about the Web site and its functionality.

Ms. Simoes presented Question 5. Norman Davis spoke and represented many nurses and physicians who expressed concerns regarding this redefinition being discussed. He thanked Chairwoman Schipske for helping to identify the points of movement that this is broader than just esthetics. He was involved in 2006 with the first discussion of this with the Figueroa bill, and he was in on the roundtables when this was discussed. It was pushed to 2009 and now,

under SB 100, it is a 2013 date. He felt the Committee made more accomplishments on this day than has been made in the last several years in the matter of addressing the issue. It is broader than IPL or RF or anything else that might be introduced in esthetics. It deals with the overlapping relationships of nurses and physicians and it applies across the board.

Mr. Davis stated nurses have been accused of unprofessional practice and even charged with unlicensed practice of medicine for injecting Botox and Restylane as a dangerous drug without having a physician order or supervision of a physician. He has defended one of those nurses who is on probation for not performing a good faith examination and yet it was clearly not stressed four years ago when the complaints were first registered that that was even necessary. It is today and he certainly has advised all of his nursing clients to do that. But, people in the field ask where are the defining guidelines on scope of practice and why are these not applicable? As Dr. Kojian said, they want more definition about competency and supervision, but they do not want to be prohibited from functioning in an office just because the doctor is out of the office. There are hundreds of nurses that are still not doing these examinations. They do not understand what they can and can't do and some have felt that because they are saving lives every day in a hospital that they ought to be able to determine whether someone has hairy legs or not. He said he appreciates what this Committee is doing for the Board, and he appreciates their efforts in a legislative capacity. Nurses should be trained to do what they do and doctors ought to be responsible for the practice, even with the overlapping function with nurses involved. Doctors ultimately ought to be responsible for everything that happens. Somehow the Committee has to come up with something like the discussed definition that articulates the concern.

Someone said in reference to Question 5 that 60 minutes of access might be realistic in Sonora or San Luis Obispo, but in the metropolitan areas the infrastructure will not allow for predictable amounts of time to be specified by 60 minutes.

Mr. Heppler said it goes to more thinking about not proceeding with this because it calls out a difference in elective cosmetic procedures vs. anything else in that realm.

Someone said the whole prospect of trying to determine mileage or time, things like this should fall under medical judgment, good judgment in nurses, and it would be very hard to put into regulations. With the help of the National Plastic Surgery Society, the nation has been canvassed to see what other states have done and what other states that have tried. There is no magic number out there whether they use 25 miles or 60 miles, there are so many variables involved anytime you try to establish a parameter like that. It is very difficult to come up with a successful formula for the sake of patient safety and it comes down to some of the things that the Committee has discussed – it is the standard of practice. A physician has to use good judgment.

Mr. Furman stated, with respect to time guidelines, there have been many situations, for example, where obstetricians could not get to the hospital in Oakland by the time they were supposed to be there because of traffic somewhere. So these time deadlines and parameters are very common and would be helpful.

Mr. Davis stated many nurses do not understand that in esthetics you still are required to do a good faith examination. He said a good faith examination has been required for a long time. Botox has required a good faith examination by a physician of record and has been required for years, but nurses went into a training program and did not understand that this really applied to

them. He is seeing the enforcement now has been focused on one or two physicians in practices where they have come in and raided the place without looking at the severity. Isn't it better to have the BRN put out a stronger indication that good faith examinations apply to this and that nurses stand to be censored under unprofessional conduct if they do not do this. Even in a procedure like laser hair removal on the legs, it still requires skin testing, etc., and you still have to do it whether it seems like a minor procedure. He agrees all nurses who are practicing in California that are doing procedures without a good faith examination are held to that responsibility.

Ms. Schipske said that in many ways the medical profession has treated esthetics as not medical. The marketing that goes on to nurses by physicians does not portray the procedure as medical. So nurses have not understood because it is viewed as a way to make some additional money, but it was not taken seriously as a medical procedure by physicians who employ nurses, who say they can put five nurses on here to go out and do Botox and laser and different things because it has not been considered medical procedures. It has always been a requirement that for a nurse to administer a medication you have to have a doctor's order. It has nothing to do with whether it is Botox or Restylane. If a nurse is administering a medication, they have to have a doctor's order and also have to have had a good faith examination done, backing up whether or not that particular medication is necessary. That has been put aside in this arena for money. People had a blind eye looking at this until it went to the Legislature. There are requirements for every medical procedure. It is either a medical procedure or it is not. If the administration of Botox is a medical proecudure, then apply the standard that goes for every medical procedure. For those who have said it is not, that is where the problem arises. That is where the nurses are going to get in trouble because they do not view it this way. They can run Botox parties, and some of the nurses are getting the medications direct from the pharmaceutical companies. They are not getting them through physicians

Mr. Heppler stated that the law now says appropriate prior examination, not good faith anymore, when it comes to prescribing.

Ms.Warren said that if everyone just stuck to their scope of practices and function as they are supposed to, there be these problems. Sh knows what her scope of practice is as an RN, and she is not supposed to administer medication without an order from a physician. It is not just medi spas or dermatology offices, it is any office.

Ms. Schipske asked Mr. Heppler if it would be permissible for the Committee to recommend to the Board to require standardized protocols to be available in all settings.

Mr. Heppler replied that since there was not a quorum present, he can offer as staff, to bring that to the Board's attention.

Ms. Schipske said that might be another avenue whereby the Committee could resolve the situation. It would be up to the education and background of the physician or the nurse to work those protocols out without the Committee specifying what needs to be in there. She understood this to be a requirement for physician assistants.

Dr. Barnard said dermatology is largely visual and he would prefer to see the patient face to face. He wanted to make it clear that he thinks it is a mechanism/forum for making everyone happy –

the patient is getting good care, the provider will have the evaluation and consultation and there has to be a relationship between the responsible physician and the patient.

Ms. Schipske stated Questiion 6 is a moot point in terms of Question 5.

Agenda Item 6 Discussion of Next Meeting Agenda and Possible Dates and Locations
Mr. Heppler advised the Chair that she might ask if there are any comments on Question 6.

Ms. Schipske asked if there were any comments on Question 6. There were no comments on this item.

Ms. Simoes said she did receive public comment from Bill Barnaby on the future agenda items. He represents the California Society of Anesthesiologists and is asking that the issue of physician supervision of certified nurse anesthetists be placed on the future agenda.

Ms. Whitney commented that she thought the next Committee meeting needed to be sometime in June or early July and asked the Committee members to please email Ms. Simoes with dates that will not work for them. She stated it is very important that the Committee continue the process as there is a specific date that the Board needs to get back to the Legislature. She added that it may not be the regulations that they may be expecting, but the Board needs to get back to the Legislature with the progress on this item. Ms. Whitney requested an off-cycle meeting and the Committee could report to the Board at the July meeting.

Ms. Schipske stated she felt they had a robust discussion and agrees that they have focused much more specifically on what can and cannot be done than has been accomplished in the past. That will be helpful as the Committee goes forward in order to make a recommendation to the full Board and to the Legislature. She thanked everyone for being there and for coming to Long Beach.

Agenda Item 7 Adjournment
There being no further business, the meeting was adjourned at 12:27 p.m.

DRAFT

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MEDICAL BOARD OF CALIFORNIA
Executive Office

MEMORANDUM

DATE	July 6, 2012
TO	Members, Committee on Physician Supervisory Responsibilities
FROM	Jennifer Simoes Chief of Legislation
SUBJECT	**Proposed Physician Availability Regulations**

Members, this memo provides information regarding proposed regulations relating to the availability of a licensed physician when lasers or intense pulse light devices are used to perform elective cosmetic procedures. As you may recall, the Committee on Physician Supervisory Responsibilities (Committee) met in Long Beach earlier this year and had a robust and animated discussion about the availability of physicians when elective cosmetic procedures using laser or intense pulse light devices are performed.

BACKGROUND

By way of background, subdivision (c) of section 2023.5 of the Business and Professions Code provides:

> "(c) <u>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</u>. 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." (Emphasis added.)

The purpose of regulations is to implement, interpret or make specific laws enforced and administered by state agencies. (See Gov. Code, § 11342.600.) Regulations have to meet certain standards to be approved by the Office of Administrative Law, and those standards are: necessity, authority, clarity, consistency, reference, and non-duplication. When exercising its regulatory function, protection of the public shall be the highest priority of the Medical Board of California (Board). (See Bus. & Prof. Code, § 2001.1.)

With that backdrop in mind, let's turn to four regulatory proposals to implement the provisions of section 2023.5 that the Committee may wish to consider. Please note the January 1, 2013 deadline for adopting regulations on this subject. It is anticipated that the Committee will select a proposal and recommend to the Board that the selected proposal be set for a regulatory hearing. Such action will be necessary if the January 1, 2013, deadline is to be met.

REGULATORY PROPOSALS

1) *Community Standard Proposal.* "Whenever an elective cosmetic procedure involving the use of a laser or intense pulse light device is performed by a licensed health care provider acting within the scope of his or her license, a physician shall be available to the provider in accordance with the standards for the community in which the procedure is being performed."

Please note that this proposal may not be consistent with the clarity standard as it would vary depending on the location. Additionally, the standard of care in a disciplinary proceeding must be established by an expert. A physician who consults the regulations for guidance would not necessarily derive the needed information; he or she would need to go further.

2) *On Premises.* "Whenever an elective cosmetic procedure involving the use of a laser or intense pulse light device is performed by a licensed health care provider acting within the scope of his or her license, a physician shall be physically present on the premises where the procedure is being performed throughout the duration of the procedure."

This is a location based requirement. Please note that the physician could be involved with other patients or otherwise engaged but yet still on the premises. The concern with this standard is that it may be too restrictive as certain health care professionals working within their scope of practice under standardized procedures or delegation agreements would not require a physician on the premises.

3) *Physically Present and Immediately Available.* "Whenever an elective cosmetic procedure involving the use of a laser or intense pulse light device is performed by a licensed health care provider acting within the scope of his or her license, a physician shall be immediately available to the provider. For the purposes of this section, "immediately available" means physically present, interruptible, and able to furnish assistance and direction throughout the performance of the procedure but without reference to any particular physical boundary."

This proposal is similar to the federal Centers for Medicaid Services regulation but that rule is not specifically aimed at elective cosmetic procedures. The Committee, when considering this proposal or proposal 2, may wish to further define the term "premises" as there may be some uncertainty as to whether "premises" means room, suite, office, complex, or other area. Again, the concern is that this standard may be too restrictive as certain health care professionals working within their scope of practice under standardized procedures or delegation agreements would not require a physician on the premises.

4) *Not Physically Present but Immediately Available.* "Whenever an elective cosmetic procedure involving the use of a laser or intense pulse light device is performed by a licensed health care provider acting within the scope of his or her license, a physician shall be immediately available to the provider. For the purposes of this section, "immediately available" means contactable by electronic or telephonic means without delay, interruptible, and able to furnish assistance and direction throughout the performance of the procedure but without reference to any particular physical boundary."

This proposal allows the physician to be remote from the location from which the procedure is performed.

As mentioned above, whenever the Board exercises its regulatory function, protection of the public is its highest priority. The Committee may wish to revise or amend these proposals.

RECOMMENDATION

Staff recommends that the Committee focus their discussion on either option 1, the community standard proposal, or option 4, the not physically present but immediately available proposal, or possibly discuss a hybrid option that combines option 1 and 4. These options seem to be most in line with the discussion at the previous committee meeting that included input from committee members. Once a decision is made, the regulatory proposal agreed upon by the Committee will need to be presented to the full Board for review, approval, and to set it for regulatory hearing.