



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.

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.

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.

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.

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

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.

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.

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

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 be 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 if 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?

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 not 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 that she 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

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?

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 itself to that. They added that what 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 the 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 procedure, 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. She 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 med 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 Question 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.