MEDICAL BOARD OF CALIFORNIA
Executive Office

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

January 27, 2011

Embassy Suites – San Francisco Airport
Mendocino/Burlingame Room
150 Anza Blvd.
Burlingame, CA 94010
650-342-4600

MINUTES

Agenda Item 1: Call to order - Dr. Moran
Dr. Moran called the meeting to order at approximately 10:30 a.m.

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

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

Staff of Committee:
Jennifer Simoes, Chief of Legislation

Medical Board Staff:
Susan Cady, Manager II, Enforcement Program
Silvia Diego, Board Member
Shelton Duruisseau, Ph.D., Board Member
Catherine Hayes, Sacramento Probation Unit
Kurt Heppler, Legal Counsel

Breanne Humphries, Licensing Program
Teri Hunley, Manager, Business Services Office
Diane Ingram, Manager, Information Systems Branch
Jennifer Kent, Board Member
Craig Leader, Sr. Investigator, Pleasant Hill
Sheronnia Little, Information Systems Branch
Ross Locke, Business Services Office
Reginald Low, M.D., Board Member
Natalie Lowe, Enforcement Program
Armando Melendez, Business Services Office
Regina Rao, Business Services Office
Leticia Robinson, Licensing Operations
Victor Sandoval, Supervising Investigator, San Jose
Kevin Schunke, Manager, Licensing
Anita Scuri, Department of Consumer Affairs, Supervising Senior Counsel
Laura Sweet, Deputy Chief of Enforcement
Kathryn Taylor, Licensing Program
Cheryl Thompson, Executive Office
Renee Threadgill, Chief of Enforcement
Linda Whitney, Executive Director
Curt Worden, Chief of Licensing
Barbara Yaroslavsky, Board President
Frank V. Zerunyan, J.D., Board Member

Audience
Zennie Coughlin, Kaiser Permanente
Norman C. Davis, Esq.
Julie D'Angelo Fellmeth, Center for Law in the Public Interest
Stan Furmanski, M.D.
Dean Grafilo, California Medical Association
Daniel Leacox, Greenberg Taurig, LLP
Kathleen McCallum, NCANA
Jennifer Morrissey, Aesthetic Accreditation Agency (AAA)
Carlos Ramirez, Senior Assistant Attorney General
Tom Riley, CA Society of Dermatology/Dermatologic Surgery
Paula Rood, AAA
Reham Sheikh, Member of the Public
Rachel Wachholz-LaSota, Inspector III, Cerritos

Agenda Item 3: Approval of Committee meeting minutes of October 20, 2010 – Dr. Moran
Mr. Heppler noted a correction was needed to the minutes — agenda item 8, page 60 of the packet, regarding the industry Mr. Riley represents. Mr. Riley made the correction that he represents the California Society of Dermatology and Dermatologic Surgery and not the Society of Dermatologic Surgery.

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

Agenda Item 4: Public Comment on items not on the agenda
No Public Comment.

Agenda Item 5: Discussion on the responsibility that physicians have in supervising affiliated health care professionals – Dr. Moran and Mr. Heppler
Dr. Moran reminded everyone that at the last meeting other licensing boards and interested parties were heard on the scope of allied health care professionals that are supervised by physicians. She explained this meeting's focus is on the issue of physician responsibility from the perspective of the Medical Board. Dr. Moran directed everyone to a handout on the back table to help guide the discussion about physician responsibility when supervising various allied health care professionals. Dr. Moran stated there is a fairly clear description from the Physician Assistant Committee and nurse practitioners about what physician supervision involves, how many practitioners a physician can supervise, and under what setting. Dr. Moran noted there needs to be clarification regarding physician supervision of registered nurses and other nursing professionals. Dr. Moran stated that at the last Board meeting, it was determined a doctor-patient relationship must be established by an appropriate medical exam before any dangerous device or drug is prescribed and administered by a registered nurse.

Dr. Moran reiterated that only after a physician and patient relationship is established can the patient be treated by a registered nurse. Dr. Moran also stated there is an exception, clearly defined in the law, where in "free clinics," a nurse can dispense drugs without the physician first seeing the patient. Dr. Moran clarified that this is not allowed in a commercial medical clinic. She noted it is very clearly defined in law that nurse practitioners and physician assistants can treat patients without that prior exam being done by the physician.

Dr. Robbins asked if a prior exam is done by a nurse practitioner or physician assistant, is the patient still the ultimate responsibility of the physician, and is the physician liable for that patient.

Dr. Moran responded that the physician has the ultimate responsibility for the care of the patient, but there is a clear definition that this can be delegated to a physician assistant or nurse practitioner.

Dr. Moran stated the questions today are:

- What is appropriate supervision?
- What is the physician's responsibility after that?
- Does the physician need to be on site?
- What training does the nurse need to have?
- What insurance does the physician need to have over the practitioner as to ongoing competence and control?
- How far away can the physician be if he or she is not on the premises?
- What kind of communication would be appropriate?
- Can the physician be out of state?

Dr. Moran asked Dr. Kilmer to address some of the concerns found in working with the different dermatologic societies and their legislative efforts. Dr. Kilmer stated she has worked with the American Academy of

Dermatology, the American Society of Dermatology Surgeons, and the American Society for Lasers and Surgery. Dr. Kilmer explained that if the doctor was not on site, it was difficult to make clear what was required. For example, can he or she respond in five minutes? Does that mean respond by phone or does it mean to show up? In most cases, it has always been that the doctor had to be on site, so someone is there if an issue did occur. Dr. Kilmer explained it had to be clear what responding meant and clear documentation as to what supervision really means.

Dr. Moran commented that she believes the physician assistant and nurse practitioner regulations are very clearly described; however, there needs to be an assurance of competency. Dr. Moran added it does not matter if the doctor is on site or in another state if the person is not competent. Dr. Kilmer agreed and reported the other big issue is "where does the supervising physician have to be in order to be able to supervise that particular activity?" Dr. Kilmer also commented that she felt that the physician should be supervising procedures within his/her primary practice of medicine. Dr. Moran stated this is clearly defined in the physician assistant laws.

Ms. Scuri wanted to clarify that they are talking about practices that are physician owned, whether it be a professional medical corporation, a medical group, or some other form of organization owned by physicians. Ms. Scuri stated many of them are not physician owned, which is a different issue. Ms. Scuri added that no amount of supervision is going to legitimize the unlicensed activity of medicine.

Dr. Moran asked Mr. Heppler to define and describe what is appropriate under what circumstances – regulation vs. legislation?

Mr. Heppler commented there are five gray areas/zones the Committee is contemplating, such as: 1) the qualifications of the supervising physicians, 2) the accessibility, 3) proximity of the supervising physician, 4) geographical limitations, and 5) competency or training of the person performing the procedure. Mr. Heppler continued that the purpose of a regulation is to implement, interpret, and make specific the statutes and the corresponding test for judicial validity or review of a regulation. The questions to ask are: Is it consistent and not in conflict with the underlying statute and is it reasonably necessary to effectuate the purpose of the statute? The scope of a statute cannot be enlarged or restricted by regulation because the relationship is inverted.

Ms. Scuri concurred with Mr. Heppler and pointed out that in situations where the legislature has wanted a physician to be practicing in a specific area, they have said so in the statute. Ms. Scuri agreed the better course of action may be a statutory change consistent with other requirements for mid level practitioners.

Ms. Schipske commented that the Board does not license to specialty. The physician can practice any type of medicine he or she wants, so how will it be possible to legislate the physician can only supervise what he or she does?

Dr. Moran stated that is a conundrum and believes it is beyond the scope of the committee. The physicians may have not been initially trained in that field; however, they could become very well qualified and certainly supervise someone else. The goal of supervision is to ensure patient safety. If something is going to be delegated to others, the physician must know how to tell them to do it safely.

Dr. Moran stated we still have to address the supervision issue. There cannot be a patient-physician relationship with the physician never meeting the patient. Physicians who are supervising allied health professionals need to know that, with the exception of physician assistants and nurse practitioners.

A committee member reported there are instances where physician assistants and nurse practitioners are doing all the work in worker's compensation practices without the physician being in the office. Dr. Moran agreed it is a global problem that is going to become larger, which is why this committee is so important.

Ms. Schipske brought up the issue of telemedicine in regard to competency and supervision.

Dr. Moran stated the results of the committee should serve a much larger goal of ensuring patient safety by answering the questions of what constitutes supervision and what kind of competency do you want to ensure?

Ms. Schipske remarked the two big issues are: How do we decide where the doctor has to be and what constitutes the ability of a doctor to supervise in a particular field?

Dr. Robbins reminded everyone that we are talking about elective procedures.

Ms. Schipske repeated her concern about putting restrictions on physicians who are practicing elective procedures when we generally license physicians without limitations. Ms. Schipske suggested we have legal counsel answer this concern. Ms. Schipske added, as a nurse practitioner, she receives numerous ads for recruitment and the med spas are not being run by physicians, and she felt this is the bigger problem.

Dr. Moran stated these are all important issues, but today she would like to focus on coming up with a general direction on the issue of supervision. She added this type of medicine is being exploited and the committee should get a general direction on what should be the level of supervision.

Dr. Moran asked what the level of definition of supervision should be with respect of to availability of the physician.

Dr. Salomonson noted the physician and patient need to have an established relationship so the patient knows the physician. She suggested the supervising physician be within 30 minutes of phone contact and physical patient follow up within 24 hours. If there was a problem, this would be adequate supervision. Dr. Salomonson stated those would be her general parameters of adequate supervision.

Dr. Moran noted if that physician is not available, obviously, he or she would have an on-call person available.

Dr. Phinney stated that an appropriate level of supervision depends on exactly what it is you are doing. If you are doing physical exams that require a different level of supervision than if you are doing some procedure that requires specialized training and ongoing demonstration that you are good at it.

Dr. Moran asked if a registered nurse could do a physical examination.

Ms. Scuri replied a registered nurse can do an assessment. That is the term used. She also commented you

would want a physician available within 30 minutes if you are doing one thing, but much more available, depending on what you are delegating the allied health care professional to do.

Dr. Salomonson stated that assuming the physician has the qualifications to be doing these procedures; she believes 30 minutes is too long and feels immediate electronic contact is essential. To be performing an invasive procedure and not have a physician available should not be done.

Dr. Salomonson commented on prescriptions being written for Botox and other injectables. There should be a specific order, which she does not believe is common practice in medi spas. The registered nurse could be alone and giving an injectable, but it still needs to be prescribed by someone.

Dr. Moran stated there is an establishment of standardized procedures and protocols that registered nurses follow and would cover most situations.

Ms. Schipske stated when nurses are allowed to give medications and/or insert devices, they should have to have a medical diagnosis; for example, that is the diagnosis, this is the treatment, and this is the protocol for it. Nurses are using a prescribed injectable, but where is the connection with the physician or practitioner. The first part of supervision and having standardized protocols is there should be the requirement that the supervising physician must verify a demonstration of competency by the person performing the procedure. The crux is twofold. One is the connection between medical diagnosis and using prescribed medication and how that has to be clarified and the other is whoever is supervising, there should be a requirement that they have verified this person's competency before they allow them to perform the procedure independently.

Dr. Moran stated some laws are already in existence. For example, the requirement of an appropriate prior examination is already in law. If you try to pass legislation that says you have to do that, it often gets dismissed as redundant, repetitive, and not necessary. There is already a requirement within the Board of Nursing and the Medical Board that the standardized procedures verify some sort of competence or assume there is a delineation of what is done under what situation. The gaps may need to be identified in legislation. One gap may be how far away the physician is and what defines supervision? Perhaps we need some sort of additional requirements for verification of competency. Another stipulation missing is that delegation is the usual and customary, not how much training or what certification you have. It does have to be the usual and customary.

Dr. Salomonson said that her 30 minutes is the standard available to a hospital patient – the physician driving from hospital A to hospital B. Personally, she would be reluctant to delegate something that could not be managed for 30 minutes without her at least getting to the phone.

Dr. Phinney said that different procedures have different levels of risk and the suggested approach to set the bar high enough to cover the maximal risk would put many physicians in a place where the level of supervision required is not appropriate to what is being done. He suggested a more general statement, such as the availability of the supervising physician needs to be appropriate to the risk involved in the procedure. Although this is open to interpretation, no physician he knows would take on a risk he or she could not manage.

Dr. Robbins stated he would like to amplify what Dr. Phinney was saying regarding significant or non-significant risk. There is a risk with any of these procedures, and nothing has been said about the necessity of

informed consent being given to the patient who is going to receive Botox or any other medical spa procedures. Any conclusions we come to have to be procedure based and we should concentrate on that.

Dr. Moran replied that there are requirements in the law about informed consent and stated she believed nurse practitioners and physician assistants can give informed consent. When a physician is delegating a procedure to a registered nurse, then informed consent must be provided.

Ms. Whitney suggested the committee research what has been established in protocols and procedures in other facilities and gather information throughout the United States to see what exists in order to see the broad picture.

Dr. Moran asked Dr. Kilmer, "in the legislation her group proposed, what were the specifics?" Dr. Kilmer responded that they talked about a five minute response, whether by phone or the ability to get to the facility. Dr. Kilmer also recommended the supervisor should have some expertise in the field and especially be able to handle the complications that may occur. She stated 30 minutes is alright, with the caveat that if there is an immediate problem, the appropriate specialist or emergency service is called. Dr. Kilmer stated, because things can happen when you do a procedure often enough, the supervisor needs to be able to respond immediately. Dr. Moran stated, hopefully that has been relayed in the practitioner's training, and a supervising physician needs to be there immediately.

Dr. Moran stated electronic communication is very important in that regard, and suggested the supervisor should be available within 30 minutes. She asked if that seemed reasonable to everyone.

Dr. Moran suggested the stipulated 30 minutes could be a problem and sometimes not appropriate; however, if the supervisor cannot be there in the 30 minutes, then there should be somebody else designated who is qualified and immediately available. Dr. Moran also noted more mid level practitioners will be taking the place of medical doctors because of the health care crisis. It is important to focus on putting safety measures into place, and the enforcement of existing laws is an ongoing issue. There are some gaps and one of them is supervision of registered nurses.

Ms. Schipske suggested the difficulty is not with mid level practitioners because they operate under standardized protocols, whereas registered nurses do not because they are not advanced practice. She also suggested requesting an opinion from the attorney general on whether registered nurses can administer Botox and perform laser procedures.

Ms. Scuri commented if the Board chooses to request an opinion from the attorney general, the question needs to be framed and your own legal counsel has to provide an answer first. It will then take over a year to get an answer. Ms. Scuri added if you get a legislator to ask for an opinion, that might be a little faster, and you do not have to have your own legal counsel's opinion. There are some rules on seeking attorney general opinion. Dr. Moran stated her concern is with the ablative lasers. She knows a lot of registered nurses are doing ablative lasers and is not sure if that is legal.

Dr. Moran stated another concern is whether or not the physicians supervising the nurses understand their responsibilities, and is there a need for further clarification. She stated we are off to a good start if we were to

specify in law that there must be immediate electronic contact. She asked if there is a ballpark sense of physical availability and is 30 minutes for physical availability sufficient with a delegated physician available in case of an emergency.

A Committee member stated that a time frame would be ideal in a perfect world, but we do not live in a perfect world. Doctors need to define what happens in their office and be responsible and accountable for it. There needs to be protocols all the way down to calling 9-1-1 to handle emergencies. A lot of the statutes are addressing that. Mr. Heppler clearly described them in two meetings. It will be hard to make them better as far as a physician's scope of practice and changing the statute as to scope of practice; how can you define competency and training? It will be an incredible task to come up with a definition that really fits well with everyone and works in the real world.

Dr. Moran stated when it comes down to it, if you are delegating a procedure that is potentially dangerous; someone needs to be available immediately. There needs to be someone who is qualified as a surrogate who is immediately available if the physician isn't. Otherwise, the procedure shouldn't be done.

A Committee member stated that anytime a procedure is done that has a certain risk, the greater the risk, the more availability there should be. Telemedicine is done and it works to some degree.

Another Committee member stated, as a physician you can do what you want, but physicians can only supervise people in what their usual and customary practice is. If a physician does not typically practice laser or inject Botox or perform skin cancer surgeries, then a physician should not be supervising anyone else doing those procedures.

Dr. Moran stated she thought that definitely goes to the point of the qualifications of a supervising physician. To close the loop on availability, there needs to be a consensus in order to move forward. As Ms. Whitney said, the Committee should look at some of the other things that have been written.

A Committee member stated that the language could be beefed up to say something like it is the responsibility of the physician who is delegating the task to demonstrate an appropriate availability to handle complications, which would be better than picking out a time frame

Dr. Moran stated she knows of several examples where complications are sent to the emergency room or are sent by a nurse to another specialty, i.e. dermatology. There have been many patients lasered in a medi spa and the supervising physician has never seen the patient. This should not happen and we need language to send that point home. As a supervising physician, it is the physician's responsibility to see that patient, make sure the practitioner is competent, and take care of any complications that occur.

A Committee member proposed adding language that says with a complication, the physician must respond within 30 minutes and appropriately triage that patient as to what needs to be done. Dr. Moran stated that gets back to immediate availability electronically to communicate and the physician assumes the full responsibility for any complications that occur and should react appropriately to the level of severity.

Dr. Bruner reminded everyone that because of rapidly changing technology with telemedicine, many changes are occurring, and whatever is decided may be influenced by these changes.

Dr. Moran summarized what has been said – the appropriate level of availability would be that the supervising physician is available electronically and takes full responsibility for any adverse outcomes within an appropriate period of time, depending on the severity of the event.

A Committee member inquired of Mr. Heppler: how much of what Dr. Moran said is already in statute?

Mr. Heppler responded that from an administrative perspective, it is inherent in the regimen now. If a physician delegates something, ultimately the physician is the responsible person. What is not in statute is the immediate availability. Mr. Heppler continued that the committee is substituting a statutory level of care for the individualized basis that the medical experts do in our current proceedings. The Committee is essentially contemplating, in an individualized case by case analysis of what is appropriate standard of care versus informed consent procedures that say the standard of care is this and this; however, there is an alternative mechanism for the committee to accomplish what it wants to accomplish. If there is a disciplinary case being reviewed akin to what you are doing here, it would be more effective to identify and adopt that as a precedential decision, meaning every time this particular set of facts came up, the Medical Board could say that issue has come up before, and here is what we think. It is not binding on the standard of care, but it would be binding in the sense that the Medical Board and the Administrative Law Judges would follow that decision. Mr. Heppler stated he wanted the committee to be aware they are substituting one standard of care, which may be warranted, but also the possibility of an alternative mechanism.

Dr. Moran stated she appreciates the comments; although, for those who practice responsible medicine they may seem ridiculous. These are obvious standards of care, but they are not having the impact they should, so that is the reason for this conversation; we have to do something more.

A Committee member asked if it is just that the Board is not enforcing existing law, and how does the Board facilitate enforcement?

Ms. Scuri stated it does not necessarily involve the Medical Board, but there are some provisions in B&P Code section 17200 on unfair competition, and there are district attorney offices that will handle unfair competition cases. If we diverge from the assumption the medical practice is owned by a physician, but in situations where medical practices are not owned by physicians and they are not subject to the requirements of the licensure and the burdens of licensure, it is an unfair playing field, and that is what B&P Code section 17200 is intended to address. District Attorney offices can file both criminal and civil unfair competition cases. There is incentive for them to take these types of cases where a medical spa is not owned by a physician or physician group, because there are penalties attached and they get a share of those penalties. The Medical Board has priorities set in statute, and unlicensed practice is not one of those priorities.
Dr. Moran commented that Operation Safe Medicine was enacted in order to elevate the unlicensed practice of medicine and asked what the status is for that program.

Ms. Whitney explained the augmentation put forward to extend the pilot program, which ends July 1, was disapproved by the prior administration. Ms. Whitney noted she will report tomorrow that the Board is putting

forth a "Spring augmentation request" to put the program into place permanently because of the harm that can be caused to the public without that office in place.

Dr. Moran stated this goes back to why we are here and what are the best strategies. Dr. Moran's philosophy has always been that some physicians who are violating the law do not realize it. One of the Committee's efforts should be to communicate to physicians these are medical procedures, there are risks involved, and that they are in violation of the law. The Committee could do this through the Newsletter, direct mail, public relations, or maybe get the newspaper involved. Dr. Moran suggested focusing on two things: A supervising physician cannot be supervising procedures that are not part of his usual and customary practice and he or she must be immediately available electronically to deal with any adverse outcomes.

A Committee member questioned the use of the word "immediate," and the unintended consequences of stipulating in a regulation a term that is not always realistic and which could open up a floodgate of litigation.

Dr. Moran asked if a phrase such as "must be available" is what he had in mind.

The member stated he would have to work with the wording, but he was uncomfortable with the word "immediate."

Ms. Grivett commented on an earlier statement about precedence. She stated her concern is that most of the relationships between a physician and registered nurse have been in a hospital setting. She commented that in the presentation from the Board of Registered Nursing, it was voiced very specifically that nurses are independent practitioners, and they are not supervised by physicians. The immediate attention to a complication with a nurse is traditionally in a hospital setting where someone is generally available. Ms. Grivett stated her concern is the physician and registered nurse relationship has not been dealt with in any other setting outside of a hospital. She believes the setting is the struggle for everyone.

Dr. Bruner responded that Ms. Grivett has a good point; however, he is concerned about trying to define a medi spa. He asked the committee to seriously consider defining a medi spa, and remarked that any time you use the word "medi" or "medical," that is a medical entity in his mind. He stated a lot of medical and surgical entities are well defined, and he would like to see the committee entertain the thought of trying to define, for the public, that these are a medical entity, then maybe we can protect the patients a little better.

Dr. Moran agreed and maybe it could be put on the agenda for next meeting when there is the discussion about corporate practice of medicine.

A Committee member stated she thinks the definition of supervision will meet opposition with physicians, as it did with supervision for midwives. She stated the issue of supervision is usually worked out between the

provider and the nurse. She further stated there is a lot of resistance about the Board defining what constitutes supervision.

Ms. Scuri stated she did not think it was so much resistance, as an inability to factor in all the potential variables. Ms. Scuri continued that, depending on the type of setting, and midwives are practicing generally in

the obstetric gynecological area, and even given that limited area, they still could not reach agreement on what was appropriate supervision. Appropriate supervision is determined as it is determined in the medical area by the testimony by experts what is the standard of care? The standard of care relates not just to the performance of the procedure, but also to the supervision that is occurring over someone who is performing that procedure, as Mr. Heppler indicated.

Dr. Moran asked if a requirement for a physician assistant and medical doctor is specified.

Ms. Grivett stated it is "available by electronic means," but it does not say immediate. Ms. Grivett said it is interpreted in different settings, but for a physician assistant to be practicing, the physician needs to be immediately available, and if that means a lay person is communicating while the doc is in surgery, that is sufficient because they are available.

Ms. Schipske stated that a nurse practitioner has the same requirements; it is just by agreement in the protocols and with the arrangements between the practitioner and the physician. Ms. Schipske explained it is the registered nurse who does not have those protocols, and that is the difficulty.

Dr. Moran stated that the Board of Registered Nursing said there were standardized protocols in place, and that this is part of the practice. It was next suggested that the mid-level practitioner gets a different set of protocols than a registered nurse would, and outside the clinic and hospital setting, they have a Policy and Procedures Manual. They do not have standardized protocols that have been worked out with administration and physicians. Ms. Grivett stated this is because they do not have that relationship with the physician.

Ms. Grivett stated a nurse is doing the nursing care and a physician is doing the medical care, which is traditionally not a collaborative team approach.

Ms. Schipske stated when you function as a mid-level practitioner, you are in a different professional relationship with that provider.

Ms. Grivett added, as a physician, you are writing an order for that procedure to be done, but you are really not supervising that procedure. There is a protocol and if there is an outflow from that protocol, the physician will be contacted.

Ms. Schipske stated we have basically allowed registered nurses to act as nurse practitioners or physician assistants without saying anything and just letting this all occur. Ms. Schipske continued that she thinks this comes because there is no separate law for nurse practitioners. They are under the Nurse Practice Act, as well as the registered nurse, and this is the dilemma. Other states have separate laws, but nurse practitioners are under the same scope of practice as if they are a registered nurse and not a registered nurse practitioner.
Ms. Scuri commented that existing law (B&P Code section 2725) does recognize the existence of overlapping functions between nurses and physicians in that sense. She added that is where standardized procedures come in, and those can be used by registered nurses and are not restricted to advance practice nurses. Ms. Scuri also commented that someone who is not a physician, but who has a license, is by definition a mid-level practitioner. The law does not distinguish between a registered nurse, a physician assistant, nurse practitioner or licensed vocational nurse, and there are others who fit into that category.

Ms. Grivett suggested making the same statement as before, but instead of starting with supervising physician, use "treating physician", or "responsible physician", or "physician of record" — it could be any of those.

Dr. Moran asked if there is an issue to using the word supervising with respect to doctors and registered nurses, and can that word be used?

Mr. Heppler stated his opinion is not so much the nomenclature, it is actually the act.

Ms. Scuri stated Ms. Whitney has offered to bring back what other models exist for this sort of a situation and suggested deferring the final decision until after the benefit of research.

Dr. Moran stated she thought the committee had accomplished the goal of identifying certain goals that they would like to have; the doctor needs to be experienced and able to supervise whatever he is delegating, and the doctor needs to be available and do the current standardized protocols needed to be more clearly defined.

Ms. Scuri stated she served as counsel 16 years ago to the Board of Registered Nursing and she remembers there is a requirement for some sort of a joint agreement between the Medical Board and the Board of Registered Nursing, as to what components need to be included in standardized procedures. It is a very brief regulation. It says that a physician and surgeon or a podiatrist who collaborates in the development of standardized procedures for registered nurses, shall comply with title 16, sections 1470-1474 of the Nursing Practice Act governing development and use of standardized procedures. The Board has placed into its regulations the requirement that a physician who collaborates on developing these standardized procedures has to comply with what the Board of Registered Nursing has. This could be a future agenda item.

Dr. Moran asked if the Medical Board could stipulate how the physician makes sure the nurse is qualified. How do you ensure competency of the nurse you are supervising and is that something we as a board can stipulate?

Ms. Scuri stated if you look at those BRN regulations, it might give you some ideas, because I think some of that is already covered in those particular regulation sections.

It was stated that one of the simplest things to do to fix this problem would be to educate all the medical doctors of what they are allowed and not allowed to do; they can only supervise four nurse practitioners or physician assistants; and physicians can only supervise what they customarily practice.

Dr. Moran talked about focusing more on an education campaign to educate physicians and patients as to the requirement of an appropriate prior examination and the standard of care. Perhaps legislatively requiring that supervising physicians be competent in what they are supervising.

Dr. Moran noted that the standard of care would certainly dictate that if physicians are going to supervise something, the physicians must know what they are doing, and that they must do a prior examination before the physicians can supervise a nurse and delegate the treatment. This is basically the definition of the practice of medicine and would really eliminate a lot of the risk and danger that is happening.

Ms. Schipske stated maybe it should be posted in a facility that the patient should have had an examination by a physician.

Dr. Moran suggested putting the Notice to Consumers sign in the medi-spas.

Dr. Newman stated that the California Society had submitted, at a previous meeting, a 10 bulletin point Bill of Rights for patients entering medical spas, which included that patients would be informed who their treating physician is, and he would be happy to resubmit it for the committee to look at.

Ms. Schipske suggested staff get some samples of the protocols from other entities, and that UC Davis has a great set of protocols for nurse practitioners, which says in them that the person who is performing the procedure shall have demonstrated their ability to perform the procedure and their level of training.

Dr. Moran reiterated the qualifications of the supervising physician is that they are qualified and the procedure is part of their daily practice and the supervising physician be immediately available, which may need to be put into law, even though it is the standard of care. Dr. Moran stated a future agenda item would be to brainstorm some ways that a public information campaign and campaign for physicians as to what their responsibilities are. There are a lot of good laws in place, and physicians just need to be reminded about their responsibilities, which may clear up the problem.

Ms. Schipske added the definition of a medi spa by the Board, because the assumption by the public is if someone is going to a medi spa, it is like a medical practice.

Ms. Grivett suggested also working with the Nursing Board to educate registered nurses.

Dr. Robbins asked to address this under advertising and marketing. There are requirements for physicians to have their name posted in a certain sized font where he works, so why not have a flyer with the physician's name on it in the medi spa or health facility, which with the physicians knowing their name is there, they will hesitate a little bit.

Dr. Moran stated that is an excellent point, and it certainly is a requirement for advertisement.

Mr. Heppler suggested that when the Committee meets next time, maybe an agenda item can be included to review the applicable advertising requirements for a medi spa.

Dr. Moran asked for public comment.

Norman Davis introduced himself as a health care attorney who has spent several years working with professionals in the field of aesthetic and cosmetic medicine. Mr. Davis referred to the Figueroa bill, which generated several years of discussion, debate, and several attempts at legislation. He stated the goal was to prevent injury because of the introduction of lasers and Botox. Mr. Davis added that over the years, the advisory committee discussions have centered on two separate, but interrelated areas of focus – the corporate practice of medicine prohibition and the supervision and training of those involved in these procedures. Mr. Davis stated the definition of how and when the prohibition is violated is unclear and ill defined. Mr. Davis

stated all areas of physician management companies should be considered. Mr. Davis asked why are only medi spas and aesthetic centers singled out for this enforcement. Why not ambulatory surgery centers, hair restoration clinics, dialysis centers, weight loss clinics, and home health agencies? Mr. Davis continued the focus today has been centered on physician supervision of registered nurses, nurse practitioners, and physician assistants providing services in the area of aesthetic medicine. Mr. Davis stated since the initial introduction of the Figueroa bill, the goal was for the Medical Board and the Nursing Board to come up with guidelines that could better define the functions' responsibilities and provide the introduction of new standards in the California Code of Regulations and the Business and Professions Code that could be understood and accepted by everyone. Mr. Davis asked the committee to expand outside aesthetic medicine and create guidelines for possible new regulations for all medical practices, which will affect the enforcement actions of the Medical Board and the Board of Registered Nurses. Mr. Davis stated he believes the Office of Safe Medicine is interviewing doctors involved in aesthetic practices and asking the following questions:

- What accreditation training have you had in performing these procedures?
- What is your level of knowledge of the laser medical device in your practice?
- Can you document your personal training of the registered nurse or the physician assistant you are supervising in your office?
- How far is your residence from your medical office?
- How do you provide supervision coverage of these licensed people when you are on vacation?
- Do you control your office lease personally?
- How much income have you derived from aesthetics?

Mr. Davis stated again that these questions are only being asked of physicians in the practice of aesthetics. Mr. Davis stated there should be defined guidelines across the board in medical practices of all types, including required training, physician supervision, physician competency to train a nurse, review of charting, patient information provided to patients, and advertising. Mr. Davis stated the challenge of this committee is not to narrowly focus on aesthetic medicine. Mr. Davis asked the committee to look at the bigger picture to define risks on a bigger scale of the physician-practitioner relationship in a meaningful, nondiscriminatory way.

Agenda Item 6: Discussion of next meeting agenda and possible dates – Dr. Moran

Items to be discussed at the nest meeting:

- Corporate practice of medicine
- Dr. Moran reiterated the committee's interest in discussing corporate practice of medicine, and that would be the main subject for discussion next time.
- Mr. Heppler suggested Dr. Bruner's suggestion of confronting the issue of defining a medical spa, at least offer some preliminary efforts in that regard.

- Dr. Moran stated Dr. Newman's recommendation to review the 10 points would be helpful
- Ms. Scuri asked if the committee would like the BRNs standardized procedure regulations as a topic

Dr. Robbins asked if without scheduling an interval meeting, which we have talked about at one of our other sessions, can we receive these materials in advance of our next meeting, because although we are going to take up corporate practice, we have not really closed the discussion yet on the supervision that we set out to do today, but we have opened up areas where that information can be obtained.

Dr. Moran stated the follow up to that would be having a presentation from Ms. Whitney on the research that has been done about other statutes and the ways the definition in availability have been defined. So, that would be another item.

Materials will be sent prior to the next meeting.

The main focus will be on corporate practice of medicine. We will also as an adjunct, somewhat related, the definition of a medi spa, how medi spas and other fictitious name permit advertisement laws play out, the 10 points of recommendation that the California Society of Facial Plastic Surgery, the review of what the standardized procedures and protocols are from the BRN, and the research on previous statutes set as far as the definition of supervision.

We will be likely mailing some possible dates, which would include meeting at the next Board meeting – May 5 and 6, or it may be determined that an interim meeting would be appropriate. We will be sending all the members of the Committee those meetings and notifying the public the date chosen. Thank you all for your patience and participation. This is obviously a very tricky and difficult subject, but I think keeping it in focus, even if we don t accomplish things as quickly or as definitively as we would like, I think the fact that we are focused on it, certainly sends a message that we do care about public safety and somehow, someway we will reach a higher level of care.

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