

MINUTES
MASSACHUSETTS BOARD OF REGISTRATION IN MEDICINE
MEDICAL SPA TASK FORCE

September 26, 2007

PRESENT

Task Force Members

Boards:

Gino Chisari, RN, Board of Registration in Nursing
Barbara Kellman, JD, Board of Registration in Nursing
Kathe Mullally, JD, Board of Cosmetology

Legislature:

Senator Joan Menard

Appointees:

Stephanie Cogliano, RE
Dianne Quibell, MD
Winifred Nee Tobin, Consumer
Jeffrey Dover, MD

Absent:

Nancy Achin Audesse, Board of Registration in Medicine
Catherine Hinds, Board of Cosmetology
Nancy Achin Audesse, Board of Registration in Medicine
Jagruti Patel, MD
Faye Marie Jenkins, RN
Jennifer Infurna, MPH

Board Staff

Russ Aims, Board of Registration in Medicine
Brenda Beaton, Esq., Board of Registration in Medicine
Fallon Onufrak, Board of Registration in Medicine

1. Welcome, Scheduling, Goals for Today's Discussion

Russ Aims, Special Assistant of the Board of Registration in Medicine called to order the meeting of the Medical Spa Task Force. His goals for this meeting are to get a consensus on the definitions and he thanked those from the Division of Professional Licensure (DPL), the Department of Public Health (DPH) and Brenda Beaton of the Board of Medicine who worked very hard to put the pen to the paper to get the thoughts of the group into a final product. For this meeting, he would like to discuss the level of procedures, and added that although the Task Force is very close to reaching its goal of completing the list of procedure levels, small issues have come up which will be discussed today. Dr. Dover sent the group an article regarding lipodissolve, specifically a Medical Spa offering this non-FDA approved procedure which Mr. Aims felt would spark an interesting conversation.

2. Approval of July 18th and August 29th Minutes

Mr. Aims brought forth a motion to approve the meeting minutes of July 18, 2007 and the August 29th Minutes of the Medical Spa Task Force Meeting. The Task Force members did not have a chance to review the minutes, and will vote on the minutes at the October meeting.

Catherine Hinds added that her students were confused because the fact that they have 1200 training hours was inadvertently left out of the July 18th minutes.

3. Discussion Topic: Definition of "Medical Spa"

Mr. Aims pointed out that Barbara Kellman has done an excellent job putting together work regarding the definition of "Medical Spa." Ms. Kellman would like to take questions from the Task Force and from the working group regarding this work.

Ms. Kellman brought up some issues that have arisen since the last time the group discussed the definition of "Medical Spa." She will add level four, surgery per request of Dr. Jagruti Patel to make it a complete list of procedures. Mr. Aims was a little troubled by adding surgery to level four. Dr. Quibell added that she had significant discussions with Dr. Dover regarding what really is surgery. She felt that they should be including new technologies that may not be surgical but that Medical Spas are incorporating. Mr. Aims added that he does not want to add surgery because he does not want to add what the Medical Spas can not do, only what they can do. The Task Force came to the agreement that they will add it to the list of procedures as one line, and they will list procedures that are considered level four.

Senator Menard added that when legislation is being prepared, it needs to be clear, which means that sometimes it needs to be redundant to be clear.

Ms. Kellman elaborated that the point the Task Force is trying to get across is that you are entitled to your one office and if you go beyond that you need to attest to DPH about the management of the second office or license the second office. If you are a group of owners, you must attest to DPH that at least one licensed professional (physician, nurse electrologist, esthetician, etc.) is at the second facility. She asked for input from Ms. Tobin and Dr. McKoy. The Task Force is basically trying to avoid a physician spreading him/herself too thin as (s)he must be able to supervise all procedures in the office.

Dr. Dover is concerned that somehow people will try to get around this, and asked for a discussion on how do deal with business owners that want to open up sites all over Massachusetts. Ms. Kellman replied that the business owner of the Medical Spa must get licenses and have clinical director in each facility. If the facility is a level three facility, it must be a physician overseeing. If it is a level two or level one facility, the clinical director could be a nurse or an electrologist. When the Task Force puts together their document of recommendations, it will be clear who can do each procedure.

Dr. Dover added that he does not remember discussing registered nurses ability to become clinical directors of Medical Spas without a physician overseeing. Dr. Quibell added that she would not like to see unqualified nurses overseeing procedures, however, a nurse like Faye Jenkins would be qualified to be a clinical director, so that is an example of how there needs to be a level of training that should be incorporated into the Task Force's recommendations.

Mr. Chisari began to discuss scope of service. He stated that level three procedures should be performed by registered nurses under physician orders (which would make Mr. Chisari and many nurses more comfortable). Mr. Chisari added that he will think about how much training he thinks is appropriate for nurses in order to be overseeing and performing procedures and discuss it with the Task Force further.

Senator Menard brought up the issue that the clinical director is being given a lot of responsibilities, so s(he) needs requirements to fulfill to ensure that s(he) has the expertise to do what needs to be done. It is crucial to have someone who is experienced. Dr. Quibell agreed and added an analogy that a physician can not be Chief of Medicine right out of the residency program, s(he) must be an attending physician for a while to gain experience.

Senator Menard added the point that even though professionals that would be working in a Medical Spa are licensed, they should also be credentialed, so therefore, the clinical director should be credentialed too. Ms. Kellman stated that this point regarding credentialing is currently in the draft of the proposed definitions.

The Task Force discussed training experience, and whether it belongs in the regulations or the legislation. The Task Force seemed to believe that the issue of training would be better suited in the regulations so that it can be updated as time changes.

At this point, Mr. Aims added that this is not an issue that is going to get settled today, however, Dr. Dover added that as Senator Menard previously pointed out, if the Task Force does not take the initiative to put the information in the regulations, they will be putting that task in the hands of someone else who may not be as close to the subject as members of the Task Force are.

Dr. Dover brought up the point that the Task Force never had a level three initially, so everything regarding the level of procedures must be shifted around. The Task Force needs to fix the definitions of what is level one, two and three very carefully and then it will be easier to allow nurses to supervise the level one and level two facilities. Dr. Dover also brought up the point that the Task Force may need to tackle assumption on who in the Medical Spa can purchase equipment, because as of now, nurses can not purchase equipment, and that is a regulation that should be kept in place.

Ms. Mullally and her staff brought to Ms. Kellman's attention on page one of the document that it should be more clear that anyone performing a level one procedure must be licensed by the Cosmetology or Electrology board.

They also brought up the point that there should be a separate space for level one procedures in Medical Spas and that those sections would be regulated differently by the individual boards. Barb had a different understanding. Ms. Kellman had a different understanding of this, as did many of the other Task Force members. This topic sparked a substantive conversation regarding space regulated by DPH.

Dr. Quibell added that it is not economically possible to have separate spaces for separate procedures. Physical space in its entirety should be regulated by DPH, and those performing procedures within the physical space should be regulated by their individual boards. Ms. Mullally disagreed with this notion and added that she feels that those at DPH who investigate should know when they go in to investigate a facility exactly who is within their jurisdiction.

Catherine Hinds brought up the point that estheticians need to work under a licensed esthetician for two years until they can stand alone in their own practice which is why there is small education, because so much training. She is afraid that the estheticians will not be able to get the jobs because they will not be able to perform the procedures and get the required training.

Ms. Hinds and Ms. Mullally are in agreement over the point that if there are multiple professionals sharing one space, there may be confusion of what belongs to each person, and who can be held accountable for any illegalities that may be present. If there is a large facility with a lot of different type of licensed professionals coming in and out of facility, there may be no way to clearly identify those using un-sterilized syringes, for example.

Senator Menard added that in a salon, there are different people using different rooms all the time and if something goes wrong you have trouble finding who is responsible, but if

there is something that goes wrong in a Medical Spa, it is the responsibility of the medical director. Ms. Mullally said that she finds professionals “practicing not within the scope of practice” when they do surprise visits, and would like DPH to continue surprise visits with Medical Spas.

Mr. Chisari added his perspective that Medical Spas is a new concept, therefore, it is a new way of doing business and is governed by a new set of rules. In a Medical Spa, we are having a greater level of supervision than we have in salons now. We can not police everybody, but Ms. Mullally would like to reserve the right to police their licensees. The Board of Registration in Medicine still has control over the licenses of the physicians overseeing the Medical Spas.

The Task Force went into significant discussion over who should regulate the physical space of Medical Spas. Dr. Quibell added her belief that as a clinical director with his or her license on the line, there is no way that a nurse or physician will allow activities in the Medical Spas that are prohibited by the regulations.

Ms. Kellman encouraged Ms. Mullally to consider DPL having jurisdiction over its licensees in the Med Spa but not over the space. Since the med Spa will have a Clinical or medical Director and be regulated by DPH, the additional oversight of physical space by another entity seems unnecessary. Ms. Mullally disagreed and said that DPL’s position is that it needs to continue having the power to oversee the space used by its licensees.

Senator Menard suggested a compromise that DPH could investigate the Medical Spa only if there was a complaint regarding the care rendered at the facility. She suggested that DPH do not do “surprise visits,” but rather investigate when a complaint is made.

Ms. Mullally added that she does not want DPH to give up the ability to make sure the licensees are up to par.

Mr. Aims added that, generally speaking, there is built in supervision in the Medical Spas already. In a Medical Spa, there is going to be built in supervision where as in a salon, it will be licensees supervising licensees.

Ms. Tobin posed the question to Ms. Mullally of how DPH would recognize what boundaries are in their jurisdiction. Ms. Mullally went on to describe how DPH would investigate each facility.

Dr. Quibell took this time to interject that she thinks that it would be helpful if everyone that applies for a Medical Spa license should receive the list of procedures that their level facility is permitted to perform to minimize illegalities.

Ms. Hinds added that cosmetologists are not allowed to be considered licensed estheticians, so just cosmetologists that do not have an esthetician license should not be allowed to practice in a Medical Spa. The group then went into a discussion of the

difference between an esthetician and a cosmetologist. A cosmetologist can work on skin, hair, and nails. They can do level one skin care. There are certain level one procedures that cosmetologists should receive more training and supervision for going forward.

Shiela added that one of DPH's major concerns is that a facility will do laser treatments one day a week, and for the rest of the week they would do manicures and pedicures which would allow them to get around having a clinical director.

Mr. Aims added that the Task Force needs to consider the difference between a salon and a Medical Spa. Ms. Mullally is going to have a discussion with DPH regarding this point and other issues and come back to the Task Force.

Dr. Dover wants to clarify who is going to be clinical director at a facility. He poses the question of whether it should be a physician with all required credentialing or if it should be a nurse. Ms. Kellman asked to get recommendations from the Training Subcommittee. Mr. Chisari added that behind every doctor, there is an excellent nurse.

Ann Hinds made a comment from the public. She wants to make sure that the Task Force takes into account the esthetician, and makes sure she has a place in the scope of things. The esthetician must work for two years under a licensed esthetician before she can get her own shop, so she asks the Task Force to consider letting the physician sign off on this paperwork so that they can get their license. Dr. Dover agrees with this notion and added that work in a Medical Spa will be an excellent opportunity for esthetician.

4. Discussion Topic: Final Assignment of Procedures by Level

After a brief intersession, Mr. Aims addressed to the Task Force how he would like to discuss the topic of levels, and which procedures belong in which levels. With the advent of level four, some of the procedures will need to be moved around.

Level one procedures are the most straightforward, however, Ms. Hinds feels that these should be performed by estheticians and not cosmetologists. Most everyone in the Task Force agreed with this notion which generated discussion on possible ways to grandfather in those with a cosmetology license so that they will be able to perform more advanced procedures. Ms. Hinds added that she believes those with a cosmetology license should go to school and get another license to be able to do more procedures, however in the past, some with just a cosmetology license were able to do skin care and were able to have salons their own salons.

Senator Menard reiterated the point that she wants to provide consumers with the best possible care from qualified people, so a major goal of the Task Force should be to ensure all professionals working in a Medical Spa setting are qualified individuals.

The Task Force moved on to look into what constitutes a level two procedure. Dr. Dover voiced his concerns with this level, because there are some laser devices in level two that should be moved to level three because these services should be provided by a physician. He wished to move ablative laser procedures to level four procedures. He asked the question of what procedures on level two should be moved to level three. Any laser or device that interrupts epidermis in part or in whole should be moved to level four because that is considered a surgical procedure.

If a Medical Spa is only offering level two procedures, it is acceptable for a nurse to be the clinical director, however, when the Medical Spa begins offering level three or four procedures, it becomes practice of medicine.

The question was posed whether a professional who has basic training in nursing or esthetics can perform a procedure on the list of level three or four. If the answer is no, they must decide which procedures will remain level three and four, and which procedures are acceptable for nurses and estheticians.

Ms. Mullally reminded the Task Force that the list of procedures that they were presented with this was not a complete list of procedures.

Dr. Dover wanted to add in what he wants each professional to do. The Task Force added into the document what each type of professional should be doing each type of procedure to minimize confusion.

Mr. Chisari informed the Task Force that the Nursing Board authorizes registered nurses to use lasers in procedures such as: hair removal, tattoo removal, photo rejuvenation, acne, spider veins, lesions, and other procedures as ordered by a physician.

Dr. Dover wanted the Task Force to address the issue of onsite supervision, and whether it should be in the same building, or does it require supervision in the same room. The Task Force had not yet discussed what type of supervision constitutes on site supervision, so the issue was in need of discussion. The document that distinguishes the level of procedures deals a lot with delegation of procedures, therefore, there is a need to distinguish what constitutes supervision.

Dr. Quibell brought up an interesting point that if she needs to be in the same room while a procedure is being performed, she might as well perform the procedure herself and save the money of the person she would be supervising. Dr. Dover added that the physician is still very legally responsible for these procedures, so The Task Force needs to define what supervision is, which will be a nationally responsive document.

Ms. Mullally added that a supervisor must at least have emergency availability. Therefore, the Task Force must also define availability.

Prior to the Task Force meeting, Dr. Quibell sent around CNN article regarding supervision, when a professional should stop a procedure when the patient is complaining of pain, and what to do if something goes wrong.

She added that some professionals may not be able to recognize melanoma issues and know enough to do a biopsy on suspicious looking tissues, which could cause permanent damage to the patient. Dr. Dover added that although we can not have a dermatologist standing by every esthetician, we can train estheticians to look for precursors of melanoma.

The Task Force went into further discussion of the different procedures and what level of supervision they felt the procedure deserved. The group felt that radiofrequency devices should require nurse and/or physician supervision. Mr. Chisari added that the higher the risk associated with the procedure, the higher level the procedure should be.

The Task Force agreed that skin tightening and photo rejuvenation are should be level two procedures, and that microdermabrasian procedures should be taken out of level two and moved to a higher level.

The group went into discussion of tattooing and which professionals can do tattooing for medical purposes. The group also decided to take eyelash tinting and permanent makeup off the list of procedures altogether because they are illegal procedures.

This list of procedures is a list of what should be performed be performed in Medical Spas, not what is currently being performed in Medical Spas.

The group began discussing the notion that lasers should be level four procedures and should only be performed by a physician. The group also went into discussion on what procedures could be done by an APRN (Advanced Practice Registered Nurse). An APRN should not be confused with a physician assistant, because there are independent APRN's, however, physician assistants must work under the scope of a supervising physician.

The Task Force decided to wait before added level four procedures to the list of procedures. Level four procedures have very, very high risk rates.. Mr. Aims is going to have a discussion with Dr. Patel regarding her thoughts on level four procedures and their position in the list of acceptable Medical Spa procedures.

5. Discussion Topic: Lipodissolve

The Task Force decided to go into a discussion regarding Lipodissolve at the October 24, 2007 meeting.

6. Recap, Next Topics for Discussion

The next meeting of the Medical Spa Task Force is tentatively scheduled for October 24, 2007.