

-DRAFT- MINUTES
MASSACHUSETTS BOARD OF REGISTRATION IN MEDICINE
MEDICAL SPA TASK FORCE

December 13, 2006

PRESENT

Task Force Members

Boards:

Nancy Achin Audesse, Board of Registration in Medicine
Gino Chisari, RN, Board of Registration in Nursing
Barbara Kellman, JD, Board of Registration in Nursing
Kathe Mullally, JD, Board of Cosmetology
Catherine Hinds, Board of Cosmetology

Legislature:

Adam Chapelain, JD (on behalf of Senator Joan Menard)
Senator Joan Menard

Appointees:

Stephanie Cogliano, RE
Jeffrey Dover, MD
Faye Marie Jenkins, RN
Karen McKoy, MD
Dianne Quibell, MD
Winifred Nee Tobin, Consumer

Absent:

Representative Peter Koutoujian
Jennifer Infurna, Rep. Koutoujian staff

Board Staff

Russ Aims, Board of Registration in Medicine
Brenda Beaton, JD, Board of Registration in Medicine
Charlene DeLoach, JD, CISR, Board of Registration in Medicine
Ann Weaver, MA, Board of Registration in Medicine

1. Welcome, Goals for Today's Discussion

Nancy Achin Audesse, Executive Director of the Board of Registration in Medicine, welcomed the group to the second meeting of the Medical Spa Task Force. Participants once again introduced themselves, as did the guests sitting in on the meeting.

The first issue of business was the approval of the draft minutes, which had been emailed to task force members for review. Ms. Achin Audesse made a motion to approve the minutes, Senator Menard approved the motion, and Mr. Chisari seconded.

Next, Ms. Achin Audesse directed the group's attention to an email sent by Paul Dryer, Director of the Division of Health Care Quality at the Department of Public Health, and her response. Though Mr. Dryer was appreciative of Ms. Achin Audesse's input, he declined to delay posting the DPH's policy on Medical Spas on the DPH website until the work of this task force is complete. Ms. Achin Audesse reassured the group that this decision does not depreciate their work; rather, any recommendations the group makes will, if necessary, result in statutory change in order to correct identified issues.

Ms. Achin Audesse explained that the focus of this meeting will be on the first of the three questions facing the group, defined at the first meeting: what procedures will be considered, who will perform the procedures, and where the procedures will take place. The goal of the meeting is to define categories of procedures in order to define the "what" of the task force's work in order to move forward with a shared understanding.

2. Medical Spa Association Glossary of Terms -- Handout

Ms. Achin Audesse thanked Ms. Bernstein for suggesting this list as a launching pad for the group's discussion on the definition of medical spa procedures. Ms. Bernstein noted that a far longer list is available, containing information on a wider variety of alternative therapies than is presented here, and Mr. Aims volunteered to email the link to this longer list to all participants. Ms. Achin Audesse then encouraged the group to offer their own suggestions, since one of the end products of this undertaking will be the group's own glossary of all the terms used in the final report.

After reviewing the glossary, several members offered their comments and criticisms. Ms. Jenkins stated that many of the definitions in this glossary do not reflect what they are actually trying to define. For example, the definition of "laser resurfacing" does not distinguish between ablative (a process that disrupts tissue) and non-ablative (a process that does not disrupt tissue) resurfacing treatments. Distinctions like this are crucial, and the group must carefully consider the semantics of all terms used to prevent gaps such as this.

Agreeing with Ms. Jenkin's assessment, Dr. Dover noted that this glossary was obviously written from an aesthetician's point of view. He argued that the document is too misleading to use as a basis for the group's own document.

In light of these comments, Ms. Achin Audesse asked whether the members of the task force could, based on their extensive knowledge and experience, submit glossary terms on procedures, along with their links, to the task force website. The group agreed

unanimously with this idea. Ms. Hinds and Dr. Dover offered to lead this work, and Dr. Quibell offered her help as well, noting that it is important that the glossary be forward-thinking. Mr. Aims will structure the resulting information and make it available in two weeks (December 27, 2006).

3. The “What”: Procedures with which the Task Force should be concerned

After some discussion as to how to organize the procedures to be considered, the group agreed that, in addition to a glossary containing all the relevant terms, the report could categorize the terms into groups. The task force agreed on the idea that the procedures will be most usefully categorized by *delivery method*.

The group also agreed that all trade terms, such as Botox®, be removed from the glossary. Additionally, laser eye surgery will not be considered a medical spa procedure. The subcategory for organization will be *treatment targets*, rather than the devices used to provide the treatments. Ms. Achin Audesse noted that the FDA has been contacted, so the group can see where they stand on the procedures discussed and how the FDA groups and understands them.

Though the following list will certainly not be exhaustive, it will identify some of the procedures on which the group will work. Additionally, it will give a sense of the order in which to look at the procedures.

Considering this list, Ms. Jenkins expressed concern that the statute for this task force grouped laser / light procedures with radiofrequency procedures, when the mechanisms of the two are completely different. She worried that the end product may end up with procedures may end up grouped inappropriately. Senator Menard replied that the statute can certainly be changed according to suggestions like this; statutes are created in light of the opinions of experts, such as those gathered here. The task force members agreed with this suggestion, and Dr. Dover further suggested that the categories above can be further defined and sub-categorized as the group continues its work.

DELIVERY METHOD:

MEDICAL SPA DEVICES

LASER & LIGHT SOURCES

- FDA Definition & Rules
- Other Current Regulatory Definitions
- Identify Treatment Targets
 - *Hair Removal
 - *Vascular
 - *Pigmentation, including Tattoo Removal
 - *Wrinkles
 - *Scars & Stretch Marks
 - *Acne
 - *Fat & Cellulite, including Skin Tightening
 - *Miscellaneous

RADIOFREQUENCY DEVICES

OTHER ENERGY SOURCES

COMBINATION MODALITIES

INJECTABLES

NEUROMODULATORS (Botulinum exotoxins)

TISSUE FILLERS

SCLEROTHERAPY

MESOTHERAPY

OTHER

TISSUE ALTERATION

MECHANICAL (Superficial, Medium, Deep)

CHEMICAL (Superficial, Medium, Deep)

CRYOTHERAPY

ELECTROCAUTERY

OTHER SURGICAL INTERVENTIONS

FACE LIFTS

EYE LIFTS

LIPOSUCTION

HAIR TRANSPLANTATION

OTHER

After agreeing on this provisional list of delivery methods, discussion moved to the question of how this task force could give advice to practitioners on how they should make decisions as to the safety and reliability of a substance or treatment when new things come out on the market. Ms. Achin Audesse wondered if there is a benchmark for product safety and reliability, and what role the FDA plays in determinations of safety.

Dr. Dover answered that, at the present time, the FDA plays this regulatory role. However, the FDA regulates companies only, that is, determines what devices and products can be sold. Therefore the FDA's work supercedes the work of the state. The task force should be clear on the fact that, in the Commonwealth of Massachusetts, practitioners only use devices that are FDA-approved. Any practitioners who imports and uses devices that are not FDA-approved, such as mesotherapy, are breaking the law.

Another issue related to FDA approval is the off-label use of approved products. Ms. Hinds offered the example of Botox®, which was only approved for cosmetic purposes in 2002, had been used for such purposes since approximately 1992. Dr. Dover noted that good practice requires that the practitioner informs the patient that the use in question is an off-label use (for example, the use of tetracycline to treat acne). However, as Ms. Achin Audesse explained, off-label use is not necessarily a bad practice. Often companies do not have the money or time to bring an already-approved drug back to the FDA in order to obtain approval for additional uses. It is also far easier to get a drug approved by the FDA for one use, rather than multiple applications. Ms. Kellman also stressed the point that the first test the FDA runs tests the safety of a product, so there is a baseline of safety for all drugs on the market. Because of this safety provision, there is an exception in FDA law that allows for off-label usage.

4. Next Steps and Quions

Ms. Achin Audesse summarized the tasks facing the task force. Mr. Aims will post the list of delivery method groups on the website, and participants can email with their input and suggestions. All participants agreed to take an active role in working on this list of definitions and categorizations.

The forum was then opened for visitor comments. Ms. Michelle Saber asked if the group intended to recommend regulations covering each procedure discussed in minute detail.

She expressed concern that such detailed regulations would be limiting in the future and exclude new therapies.

Ms. Achin Audesse answered that this task force will work with these minute details. However, the group's final report will contain more general suggestions as to how medical spa procedures should be regulated. A draft of the group's final report will be offered for public comment before it is submitted. Senator Menard added that the law is flexible, and can always be changed to meet new approvals and new developments.

Janet DeAngelo, an author that contributes to textbooks for the aesthetics industry, offered to email the group an extensive glossary contained in one of these books. She also approved of the group's interest in FDA involvement. She then asked if there was a plastic surgeon on the task force. Ms. Achin Audesse answered that the plastic surgeon originally appointed had to turn down the appointment, but the group is waiting for the Society of Plastic Surgeons to recommend another representative.

On the topic of the makeup of the task force, Susan Gorman, a representative from the Catherine Hinds Companies, asked if a list of members' names, perhaps with links to their resumes, could be posted on the website. Mr. Aims agreed to post this information. She went on to express concern that the task force does not include a practicing aesthetician. Ms. Achin Audesse explained that the group had been carefully chosen, and that Ms. Hinds, with a great deal of experience practicing in the field, serves as a very well-suited representative.

Ms. Saber raised a second question, asking if the task force will talk to public groups of the Society of Medical Spas, which has provided data on procedures for the last ten years. The committee will publicize any data collected through the website for general review.

Senator Menard added that she would be more interested in data from independent sources than from the companies performing the procedures from which the data is gathered. Ms. Achin Audesse suggested the task force query the Boards included in this statute and see what information is available. Also, Mr. Aims has reached out to medical liability insurers, seeking their input. The information he gathers will be presented at a future meeting. Representatives from the FDA will also be visiting the task force, and can bring in data they have collected. However, any data that any member or visitor has available could be helpful, and should be submitted via the website.

At the conclusion of the discussion, Ms. Kellman noted that the Board of Nursing has a conflict with the current Wednesday of the month as the task force meeting date. Members offered to consider other dates, preferably at the same time on a Wednesday, but perhaps on a different Wednesday of the month. Mr. Aims will email all members asking for time conflicts, and the best possible schedule will be determined.

The next meeting of the Medical Spa Task Force is tentatively scheduled for Wednesday, January 10, 2007 from 8:00-10:00 am.

****UPDATE: The meeting was re-scheduled to January 17, 2007 from 8:00-11:00am.**