

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

**June 21, 2007**

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**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

*Legislature:*

Senator Joan Menard  
Representative Peter Koutoujian

*Appointees:*

Stephanie Cogliano, RE  
Faye Marie Jenkins, RN  
Dianne Quibell, MD  
Jagruti Patel, MD  
Winifred Nee Tobin, Consumer

*Absent:*

Karen McKoy, MD  
Catherine Hinds, Board of Cosmetology  
Jeffrey Dover, MD

**Board Staff**

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

**Guests**

Josephine Torrente, Manufacturers of Equipment for Light-Based Aesthetics (MELA)

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

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Nancy Achin Audesse, the Executive Director of the Board of Registration in Medicine called to order the meeting of the Medical Spa Task Force. Mr. Russell Aims addressed the issue of scheduling and the Task Force agreed that the next meeting will be scheduled for July 18<sup>th</sup>. During today's meeting of the Task Force, we will hear from both members of our own Task Force, as well as experts in the field.

## **2. Approval of Minutes**

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Ms. Achin Audesse brought forth a motion to approve the meeting minutes of the May 23, 2007 Medical Spa Task Force meeting.

Dr. Quibell prepared a list of corrections and comments that she wishes to address and share with the group. Corrections to the May 23, 2007 meeting minutes will be made to reflect Dr. Quibell's proposed changes and distributed to the Task Force members.

## **3. Presentation/Q&A by Josephine Torrente, immediate past president of Manufacturers of Equipment for Light-Based Aesthetics (MELA)**

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Ms. Josephine Torrente, the immediate past president of Manufacturers of Equipment for Light-Based Aesthetics (MELA) appreciates the opportunity to speak, as she feels that the Task Force and MELA share the same common goal of patient safety. Ms. Torrente believes that the dedication of manufacturers and training of people that use the devices contribute to the safety and efficacy of the products. These are the two major components of laser product safety. Additional safety procedures are being updated continuously with lectures, training and hands on training all the time. These tools help refresh and serve as a reference to the users. Ms. Torrente believes that 100% safety is the goal of MELA and should be the goal of all products. MELA committed to working with Task Force to create training guidelines and thinks that levels of procedures is a perfect way to begin to create the training guidelines.

Ms. Torrente does not believe that physician oversight is the answer. She has found no data to show that having a physician on sight eliminates the adverse affects of laser procedures. Even though groups can come up with pictures and data, there is still a less than 1% adverse effect rate of these products and this is related to the training, not the degree or the level of the person in the room supervising.

Ms. Torrente shared a definition of the practice of medicine that included the prevention and alleviation of disease. Ms. Achin Audesse disagreed with this definition and stated that the Board of Medicine (BORIM) determines what the practice of medicine is. After a brief discussion of the origin of the definition of the practice of medicine, the Task Force came to the conclusion that it is incorrect to define a procedure as the practice of medicine by the level of risk involved in the procedure. Ms. Torrente shared with the Task Force her belief that BORIM and the Board of Registration in Nursing (BORIN) have conflicting policies and MELA is happy that the legislature has taken a stand in

helping to come to a common ground. This statement will be addressed later in the meeting. Ms. Torrente explained that she is enthusiastic about balancing cost and safety; however, she does not believe that increasing physician oversight would increase safety and it would only be increasing cost.

MELA urges the Task Force to promote safety to lower the already low instances of adverse affects without coming at cost for the businesses of Massachusetts. Ms. Achin Audesse addressed the point that the Task Force does not wish to over regulate or over define procedures, which has been championed by the physicians on the Task Force. She believes if you make market too difficult, you may drive it into home based procedures, which is more dangerous than procedures done by licensed professionals.

The Task Force and Ms. Torrente agreed that they must work in collaboration to ensure that there is no undermining the industry for profit. At this point, Mr. Chisari cleared up Ms. Torrente's notion that there is a conflict in the policies of BORIN and BORIM. He stated that by law, a nurse must have a physician's order, therefore, there is no inconsistency in any law and hopes that the industry and the people of the Task Force will understand this law.

Dr. Quibell also added to the conversation by adding her opinion on the law. As a physician, she must write an order and take history and write exam. In order to give nurse order, she must see the patient. Dr. Quibell believes there is a disconnect here because in many places, the nurses are getting orders from physicians that have not seen patients. As a registered nurse, Ms. Jenkins added to the conversation by saying that she always collects the medical history of patients, and flags the medical history anytime it need to be checked and taken to the Medical Director or primary care physician.

Dr. Quibell believes that nurses should be able to practice independently. She does not want to see physicians come into the industry just to make a profit and not for the sake of the consumer. She wants the physician to be involved and try to make a difference. Dr. Quibell also made the point that many people that come to see her for treatment are people that have been under treated, not over treated. She believes this is because the professionals at Medical Spas are afraid of harming the patient and not as aggressive so that they may not do the procedures to show results.

Senator Menard informed the group that there are bills being filed as we speak to strengthen laws and penalize Medical Spas, so the Task Force needs to do the right thing. There is very little turf protection in this task force. Everyone here is very cooperative and agrees that everyone can use more training.

Representative Koutoujian spoke about a recent hearing he was at in which many people testified that if the state were to regulate the procedures, they would suffer. Many people that care deeply about the people that they are treating that would suffer if we would restrain them from being able to practice. The Representative was personally struck by the professionals that were in and pleaded with the Legislature to not put them out of business.

Senator Menard attested that estheticians in particular were concerned that the Task Force was going to do away with certain procedures and regulate others so that only physicians could perform them.

Ms. Achin Audesse spoke about how she is upset with the industry over the marketing of products to physicians to no training whatsoever. She spoke about the letters that are being sent to OB-GYNs saying that if they purchase the products, they can receive training in only a few hours. Ms. Torrente spoke about how she is willing to help with Nancy to look into those that are targeting physicians with little to no training.

Ms. Torrente then spoke about the standards of training for professionals that purchase the equipment. The expectation is a day long in office training of lecture and hands on training. The professional is then left with CD ROMs, videos and manuals for reference. The professional will then have the opportunity to attend several lectures for free.

Dr. Patel agrees that we need to protect our business, however, she concerned about the woman that wants to set up business that has no training and when it falls out of the realm of the BORIM. She feels that a 1% complication rate is excellent and it would be extremely difficult to try to improve this complication rate. Instead, we should find a way to keep it where it is in order to keep it down. We need to make sure it does not go up. Ms. Torrente replied that she is constantly striving to be better and added that as the numbers of procedures are going up the adverse levels are staying same.

Ms. Kellman asked Ms. Torrente to provide actual data used for rates because wants to see levels of training, what types of procedures, etc. When the question was raised of who can purchase the equipment, Ms. Torrente admitted that she does not personally know who they are selling the equipment to, because she does not receive that information “blocks herself from that information.”

Senator Menard brought up the point that if the manufacturers and sellers of the equipment are offering the training, but the buyers are not taking advantage of it, it is not the fault of the manufacturer, but that is where Task Force can help out with everything. Dr. Patel agreed and pointed out those physicians and professionals that use the equipment need to be recertified to use the equipment all the time.

Representative Koutoujian brought up his curiosity of cost of machines and felt that it would be good for the Task Force know how much the professionals are paying for the machines. Dr. Quibell answered cost of machines can run from 50 thousand dollars to machines in the hundreds of thousands of dollars.

After a brief intermission, Dr. Quibell presented to the Task Force an actual machine that is used to perform esthetic procedures. Although she did not actually perform a procedure on any individual, she invited individuals in the room to come up to the machine and ask her any questions. She explained how through the use of different hand pieces, one machine can do several different procedures. The Task Force went into a

discussion of the education of these machines, and how the replacement and upkeep of the equipment is almost as important to the consumer safety as the professional training.

#### **4. PowerPoint presentation by Gino Chisari regarding refinements to “Levels” and qualifications of spa medical directors**

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Mr. Chisari, a member of the Medical Spa Task Force gave the group an update of a recent meeting of the Lawyers Subgroup. At this point, Carol Balulescu, counsel at the Department of Public Health (DPH) and invited guest to the subgroup, joined Mr. Chisari in the presentation. Mr. Chisari gave a PowerPoint presentation that is available on the website at [http://www.massmedboard.org/public/med\\_spa.shtm](http://www.massmedboard.org/public/med_spa.shtm).

Ms. Brenda Beaton, a member of the lawyers subgroup explained that the group was not created to come up with recommendations regarding the training and expertise of various levels of procedures, the group is simply creating a framework for the Task Force to work on while creating their recommendations for legislature.

Mr. Chisari urged the Task Force that it is time to “get off the ‘whos’ and the ‘whats’” and begin looking at the “hows.” The biggest “how” is the question of supervision and the presence of the supervisor.

Ms. Cogliano raised her concern of the electrologist and hair removal, specifically those with independent offices. The group went into discussion about laser procedures and how they should not require supervision by a physician. Mr. Chisari pointed out that supervision and collaboration are two very different things. Nurses are able to work independently without supervision, but encourage collaboration in the workplace.

Dr. Quibell added that hair is generally a cosmetic problem except where there is a medical problem behind it, for instance, an abundance of hair growing could trigger a deep underlying medical problem. Are we willing to take hair removal and separate it from the other levels that we are working to group into “tiers” and levels?

Ms. An Hinds, a representative of the Catherine Hinds Institute brought forth her concerns about where the group left the role of the esthetician because this is a huge part of the Catherine Hinds Institute. There will be a huge additional training for skin care issues, An thinks that all school could extended training. 300 hours of training is not enough to make it an acceptable capacity for training, however, Ms. Hinds can only speak for her training. Ms. Hinds stated that 600 hours minimum should be the standard training across the state.

Ms. Achin Audesse addressed her concerns that the “devil is in the details” and how the Task Force will grandfather in those that have a high amount of experience, and how to ensure a high level of competency is retained. In order to come up with how much training should be achieved, the Task Force should look at how long it takes to learn how to use the equipment.

The Task Force agreed that they would like to hear from different Boards about how they handle the training with the professionals licensed under their Board, especially with regard to hair removal. Mr. Chisari added the comment that machines and technology are changing every day, and so the Task Force must keep that in consideration.

An electrologist from Danvers spoke from the audience about how the electrologist is only asking to do hair removal and they are not asking to do anything else. She asks that the Task Force keep an open mind to look at online and other certification programs. Ms. Achin Audesse responded that the Task Force would need verification that these programs are appropriate.

**The next meeting of the Medical Spa Task Force is tentatively scheduled for Wednesday, July 18, 2007 from 8:00-11:00 am.**