

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

**November 22, 2006**

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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:*

Adam Chapelain, JD (on behalf of 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  
Catherine Hinds, Board of Cosmetology

**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

**Guests**

Carol Balulescu, Deputy General Counsel at the Department of Public Health  
Roberta Bernstein, Special Project Coordinator in the Department of Quality at DPH,

## **1. Welcome, Introductions, Organization and Charge of Task Force; Overview of Binders and Handouts**

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Nancy Achin Audesse, Executive Director of the Board of Registration in Medicine, welcomed the group to the first meeting of the Medical Spa Task Force. She explained that the members selected to participate in this task force were chosen from among a large group of highly-qualified individuals. The members that were present represent those interested in moving forward with new services while maintaining a high level of safety through regulation of these services. After this introduction, the Task Force members introduced themselves to one another.

Over the course of the Task Force meetings, the questions the group will address fall into the categories of Who, What, and Where: who should perform medical spa services, what services should be offered and how regulated, and the type of environment necessary for the safe practice of these procedures.

The discussion of what services this group will examine can be addressed at this first meeting. The most common examples are the use of lasers, injectables, and chemicals. In the case of these services, the available research and standards that have been set across the nation are plentiful. Russ Aims, Special Assistant to the Board, directed participants to the articles and state frameworks included in the binders distributed at the meeting's opening.

## **2. Presentation by Board of Medicine Staff**

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After Ms. Achin Audesse's overview of the Task Force's mission, Brenda Beaton, General Counsel for the Board of Registration in Medicine, provided a general introduction to function and scope of the Board's actions. The Board's regulations define what comprises the "practice of medicine," and, currently, the use of lasers for hair removal falls into this category. The "practice of medicine" therefore encompasses not only medical practitioners, but also the use of specific implements.

The Board voted to include the use of these lasers in the practice of medicine on June 24, 1998. However, the use of lasers for medical and cosmetic procedures has greatly expanded, both in prevalence and scope, since that time. It is the growth and expansion of such procedures and technologies that produced the mandate for this group and its final report. The due date for this report was set at one year after the bill mandating the task force was signed, which is May 26, 2007.

## **3. Presentation by the Department of Public Health**

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Ms. Achin Audesse then introduced Carol Balulescu, Deputy General Counsel at the Department of Public Health, and Roberta Bernstein, Special Project Coordinator in the Department of Quality at DPH, who has researched the issue of medical spas extensively.

Summarizing the role of DPH in the oversight and licensing of medical facilities, Ms. Balulescu explained that the DPH has the authority to license clinics, that is, any place that provides medical services that is not wholly owned by one or more of its practitioners. The latter are considered individual office practices and are not regulated by DPH. She distributed an advisory to the group that DPH would like to issue regarding certain facilities that perform medical spa procedures that are not wholly owned and controlled by the licensed practitioner and therefore should be licensed as clinics.

She then asked that during this meeting the group compile a list of entities that could oversee these procedures, and suggested that the advisory, when finalized, include contact information regarding this Task Force. Ms. Achin Audesse agreed with this idea, and explained that, since this is a public meeting, its proceedings will also be posted on the Board's website. Mr. Aims will serve as the Board's contact.

To summarize the regulatory roles of DPH and the Board, Ms. Achin Audesse explained that the Board looks at individual physicians' offices, while the DPH oversees the running of any entity defined as a clinic. In light of this, one of the questions facing this Task Force is to determine what elements of the procedures considered will be defined as the "practice of medicine" and would therefore fall under the umbrella of "clinic" if not wholly owned and controlled by the practitioner. If the group determines that statutory changes are needed, this is an option for the final recommendations, as are suggestions regarding the DPH or Board regulations. Ms. Achin Audesse reminded Task Force members that they should not feel constrained by current statute and/or regulations in making their recommendations, as it is perfectly appropriate for the Task Force's final report to include recommendations for statutory changes should the current regulatory environment be found lacking in terms of its ability to address the public protection and patient safety issues related to medical spa services.

#### **4. Discussion**

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##### ***1. What procedures should the Task Force consider?***

The group raised several issues concerning specific procedures, the "What" aspect of the group's mission. First, Dianne Quibell, MD, asked if, when the group spoke of "laser" procedures, whether this term also included pulsed-light treatments. Dr. Jeffrey Dover, MD, suggested that these procedures be regulated in the same way, and therefore, when discussed, should be referred to as "laser and light sources." The group agreed with this suggestion.

Karen McKoy, MD, explained that, being new to this aspect of medical practice, her main concern is maintaining a sense of professionalism in this commercial enterprise. She wondered if the discussion here would touch on the issue of the efficacy of the procedures under consideration – recommending sham treatment, in her opinion, does not demonstrate professionalism.

Further questions arose concerning practices not approved by the FDA, such as mesotherapy and chelation therapy. Barbara Kellman, General Counsel for the Board of Nursing, suggested that looking at the FDA guidelines for all devices considered may be helpful in order to understand who owns the equipment in question and how the users are insured. Ms. Achin Audesse agreed, and suggested that Ms. Beaton construct the correct language for these concerns about “the corporate structure of the practice of medicine.”

In sum, the group agreed that all the relevant terms and practices be clearly defined so that all involved will have a common understanding of the issues under consideration. Ms. Bernstein noted that the Medical Spa Association has a glossary of all possible procedures available on their website. The FDA does not have such a list. Ms. Achin Audesse stated that this list will be distributed at the next meeting.

## ***2. Who should perform these procedures?***

Opening this discussion, Ms. Balulescu explained that the DPH has been careful to describe the procedures in question as “medical services,” not “practice of medicine,” as the latter is the realm of the Board. Many of the services in question are performed by nurses and other medical personnel. Ms. Bernstein explained how DPH originally approached this issue: the standards of practice for each type of practitioner defines what procedures they can perform. In light of this, Gino Chisari, Nursing Practice Coordinator at the Board of Registration in Nursing, distributed the Board of Registration in Nursing guidelines to the group, and Ms. Achin Audesse distributed a report on “Recommendations for the Scope of Practice of Medicine,” the product of a task force in which she participated.

Dr. Quibell added that the issue to be considered is not only who will perform procedures, but also how these individuals are trained. Ms. Achin Audesse agreed that the question of “who” is twofold: licensing practitioners, but also establishing competence. Currently, doctors are required to practice “in a competent manner”; however, there are no regulations that specifically prohibit a doctor from taking the position of Medical Director at a medical spa, even if the doctor in question is not actively involved in the spa’s procedures or even has the specialized knowledge to understand these procedures.

Explaining the position of the Board of Nursing to the task force, Mr. Chisari noted that the Nursing Board has tried to bring congruence to the fact that the patients undergoing these procedures are well people who understand their choices and have the means to finance these treatments. These patients may see regulation of their practitioner as a barrier to care. While the Boards have authority to regulate practitioners, the current statute regarding the individual practice of nursing is limited to the sick and infirm and does not address well patients. The Nursing Board has, however, acknowledged that looking good is a “health-promotional” activity and has taken the stance that FDA-approved treatments can be considered a therapy.

Massachusetts State Law says very little about the unlicensed practice of medicine; it is not even considered a felony. Ms. Achin Audesse asked the group to consider what the reporting, training, oversight, and penalties *should* be for substandard practice. Overall, there is much room for interpretation in the regulations of every Board and DPH.

### *3. Where should these procedures be performed?*

Dr. Quibell raised the concern of the potential impact that this group's decisions may have on home use of future FDA-approved products that perform some of the treatments currently done only at medical spas.

Finally, Ms. Achin Audesse summarized the current situation: most of these procedures are done by individual practitioners who are not affiliated with a hospital or a practice defined as a clinic, and the procedures they perform are, for the most part, not covered by insurance. There is no way to oversee these practitioners -- no credentialing, peer, or insurance oversight. These are the frightening issues facing this Task Force.

## **5. Meeting Schedule and Next Steps**

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Bringing the meeting to a close, Ms. Achin Audesse explained that, for visitors, all the handouts, binder materials, and meeting minutes will be posted on the Board website, since this is a public meeting. She also instructed participants to look at the Board's Guidelines for Office-Based Surgery, which was then distributed, and think about it as a framework for the group's final recommendations. In addition, Mr. Aims will include an email link on the website for interested parties to submit any materials the group may find useful.

The next meeting of the Medical Spa Task Force will take place on **Wednesday, December 13, 2006, from 8:00-10:00 am**. The meeting initially scheduled for Wednesday, December 27, 2006 will be cancelled. Task Force members will be notified in advance of the specific subject matter for the December 13 meeting.