



# Proposed Legislation in Florida & California

## THE IMPACT UPON THE MEDICAL SPA INDUSTRY

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**T**There are many of us in the medical, spa, and medical spa industry who have comments about proposed legislation in Florida and California which might limit who may own a "medical spa," who may perform services in a medical spa, and who may supervise such personnel. I have noted quite a bit of misinformation on the subject so the intention of this article is to clarify the issues and offer some guidance.

### PROPOSED LEGISLATION

There has been a lot of commentary that the proposed legislation in Florida and California is being driven by the special interests and money from dermatologists and plastic surgeons. I would like to offer a different view. These proposed legislations (as well as many more certain to follow) are more the result of the negligent acts and abuse of a few

and the effect of this on the rest of the medical community. There has been tremendous greed which has caused franchise centers and other medical entrepreneurs to stretch the rules. Many physicians are practicing outside of their specialty as well; and this, too, is a recipe for increased legislation.

This alerted the attention of medical boards and various state legislatures. Also, there have been serious injury and, unfortunately, even deaths as a result of aesthetic procedures performed in medical spas.

To suggest that the legislation and/or actions by state medical boards are being fueled by dermatologists and plastic surgeons is denial of the underlying problems. Dermatologists and plastic surgeons combined comprise less than 5% of the

physicians in this country. Their political clout is minimal at best. Their lobbying efforts have minimal impact as well.

Whenever the public is being harmed, legislative action will certainly follow. Rest assured, many

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patients are being harmed and mistreated in medical spas across the country.

Whenever there has been serious injury or death as a result of a procedure, regulation has followed. For example, as deaths from liposuction (or lidocaine toxicity during liposuction procedures) became publicized, regulations began to

emerge regarding the procedure, where it can be performed, and the type of anesthesia that may be utilized. The actual amount of aspirate and fat which can be removed during certain types of procedures also became the subject of regulation. Regulations were also adopted which addressed where the procedure can be performed (in an office versus a surgical center or hospital). This was a natural consequence from a situation in which patients were being harmed. The occurrence of serious injury was rare, but regulations were enacted nonetheless.

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Another example would be the "I-Pledge" regulations regarding the prescribing of Accutane®. Dermatologists must face incredible bureaucratic challenges to write a prescription for an acne medication which has been available since 1972. Accutane has an exceptionally high safety profile, yet it has only recently become one of the more heavily regulated drugs currently on the market. Why? The reason is that a politician's child committed suicide, and the allegation was that perhaps Accutane contributed to the depression which may have led to the suicide. There was no medical or legal connection between the drug and the suicide, yet a tremendous amount of regulatory intervention has resulted.

Any dermatologist will tell you that this was severe over-reaction to a

situation, especially given the safety profile of the drug. However, this is another illustration of how and why regulations come to fruition.

### A LOOK AT THE FUTURE

My suggestion is to focus on the medical spa industry and the procedures being performed and not worry so much about who is initiating the legislative action. It has begun, so we need to deal with it and address it. It no longer matters who is initiating these regulations or why they are being initiated. Other states will certainly follow these two examples.

Florida and California tend to be states which respond quickly to such matters so it is not unreasonable to conclude that many other states will surely follow and enact rules, regulations, and laws. As a matter of fact, as of today, I am aware of activity in several other states. We must also have faith in our system that logic will prevail based upon regulations in other areas of medicine.

The new regulations would limit the number of locations that a physician can supervise. Historically, physicians were permitted to supervise additional locations in order to serve the public need. Physicians were able to have "satellite" offices because many areas of the country were medically underserved. Existing supervisory regulations were relaxed to accommodate this need. The public benefited.

Shortly after this, the use of physician extenders began to increase as well. The number of Physician Assistants and Nurse Practitioners has

grown tremendously in the past ten years. Practice of medicine standards were relaxed to allow such providers greater flexibility in treating patients. Once again, the public need was served, medical care was improved, and patients had better access to quality care.

However, as the rules and regulations were eased, the abuse of the system increased. This is the type of situation which leads to regulation. Facilities are establishing "medical directors" to oversee multiple locations, and frequently the medical director has little or no training in the area of medicine which he or she is supervising. It is unreasonable to expect or conclude that physicians will be able to "supervise" more than one or two locations in the future. There are practical and legal concerns. How can one person supervise more than one or two locations in a geographic location?

The number of locations being supervised is only one issue. The training of the physician will now also matter. In Florida, for example, the bill would limit the supervising physicians of a medical spa to dermatologists and





plastic surgeons. This is not as different from existing regulations as one might think. Physicians are only able to supervise employees in procedures which are consistent with their training and experience. This is true in all 50 states. So for example, a urologist cannot supervise a Physician Assistant who is performing dermatologic procedures. Only a dermatologist can do so. Proposed Florida regulation in this regard is reflective of the current situation! Once again, however, abuse of this situation is what is driving further legislative action.

I have read commentary by physicians asserting that the legislation is fueled by dermatologists and plastic surgeons. I have even read commentary that Family Practice doctors were more suitable to oversee medical spa procedures.

Frankly, this is ludicrous. The aesthetic procedures being performed in medical spas are dermatologic in nature. The equipment (lasers, for example) is cleared by the United States Food & Drug Administration for dermatologic procedures. Botox® Cosmetic, Restylane®, Sculptra®,

Juvéderm® and other injectible fillers and facial enhancement products are similarly cleared for dermatologic use. Any physician utilizing these devices and materials who is not a dermatologist is arguably practicing outside the scope of his or her specialty.

This is in no way to suggest that only dermatologists should utilize these materials. However, it is reasonable to conclude that they are most likely best suited to supervise others utilizing these materials. Also, dermatologists and plastic surgeons are best equipped from training and experience to fix a problem if one arises. There are a large number of patients who have been harmed as a result of aesthetic medical spa treatments. Further, dermatologists and plastic surgeons are receiving training in the aesthetic procedures being performed in the medical spa setting during their residency programs. This further distinguishes them as the leaders in aesthetic medicine.

I interviewed Birgit Toome, M.D., a Board Certified Dermatologist in Voorhees, NJ, regarding these issues. She stated, "Hardly a day goes by that I do not see and treat patients with hyper- and hypo-pigmentation or burns and scarring from local 'medical spas' offering laser treatments." Her experience is regrettably not uncommon.

A potentially even bigger issue in the future is ownership issues of

medical spas. Current abuses of the system will likely lead to future regulation in this regard. The reality is that non-physicians are not permitted to own medical practices in 45 of the 50 states. However, even a cursory look at ownership of self-professed "medical spas" will indicate that this situation is being abused as well.

### SEEKING THE ADVICE OF EXPERTS

There are many correct and appropriate ways to own and operate a medical spa. However, current abuses are leading to increased regulation; and it is my opinion that we are only in the beginning of a wave of regulation in this area. There is no replacement for competent legal and consultative advice from credible sources.

However, as with a lot of current trends, there are a lot of people giving advice in this area; but only a precious few which actually know all of the issues. I have frequently heard many remarks from alleged "experts" in the field, but all too frequently, the information is incorrect or incomplete. ❗



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