

putting the “med” back in medspa

Appropriate regulation helps to ensure patient safety is prioritized over financial gain

Recent high-profile medspa deaths, as well as a new framework for addressing the regulation of medspas means that 2010 is likely to be a big year for attempts by policymakers to address these non-traditional settings for medical treatment. Add these to the booming medspa business numbers and socioeconomic indications that these will continue to grow, and there’s a recipe for much-needed legal oversight.

According to the International Medspa Association, the number of medspas has grown by 85% in the past 2 years, and is currently up to 2,500 nationally. The *Aesthetic Medicine News* reports that annual revenues from medspas are in excess of \$2 billion. Socioeconomic factors indicate that this growth will continue. According to the AARP, there are 12,000 Americans turning 50 every day, or 1 every 8 seconds. An NBC Report from November 2009 said, “As a result of the need to compete longer in the workforce, more men are seeking procedures to keep them looking young and fit.”

One has only to look at recent news reports to see the resulting patient injury due to a lack of appropriate regulatory oversight, as well as enforcement of existing law. This past September, 37-year-old Rohie Kah-Orukotan fell into a coma and ultimately died as a result of complications associated with liposuction performed in a Florida tanning salon, which was not an appropriately licensed medical facility. The physician performing the procedure learned liposuction at a 3-day cosmetic surgery course. Reports regarding circumstances surrounding the death are conflicting and the tragedy is still under investigation.

Massachusetts Task Force Recommendation Outcome in the Balance

Several states, as well as the Federation of State Medical Boards (FSMB), have been eyeing a new approach to medspa regulation. As the result of a bill by Senator Joan Menard, the Massachusetts Medical Spa Task Force was created in 2006. The Task Force, charged

with addressing the questions 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,” consisted of representatives from the Board of Registration in Nursing, the Board of Cosmetology, the Board of Medicine and the Board of Professional Licensure, as well as State Representative Peter Koutoujian, Senator Menard, a member of the general public, a registered electrologist, a registered nurse, an internist, a plastic surgeon, dermatologist Karen McCoy, MD and current ASDSA President Jeffrey Dover, MD, FRCPC.

The Task Force met for two years and examined other state laws and regulation of medspas and cosmetic medical procedures, and heard presentations from the State Department of Public Health (DPH); the National Coalition of Estheticians, Manufacturers/Distributors & Associations; Manufacturers of Equipment for Light-Based Aesthetics (MELA); the ASDS and the American Society of Cosmetic Dermatology and Aesthetic Surgery; as well as an aesthetic school called the Catherine Hinds Institute; and a large day spa, “skin care salon,” and esthetician school franchise called the Elizabeth Grady Companies, which claims to be the largest employer of estheticians in the country. According to the Task Force’s minutes, the Elizabeth Grady Companies’ presentation included a presentation of how estheticians assess patients prior to administering Botox®, a practice that was praised by the Task Force’s internist.

The MELA representative’s presentation was also troubling. After stating the products manufactured by the companies which belong to MELA have a less than one percent adverse effect rate, MELA Immediate Past President Josephine Torrente rather inartfully dodged a question regarding to whom their members’ laser devices were sold, saying she “blocks herself from that information.”

The Task Force’s final report and model

legislation, which is currently being considered by the state legislature, recommended regulating oversight of medical spas according to three categories, based on the relative risks associated with the procedures performed therein. Additionally, the Task Force also recommended that medical spa facilities should be licensed by the DPH in a manner similar to the way DPH licenses medical clinics. Both of the dermatologic surgeons that served on the Task Force, the ASDSA, the Massachusetts Academy of Dermatology, the AADA, and others oppose the bill’s exclusion of laser hair removal from consideration as the practice of medicine and allowance of non-physicians to perform non-ablative laser procedures without on-site physician supervision.

Of the thirteen voting members that comprised the Task Force, only three members were physicians (the plastic surgeon was not present at the vote on the final recommendations). Although ASDSA members deeply value our relationship with physician extenders, it is worth noting that many of these physician extenders as well as non-medical personnel are seeking scope of practice expansions in states across the country. According to the American Medical Association, last year nurses sought some form of scope of practice expansion in 29 states, including but not limited to, independent practice, independent prescribing rights, authority to perform any medical procedure, including but not limited to, interventional pain management, and more. Given this information, it is not surprising that the physicians on the Task Force would be out-voted by nurses, estheticians, and cosmetologists on issues regarding appropriate physician oversight for medical spas.

The ASDSA has several policy recommendations that we believe are better models for addressing patient safety concerns in non-traditional medical settings, such as medical spas.

Recommendation: Strengthen Penalties and Enforcement of Existing Laws
The ASDSA’s experience in California provides

a good picture of how strengthening penalties and enforcement of existing corporate practice of medicine prohibitions might assist with lessening the incidence of both patient injury due to treatments and procedures performed by unsupervised non-physicians and garden variety fraud in the form of systematic under-treatment or inappropriate treatment which results in patients returning to the facility several times for costly procedures which yield little or no result.

The ASDSA and CalDerm's testimony before the joint committee of the Medical Board of California (MBC) and the Board of Nursing's forum on laser safety demonstrated that several patients and physicians have filed complaints on unsafe medical spa practices with either no or very slow follow-up by the MBC. Several of these unsafe practices occur in large medical spa and laser chains, which are already in violation of the existing corporate practice of medicine prohibition. This prohibition disallows medical procedures from being performed within a facility that is less than fifty-one percent physician ownership. Many of these facilities operate in flagrant disregard of the law, actively recruiting physicians to serve as "medical directors" by attaching their name to the facility without having to provide any real oversight. A member forwarded one such solicitation letter to the ASDSA. The letter reads, "...we are very excited to announce our Medical Director program. This opportunity allows Doctors and Physicians to earn up to \$400 per month/per spa in their area. We have several DaySpas that anxiously await a Medical Director and we would anticipate a large number of client referrals to your practice."

One such example of this gross negligence exists within a complaint which was first filed with the MBC in September 2007. In that case, the named physician was licensed in California but lived in Utah. This physician served as a so-called "medical director" of several medical spa and laser chains up and down the coast of California. Had this medical director actually set foot in any of the facilities that he "supervised," he wouldn't have had the training to be of any help. According to the complaint, which is a matter of public record available on the MBC's Web site, "Respondent is a board certified emergency physician... Respondent has no medical training with any

kind of lasers or intense pulsed light ('IPL'). Respondent describes himself as self-taught because medical laser training is not available. Further, Respondent lacks knowledge about the causes, prevention and treatment of common IPL and laser injuries. Further, Respondent lacks knowledge about the causes, prevention and treatment of injuries from injection treatments." Recently, a young woman in Washington State died as a result of complications associated with liposuction in a medical spa for which the same Utah-based physician served as medical director.

The ASDSA and CalDerm believe a significant reason for this lack of enforcement is that the MBC has limited resources, which leads to the need to prioritize complaints by degree of injury and level of penalty. In California, which bars the corporate practice of medicine that arises in the form of corporate entity employment of, or contracting with, "rent-a-docs" to create the facade of physician-overseen networks of medispas (if not, necessarily, attention to patient care) existing law puts the Medical Board of California in the awkward case-making position of having to "cobble together" a finding that an M.D. is "aiding and abetting (the violation of) any provision" of the Medical Practice Act (Bus. & Prof. Code Sec. 2234).

Corporations and other artificial legal entities, which have no professional rights, privileges, or powers, are only subject to nominal penalties, usually reserved for instances of medical malpractice in which there is patient abuse, or physician substance abuse, of potential "low misdemeanor" punishment of a fine of not less than two hundred dollars (\$200) nor more than one thousand two hundred dollars (\$1,200) or by imprisonment for a term of not less than 60 days nor more than 180 days, or by both such fine and imprisonment. (Bus. & Prof. Code Sec. 2315). To solve this issue, in both 2008 and 2009, the ASDSA and CalDerm proposed bills to strengthen penalties and enforcement of the existing corporate practice of medicine prohibition by assigning a penalty of \$25,000 for the first offense to facilities violating the law. Existing law provides the MBC the ability to revoke the license for those so-called "medical directors" who knowingly aid and abet the unlicensed practice of medicine. In 2009, the bill, which was widely endorsed by medical societies, including physicians assistants and

nurses, passed through the House and Senate with only one "no" vote before being vetoed by Governor Schwarzenegger, who called the bill, "redundant." The ASDSA and CalDerm are still in the process of planning our next move with relation to that legislative proposal. In the meantime, the issue has gained enough visibility to encourage the Medical Board to re-launch "Operation Safe Medicine" and convene its own task force to address the medical spa issue. The MBC re-established its Operation Safe Medicine unit in Southern California on July 1. The program, which had previously closed in 2003 due to budget cuts, is designed to target unlicensed activity, corporate practice of medicine, and lack of supervision violations. The MBC's Advisory Committee on Medspa Supervision will "review the issue of physician availability and adopt the necessary regulations to implement changes necessary to ensure the continued protection of California consumers who are increasingly using the services of medical spas." ASDSA Board Member Suzanne L. Kilmer, MD, will represent the ASDSA on the Committee; its first meeting will be held on January 28.

Recommendation: Crack Down on Consumer Fraud

As demonstrated in the lack of enforcement of the prohibition of the corporate practice of medicine example cited above, other regulatory agencies, even as large as the Food and Drug Administration (FDA), frequently lack the resources to crack down on clear cases of consumer fraud. One prevalent problem that is particularly rampant in medspa settings is the marketing of drugs which are not-FDA approved, such as the mesotherapy drug Lipodissolve. According to a transcript of the FDA Voice radio program entitled, "Measures Undertaken to Address Concerns about Marketing of Unapproved Drugs," the FDA estimates that about 2% of the types of prescribed drug products that are on the market are unapproved. Dr. Jason Woo, the Associate Director for Scientific and Medical Affairs in the Office of Compliance for the Center for Drug Evaluation and Research of the FDA states, "It's not that FDA doesn't allow these drugs to be marketed illegally; we simply don't have the sufficient resources to identify and pursue them all at once."

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The Kansas State Medical Board attempted to ban the use of Lipodissolve in the state in 2007, before a lawsuit by Lipodissolve provider Fig, formerly known as Advanced Lipodissolve, blocked its implementation. Later the same year Fig, abruptly filed for chapter 11 bankruptcy, leaving patients that had pre-paid for the treatments out in the cold. In 2008, Nebraska State Senator Rich Pahls introduced a bill to attempt to ban Lipodissolve in that state, along with the use of any combination of phosphatidylcholine or sodium deoxycholate, by subcutaneous injection for the purposes of eliminating or reducing localized fat accumulation. Reports of sales of the drug are still widespread; one only has to Google the drug to find a host of providers offering the treatment.

A favorite patient recruitment technique of one very large laser hair removal chain is to give patients the opportunity the opportunity to “win” a free consultation. The “winner” is then subjected to high pressure sales to convince her to sign a nonrefundable contract for several expensive treatments. Lawsuits against that company allege that deceives customers as to their cancellation rights, and refuses to allow cancellations and refunds even though services have not yet been rendered. One investigative news report on the chain includes the release of the company training manual, which instructs employees to point out “imperfections” to potential clients during consultation, and stipulates the company’s “upselling” requirement.

Thankfully, State Attorney Generals have begun to take notice. In December, Illinois Attorney General Lisa Madigan charged the Nu U Medspa chain with consumer fraud for advertising the non-FDA approved LipoDissolve mesotherapy treatment. Additionally, the Attorney General’s complaint alleges that Nu U Medspa violates several state laws, including the including the Consumer Fraud and Deceptive Business Practices Act for deceptively tricked signing up patients for financing a series of treatments. The ASDSA is reaching out to Attorney General Madigan to encourage her to adopt this issue on a larger scale.

Recommendation: Ensure Truth in Advertising

Patients have a right to know the level of training, licensure, and board certification of the person providing their medical treatment. Too often consumers are led into non-traditional medical facilities, such as spas and salons, by misleading advertising phony “medical-like” individuals.

Florida law requires practitioners to disclose their level of licensure both in person and in advertising. Minnesota, Missouri, New Hampshire, Rhode Island require all personnel in hospital facilities and in some cases other licensed medical facilities to wear identification displaying their level of licensure. In 2005, the state of Tennessee passed a law requiring all boards of healing arts to create laws governing the use of the professional titles under their jurisdiction, including advertising pertaining to board certification and specialty. Arizona, California, Massachusetts, and Pennsylvania proposed legislation relating to truth in advertising in 2009 While Arizona and California’s bills died with the adjournment of the state legislature and will be re-introduced in 2010, proposals in Massachusetts and Pennsylvania are still active.

In 2010, the ASDSA is providing support to the Pennsylvania Academy of Dermatology and Dermatologic Surgery and the Pennsylvania Medical Association in passing House Bill 1482, which would require the Department of Public Health to “promulgate regulations to require each employee of a home care agency, home health care agency and hospital to wear a photo identification tag at all times when the employee is working. The photo identification tag shall include a recent photograph of the employee, the employee’s name, the name of the home care agency, home health care agency or hospital, the certificate or license number for the home care agency, home health care agency or hospital and the expiration date of the certificate or license.”

Laws in Georgia, Oklahoma Oregon ensure that the use of the title “doctor” as it relates to medical training is clearly specified in any advertising, which will be particularly helpful as the controversial “Doctor of Nursing Practice” degree becomes prominent in medical settings. The National Board of Medical Education’s

(NBME) decision to use questions from the United States Medical Licensing Examination® (USMLE) Step 3 Physician Licensing Exam for Doctor of Nursing Practice (Dr. NP) has prompted a great deal of concern on the part of the physicians regarding not only the use of the title “Dr” to indicate a doctorate of Nursing Practice, but also the potential ability to mislead the public that the Dr. NP certification is equivalent to the training and examination of licensed physicians.

In addition to advocating for transparency and full disclosure in communicating level of licensure and training by providers of medical care, the ASDSA takes the position that advertisers should be able to document and substantiate claims made in ads about safety, efficacy, benefits and risks, as well as unique skills and remedies.

Recommendation: Include Cosmetic Medical Procedures in Legal Definition of the Practice of Medicine

As has been reported in previous editions of Currents, several states do not have an explicit legal definition of the practice of medicine, or restrict that definition to the treatment of illness or disease. When cosmetic medical procedures are excluded from a state’s definition of the practice of medicine, they become subject to an entrepreneurial environment, where “patients” become “consumers,” and the bottom line is frequently prioritized over the best treatment for the patient’s condition.

At least fifteen states and the District of Columbia do not have definitions of the practice of medicine that extend beyond the treatment of illness or disease. The states of Georgia, New York, and Virginia explicitly exempt laser hair removal from consideration as the practice of medicine; however both Georgia and Virginia law specify training and physician oversight requirements despite this exclusion.

2010: A Hot Year for MedSpa Regulation

As of this writing, 15 states are projected to have bills, regulatory proposals, or Attorney Generals actions pertaining to medspas in 2010. To see a forecast of these actions, go to www.asds.net/medspa2010.aspx. ■