DEPARTMENT OF HEALTH
ELECTROLYSIS COUNCIL
RULES WORKSHOP
December 10, 2014
9:30 a.m. EST

Florida Department of Health
Southwood Capital Circle Office Complex
4052 Bald Cypress Way, Conference Room 301
Tallahassee, FL

PUBLIC COMMENTS

Received as of:
December 3, 2014
Electrologist are trained well, then we can take our 30 hour laser training which many of us have. With that said every time we are hired or deal with a new machine, that by the way are all different we are trained on all the parameters of said machine. I have to say if you sit on continuing education for laser classes in my opinion are of no value, many others agree they are boring no one wants to be there only because they lack in any new information most of the time the class is not even relevant. there is actually no more to learn, the classes are very expensive to keep this license becomes very expensive and the compensation for the service has dropped dramatically practicing laser hair removal is relatively easy as long as you become very familiar with the laser device you use.

That my opinion, Thank you

Marilyn Cruz
LIC# EO 1432
Cell 786-299-6521
My name is Shirley Freistat.

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Thank you, for accepting my opinion
Shirley Freistat, CCE,CME
Licence # EO 1560
PHONE # 305-962-4352
King, Anna

From: Jon Pellett <jpellett@barrmurman.com>
Sent: Monday, November 24, 2014 1:34 PM
To: zzzz Feedback, MQA_Electrolysis
Cc: Hall, Allen; Prine, Chandra; Sanford, Crystal; King, Anna; Walker, Pauline;
'Marlene.Stern@myfloridalegal.com'; 'Ed Tellechea'; Lisa Nelson; Meadows-Keefe Julie;
Pat Cunningham
Subject: December 10 workshop - SCMHR
Signed By: jpellett@barrmurman.com

Good afternoon,

Attached please find additional information to be included in the comments from my clients, SCMHR concerning the upcoming December 10, 2014 workshop.

/s/ Jon M. Pellett, Of Counsel
Barr, Murman, & Tonelli, P.A.
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October 2, 2014

TO: Whom It May Concern
RE: Changes to the FL Law

Dear Sir or Madam:

For 12 years our agency has been providing insurance to laser/IPL centers throughout the United States, including many clients in Florida. Our carrier is Lloyds of London. Before we started insuring laser/IPL clients, we studied the industry for 6 months. We used the services of a physician who spent 2 days training our office and a laser repair technician who enabled us to better understand how a laser works. Many industry educators also offered their assistance.

What we found, and our subsequent experience supports, is that education in lasers/IPL and light sources are the most crucial requirement to avoid claims. Our suggestion for education is a minimum of 30 hours of training for all backgrounds. We find that it really does not matter if the person operating a laser/IPL is a nurse, a doctor, a physician’s assistant, an electrologist, a laser/IPL technician or an esthetician. With proper education, our insurance experience shows that anyone can operate a laser/IPL. That being said, we have found that with emerging changes in the functionality of modern lasers/IPLs as well as various procedures and skin types, there is truly a need for continued education in this field.

The claims that we have on laser/IPL work almost always have to do with burns and hyper- or hypo-pigmentation at the site of the laser/IPL work. These conditions manifest themselves, sometimes over time, and in fact most skin problems end up going away in the normal healing process, usually about six months, as long as the laser is set for the right skin type. Since the United States has become such a melting pot of cultures and ethnicities, it is getting more difficult to determine the proper skin types of clients. Most of the claims are misclassification of skin types. Continuing education is needed to stay up to date with how skin types relate to modern lasers/IPLs, as the technologies being used are continually changing. Many lasers can now target a greater variance of problems such as allergy relief, tattoo removal and smoking cessation. As the technology changes, technicians need to receive new training.

Florida requires 20 hours of continuing education for an electrology license, yet requires no continuing education for laser/IPL technicians to maintain their licenses. We have found that the number of claims for laser/IPL procedures far exceed those that we have received for electrology procedures, by the hundreds. We have also found that there are far more claims for laser/IPL procedures in states that are more lenient with their licensing and training requirements for laser/IPL technicians, such as New York, which requires no continuing education and no real training. The average claim pay out in states like this is about $50,000.

In closing, we urge you to reconsider your position on the continuing education requirements for laser/IPL technicians in the State of Florida.

Sincerely,

Susan Preston
President
Professional Program Insurance Brokerage
Good morning,

Attached please find information to be considered at the Rules Workshop scheduled for December 10, 2014.

When a final agenda is prepared, please forward a complete copy of the agenda materials being considered/gathered as provided under Section 120.525, Florida Statutes.

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Increased Risk of Litigation Associated With Laser Surgery by Nonphysician Operators

H. Ray Jalian, MD; Chris A. Jalian, JD; Mathew M. Avram, MD, JD

IMPORTANCE Controversy exists regarding the role of nonphysicians performing laser surgery and the increased risk of injury associated with this practice.

OBJECTIVE To identify the incidence of medical professional liability claims stemming from cutaneous laser surgery performed by nonphysician operators (NPOs).

DESIGN, SETTING, AND PARTICIPANTS Search of an online national database of public legal documents involving laser surgery by NPOs.

EXPOSURE Laser surgery by nonphysicians.

MAIN OUTCOMES AND MEASURES Frequency and nature of cases, including year of litigation, certification of provider and operator, type of procedure performed, clinical setting of injury, and cause of legal action.

RESULTS From January 1999 to December 2012, we identified 175 cases related to injury secondary to cutaneous laser surgery. Of these, 75 (42.9%) were cases involving an NPO. From 2008 to 2011, the percentage of cases with NPOs increased from 36.3% to 77.8%. Laser hair removal was the most commonly performed procedure. Despite the fact that approximately only one-third of laser hair removal procedures are performed by NPOs, 75.5% of hair removal lawsuits from 2004 to 2012 were performed by NPOs. From 2008 to 2012, this number increased to 85.7%. Most cases (64.0%) by NPOs were performed outside of a traditional medical setting.

CONCLUSIONS AND RELEVANCE Claims related to cutaneous laser surgery by NPOs, particularly outside of a traditional medical setting, are increasing. Physicians and other laser operators should be aware of their state laws, especially in regard to physician supervision of NPOs.

Published online October 16, 2013.

Cutaneous laser surgery remains one of the most popular elective procedures performed in the United States. Among dermatologic surgeons alone in 2011, more than 1.6 million laser treatments were performed. Many more procedures were performed by physicians in other specialties and by nonphysician operators (NPOs). As the numbers of these procedures increase, a concomitant growth has occurred in laser injury-related litigation. The practice of delegation to NPOs has accompanied the burgeoning trend toward greater availability of laser surgery and is hypothesized to be in part responsible for the increase in injury and litigation. Moreover, the past decade saw the massive expansion of the so-called medical spas, nonmedical facilities offering aesthetic and cosmetic procedures. Many of these facilities are owned by or retained by physicians; however, most of the procedures are performed by NPOs of varying certifications as permitted by state regulation. The degree of supervision varies among states, and often the physician supervisor is not required to be on the premises at the time of rendering of services.

Many physicians are increasingly using physician extenders (PEs) within their practice to meet rising demand and falling reimbursements. Among dermatologists, almost 30% reported using a PE within their practice, a 40% increase over the preceding 5 years. Although no data have emerged regarding increased litigation associated with this practice, legal precedence and numerous investigations are clear on liability. When a physician delegates duties to a PE, responsibility and liability remain squarely on the supervising physician provided that the services rendered fall within the scope...
Results

NPO as a Function of Year of Litigation

Of 175 cases identified, the first occurrence of an NPO was in 1999. From January 1999, to December 2012, a total of 75 cases with NPOs were identified. This represents 42.9% of the total cases during the same time frame. Stratification of laser operators by year of litigation revealed a striking trend. From 2004 to 2012, a trend was observed toward an increased proportion of lawsuits stemming from cutaneous laser surgery performed by NPOs. This trend is most notable from 2008 to 2011, our most recent data, during which time the percentage of cases involving an NPO increased from 36.3% to 77.8%. Of the 2 cases in 2012, both were performed by an NPO. These results are summarized in the Figure.

Procedures

In line with our previously published data, the most commonly performed procedure (n = 40) from 2004 to 2012 that resulted in injury and litigation by an NPO involved laser hair removal. Rejuvenation, composed mainly of intense pulsed light treatments, was the second most commonly litigated procedure (n = 7). Among the NPO cases, a notable trend is evident when expressing the number of NPO cases as a percentage of the total number of cases for the same procedure. 75.5% of laser hair removal lawsuits from 2004 to 2012 were performed by an NPO. This number is even more dramatic in the years 2006 to 2012, when 85.7% of all laser hair removal lawsuits were performed by an NPO. From 2010 to 2012, a total of 90.0% (18 of 20) of laser hair removal cases were performed by an NPO. The remainder of the litigated procedures by NPOs and the proportion of total cases are given in Table 1.

Location of Services

From 1999 to 2012, a total of 64.0% (n = 48) of the NPO cases arose in a nonmedical practice setting. These include medical spas and other nonmedical facilities offering cosmetic services (eg, salons, spas, etc). In 2008 to 2011, NPO procedures performed in medical spas represented almost 80% of lawsuits. Of the 2 cases in 2012, one was performed in a medical spa setting and the other in a physician office. When looking at the type of procedure performed in this setting, most of these cases were laser hair removal procedures. From 2008 to 2012, a total of 68.6% (n = 24) of laser hair removal litigation cases involved an NPO in a medical spa setting. These results are summarized in Table 2.

Specific Allegations

Not surprisingly, the injuries sustained following laser surgery by NPOs and the causes of action in these cases mirror those previously reported by our group. However, the specific allegations in these cases offer insight into various liabilities imposed on physician supervisors. It is necessary to first examine the 2 different forms of liability (direct and vicarious) that a physician could face arising from allegedly improper laser treatment. A physician is directly liable for any negligence that can be attributed to an...
individual capacity (ie, the personal failure to perform his or her duties at the requisite standard of care). A physician's duties often extend beyond the laser procedure; for instance, a physician may be directly liable for any negligent hiring, supervision, or training and so forth.

Conversely, a physician is vicariously liable for the negligence of his or her employees. A physician's vicarious liability is rooted in the doctrine of respondeat superior (Latin for "let the master answer"). This common law doctrine is often used to hold the employer responsible for the actions of his or her employees if and when the employee is acting within the scope of his or her employment. The rationale underpinning the application of vicarious liability to an employer is 2-fold. First, an employer has the ability and duty to control his or her employees. Second, presumably an employee is performing duties that will result in a benefit to the employer and is so doing is acting under the direction or authority of the employer. Therefore, in a medical malpractice context, a physician can be vicariously liable for the negligence of his or her subordinates, including nurses, NPOs, and other staff.

Almost all of the malpractice cases arising from the negligence of NPOs are coupled with vicarious liability claims against the employer, often a medical spa but at times a physician owner. Notably, 25 of 58 cases (43.1%) with NPOs from 2004 to 2012 represented instances in which no direct physician supervisor was identified. In these cases, the facility was often named as the defendant. As for a physician's direct liability in NPO cases, by far the most common specific allegation (n = 27) was failure to supervise the delegate. Failure to supervise represents the physician's failure to properly oversee the procedure. Failure to train and hire appropriate staff was the second most common specific allegation (n = 23). In addition to these allegations, negligent entrustment (n = 2) was alleged against the physician employers in their individual capacity. Negligent entrustment arises when one party (the entrustor) is held liable for providing another individual (the employee) with a potentially dangerous instrument. In this context, a physician can be held liable for providing an NPO with a laser if this instrument is used for a procedure that results in injury to a patient. The physician liability is predicated on the fact that a reasonable person in like circumstances would not have entrusted the NPO with the equipment. A summary of specific allegations (where available) relating to injury sustained as a result of laser surgery by NPOs from 1999 to 2012 includes the following: failure to properly hire, train, or supervise staff (n = 27); failure to properly perform treatment or operate a laser (n = 23); failure to conduct a test spot (n = 10); lack of a license to perform a procedure (n = 6); failure to recognize or treat an injury (n = 5); and negligent entrustment (n = 2). As can be seen from the foregoing definitions, a physician's direct liability is predicated on his or her negligence, not the negligence of his or her employee or agent.

Discussion

Physician delegation of laser surgery has grown significantly during the past decade. In addition, nonphysician-supervised NPO laser surgery is being performed legally in many states at nonmedical facilities. Data on the safety of NPO performance of cutaneous laser surgery are lacking in the medical literature. Most important, a clear trend demonstrates a dramatic increase in the number of lawsuits associated with NPO performance of laser surgery. The NPOs comprise a vast diversity of operators, including nurse practitioners, registered nurses, medical assistants, electrologists, and aestheticians, among others. In 2011, the latest year with a presumed complete data set, 77.8% of the cases involved an NPO. In addition, of the cases with NPOs, almost two-thirds occurred outside of a traditional medical practice. From an examination of
the specific allegations available in this study, the following 2 themes emerged: (1) both vicarious and direct liability of the supervising physician and (2) the prevalence of nonmedical personnel failing to perform procedures commensurate with the standard of care, including recognizing and treating complications.

We propose that the overall trend in increased litigation for laser surgery is in part explained by greater numbers of NPOs performing these procedures, in particular those practicing without direct supervision in the medical spas. This is the first study to date to offer such quantitative evidence. Of the procedures performed, laser hair removal accounted for most of these cases. Indeed, laser hair removal is the most frequently performed laser procedure in the United States. However, if one takes into account the number of procedures performed by operators (physician vs NPO), the data become even more compelling. Only one-third of laser hair removal procedures in 2012 were performed by an NPO; the remaining two-thirds were performed by physicians. Despite the fact that physicians perform most laser hair removal, 85.7% of laser hair removal lawsuits in our study from 2008 to 2012 are cases involving an NPO. In 2011, a remarkable 90.99% (30 of 11) of laser hair removal litigation was against NPOs. One way to interpret these data is that some increased inherent risk of injury exists with an NPO.

The inconsistency and ambiguity of the state laws exemplify the lack of uniformity of the practice of delegation. For example, in Maine only a physician may operate a laser for hair removal. At the other end of the spectrum, Nevada as of June 2011 had no regulations regarding the use of a laser. In addition to the ability to delegate these procedures is the degree of supervision required. Some state statutes are explicit in stating the need for a written protocol, the requirement to appropriately train and document the training of personnel, and the necessity for adequate supervision. Many physicians “lead” their medical license to these facilities without meeting the legal requirements for supervision. In line with this, California recently passed a bill (California Assembly Bill 1548, Chapter 140) that increases penalties for illegally owning and operating a medical spa, with fines up to $50,000 and a maximum of 2 to 5 years in state prison. The lack of overarching federal law makes it difficult to uniformly require qualifications of personnel allowed to render laser treatments. Despite appropriate certification, regulations regarding appropriate training are ambiguous and are subject to interpretation. Because laws and regulations are constantly evolving, it is imperative for physicians who use PEs to be up to date. Current guidelines can be found at state medical board and state legislature websites.

In the correct setting, with close on-site supervision and appropriate training, the use of NPOs can prove to be a fruitful, productive, and safe environment for patients. Perhaps a larger issue is the role of NPOs, as well as physicians without adequate training, in the operation of a laser. Technology related to laser surgery has evolved rapidly since the description of selective photothermolysis by Anderson and Parrish in 1983. Despite the propagation of nonmedical facilities performing these procedures, the tremendous amount of physics and medicine related to cutaneous surgery should not be overlooked. The American Society for Dermatologic Surgery Association position promulgates the use of energy devices capable of altering or damaging living tissue to physicians who are “trained appropriately in the physics, safety, and surgical techniques involved in the use of energy devices capable of damaging living tissue prior to performing procedures using such devices.” Moreover, in the setting of delegation, a physician “should be fully qualified by residency training and preceptorship or appropriate course work prior to delegating procedures to licensed allied health professionals and should directly supervise the procedures. The supervising physician shall be physically present on-site, immediately available, and able to respond promptly to any question or problem that may occur while the procedure is being performed.” Finally, the position statement underscores the need for “appropriate documented training in the physics, safety, and surgical techniques of each system. The licensed allied health professional should also be appropriately trained by the delegating physician in cutaneous medicine, the indications for such surgical procedures, and the pre- and post-operative care involved in treatment.”

Several limitations are inherent in conducting research using a legal database. First, although it is a massive data bank, only one legal database was searched. Cases within the database are those in which some form of legal action was taken and exclude complaints handled outside of the judicial system (ie, third-party arbitration through a malpractice carrier). This is likely to have excluded many frivolous claims with little merit. Second, the query was a retrospective review and was limited by the search terms selected; it is likely that some decisions exist that did not contain the searched terms. Third, these legal pleadings are layman documents (ie, not medical records), and the veracity of the facts was assumed to be true. Furthermore, layman terms may have eluded a database search for the purposes of this study. Fourth, because of the limited number of cases with NPOs for certain procedures, it is difficult to interpret the trends for less commonly performed surgery. Nonetheless, the actual data likely understate the true incidence of NPO laser complications. Generally, plaintiffs’ attorneys do not pursue litigation against uninsured operators. Unlike physicians, NPOs (especially in a nonmedical office setting) are less likely to possess liability insurance that can satisfy a potential malpractice or other legal judgment.

A dramatic increase in litigation has been filed against NPOs performing cutaneous laser procedures in medical and nonmedical office settings. This has important implications for the safety of patients undergoing these procedures. When a physician delegates duties to a PE, responsibility and liability remain squarely on the supervising physician provided that the services rendered fall within the scope of duty of the PE. This holds true for physicians supervising NPOs in the setting of cutaneous laser surgery. Given the increase in NPO laser surgery procedures and a parallel trend in greater frequency of lawsuits, further studies are needed to examine this troubling trend in laser safety.
The Man Behind Miescher Nevi: Alfred Guido Miescher

Fabrizio Vaira, MD; Gianluca Nazzaro, MD; Carlo Crosti, MD; Stefano Veraldi, MD

The man behind Miescher nevus is Alfred Guido Miescher. He was born on November 4, 1887, in Naples, Italy. His mother was Marietta Berner, and his father, Max Eduard Miescher, was a businessman. He was the nephew of Johannes Friedrich Miescher (1844-1895), professor of pathophysiology at the University of Basel, Switzerland, and discoverer of nucleic acids. After the father’s death, he followed his mother to Basel, her hometown, where Guido completed his school.

He startled his studies in engineering at the Eidgenössische Technische Hochschule in Zurich, Switzerland, and then switched to medicine, studying in Basel, Zurich, and Munich, Germany. Working as an assistant of the dermatologist Bruno Bloch, he wrote his thesis on a case of mycetoma. In 1933, after the death of his mentor, Miescher became professor and director of the University Dermatology Clinic in Zurich. Miescher was an excellent clinician, and he was passionate about clinical dermatology and Dermatopathology. Indeed, he said that “Dermatology is more than morphology.”

In his original landmark work, Histologie de 100 cas de naevi pigmentaires d’après les methods de Masson, published in 1935, Miescher studied 100 hemispherical naevi found mostly on women’s faces. They are dome-shaped papules in which melanocytes are distributed mostly endophytically, often in a wedge, and they reach the deep reticular dermis. Miescher was a pioneer in the treatment of skin diseases with phototherapy and of cutaneous tumors with ionizing radiation. Indeed, he helped to improve dermatological radiotherapy, through determining the safest doses and innovative fractionation schemes to reduce the toxic effects. Miescher was skilled in identifying new aspects of already known diseases. He reclassified granulomatosis disciformis chronic et progressiva, and, in 1945, he was the first to describe the chelitis granulomatosa, subsequently also called Miescher chelitis.

His students said that he cared about only 3 things: dermatology, music, and mountains. Miescher was a gifted cellist and a lover of mountaineering, as well as an illustrious dermatologist. He bravely climbed numerous Swiss peaks. But his most important venture was an expedition to the Caucasus Mountains. Miescher was the first person to climb Mount Elbrus (5,629 m) and ski down. After a life full of medical and sporting achievements, he fought against the cancer and died in 1961.

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King, Anna

From: Tali Arviv <arvivmd@gmail.com>
Sent: Friday, November 07, 2014 6:58 PM
To: zzzz Feedback, MQA_Electrolysis
Subject: Proposed Agenda Items for 12/8/14

Dear board and counsel members,

I would like to join in on the meeting on December 8, 2014 and would like to add agenda items to the list of items to be discussed if possible. This is my first time joining this meeting so I am unsure as to what has been discussed in the past, what is relevant, and what I can request to be added to the agenda. Below is what I would like the board to consider discussing at the upcoming meeting or future meetings if appropriate.

1) I understand that there is a rules workshop on December 10th and would like to discuss the separation of laser hair removal and electrolysis in the Florida Administrative Code, i.e., facilities and equipment required for inspection. I would like to participate in this workshop however, if this topic is going to be discussed in this meeting, I would like to address these rules. In addition, I would like discuss how they apply to an independent contractor who is a CME working with and under supervision of an MD vs Employee of MD with regards to Facility licensing in the MDs primary medical practice.

2) Propose to legislature an amendment to 458.348 and 459.025, Florida Statutes, for general supervision as opposed to direct supervision, with the supervising physician being present for all new patients and then allowed to decide when direct vs general supervision is needed based on patient as well as level of training and experience of the technician.
   2a) Consider implementing "follow up" patient protocols for patients already seen by an MD on initial consultation to ensure patient safety and have it be a required part of the protocol agreement.
   2b) Consider implementing emergency protocols and an annual review in the form of "online" or "on site" continuing education pertaining to adverse events and management, new technology, updates in rules, laws, regulations in laser based light devices.

3) Internal Medicine or other MD/DO vs Dermatologists or Plastic Surgeons and the rules for supervision of satellite offices/indirect supervision of ARNP/PA. If all MDs have the same responsibility/liability on themselves when supervising LHR, please clarify the difference and reasoning behind this rule, that only Dermatologist and Plastic Surgeons have these privileges of supervising satellite offices and indirect supervision.

4) Consider that there is government funding for education for electrology/CME courses; how can we assist with job security for electrologists and CME. There has been a shift in employment away from CME and toward ARNPs and PAs in the LHR industry simply due to restrictions on physicians and supervisory role.

5) Consider additional training hours for ARNPs/PAs for LHR, particularly incorporating more training about the skin and skin conditions, as well as having more hands on training at a facility that does LHR to allow for more clinical application. Hands on training in a clinical setting should apply to CMEs as well.
I appreciate your consideration of discussion of these items and look forward to participating in this meeting. Thank you for your time.

Sincerely,

Tali Arviv, MD

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