

Excerpt from the June 4, 2005 Quality Assurance Committee Meeting

Tab 3 - Laser Issues

The Committee reviewed several correspondence items from various individuals, including Nancy Snurkowski, General Counsel for the Unlicensed Activity Office, regarding the use of lasers. The Committee also heard several presentations from interested parties.

Mr. McPherson presented the tab and outlined the various questions being asked of the Board related to lasers. He thanked Ms. List for assembling the agenda materials. He said the Board has previously issued the opinion that IPL's are the same as lasers, but there was no reason that could not be re-examined.

Mr. Tellechea stated there was material in the agenda book that indicated IPL's were approved by FDA for home use.

Mr. McPherson stated the Committee may want to re-examine that opinion and suggested hearing public testimony to discuss lasers in general.

Laura Knickman, Marketing Director for a new medical spa, addressed the Committee. She explained that there is an intense pulse light that has been approved by the FDA and then there is an intense pulsed light which is a very bright light and may cause damage if used inappropriately. She said these lasers should be used by health care practitioners such as ARNP's or PA's. She explained it is not the light that is the problem, but any adverse reaction caused by the laser. She asked for clarification of who could use lasers because current Florida law stated that only physicians and electrologists under direct supervision could use lasers.

Mr. Tellechea stated that statute only applies to hair removal.

Ms. Knickman then asked who could use lasers or light devices for hair removal.

Mr. Tellechea explained that was the Board of Medicine's position and that the Board of Nursing has taken the same position that ARNP's and PA's could use lasers for hair removal. He stated the use of lasers for hair removal is the practice of medicine and the statute provides an exemption for electrologists. ARNP's under protocols and PA's under supervision practice medicine.

Mayssa A. Toppino, M.D., Florida Society of Ophthalmology, addressed the Committee. She said that lasers and IPL's are harmful to the eye of the patient, bystanders and healthcare providers. She said lasers should be used under the supervision of a physician. She also recommended the Committee remain specific about the lasers and their use because ophthalmic lasers have been in use, require training, skill and precision.

James Knight, M.D., Florida Society of Dermatology and Dermatologic Surgery, addressed the Committee. He stated that in his clinical practice he has seen complications from non-licensed individuals using lasers. He said it's dangerous when used under the wrong settings and can lead to side effects. He stated he has heard of lasers being used for wrinkles and freckles, but not for fat reduction or smoking cessation.

Mr. Tellechea asked Dr. Knight if there was a broad range of IPL devices.

Dr. Knight confirmed that and said it can lead to scarring among other problems.

Mr. Tellechea stated this was a complicated issue.

Dr. Knight stated he attended an exposition recently that was attended by at least 30 vendors of various lasers. He stated lasers were also good for removing tattoos.

Mr. McPherson asked if lasers used for tattoo removal was of intensity that it could cause harm.

Dr. Knight stated absolutely because it could cause a scar, but said that use has been in existence since the early 1980's.

Mr. McPherson asked if that procedure was being done by non-physicians.

Dr. Knight stated he has not seen that in Florida.

Mr. Tellechea stated that tattoo parlors are being told by laser companies they do not have to be a licensed physician to use the lasers for tattoo removal.

Mr. Tellechea stated the use of lasers as applied to the definition of the practice of medicine includes the removal of tattoos.

Mr. McPherson said if an unlicensed individual does this it is considered unlicensed activity.

Dr. McCoy said lasers are varied with all kinds of uses and asked what kind of liability was required.

Mr. McPherson stated that tattooists are not required to carry liability insurance.

Dr. McCoy stated that physicians, ARNP's and PA's are required to carry malpractice insurance.

Ron Knipe, M.D., Florida Society of Dermatology & Dermatologic Surgery, addressed the Committee. He said the use of lasers and laser like devices was the practice of

medicine. He stated the use of lasers should be performed by physicians because physicians are responsible for the wellbeing and safety of the patients.

Dr. Vijayanagar agreed and stated there are articles in the agenda material concerning burns as a result of the improper use of lasers.

Dr. Knipe stated that he sees lots of complications from inappropriate use.

Christopher Nuland, Esquire, Florida Society of Plastic Surgeons and the Florida Society of Dermatology & Dermatologic Surgery, addressed the Committee. He said he agreed that the use of lasers and laser like devices was the practice of medicine and requires the direct involvement of a physician.

Mr. Tellechea asked Mr. Nuland to respond to the FDA approval of IPL devices.

Mr. Nuland said what an individual does to him/herself at home was one side and the other, commercial use, was the practice of medicine.

Mr. McPherson asked Mr. Nuland if he could comment on the use of lasers or IPL for smoking or weight loss.

Mr. Nuland stated he was not aware of those uses, but could research further.

Mern Henry, R.N. addressed the Committee. She stated she was a member of the Board of Nursing for two terms and that she currently owns a smoking cessation and weight loss facility. She said she was turned in to the Department of Health for practicing medicine without a license. She explained she practices under protocols provided by Ms. Snukowski. She further explained that the laser, used in countries such as England, Canada and Scotland, for over 30 years, is low light and cannot injure. She indicated she is operating under and IRB for smoking cessation, but not for weight loss. She said the IRM requires low level lasers and strict guidelines. She urged the Committee not to place restriction on the use of lasers for smoking because it is the #1 killer. She suggested requiring the facility by under a IRB.

When asked how lasers can be used to stop smoking or lose weight, Ms. Henry stated it is stimulation of acupuncture like points in the ear, nose and hand. She explained this stimulates energy points that help with weight loss be relaxing the patient and cause the release of endorphins. She stated the procedure must be in conjunction with a diet.

Dr. McCoy asked how much the procedure costs.

Ms. Henry stated that depended on the clinic, but could cost from \$200-\$400.

Dr. McCoy asked the name of her supervising physician.

Ms. Henry stated George Alphonso, M.D., an internal medicine physician, was her supervisor. When asked if he was trained on the laser, she said no.

Mr. McPherson asked the Committee if offering to do weight loss or weight loss is the practice of medicine.

Dr. Vijayanagar stated that hypnotism, often used for those purposes, was not the practice of medicine.

Mr. McPherson asked Ms. Henry if she was placed under protocols because she was practicing medicine.

Ms. Henry said no.

Dr. Farmer stated anyone could help with weight loss.

Mr. McPherson asked if the use of lasers for smoking cessation or weight loss was the practice of medicine.

Mr. Tellechea suggested asking the General Counsel for the Department of Health why the protocols were issued to Ms. Henry.

Dr. Farmer stated the use of lasers was the practice of medicine and assumes that was the reason Ms. Henry is under the protocols of a physician.

Dr. Vijayanagar agreed with Dr. Farmer.

Francie Plendl, Florida Medical Association (FMA), addressed the Committee and stated there was no scientific support for the use of lasers for weight loss or smoking cessation. She said if a patient feels he/she is being taken advantage of, a complaint can be filed and action can be taken against the physician. Safety mechanisms are need for the patient's wellbeing.

Dr. Toppino reiterated the need for supervision. She said smoking cessation and weight loss fell into grey areas because of the use of a medical device for an off-label use. It's being conducted under general supervision and the physician is taking responsibility. She said lasers should be treated as medical devices and reminded the Committee that lasers can cause a biochemical reaction throughout the body.

Alan Voss with AL Voss Associates addressed the Committee next. He said the marketplace is asking the laser industry to develop non-medical devices. He said the general thought has been if the device is approved by the FDA then it is a medical device and can only be used by physicians or by individuals supervised by physicians. He stated that training is the key to safety. He explained that often times physicians sends in a nurse or health care practitioner to obtain the training and the physician never gets it. He stated Texas, Ohio and Arkansas have training requirements.

Dr. McCoy reiterated there was no evidence to support the use of lasers for weight loss.

Mr. McPherson summarized the question into whether someone offering to use lasers for smoking cessation or weight loss is practicing medicine.

Dr. Farmer elaborated that the use of laser for any condition is the practice of medicine.

After discussion, the Committee made the following statement:

The use of lasers for any medical condition is the practice of medicine. There are a wide range of laser and laser like devices being used and questions about specific lasers will be addressed on a case-by-case basis. Consideration will include:

- *Who the laser will be used by*
- *Requirements for regulation by the Department of Health*
- *Appropriate safety standards*

The Committee made the following specific responses to Ms. Snurkowski's questions are as follows:

Business opens and advertises "If you find yourself struggling with weight control or craving a smoke, laser therapy might be the answer for you." The advertisement represents that using a laser stimulates the nerve endings and some areas of the ears, nose, hands and wrists. The laser treatment is a one-time treatment that totally removes cravings for cigarettes, provides appetite suppression, relaxation and stress release, without medications.

1. Is this the offer to practice medicine? *See general response above.*
2. Is using a laser the practice of medicine? *See general response above.*
3. Does it make a difference if the business calls itself a clinic and has a medical director? Or, advertises that a PA is "trained in laser therapy?" *No*
4. Does it make a difference if no health care practitioner is affiliated with the business or actually performing the laser therapy? *The business must have a physician involved.*
5. Does it make a difference that the advertisement states that acupuncture points are used to identify the areas to be used in the laser therapy? *No*
6. Does it make a difference that the business has obtained an IRB from the FDA approving the use of the laser for smoking cessation or weight loss? *No. A physician must be involved and responsible.*

Business opens and advertises that laser therapy can improve acne and improve sun damaged skin. The "clinic" has a medical director (not on the premises) but the person performing the laser therapy treatments is not a licensed health care practitioner. The "laser" being used is an Intense Pulse Light (IPL) device or a Class IIIB laser.

Is this the practice of medicine? Yes, this is the practice of medicine.

Flyers are distributed to church members or to the general public. The advertisements state that for reduced costs, a person can be tested for stroke screening, aortic aneurysm,

peripheral arterial disease, and osteoporosis . . .to name a few. There is no offer for the tests to be sent to the patient's doctor or for a consultation to be conducted with the patient's doctor. The tests are simply conducted, sent to an unnamed physician and the results are sent directly to the patient. The tests are done either at a church hall or hotel conference room.

1. Is this the practice of medicine? *Yes*
2. Does it make a difference that the physician is a non-Florida licensed physician? *Yes. That would be considered unlicensed activity.*
3. Does it make a difference that the physician is licensed in Florida? *Yes, the physician should be licensed in Florida. The physician must adhere to Florida laws and rules such as the maintenance of patient records as well as other requirements. The patient/physician relationship begins the moment the patient enters the facility to obtain the test.*

Can aestheticians use lasers? *No. If lasers are used for medical purposes, it is considered the practice of medicine unless allowable in the health care practitioner's practice act as being within the scope of their practice.*

Dr. Vijayanagar asked who was approved to perform microderm abrasion.

Dr. Knight stated that he has seen no complications related to this procedure. He said it could be performed by an aesthetician and said it is usually part of a facial and is non-invasive.

Ms. Plendl stated that an individual may have to be a cosmetologist to perform microderm abrasion.

Action taken: The Committee responded to each of Ms. Snurkowski's questions as outlined above.

Transcript ordered.

The meeting adjourned at 3:45 p.m.

