Office of Professional Regulation Sunrise Assessment on Electrologists November 5, 2004

REVIEW OF REGULATION OF ELECTROLOGISTS

History of Regulation of Electrology in Vermont

In 1999 The Office of Professional Regulation submitted a sunrise preliminary assessment for state regulation of electrologists.

The Sunrise Assessment is attached hereto as appendix A. Electrology is an allied health care practice. Electrology is a "parenteral" procedure which involves a foreign object entering the body. Hair is removed from the human body using a needle inserted in the hair follicle and using direct electrical current (direct current/DC), thermolysis (shortwave alternating current) or a combination, to disable the follicle. For a variety of reasons breaks in the blood barrier can occur during this process. The Food and Drug Administration classifies the epliator as a medical device subject to general regulatory controls. 1999 Sunrise Assessment.

The 1999 Sunrise Assessment noted that there had been no evidence of actual harm occurring in Vermont as the result of lack of regulation of electrologists. For that reason the assessment concluded that electrologists should not be regulated on the licensure level. The assessment noted, "that the profession would require inspection of equipment and premises of practitioners, to insure the proper sterilization and infection control procedures are followed."

The Sunrise Assessment concluded that, "the consumer may have a substantial interest in relying on the qualifications of the practitioner of electrolysis; therefore, regulation should be through a system of certification."

Legislation calling for a voluntary system of certification was passed in 1999 and became effective in 2001. Minor amendments occurred in 2002. The conclusion of the Sunrise Assessment was reflected in that legislation.

"The general assembly finds that the public's health would be better protected if services by electrologists were regulated, because the unregulated practice of electrology can harm or endanger the health, safety, or welfare of the public through use of improper sterilization and infection control procedures." 26 V.S.A. § 4401.

The legislation limits the location of the practice of electrology to offices registered with the Office of Professional Regulation, hereafter the "Office." Practitioners *may* elect to become certified under the statute. They are not required to be.

The statutes governing the profession of electrolysis authorize the Director after consultation with the advisors "to adopt rules necessary to perform the director's duties under

this chapter." The rule making authority includes cleanliness and sanitation requirements, continuing education requirements, certification of applicants, denial or renewal of certification, and inspection of offices. The Office promulgated rules beginning in 2002. Those rules spanning twenty pages were approved by ICAR and LCAR and took effect in September 2003.

During the rulemaking process the Office performed significant legal and factual research. We consulted with the Department of Health about the infectious disease implications of the practice of electrolysis and the sterilization needs for its safe practice. The Department of Health reviewed and approved the extensive infectious disease control, blood-borne pathogens prevention, and sterilization techniques contained within the rules. It suggested some additions which were incorporated into the rules as "Electrology Practice Considerations." These include references to the latest information from the CDC on universal precautions for prevention of transmission of HIV and other blood borne infections, and the most up to date information on blood exposure procedures.

The rules prescribe specific standards for cleanliness, use of gloves, coordination of instruments, cleaning and sterilizing instruments and other safety precautions. They specify the types of needles which can be used (single use, disposable only), control measures for sterilization, control measures for cleaning and disinfecting, standards for environmental control, patient record keeping health assessments, procedures for pre and post treatment of sites, control measures for patient/client considerations, a hepatitis B vaccination requirement, follow up procedures for potential exposure to hepatitis B, and C, and HIV and other blood borne pathogens, a puncture injury protocol, limitations on practice (practitioner considerations), limitation of practice (patient considerations). The standards of practice represent nationally accepted standards. The complete rules are attached as Appendix B.

The Office under current law has the authority to ensure that electrology offices are clean and sanitary. The Office has authority to discipline *certified electrologists* if they do not maintain appropriate standards of practice.

The rulemaking process suggested that the practice of electrology, like acupuncture, body piercing or tattooing, can be performed safely when strict safety guidelines and practices are adhered to. The track record of electrology practitioners certified under the statutes and offices registered with the Office has been excellent. The Office believes that unregistered offices still exist in the state. We know that there are 13 certified electrologists. There are approximately 16 additional practitioners who are not certified. **Not one of the non-certified practitioners is individually subject to the practice requirements contained in the rules and mentioned above.**

The certified practitioners must take continuing education classes. The classes contain updates on infection control procedures and safe practices. Uncertified practitioners have no such requirement.

Should uncertified practitioners not follow generally accepted guidelines, "whether or not

actual injury to a client, patient or customer has occurred." 3 V.S.A. § 129a (12), the Office has no direct authority to discipline them. If a practitioner is self employed, the statutes permit action against the shop only. A practitioner could conceivably suffer the closing of an office and still face no impediment to his or her obtaining employment with someone else.

The realities of practice and the medical and safety implications which became more apparent during the rulemaking process led the advisors and Office to re-examine the statutory scheme. After consultation with the advisors we notified every registered electrology office and every certified practitioner that on November 17, 2003 the Office would hold a public hearing on a proposal to move from a system of certification to a system of licensure. The hearing took place as scheduled.

With one dissenting opinion from a non-certified but properly registered shop owner¹, the rest of the participants favored mandatory licensure. Those who wrote to the Office in response to the notice supported a change from optional certification to licensure for all.

Arguments for Mandatory Licensure:

Many members of the public expect and assume that electrologists's competency is subject to regulation. Even some of the certified practitioners who attended the public hearing thought certification was mandatory. They support changing from certification to licensure. One can only speculate that public believes all electrologists are individually regulated. Approximately once a month the Office receives a call asking us to recommend an electrologist. The Office provides the list of certified practitioners.

Licensure would ensure consistent and uniform educational backgrounds for practitioners. It would ensure minimal competence of every practitioner. Customers who now see a certificate are assured that their electrologist has sufficient training and education to be minimally competent. Members of the public look to the OPR website to learn their practitioner's disciplinary status. Licensure would meet public expectations.

With licensure, all practitioners would have continuing educational requirements. These would enable all to be up to date on the latest health related aspects of their practice, e.g., infectious disease and blood borne pathogens. Given heightened awareness and public safety implications of infectious diseases and blood borne pathogens, mandatory continuing education seems a small requirement.

Under regulation by licensure, electrology office owners, like members of the public, can know that licensed hires are qualified to practice. Conversely, a licensee who is disciplined for not performing competently would be unable to "pack up and go" to new employment. The practitioner has a regulatory "score card" which protects the public.

¹ She was unable to personally attend. Her husband appeared on her behalf.

All licensees would have an direct stake in ensuring that their practice environment meets all guidelines.

Licensure would assure that every practitioner is aware of and subject to the recognized current standards of practice and safety. Licensure would eliminate the anomaly which now permits practitioners to "opt out" of compliance with the rules.

Arguments Made Against Licensure:

Licensure would increase costs to the public. When this argument was made at the public hearing, it was clearly intended as an argument against regulation in general. In fact, moving from a certification profession to a licensed profession would require only the additional administrative burden of processing applications of fewer than 20 individuals who are not currently certified. The only additional cost to those not currently certified would be the biennial licensing fee of \$175.00 which, if passed on to the public over the two year licensing period would have a negligible cost effect on electrology services.

Self-employed practitioners would have to pay two biennial fees, one for their offices and one for their personal licenses. This is true of self-employed certified electrologists now. Those employed by others pay only their own certification fee. This is true for other professions now, such as body piercers, tatooists, cosmetologist, and pharmacists.

Office records show no complaints against the practitioners who elected to be certified. However, the real potential for harm found by the initial sunrise assessment and by the legislature is more clearly defined at this time. The rules show how important it is that practitioners of this invasive procedure all be accountable and subject to rules of this profession.

Conclusion

26 V.S.A. § 3105(b) provides, ... "if the legislature finds that it is necessary to regulate a profession or occupation, the least restrictive method of regulation shall be imposed, consistent with the public interest and this section:....

(4) if the consumer may have a substantial interest in relying on the qualifications of the practitioner, regulation should be through a system of certification; or (5) if it is apparent that the public cannot be adequately protected by any other means, a system of licensure should be imposed."

At this time with less than half of the electrologists certified, the current "opt in" or "opt out" voluntary certification scheme for electrologists does not adequately serve Vermont consumers' substantial interest in relying on the qualifications of the practitioner. Certification alone does not adequately protect the public. To ensure uniform adherence to nationally recognized standards, to require continuing education, and to permit discipline of those who do not follow those standards, no other means other than a system of licensure is sufficient.

The Office recommends licensure of electrologists.

November 5, 2004 Jessica G. Porter, Director, Office of Professional Regulation