

Legislative Analysis



DERMATOLOGY LASERS

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House Bill 5134 as enrolled

Public Act 144 of 2004

Sponsor: Rep. Edward Gaffney

House Committee: Health Policy

Senate Committee: Health Policy

First Analysis (1-19-05)

BRIEF SUMMARY: The bill would require a licensed physician to supervise dermatological procedures that use a laser.

FISCAL IMPACT: Enforcement of the provisions of House Bill 5134, as enrolled, and promulgation of rules will be the responsibility of the Department of Community Health's Bureau of Health Professions; thus the bill may have a fiscal impact on the operations of the Bureau. Individuals will be subject to discipline for licensure violations or unlawful practice without licensure, which may include fines.

THE APPARENT PROBLEM:

For over a decade, according to the federal Food and Drug Administration, medical lasers have been used for dermatology purposes such as removal of port wine stains, tattoos, acne scars, and dark spots. In recent years, lasers have also been used for a number of cosmetic procedures that include hair removal and treatment of wrinkles. Though some consumers seek the services of dermatologists and other licensed physicians, there has been a growing trend for spas and salons to offer laser treatments for cosmetic reasons. Often these laser treatments are performed by non-medical personnel with little training or physician oversight, which has resulted in injuries to clients.

A 2002 survey conducted by the American Society for Dermatologic Surgery (ASDS) revealed that almost 41 percent of respondents saw an increase in patients seeking corrective treatment during the preceding year due to damage caused by untrained non-physicians performing laser/light hair removal, subsurface laser/light rejuvenation techniques, chemical peels, and acne therapy, in addition to the misdiagnosis or delayed treatment of skin cancers and rosacea. Most of the complications were associated with laser and light-based hair removal procedures that had been performed by non-physicians (the incidence of complications increased from 24 percent in 2001 to 31 percent in 2002). Adverse effects included second- and third-degree burns, permanent nerve damage, and scarring. Skin damage from laser treatments is often irreversible.

In light of the potential for serious and permanent injuries from procedures using lasers for cosmetic purposes, the ASDS has conducted a campaign since 2001 to inform and warn consumers that laser treatments, as well as several other cosmetic treatments such as chemical peels, are medical/surgical procedures that should be performed by qualified

physicians or under the direct supervision of a physician. The medical boards and health departments of several states have issued guidelines or adopted resolutions requiring laser procedures to be performed only by a physician or under the direct supervision of a physician. Some people have suggested that Michigan follow suit through legislation.

THE CONTENT OF THE BILL:

The bill would add a new section to the Public Health Code to require that lasers be used for dermatological purposes only under the supervision of a licensed physician. Under the bill, a person licensed or registered under the code or any other individual could not perform a procedure using a laser for dermatological purposes unless the procedure was supervised by a licensed physician and the patient had knowledge and consented to the procedure being performed by that licensee, registrant, or other individual.

The bill would not apply to a licensed physician or a certified nurse practitioner or licensed physician's assistant performing a procedure in a health care facility. The Department of Community Health could promulgate rules to further prohibit or restrict the use of lasers for dermatological purposes.

"Practice of dermatology" would be defined as the diagnosis and treatment of medically necessary and cosmetic conditions of the skin, hair, and nails by various surgical, reconstructive, cosmetic, and nonsurgical methods.

"Supervision" would mean the overseeing of, or participation in, the work of another individual by a health professional licensed under Article 15 in circumstances where at least all of the following conditions existed:

- The continuous availability of direct communication in person or by radio, telephone, or telecommunication between the supervised individual and a licensed health professional.
- The availability of a licensed health professional on a regularly scheduled basis to review the practice of the supervised individual, to provide consultation to the supervised individual, to review records, and to further educate the supervised individual in the performance of his or her functions.
- The provision by the licensed supervising health professional of predetermined procedures and drug protocol.

MCL 333.16276

BACKGROUND INFORMATION:

Laser hair removal. Laser hair removal is a non-invasive procedure used to permanently reduce unwanted hair by using a low-energy laser. Energy from the laser passes through a patient's skin and is absorbed by the pigment in the hair follicle. Heating by the laser

causes the follicle to be disabled. Almost any area of the body can be treated, though facial hair and hair on the legs, underarms, and back are the most common areas requested for treatment. Laser hair removal is most effective on patients with light skin and dark hair. Because pigment in dark skin can also absorb energy from the laser, patients with dark skin have not been good candidates for laser hair removal until more recently when machines with longer wavelengths and skin cooling devices have become available. To reduce the risk of scarring or other adverse effects, patients with tanned skin are advised to wait until their tans fade before attempting laser treatments for hair removal. In 2002, close to 600,000 people underwent laser hair removal procedures. (Information obtained from the American Academy of Dermatology web site – www.aad.org.)

ARGUMENTS:

For:

Laser treatments for hair removal, wrinkle treatment, and other dermatologic procedures such as removal of tattoos, port wine stains, and dark spots are considered to be low risk procedures when performed by qualified physicians (generally, those trained in dermatology) but become dangerous when performed by untrained or undertrained individuals. Lasers produce an intense beam of light that can cut, seal, or vaporize skin tissue and blood vessels. A person's pigmentation, skin type, level of hydration, and other factors can influence the results of laser treatments, as can the intensity of the laser beam or duration of time the beam is directed at the skin.

According to the American Society for Dermatologic Surgery (ASDS), thousands of people have been harmed in recent years after undergoing dermatologic procedures that include laser skin resurfacing and hair removal. Many of these procedures were performed by technicians with little to no medical training and were offered in nonmedical settings such as spas and salons. In particular, respondents (dermatological surgeons) to an ASDS survey reported that the majority of patients seeking corrective treatment for complications of dermatologic procedures had been injured by laser hair removal treatments performed by non-physicians. Injuries included minor to severe scarring, disfigurement, second- and third-degree burns, and permanent nerve damage. As more and more salons and spas offer laser hair removal or wrinkle treatments, the numbers of consumers suffering adverse effects are sure to increase. Indeed, dermatologic surgeons saw a seven percent increase from 2001 to 2002 in the number of patients requesting corrective treatment for complications of laser hair removal. However, it is believed that due in part to feelings of embarrassment for seeking cosmetic enhancements, adverse outcomes are vastly underreported.

In addition, some people are concerned that laser skin treatments by nonmedical technicians – e.g., by mistaking a cancerous lesion for a freckle or lightening a precancerous or cancerous lesion – may interfere with or delay the proper diagnosis of serious skin conditions and skin cancers. The ASDS believes that consumers need to be protected from non-physicians "who typically do not have the necessary medical training and qualifications to diagnose the condition, perform the procedure or adequately address

complications when they arise, particularly when treatment is administered outside the medical setting". (From a July 17, 2002 article entitled "2002 Survey Shows Significant Rise in Patients Seeking Corrective Treatment from Laser/Light Hair Removal Procedures" posted on the ASDS web site – www.asds-net.org.)

The bill would address these concerns by prohibiting laser treatments for dermatologic purposes, which would include laser hair removal and skin resurfacing, by an individual who is not a licensed physician, licensed physician's assistant, or certified nurse practitioner or who is not under the supervision of a licensed physician. A supervising physician would either have to be onsite or available for direct communication by other means. The supervising physician would also have to, on a regularly scheduled basis, review the practice of the technician performing the laser procedures, provide consultation, review records, and continue to educate the technician regarding his or her performance of the laser procedures. In addition, predetermined procedures (e.g., what to do in case of an emergency or apparent adverse reaction to the treatment) as well as drug protocols would have to be established by the supervising physician. Violations would be subject to the penalties prescribed in the code, which include injunctions from performing the procedures as well as criminal charges.

Against:

Proponents of the legislation have made a case for the need to protect consumers; however, the bill falls far short of what is needed. According to media reports, a significant number of injuries from laser dermatologic procedures also occur with physicians who have no dermatology training; obstetrician/gynecologists and primary-care doctors comprise one of the fastest-growing markets for the purchase of cosmetic laser equipment. Experts therefore recommend that consumers seek cosmetic laser treatment from board-certified dermatologists or plastic surgeons. How then would the bill – which would allow any physician (and any certified nurse practitioner or physician's assistant working in a health facility) to perform a dermatologic procedure with a laser regardless of his or her training – protect the public from an untrained or undertrained provider? House Bill 5078, which pertains to needle electromyography and nerve conduction tests and which has been passed by the House, would restrict such procedures to licensed physicians who had also undergone specialized training in the performance of these procedures. The provisions of House Bill 5134 should be similarly amended.

In addition, the bill would allow any licensed physician to supervise any individual, such as a spa employee, to perform laser dermatologic procedures. Again, if the physician is not trained in dermatology, the question must be raised as to the quality of supervision and training that the physician could provide to that spa employee. Moreover, the definition of "supervision" contained in the bill is lacking, as it is conceivable that a physician with no training in dermatology could "supervise" laser hair removal at an electrolysis or other establishment merely by being available to take a phone call and regularly reviewing the business' case records.

People have long complained that the state's medical boards and licensing agency are lax in taking disciplinary measures against negligent doctors; it can only be hoped that the state's regulators will keep a careful eye out for physicians who do not provide adequate supervision and training of individuals performing laser procedures for dermatological purposes.

Furthermore, far from closing the door on who could do laser hair removal, the use of definitions in the bill appears to be throwing the door wide open. For example, the bill would allow any physician, or any individual "supervised" by a physician, to perform any procedure using a laser for dermatological purposes. "Dermatological" is defined in the bill as relating to the practice of dermatology. The "practice of dermatology" is defined as the diagnosis and treatment of medically necessary and cosmetic conditions of the skin, hair, and nails by various surgical, reconstructive, cosmetic, and nonsurgical methods. It would appear that the bill could be interpreted to mean that any individual could, with potentially minimal supervision by a physician with no training in dermatology, perform laser treatments to treat even serious skin conditions such as skin cancer, rosacea, tattoo removal, etc. in a nonmedical setting with no physician present. And, since "diagnosis" is generally accepted as being within a physician's scope of practice, does this mean the bill would carve out an exception from the ban on practicing medicine without a license for those nonphysicians who use lasers for dermatological purposes?

Instead, the bill should follow the example established in House Bill 5078, which would only allow delegation of certain tests to a nonphysician under the direct supervision of a specialty trained physician and only if that nonphysician was qualified by education, training, or experience.

Response:

The bill also allows the Department of Community Health, which is the state agency with regulatory oversight, to promulgate rules to further prohibit or otherwise restrict the use of lasers for dermatological purposes. Therefore, if problems of interpretation or implementation of the bill occur, the department could take corrective action by developing rules to ensure the public is appropriately protected. It also should be remembered that when considering any medical or cosmetic procedure, consumers are always encouraged to seek the services of appropriately trained and credentialed providers.

In addition, though a supervising physician would not have to be physically present, he or she would bear administrative and civil penalties should a client or patient suffer injury. In light of the expenses and time involved in litigating a malpractice suit, plus possible administrative fines or license sanctions, it would behoove a physician to ensure that proper training and supervision of the laser operators be adhered to.

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