

BILL ANALYSIS

C.S.H.B. 449
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Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

Laser hair removal has been performed throughout the country since 1997. The procedures are performed primarily by individuals trained to use a laser/pulse light device for the removal of hair. The vast majority of laser hair removal facilities in Texas ensure client safety by using a licensed physician to oversee the protocol for operations at each facility. Over the 12 years that laser/pulse light devices have been in use, there have been very few complaints from or injuries to clients from procedures performed by non-physicians trained on these devices.

In 2003, after little debate and little public input, the Texas State Board of Medical Examiners adopted Rule 193.11, which would virtually end the practice of laser hair removal by non-physicians by requiring the presence of a physician in the office or in the building where the laser hair removal procedures are performed. The rule was promulgated at the request of a small number of physicians and was not a result of any public appeal for the rule.

Rule 193.11 was scheduled to be enforced beginning December 1, 2004. If the rule had been enforced and the existing non-physician practitioners had continued to operate in the manner they operated prior to December 1, 2004, these practitioners could have been indicted for practicing medicine without a license, which is a third-degree felony.

On December 2, 2004, the Laser Hair Removal Stakeholders Group obtained a temporary restraining order from the state district court in Travis County that prevented the board from enforcing Rule 193.11. Subsequently, the board and the stakeholders group entered into an agreement to abate enforcement of Rule 193.11 to allow the stakeholders group to pursue legislation that would provide for licensing and certification requirements of laser hair removal practitioners under the auspices of the Department of State Health Services (DSHS). The agreement to abate enforcement of Rule 193.11 was extended by agreement of the parties numerous times until the fall of 2008, when the board repealed Rule 193.11.

Subsequent to the board's decision to repeal Rule 193.11, DSHS personnel entered several laser hair removal facilities with no prior notice or hearing, and based their raids on anonymous complaints. Upon entering the facilities, DSHS personnel requested to see client files to determine if prescriptions had been written for each laser hair removal procedure performed at the facility. When the prescriptions were not produced, several laser hair removal devices were seized and the owners were not allowed to use them, which effectively shut down their businesses. The basis of these raids was the absence of a prescription as opposed to any harm to clients. One of the facility owners, whose device was seized by DSHS, filed and was granted a temporary injunction by a state district judge in Travis County. The injunction released the embargo on the facility's device and did not require a written prescription for each procedure or client, provided that the facility owner give DSHS a copy of a signed agreement with its consulting physician and a copy of the facility's guidelines for procedures signed by the consulting physician. The facility owner provided the documents.

C.S.H.B. 449 requires laser hair removal processes to be performed by a certified laser hair removal professional or by an individual under the supervision of a certified professional. The

bill establishes levels of expertise in laser hair removal to be regulated by DSHS. The bill requires each laser hair removal facility to be licensed and requires each facility to retain the services of a consulting physician to develop and review each facility's procedures and protocol.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted the executive commissioner of the Health and Human Services Commission in SECTIONS 1 and 3 of this bill.

ANALYSIS

C.S.H.B. 449 amends the Health and Safety Code to prohibit a person from performing or attempting to perform laser hair removal unless the person holds the appropriate certificate. The bill exempts from the certification requirement a licensed health professional whose scope of professional practice includes laser hair removal, as determined by the professional's licensing board, and a physician or a physician's employee or delegate. The bill creates the certification categories of certified laser hair removal professional, senior laser hair removal technician, laser hair removal technician, and laser hair removal apprentice-in-training and provides the professional and training experience required for each category, minimum age requirements, and conditions relating to which positions are authorized to perform work functions independently and which positions require supervision. The bill specifies that a certificate authorizes a person to perform nonablative cosmetic laser hair removal only and does not authorize the person to diagnose, treat, or offer to treat any client for any illness, disease, injury, defect, or deformity of the human body. The bill requires the certificate holder to specifically disclose this limitation in writing to all clients and perspective clients. The bill creates a laser hair removal facility license, prohibits a person from operating such a facility unless the person holds a license to operate the facility or the facility is owned or operated by a physician for the practice of medicine, and requires a separate license for each such facility. The bill sets forth the process by which a person applies for a certificate or license relating to laser hair removal. The bill requires the executive commissioner of the Health and Human Services Commission (HHSC) to adopt rules to govern the development of an examination for an applicant.

C.S.H.B. 449 requires the Department of State Health Services (DSHS) to recognize, prepare, or administer continuing education programs for certificate holders and requires a certificate holder to participate in the programs to the extent required by DSHS rule to renew the person's certificate. The bill authorizes the executive commissioner of HHSC by rule to adopt a system under which certificates and licenses expire on various dates during the year. The bill provides that a certificate or license expires on the second anniversary of the date of issuance, requires a person to renew the person's certificate or license on or before the expiration date, and requires DSHS to issue a renewal certificate or license on receipt of a renewal application in the form prescribed by DSHS, accompanied by a renewal fee in an amount equal to the original certificate or license fee.

C.S.H.B. 449 requires a person holding a license or certificate for laser hair removal to display the license or certificate in an open public area of the facility. The bill requires a laser or pulsed light device used for laser hair removal in a facility to comply with all applicable federal and state laws and rules and specifies that a person who adulterates or misbrands a laser or pulsed light device is in violation of the Texas Food, Drug, and Cosmetic Act. The bill authorizes DSHS to investigate a person accused of adulterating or mishandling a laser or pulsed light device. The bill authorizes a person to only use a laser or pulsed light device approved for laser hair removal by the federal Food and Drug Administration for that purpose and only at the setting expected to safely remove hair.

C.S.H.B. 449 requires a facility to give each customer a written statement outlining the relevant risks associated with laser hair removal, requires the executive commissioner of HHSC to adopt rules relating to this notice, and specifies that compliance with this notice requirement does not

affect the liability of a facility operator or a manufacturer of a laser or pulsed laser light device. The bill requires a facility to post a warning sign about the potential dangers involved in laser hair removal in a conspicuous location readily visible to a person entering the facility that provides a toll-free telephone number for DSHS. The bill requires the executive commissioner of HHSC to adopt rules specifying the characteristics of the sign. The bill requires the sign to provide a toll-free telephone number for DSHS and inform the customer that the customer may call DSHS and requires DSHS to include with an application for an original or renewal facility license a description of the design standards required for the sign.

C.S.H.B. 449 requires a laser hair removal facility to have a certified laser hair removal professional or a licensed health professional authorized to perform laser hair removal present to supervise the laser hair removal procedures performed at the facility during the facility's operational hours, except the facility may continue to perform the procedures after its certified laser hair removal professional leaves the facility if certain supervisory and replacement requirements are met. The bill establishes that a laser hair removal facility operator is responsible for maintaining the facility's compliance with the requirements of the bill's provisions and with DSHS rules relating to laser and pulsed light devices. The bill prohibits a facility operator from claiming, advertising, or distributing promotional materials that claim that laser hair removal is free from risk or provides any medical benefit and from producing false and misleading advertising regarding the services offered at the facility.

C.S.H.B. 449 requires a laser hair removal facility to have a written contract with a consulting physician to establish proper protocols for the services provided at the facility and to audit those protocols and the facility's operations. The bill requires the facility, under DSHS rules, to document with DSHS the facility's contractual relationship with the physician. The bill requires the physician to be available for emergency consultation with the facility including an emergency appointment with a client and, if the physician is unavailable for such a consultation, requires another physician to be available for that purpose. The bill establishes that these provisions do not relieve a consulting physician or another health care professional from complying with applicable regulations prescribed by a state or federal agency.

C.S.H.B. 449 prohibits a facility operator or other person from disclosing a customer record required to be kept by DSHS, with certain exceptions. The bill prohibits a person other than a physician or a person acting under a physician's order from operating a laser or pulsed light device to treat an illness, disease, injury, or physical defect or deformity and specifies that a person is in violation of and subject to penalties provided by the Medical Practice Act for operating a device in violation of the prohibition. The bill authorizes DSHS to impose an administrative penalty in an amount not to exceed \$5,000 for each violation on a person who violates a provision or rule introduced in this bill and to suspend or revoke a license or certificate relating to laser hair removal in addition to or instead of the administrative penalty. The bill requires the executive commissioner to adopt rules to implement and enforce these penalties.

C.S.H.B. 449 extends the exemption from penalties relating to the possession of a dangerous drug to include a certified hair removal professional who uses a laser or pulsed light device approved by and registered with DSHS and in compliance with DSHS rules for the sole purpose of cosmetic nonablative hair removal. The bill defines "department," "executive commissioner," "laser hair removal," "laser hair removal facility," "laser or pulsed light device," "nonablative hair removal procedure," and "operator."

C.S.H.B. 449 requires the executive commissioner of HHSC to adopt required rules not later than March 1, 2010. The bill requires a laser hair removal facility in operation on the effective date of the bill to obtain the required licenses and certificates not later than September 1, 2010. The bill makes its provisions on the requirement for an individual to be certified and a facility to be licensed, on certain operational requirements, on prohibited practices, and on enforcement and penalties effective September 1, 2010.

EFFECTIVE DATE

Except as otherwise provided, September 1, 2009.

COMPARISON OF ORIGINAL AND SUBSTITUTE

C.S.H.B. 449 adds a provision not in the original to specify that a certificate relating to laser hair removal only authorizes a person to perform nonablative cosmetic laser hair removal and does not authorize the person to diagnose, treat, or offer to treat any client for any other condition. The substitute differs from the original by adding the requirement that a certificate holder specifically disclose this limitation in writing to all clients and perspective clients. The substitute adds an exemption to the prohibition against the performance of laser hair removal without a proper certificate not in the original for a physician or a physician's employee or delegate. The substitute differs from the original by adding a clarification that the authorization for a certified laser hair removal professional to perform laser hair removal without supervision applies if the professional is acting under the protocol established with a consulting physician.

C.S.H.B. 449 adds training requirements not in the original for an applicant for a laser hair removal apprentice-in-training certificate to require the applicant to have training in burns, eye protection, and emergencies. The substitute differs from the original by adding the minimum age requirement for an applicant for a laser hair removal apprentice-in-training certificate.

C.S.H.B. 449 adds a provision not in the original exempting a facility owned or operated by a physician for the practice of medicine from laser hair removal facility license requirements. The substitute adds a provision not in the original clarifying that a person authorized to perform a laser hair removal is authorized only to use a laser or pulsed light device approved for laser hair removal by the federal Food and Drug Administration for that purpose and only at the setting expected to safely remove hair.

C.S.H.B. 449 adds a provision not in the original to require the warning sign required to be posted in a laser hair removal facility to include a toll-free telephone number for the Department of State Health Services (DSHS). The substitute differs from the original by adding a claim that laser hair removal provides any medical benefit to the matters a laser hair removal operator is prohibited from claiming, advertising, or distributing in promotional materials. The substitute includes a prohibition not in the original prohibiting an operator from producing false or misleading advertising regarding the services offered by the facility.

C.S.H.B. 449 differs from the original by adding the requirement that a laser hair removal facility contract with a consulting physician be a written contract, whereas the original requires a facility to either employ or contract with a consulting physician. The substitute differs from the original by requiring a laser hair removal facility to document with DSHS the facility's relationship with the consulting physician and specifying that the documentation be under department rules, whereas the original requires the consulting physician to document the relationship with DSHS.

C.S.H.B. 449 adds a provision not in the original to require a consulting physician to be available for an emergency appointment with a client and to require that if the physician is unavailable for an emergency consultation, another physician be available for that purpose. The substitute adds provisions not in the original to prohibit a person other than a physician or person acting under a physician's order from operating a laser or pulsed light device to treat a condition not authorized to be treated by the person with the device, to specify that a person operating a device in such a manner is in violation of and subject to penalties provided by the Medical Practice Act, to create penalties for such a violation, and to require the executive commissioner of the Health and Human Services Commission to adopt rules to implement and enforce these penalties.

C.S.H.B. 449 differs from the original by including the Texas Medical Board among the individuals and entities to whom an operator or other person may disclose a customer record on request.

C.S.H.B. 449 differs from the original by making conforming and technical changes to the provision exempting a certified laser hair removal professional from penalties relating to the possession of a dangerous drug and to effective date provisions.