



Memorandum

TO: Kathryn C. Perkins, RN, MBA, Assistant Commissioner
Division for Regulatory Services

FROM: Lisa Hernandez, General Counsel *MAC for LH*

DATE: May 4, 2010

SUBJECT: Policy regarding Purchase, Possession and Use of Laser Hair Removal Devices pursuant to Subchapter M, Chapter 401, Health and Safety Code

Subchapter M of Chapter 401, Health and Safety Code (hereinafter the Laser Hair Statute, or LHS) was added during the 81st Legislative Session by HB 449. This statute regulates the operation of facilities that provide hair removal using laser or pulsed light devices, and the training and registration of the persons who use those devices. In order to harmonize this new Subchapter with current federal and state laws and rules on the use of laser or pulsed light devices, DSHS has developed the following guidance.

Typically, lasers and pulsed light devices for hair removal are categorized by the U.S. Food and Drug Administration (FDA) as prescription devices. As such, federal law requires any use of the lasers be under the supervision of a practitioner pursuant to a valid prescription for use. The requirement for prescription use is found at Title 21, Code of Federal Regulations (CFR) 801.109. The LHS and the regulations as proposed have several requirements that we believe will satisfy the federal requirements as they apply to prescription laser and pulsed light devices used strictly for hair removal purposes under the LHS.

Section 401.519 of the LHS requires that a laser hair removal facility have a written contract with a consulting physician that includes protocols for the services provided at the facility. Further, this section also requires that the consulting physician audit the facility's protocols and operations. We will interpret valid consulting physician involvement and protocol development and implementation as outlined in this section and as further outlined in 25 Texas Administrative Code 289.302 to meet the requirements of 21 CFR 801.109 in regard to physician supervision and a prescription for each use.

The federal regulations also require that a prescription device be "sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice." (21 CFR 801.109(a)(2)) Practitioners in Texas are enumerated in 483.001(12) of the Health and Safety Code, and do not include any of the certified individuals outlined in the LHS. Therefore a laser device used by a laser hair removal facility may either be purchased by a physician (such as the consulting physician or other designated physician for emergencies) or by a laser hair removal facility pursuant to an order by or prescription of a physician.

Therefore, for purposes of harmonization:

- A consulting physician with a valid contract satisfies the supervision requirement of 21 CFR 801.109
- Protocols developed, implemented, and audited by the consulting physician under 401.519 satisfy the prescription for each use requirement of 21 CFR 801.109
- A laser hair removal device must be purchased by or on the prescription or order of a physician