

By: Hinojosa

S.B. No. 2347

A BILL TO BE ENTITLED

AN ACT

relating to the establishment of a laser and intense pulsed light device registry; providing a civil penalty.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Chapter 401, Health and Safety Code, is amended by adding Subchapter M to read as follows:

SUBCHAPTER M. LASER OR SIMILAR MEDICAL DEVICE REGISTRY

Sec. 401.501. DEFINITIONS. In this subchapter:

(1) "Laser or similar medical device" means a laser or intense pulsed light device defined as a prescription device under 21 C.F.R. Section 801.109 and approved by the United States Food and Drug Administration for use in general and plastic surgery and dermatology, including hair removal.

(2) "Practitioner" has the meaning assigned by Section 483.001.

Sec. 401.502. RESTRICTED POSSESSION OF LASER OR SIMILAR MEDICAL DEVICE. A person may not purchase or possess a laser or similar medical device unless the person is a practitioner who, under the practitioner's prescriptive authority in this state, may use a laser or similar medical device in the provision of medical, dental, podiatric, optometric, or veterinary care.

Sec. 401.503. NOTIFICATION OF POSSESSION OF LASER OR SIMILAR MEDICAL DEVICE. (a) A practitioner who purchases or takes possession of a laser or similar medical device shall notify the

1 department not later than the seventh day after the date the
2 practitioner takes possession of the laser or device.

3 (b) The notification required under Subsection (a) must be
4 on the form prescribed by the department and must include:

5 (1) the name, address, and telephone number of the
6 practitioner who took possession of the laser or similar medical
7 device and the date the practitioner took possession of the laser or
8 device;

9 (2) the type of laser or device;

10 (3) the address of the premises where the laser or
11 device is used; and

12 (4) the name of each practitioner who uses the laser or
13 device.

14 (c) A practitioner who has possession of a laser or similar
15 medical device shall notify the department of any change in the
16 information provided to the department under Subsection (b) not
17 later than the seventh day after the date of the change.

18 Sec. 401.504. ESTABLISHMENT OF REGISTRY. The department
19 shall establish a central registry of laser or similar medical
20 devices and include in the registry the information submitted to
21 the department under Section 401.503.

22 Sec. 401.505. INSPECTION; RECORDS. (a) The department may
23 exercise the general inspection authority granted to the department
24 under Section 401.063 to determine whether a person is complying
25 with this chapter and department rules.

26 (b) A practitioner required to submit notification under
27 Section 401.503 shall retain a copy of all maintenance records and

1 records relating to the use, receipt, storage, transfer, or
2 disposal of the laser or similar medical device as provided by
3 department rules.

4 Sec. 401.506. RULES. The executive commissioner of the
5 Health and Human Services Commission shall adopt rules necessary to
6 implement this subchapter, including rules on inspections and on
7 maintenance of records.

8 Sec. 401.507. CIVIL PENALTY. (a) A person who violates
9 this subchapter or any rule adopted under this subchapter is liable
10 to this state for a civil penalty of \$1,000 for each violation.
11 Each day a violation continues constitutes a separate violation.

12 (b) The amount of the penalty shall be based on:
13 (1) the seriousness of the violation;
14 (2) the history of previous violations;
15 (3) the amount necessary to deter a future violation;
16 and
17 (4) any other matter that justice may require.

18 (c) The department or the attorney general may sue to
19 collect a civil penalty under this section. In the suit the state
20 may recover the reasonable expenses incurred in obtaining the
21 penalty, including investigation and court costs, reasonable
22 attorney's fees, witness fees, and other expenses.

23 SECTION 2. (a) Not later than November 1, 2009, the
24 executive commissioner of the Health and Human Services Commission
25 shall adopt the rules required by Subchapter M, Chapter 401, Health
26 and Safety Code, as added by this Act.

27 (b) Not later than December 31, 2009, the Department of

1 State Health Services shall prescribe the form required under
2 Section 401.503, Health and Safety Code, as added by this Act, and
3 establish the registry required by Section 401.504, Health and
4 Safety Code, as added by this Act.

5 SECTION 3. Notwithstanding Subchapter M, Chapter 401,
6 Health and Safety Code, as added by this Act, a practitioner is not
7 required to submit the notification required by Section 401.503,
8 Health and Safety Code, as added by this Act, before January 1,
9 2010.

10 SECTION 4. This Act takes effect September 1, 2009.