

1-1 By: Wentworth S.B. No. 1193
1-2 (In the Senate - Filed February 26, 2009; March 13, 2009,
1-3 read first time and referred to Committee on Health and Human
1-4 Services; April 24, 2009, reported adversely, with favorable
1-5 Committee Substitute by the following vote: Yeas 9, Nays 0;
1-6 April 24, 2009, sent to printer.)

1-7 COMMITTEE SUBSTITUTE FOR S.B. No. 1193 By: Deuell

1-8 A BILL TO BE ENTITLED
1-9 AN ACT

1-10 relating to the maintenance and service of certain medical devices
1-11 in health care facilities; providing a criminal penalty.

1-12 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

1-13 SECTION 1. Subchapter B, Chapter 431, Health and Safety
1-14 Code, is amended by adding Section 431.0215 to read as follows:

1-15 Sec. 431.0215. ADDITIONAL PROHIBITED ACTS; CRIMINAL
1-16 PENALTY. (a) In this section, "facility" means a hospital,
1-17 ambulatory surgical center, physician's office, or medical clinic
1-18 that is authorized under the laws of this state to provide health
1-19 care in this state.

1-20 (b) Except as provided by Subsection (c), a person may not
1-21 calibrate, repair, or perform preventive maintenance on or
1-22 otherwise service a device designated by the United States Food and
1-23 Drug Administration as a class II or class III medical device in a
1-24 facility unless the person:

1-25 (1) holds at least an associate of applied science
1-26 degree issued by an accredited college or university in engineering
1-27 or as a biomedical equipment technician or medical imaging
1-28 specialist, or holds a similar degree focused on the service,
1-29 maintenance, or service and maintenance of medical devices;

1-30 (2) holds satisfactory evidence of completion of a
1-31 program of service, maintenance, or service and maintenance of
1-32 medical devices issued by the United States military;

1-33 (3) holds at least an associate degree in an
1-34 electronics field or an information management field and has been
1-35 actively engaged in the service, maintenance, or service and
1-36 maintenance of medical devices for at least two of the preceding
1-37 four years under the direct supervision of an individual who meets
1-38 the requirements of Subdivision (1) or (2); or

1-39 (4) holds satisfactory evidence of successful
1-40 completion of service, maintenance, or service and maintenance
1-41 training from a medical device manufacturer, provided the person
1-42 only provides service or maintenance for devices made by that
1-43 manufacturer unless the person otherwise meets the requirements of
1-44 Subdivision (1), (2), or (3).

1-45 (c) Subsection (b) does not apply to:

1-46 (1) the calibration, repair, maintenance, or service
1-47 of a class II or class III medical device that is used only for
1-48 teaching and research purposes;

1-49 (2) in-service or software upgrades of a medical
1-50 device performed by an employee or authorized sales representative
1-51 of a medical device manufacturer; or

1-52 (3) routine evaluations specified by the medical
1-53 device manufacturer performed by the owner or person designated by
1-54 the owner of the medical device.

1-55 (d) A person commits an offense if the person violates
1-56 Subsection (b). An offense under this subsection is a Class C
1-57 misdemeanor.

1-58 SECTION 2. This Act takes effect September 1, 2009.

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