

BILL ANALYSIS

Senate Research Center
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C.S.S.B. 1193
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Health & Human Services
4/22/2009
Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Class II and class III medical devices, such as infusion pumps, replacement heart valves, and implanted cerebella stimulators are used in hospitals and ambulatory surgery centers throughout the state. Currently, there are no certification requirements for individuals who repair and calibrate these devices. Given the critical nature of certain medical devices, patient safety may be compromised when these devices are serviced or repaired by unqualified individuals. While most facilities hire only certified biomedical technicians, there are individuals who represent themselves as capable of servicing these devices who have not received the proper training.

C.S.S.B. 1193 amends current law relating to the maintenance and service of certain medical devices in health care facilities and provides a criminal penalty.

RULEMAKING AUTHORITY

This bill does not expressly grant any additional rulemaking authority to a state officer, institution, or agency.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subchapter B, Chapter 431, Health and Safety Code, by adding Section 431.0215, as follows:

Sec. 431.0215. **ADDITIONAL PROHIBITED ACTS; CRIMINAL PENALTY.** (a) Defines "facility."

(b) Prohibits a person, except as provided by Subsection (c), from calibrating, repairing, or performing preventative maintenance on or otherwise servicing a device designated by the United States Food and Drug Administration as a class II or class III medical device in a facility unless the person:

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

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

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

(4) holds satisfactory evidence of successful completion of service, maintenance, or service and maintenance training from a medical device manufacturer, provided the person only provides service or maintenance

for devices made by that manufacturer unless the person otherwise meets the requirements of Subdivision (1), (2), or (3).

(c) Provides that Subsection (b) does not apply to the calibration, repair, maintenance, or service of a class II or class III medical device that is used only for teaching and research purposes; in-service or software upgrades of a medical device performed by an employee or authorized sales representative of a medical device manufacturer; or routine evaluations specified by the medical device manufacturer performed by the owner or person designated by the owner of the medical device.

(d) Provides that a person commits an offense if the person violates Subsection (b) and that an offense under this subsection is a Class C misdemeanor.

SECTION 2. Effective date: September 1, 2009.