

## **BILL ANALYSIS**

Senate Research Center  
81R8758 YDB-F

S.B. 1193  
By: Wentworth  
Health & Human Services  
3/18/2009  
As Filed

### **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.

As proposed, S.B. 1193 prohibits a person from calibrating, repairing, or performing preventative maintenance on a class II or class III medical device in a hospital, ambulatory surgical center, physician's office, or medical clinic unless the person holds a certain credential.

### **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 holds a certain credential.

(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.

(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.