By: Wentworth S.B. No. 1193

A BILL TO BE ENTITLED

AN ACT

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

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

SECTION 1. Subdivision (13), Section 431.002, Health and Safety Code, is amended to read as follows:

(13) "Device," except when used in Sections 431.003, 431.021(l), 431.0215, 431.082(g), 431.112(c), and 431.142(c), means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is:

(A) recognized in the official United States Pharmacopoeia National Formulary or any supplement to it;

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(C) intended to affect the structure or any function of the body of man or other animals and that does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and is not dependent on metabolization for the achievement of any of its principal intended purposes.

SECTION 2. Subchapter B, Chapter 431, Health and Safety Code, is amended by adding Section 431.0215 to read as follows:

Sec. 431.0215. ADDITIONAL PROHIBITED ACTS; CRIMINAL PENALTY. (a) In this section:

(1) "Electronic direct care medical device" means a device used in the treatment, monitoring, or diagnosis of a patient.

(2) "Facility" means an ambulatory surgical center, physician's office, or medical clinic, other than an ambulatory surgical center, physician's office, or medical clinic owned or operated by a hospital, that is authorized under the laws of this state to provide health care in this state.

(b) Except as provided by Subsection (c), a person may not calibrate, repair, or perform preventive maintenance on or otherwise service an electronic direct care 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 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 or maintenance of medical devices issued by the United States military;

(3) for at least two of the preceding four years has been actively engaged in and holds documented evidence of proficient performance of electronic direct care medical device service or maintenance apprenticeship or training, including experience under Subdivision (4);

(4) holds at least an associate's degree in an electronics field or an information management field from an accredited college, university, or vocational school, or is actively pursuing such a degree or pursuing an associate's degree described in Subdivision (1), and is servicing or maintaining electronic direct care medical devices under the supervision of an individual who meets the requirements of Subdivision (1) or (2);

(5) holds satisfactory evidence of successful completion of service or maintenance training from an electronic direct care medical device manufacturer or designated trainer, provided the person only provides service or maintenance for devices made by that manufacturer and specifically covered by the training; or

(6) holds a certification issued by the International Certification Commission as a certified biomedical equipment technician, certified laboratory equipment specialist, or certified radiology equipment specialist, provided the person only provides service or maintenance for the type of electronic direct care medical devices covered by the certification.

(c) Subsection (b) does not apply to:

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

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

(3) routine evaluations specified by the medical

device manufacturer performed by the owner or person designated by the owner of the medical device.

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

SECTION 3. (a) Except as provided by Subsection (b) of this section, this Act takes effect September 1, 2010.

(b) Subsection (d), Section 431.0215, Health and Safety Code, as added by this Act, takes effect September 1, 2011.