

AMENDED IN ASSEMBLY JUNE 23, 2010

AMENDED IN SENATE APRIL 28, 2010

SENATE BILL

No. 1237

**Introduced by Senator Padilla
(Coauthor: Senator Alquist)**

February 19, 2010

An act to add Section 115111 to the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1237, as amended, Padilla. Radiation control: health facilities and clinics: records.

Under existing law, the State Department of Public Health licenses and regulates health facilities and clinics, as defined.

Under existing law, the Radiation Control Law, the department licenses and regulates persons that use devices or equipment utilizing radioactive materials. Under existing law the department may also require registration and inspection of sources of ionizing radiation, as defined. Violation of these provisions is a crime.

This bill would, commencing January 1, 2012, require ~~health facilities~~ *hospitals* and clinics, as specified, that use computed tomography (*CT*) *X-ray systems* for diagnostic purposes to record, *where currently possible*, the dose of radiation ~~used~~ *produced* during the administration of the radiation on the radiology image, if technologically feasible, and ~~to record the dose of radiation a CT X-ray examination~~ in the patient's medical record *and on an image produced by the examination, as specified*. This bill would not require small and rural hospitals, as defined, or hospitals and clinics that are located in an area that is

designated as a medically underserved area pursuant to federal law, to comply with these requirements until January 1, 2013.

This bill would, commencing January 1, 2012, ~~require physicians or other practitioners, facilities, or other entities, that furnish diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine CT X-ray services to be accredited by an organization that is approved by the federal Centers for Medicare and Medicaid Services. The bill would also require the facility to report, immediately and in writing, certain information to the department, the affected patient, and the patient's treating physician.~~

Because this bill expands the definition of a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 115111 is added to the Health and Safety
2 Code, to read:
3 115111. (a) Except as provided in subdivisions (b) and (c),
4 commencing January 1, 2012, general acute care hospitals, acute
5 psychiatric hospitals, and special hospitals licensed pursuant to
6 Article 1 (commencing with Section 1250) of Chapter 2 of Division
7 2, clinics licensed pursuant to Article 1 (commencing with Section
8 1200) of Chapter 1 of Division 2, and clinics exempt from licensure
9 pursuant to Section 1206 that use computed tomography (CT)
10 X-ray systems for diagnostic purposes shall record the dose of
11 radiation ~~used produced~~ during the administration ~~of the radiation~~
12 ~~on the radiology image and in the patient's medical record.~~ *of a*
13 *CT X-ray examination. The dosage shall be recorded using both*
14 *dose length product (DLP) and volume computed tomography*
15 *index (CTDI vol), as defined by the International Electrotechnical*
16 *Commission (IEC) and recognized by the federal Food and Drug*
17 *Administration (FDA). The facility shall ensure that the CTDI vol*

1 *is recorded in the patient's medical record and on any image*
2 *produced from the examination.*

3 (b) The requirement specified in subdivision (a) shall be limited
4 ~~to computed tomography machines for which it is technologically~~
5 ~~feasible to record the dose of radiation directly or through the use~~
6 ~~of added software or features.~~ *to CT examinations performed on*
7 *equipment where it is currently possible to record the CTDI vol*
8 *directly or through the addition of updates that have been approved*
9 *or cleared by the FDA.*

10 (c) Small and rural hospitals, as defined in Section 124840, and
11 health facilities and clinics specified in subdivision (a) that are
12 located in an area that is designated as a medically underserved
13 area pursuant to federal law, shall not be required to comply with
14 the requirements of subdivision (a) until January 1, 2013.

15 (d) Commencing January 1, 2012, ~~physicians or other~~
16 ~~practitioners, facilities, or other entities that furnish diagnostic~~
17 ~~magnetic resonance imaging, computed tomography, and nuclear~~
18 ~~medicine services, including positron emission tomography, shall~~
19 *facilities that furnish CT X-ray services shall be accredited by an*
20 *organization that is approved by the federal Centers for Medicare*
21 *and Medicaid Services or an accrediting agency approved by the*
22 *Medical Board of California.*

23 (e) *A facility that uses CT X-ray systems shall notify the*
24 *department, the affected patient, and the patient's treating*
25 *physician immediately, in writing, of the occurrence of any of the*
26 *following events:*

27 (1) *Repetition of a CT X-ray exposure due to equipment defect*
28 *or malfunction.*

29 (2) *Irradiation of the wrong patient or irradiation of a body*
30 *part other than that intended by the ordering physician and*
31 *surgeon.*

32 (3) *A diagnostic dosage that exceeds by 50 percent or more the*
33 *protocols established in subdivision (a).*

34 (f) *Each facility that utilizes therapeutic X-ray systems operating*
35 *at energies below one million electron volts (MeV) shall notify*
36 *and report to the department, in accordance with department*
37 *regulations, and shall also notify the affected patient and his or*
38 *her treating physician within 10 days, in writing, of the occurrence*
39 *of any of the following events:*

40 (1) *Irradiation of the wrong individual or wrong treatment site.*

1 (2) Any treatment consisting of three or fewer fractions, with
2 the calculated total administered dose differing from the total
3 prescribed dose by more than 10 percent of the total prescribed
4 dose.

5 (3) Any exposure resulting in a calculated total administered
6 dose differing from the total prescribed dose by more than 10
7 percent of the total prescribed dose.

8 (g) Each facility that utilizes therapeutic X-ray systems operating
9 with energies at or above one Mev shall notify and report to the
10 department, in accordance with department regulations, and shall
11 notify the affected patient and his or her treating physician within
12 10 days, in writing, of the occurrence of any of the following
13 events:

14 (1) Any event involving irradiation of the wrong individual,
15 administration of the wrong type of radiation or the wrong energy,
16 or irradiation of the wrong treatment site.

17 (2) Any treatment consisting of three or fewer fractions, with
18 the calculated total administered dose differing from the total
19 prescribed dose by more than 10 percent of the total prescribed
20 dose.

21 (3) Any exposure resulting in a calculated total administration
22 dose differing from the total prescribed dose by more than 20
23 percent of the total prescribed dose.

24 SEC. 2. No reimbursement is required by this act pursuant to
25 Section 6 of Article XIII B of the California Constitution because
26 the only costs that may be incurred by a local agency or school
27 district will be incurred because this act creates a new crime or
28 infraction, eliminates a crime or infraction, or changes the penalty
29 for a crime or infraction, within the meaning of Section 17556 of
30 the Government Code, or changes the definition of a crime within
31 the meaning of Section 6 of Article XIII B of the California
32 Constitution.