

AMENDED IN ASSEMBLY AUGUST 20, 2010

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~~ *Sections 115111, 115112, and 115113* 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~~ *July* 1, 2012, require hospitals and clinics, as specified, that use computed tomography (CT) X-ray systems for ~~diagnostic purposes~~ *human use* to record, where currently possible, the dose of radiation *on every CT study* produced during the administration of 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. The bill would require the dose to be verified annually by a medical physicist, as specified, unless the facility is accredited.~~

This bill would, commencing ~~January 1, 2012~~ *July 1, 2013*, require facilities that furnish CT X-ray services to be accredited by an organization that is approved by the federal Centers for Medicare and Medicaid Services, *an accrediting agency approved by the Medical Board of California, or the State Department of Public Health*. 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) Commencing July 1, 2012, subject to subdivision*
- 4 *(e), a person that uses a computed tomography (CT) X-ray system*
- 5 *for human use shall record the dose of radiation on every CT study*
- 6 *produced during a CT examination.*
- 7 *(b) The facility conducting the study shall electronically send*
- 8 *each CT study and protocol page that lists the technical factors*
- 9 *and dose of radiation to the electronic picture archiving and*
- 10 *communications system.*
- 11 *(c) The displayed dose shall be verified annually by a medical*
- 12 *physicist to ensure the displayed doses are within 20 percent of*
- 13 *the true measured dose measured in accordance with subdivision*
- 14 *(f) unless the facility is accredited.*
- 15 *(d) Subject to subdivision (e), the radiology report of a CT study*
- 16 *shall include the dose of radiation by either recording the dose*

1 *within the patient's radiology report or attaching the protocol*
2 *page that includes the dose of radiation to the radiology report.*

3 *(e) The requirements of this section shall be limited to CT*
4 *systems capable of calculating and displaying the dose.*

5 *(f) For the purposes of this section, dose of radiation shall be*
6 *defined as one of the following:*

7 *(1) The computed tomography index volume (CTDI vol) and*
8 *dose length product (DLP), as defined by the International*
9 *Electrotechnical Commission (IEC) and recognized by the federal*
10 *Food and Drug Administration (FDA).*

11 *(2) The dose unit as recommended by the American Association*
12 *of Physicists in Medicine.*

13 *SEC. 2. Section 115112 is added to the Health and Safety Code,*
14 *to read:*

15 *115112. Commencing July 1, 2013, facilities that furnish CT*
16 *X-ray services shall be accredited by an organization that is*
17 *approved by the federal Centers for Medicare and Medicaid*
18 *Services, an accrediting agency approved by the Medical Board*
19 *of California, or the State Department of Public Health.*

20 *SEC. 3. Section 115113 is added to the Health and Safety Code,*
21 *to read:*

22 *115113. (a) Except for an event that results from patient*
23 *movement or interference, a facility shall report to the department*
24 *an event in which the administration of radiation results in and of*
25 *the following:*

26 *(1) Repeating of a CT examination, unless otherwise ordered*
27 *by a physician or a radiologist, if the following dose values are*
28 *exceeded:*

29 *(A) 0.05Sv (5 rem) effective dose equivalent.*

30 *(B) 0.5 Sv (50 rem) to an organ or tissue.*

31 *(C) 0.5 Sv (50 rem) shallow dose equivalent to the skin.*

32 *(2) CT X-ray irradiation of a body part other than that intended*
33 *by the ordering physician or a radiologist if one of the following*
34 *dose values are exceeded:*

35 *(A) 0.05 Sv (5 rem) effective dose equivalent.*

36 *(B) 0.5 Sv (50 rem) to an organ or tissue.*

37 *(C) 0.5 Sv (50 rem) shallow dose equivalent to the skin.*

38 *(3) CT or therapeutic exposure that results in unanticipated*
39 *permanent functional damage to an organ or a physiological*

1 system, hair loss, or erythema, as determined by a qualified
2 physician.

3 (4) A CT or therapeutic dose to an embryo or fetus that is
4 greater than 50 mSv (5 rem) dose equivalent, that is a result of
5 radiation to a known pregnant individual unless the dose to the
6 embryo or fetus was specifically approved, in advance, by a
7 qualified physician.

8 (5) Therapeutic ionizing irradiation of the wrong individual,
9 or wrong treatment site.

10 (6) The total dose from therapeutic ionizing radiation delivered
11 differs from the prescribed dose by 20 percent or more. A report
12 shall not be required pursuant to this paragraph in any instance
13 where the dose administered exceeds 20 percent of the amount
14 prescribed in a situation where the radiation was utilized for
15 palliative care for the specific patient. The radiation oncologist
16 shall notify the referring physician that the dose was exceeded.

17 (b) The facility shall, no later than five business days after
18 discovery of an event described in subdivision (a), provide
19 notification of the event to the department and the referring
20 physician of the person subject to the event and shall, no later than
21 15 business days after discovery of an event described in
22 subdivision (a) provide written notification to the person who is
23 subject to the event.

24 (c) The information required pursuant to this section shall
25 include, but not be limited to, information regarding each
26 substantiated adverse event, as defined in Section 1279.1, reported
27 to the department, and may include compliance information history.

28 SECTION 1. Section 115111 is added to the Health and Safety
29 Code, to read:

30 ~~115111. (a) Except as provided in subdivisions (b) and (c),~~
31 ~~commencing January 1, 2012, general acute care hospitals, acute~~
32 ~~psychiatric hospitals, and special hospitals licensed pursuant to~~
33 ~~Article 1 (commencing with Section 1250) of Chapter 2 of Division~~
34 ~~2, clinics licensed pursuant to Article 1 (commencing with Section~~
35 ~~1200) of Chapter 1 of Division 2, and clinics exempt from licensure~~
36 ~~pursuant to Section 1206 that use computed tomography (CT)~~
37 ~~X-ray systems for diagnostic purposes shall record the dose of~~
38 ~~radiation produced during the administration of a CT X-ray~~
39 ~~examination. The dosage shall be recorded using both dose length~~
40 ~~product (DLP) and volume computed tomography index (CTDI~~

1 vol), as defined by the International Electrotechnical Commission
2 (IEC) and recognized by the federal Food and Drug Administration
3 (FDA). The facility shall ensure that the CTDI vol is recorded in
4 the patient's medical record and on any image produced from the
5 examination.

6 (b) ~~The requirement specified in subdivision (a) shall be limited~~
7 ~~to CT examinations performed on equipment where it is currently~~
8 ~~possible to record the CTDI vol directly or through the addition~~
9 ~~of updates that have been approved or cleared by the FDA.~~

10 (e) ~~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, facilities that furnish CT~~
16 ~~X-ray services shall be accredited by an organization that is~~
17 ~~approved by the federal Centers for Medicare and Medicaid~~
18 ~~Services or an accrediting agency approved by the Medical Board~~
19 ~~of California.~~

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

24 (1) ~~Repetition of a CT X-ray exposure due to equipment defect~~
25 ~~or malfunction.~~

26 (2) ~~Irradiation of the wrong patient or irradiation of a body part~~
27 ~~other than that intended by the ordering physician and surgeon.~~

28 (3) ~~A diagnostic dosage that exceeds by 50 percent or more the~~
29 ~~protocols established in subdivision (a).~~

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

36 (1) ~~Irradiation of the wrong individual or wrong treatment site.~~

37 (2) ~~Any treatment consisting of three or fewer fractions, with~~
38 ~~the calculated total administered dose differing from the total~~
39 ~~prescribed dose by more than 10 percent of the total prescribed~~
40 ~~dose.~~

1 ~~(3) Any exposure resulting in a calculated total administered~~
2 ~~dose differing from the total prescribed dose by more than 10~~
3 ~~percent of the total prescribed dose.~~

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

10 ~~(1) Any event involving irradiation of the wrong individual,~~
11 ~~administration of the wrong type of radiation or the wrong energy,~~
12 ~~or irradiation of the wrong treatment site.~~

13 ~~(2) Any treatment consisting of three or fewer fractions, with~~
14 ~~the calculated total administered dose differing from the total~~
15 ~~prescribed dose by more than 10 percent of the total prescribed~~
16 ~~dose.~~

17 ~~(3) Any exposure resulting in a calculated total administration~~
18 ~~dose differing from the total prescribed dose by more than 20~~
19 ~~percent of the total prescribed dose.~~

20 ~~SEC. 2.~~

21 ~~SEC. 4.~~ No reimbursement is required by this act pursuant to
22 Section 6 of Article XIII B of the California Constitution because
23 the only costs that may be incurred by a local agency or school
24 district will be incurred because this act creates a new crime or
25 infraction, eliminates a crime or infraction, or changes the penalty
26 for a crime or infraction, within the meaning of Section 17556 of
27 the Government Code, or changes the definition of a crime within
28 the meaning of Section 6 of Article XIII B of the California
29 Constitution.