

CHAPTER _____

An act to add Sections 115111, 115112, and 115113 to the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1237, 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 July 1, 2012, require hospitals and clinics, as specified, that use computed tomography (CT) X-ray systems for human use to record, if the CT systems are capable, the dose of radiation on every CT study produced during the administration of a CT examination, as specified. 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 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 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.

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

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

115111. (a) Commencing July 1, 2012, subject to subdivision (e), a person that uses a computed tomography (CT) X-ray system for human use shall record the dose of radiation on every CT study produced during a CT examination.

(b) The facility conducting the study shall electronically send each CT study and protocol page that lists the technical factors and dose of radiation to the electronic picture archiving and communications system.

(c) The displayed dose shall be verified annually by a medical physicist to ensure the displayed doses are within 20 percent of the true measured dose measured in accordance with subdivision (f) unless the facility is accredited.

(d) Subject to subdivision (e), the radiology report of a CT study shall include the dose of radiation by either recording the dose within the patient's radiology report or attaching the protocol page that includes the dose of radiation to the radiology report.

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

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

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

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

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

115112. Commencing July 1, 2013, facilities that furnish CT X-ray services shall 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.

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

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

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

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

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

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

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

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

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

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

(3) CT or therapeutic exposure that results in unanticipated permanent functional damage to an organ or a physiological system, hair loss, or erythema, as determined by a qualified physician.

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

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

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

(b) The facility shall, no later than five business days after discovery of an event described in subdivision (a), provide notification of the event to the department and the referring physician of the person subject to the event and shall, no later than 15 business days after discovery of an event described in

subdivision (a) provide written notification to the person who is subject to the event.

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

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