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 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 during the administration of the radiation on the radiology image, if technologically feasible, and to record the dose of radiation on 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.


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) Except as provided in subdivisions (b) and (c), commencing January 1, 2012, general acute care hospitals, acute psychiatric hospitals, and special hospitals licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2, clinics licensed pursuant to Article 1 (commencing with Section 1200) of Chapter 1 of Division 2, and clinics exempt from licensure pursuant to Section 1206 that use computed tomography (CT) X-ray systems for diagnostic purposes shall record the dose of radiation used produced during the administration of the radiation on the radiology image and in the patient’s medical record of a CT X-ray examination. The dosage shall be recorded using both dose length product (DLP) and volume computed tomography index (CTDI vol), as defined by the International Electrotechnical Commission (IEC) and recognized by the federal Food and Drug Administration (FDA). The facility shall ensure that the CTDI vol
is recorded in the patient's medical record and on any image produced from the examination.

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

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

(d) Commencing January 1, 2012, physicians or other practitioners, facilities, or other entities that furnish diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine services, including positron emission tomography, shall 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 or an accrediting agency approved by the Medical Board of California.

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

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

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

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

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

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

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

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

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

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

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

SEC. 2. 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.