

Assembly Bill No. 510

CHAPTER 106

An act to amend Sections 115111, 115112, and 115113 of the Health and Safety Code, relating to public health, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor July 13, 2012. Filed with
Secretary of State July 13, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

AB 510, Bonnie Lowenthal. 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 the existing Radiation Control Law, the department licenses and regulates persons that use devices or equipment utilizing radioactive materials. Under existing law, the department is authorized to require registration and inspection of sources of ionizing radiation, as defined. Existing law, commencing July 1, 2012, requires that a facility using a computed tomography (CT) X-ray system record the dose of radiation on every CT study produced. Existing law requires that the displayed dose of radiation be verified annually by a medical physicist to ensure the accuracy of the displayed dose unless the facility is accredited. Violations of these provisions are a crime.

This bill would require the facility to record the dose of radiation on every diagnostic CT study in each patient's record and would exempt the dose of radiation in specified CT studies from having to be recorded. This bill would delete the exemption for accredited facilities and would authorize a facility with an accredited CT X-ray system to elect not to annually verify the displayed dose of radiation, as specified. Because accredited facilities could now be subject to these provisions, and because a violation of these provisions is a crime, the bill would impose a state-mandated local program by expanding the scope of a crime. The bill also would require the dose to be verified for the facility's standard adult brain, adult abdomen, and pediatric brain protocols.

Existing law, commencing July 1, 2013, requires facilities that furnish CT X-ray services to be accredited by an approved organization, as specified.

This bill instead would require CT X-ray systems, with specified exceptions, to be accredited by an approved organization, as specified.

Existing law, commencing July 1, 2012, requires a facility to report the discovery of certain information about an event in which the administration of radiation results in prescribed occurrences, including the CT X-ray irradiation of an area of the body other than that intended, within 5 business

days of the discovery of the event, to the department and the patient's referring physician.

This bill would instead require a facility to report a CT X-ray examination for any individual for whom a physician did not provide approval for the examination, as well as a CT X-ray examination that does not include the intended area of the body, if specified dose values are exceeded. This bill would require that these reports be made within 5 business days of the discovery of a therapeutic event and within 10 business days of the discovery of a CT event.

The bill would also make technical and clarifying changes.

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.

This bill would declare that it is to take effect immediately as an urgency statute.

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

SECTION 1. Section 115111 of the Health and Safety Code is amended 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 diagnostic CT study produced during a CT examination in the patient's record, as defined in Section 123105. CT studies used for therapeutic radiation treatment planning or delivery or for calculating attenuation coefficients for nuclear medication studies shall not be required to record the dose.

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

(c) (1) Until July 1, 2013, the displayed dose shall be verified annually by a medical physicist for the facility's standard adult brain, adult abdomen, and pediatric brain protocols, to ensure the displayed doses are within 20 percent of the true measured dose measured in accordance with subdivision (f).

(2) A facility that has a CT X-ray system that is 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 may elect not to perform the verification described in paragraph (1).

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

(g) For purposes of this section, “CT X-ray system” means the same as provided in Section 892.1750 of Title 21 of the Code of Federal Regulations.

SEC. 2. Section 115112 of the Health and Safety Code is amended to read:

115112. (a) Except as provided in subdivision (b), commencing July 1, 2013, CT X-ray systems shall be accredited by an accrediting organization that is approved by the federal Centers for Medicare and Medicaid Services, an accrediting organization approved by the Medical Board of California, or the State Department of Public Health. A facility that is subject to accreditation may elect to have the CT X-ray system accredited pursuant to a single accreditation survey that includes the CT service by the accrediting organization.

(b) A CT X-ray system shall not be subject to accreditation if any of the following apply:

(1) The system is used for therapeutic radiation treatment planning or delivery.

(2) The system is used for calculating attenuation coefficients for nuclear medicine studies.

(3) The system is dedicated for image guidance for interventional radiologic procedures.

SEC. 3. Section 115113 of the Health and Safety Code is amended 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 any of the following:

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

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

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

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

(2) A CT X-ray examination for any individual for whom a physician did not provide approval for the examination if one of the following dose values is exceeded:

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

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

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

(3) A CT X-ray for an examination that does not include the area of the body that was intended to be imaged by the ordering physician or radiologist if one of the following dose values is exceeded:

- (A) 0.05 Sv (5 rem) effective dose.
- (B) 0.5 Sv (50 rem) to an organ or tissue.
- (C) 0.5 Sv (50 rem) shallow dose to the skin.

(4) 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.

(5) A CT or therapeutic dose to an embryo or fetus that is greater than 50 mSv (5 rem) dose, 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.

(6) Therapeutic ionizing irradiation of the wrong individual or the wrong treatment site, excluding the area of the body that was intended to be irradiated.

(7) 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 if the dose administered exceeds 20 percent of the amount prescribed in a situation if 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 the discovery of a therapeutic event described in paragraphs (3) to (7), inclusive, of subdivision (a) and no later than 10 business days after discovery of an event described in paragraphs (1) to (4), inclusive, of 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) This section shall become inoperative on the effective date of the act that added this subdivision, and shall remain inoperative until July 1, 2012.

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.

SEC. 5. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to protect the health and safety of Californians and ensure that certain facilities using a computed tomography (CT) X-ray system fully

comply with the reporting requirements that go into effect on July 1, 2012, it is necessary for this act to take effect immediately.

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