

**As of June 14, 2010**

**CALIFORNIA HEALTH AND SAFETY CODE**

**1280.15.** (a) A clinic, health facility, home health agency, or hospice licensed pursuant to Section 1204, 1250, 1725, or 1745 shall prevent unlawful or unauthorized access to, and use or disclosure of, patients' medical information, as defined in subdivision (g) of Section 56.05 of the Civil Code and consistent with Section 130203. The department, after investigation, may assess an administrative penalty for a violation of this section of up to twenty-five thousand dollars (\$25,000) per patient whose medical information was unlawfully or without authorization accessed, used, or disclosed, and up to seventeen thousand five hundred dollars (\$17,500) per subsequent occurrence of unlawful or unauthorized access, use, or disclosure of that patients' medical information. For purposes of the investigation, the department shall consider the clinic's, health facility's, agency's, or hospice's history of compliance with this section and other related state and federal statutes and regulations, the extent to which the facility detected violations and took preventative action to immediately correct and prevent past violations from recurring, and factors outside its control that restricted the facility's ability to comply with this section. The department shall have full discretion to consider all factors when determining the amount of an administrative penalty pursuant to this section.

(b) (1) A clinic, health facility, home health agency, or hospice to which subdivision (a) applies shall report any unlawful or unauthorized access to, or use or disclosure of, a patient's medical information to the department no later than five business days after the unlawful or unauthorized access, use, or disclosure has been detected by the clinic, health facility, home health agency, or hospice.

(2) Subject to subdivision (c), a clinic, health facility, home health agency, or hospice shall also report any unlawful or unauthorized access to, or use or disclosure of, a patient's medical information to the affected patient or the patient's representative at the last known address, no later than five business days after the unlawful or unauthorized access, use, or disclosure has been detected by the clinic, health facility, home health agency, or hospice.

(c) (1) A clinic, health facility, home health agency, or hospice shall delay the reporting, as required pursuant to paragraph (2) of subdivision (b), of any unlawful or unauthorized access to, or use or disclosure of, a patient's medical information beyond five business days if a law enforcement agency or official provides the clinic, health facility, home health agency, or hospice with a written or oral statement that compliance with the reporting requirements of paragraph (2) of subdivision (b) would be likely to impede the law enforcement agency's activities that relate to the unlawful or unauthorized access to, and use or disclosure of, a patient's medical information and specifies a date upon which the delay shall end, not to exceed 60 days after a written request is made, or 30 days after an oral request is made. A law enforcement agency or official may request an extension of a delay based upon a written declaration that there exists a bona fide, ongoing, significant criminal investigation of serious wrongdoing relating to the unlawful or unauthorized access to, and use or disclosure of, a patient's medical information, that notification of patients will undermine the law

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enforcement agency's activities, and that specifies a date upon which the delay shall end, not to exceed 60 days after the end of the original delay period.

(2) If the statement of the law enforcement agency or official is made orally, then the clinic, health facility, home health agency, or hospice shall do the following:

(A) Document the oral statement, including, but not limited to, the identity of the law enforcement agency or official making the oral statement and the date upon which the oral statement was made.

(B) Limit the delay in reporting the unlawful or unauthorized access to, or use or disclosure of, the patient's medical information to the date specified in the oral statement, not to exceed 30 calendar days from the date that the oral statement is made, unless a written statement that complies with the requirements of this subdivision is received during that time.

(3) A clinic, health facility, home health agency, or hospice shall submit a report that is delayed pursuant to this subdivision not later than five business days after the date designated as the end of the delay.

(d) If a clinic, health facility, home health agency, or hospice to which subdivision (a) applies violates subdivision (b), the department may assess the licensee a penalty in the amount of one hundred dollars (\$100) for each day that the unlawful or unauthorized access, use, or disclosure is not reported, following the initial five-day period specified in subdivision (b). However, the total combined penalty assessed by the department under subdivision (a) and this subdivision shall not exceed two hundred fifty thousand dollars (\$250,000) per reported event.

(e) In enforcing subdivisions (a) and (d), the department shall take into consideration the special circumstances of small and rural hospitals, as defined in Section 124840, and primary care clinics, as defined in subdivision (a) of Section 1204, in order to protect access to quality care in those hospitals and clinics. When assessing a penalty on a skilled nursing facility or other facility subject to Section 1423, 1424, 1424.1, or 1424.5, the department shall issue only the higher of either a penalty for the violation of this section or a penalty for violation of Section 1423, 1424, 1424.1, or 1424.5, not both.

(f) All penalties collected by the department pursuant to this section, Sections **1280.1**, **1280.3**, and **1280.4**, shall be deposited into the Internal Departmental Quality Improvement Account, which is hereby created within the Special Deposit Fund under Section 16370 of the Government **Code**. Upon appropriation by the Legislature, moneys in the account shall be expended for internal quality improvement activities in the Licensing and Certification Program.

(g) If the licensee disputes a determination by the department regarding a failure to prevent or failure to timely report unlawful or unauthorized access to, or use or disclosure of, patients' medical information, or the imposition of a penalty under this section, the licensee may, within 10 days of receipt of the penalty assessment, request a hearing pursuant to Section 131071. Penalties shall be paid when appeals have been exhausted and the penalty has been upheld.

(h) In lieu of disputing the determination of the department regarding a failure to prevent or failure to timely report unlawful or unauthorized access to, or use or disclosure of, patients' medical information, transmit to the department 75 percent of the total amount of the administrative penalty, for each violation, within 30

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business days of receipt of the administrative penalty.

(i) Notwithstanding any other law, the department may refer violations of this section to the Office of Health Information Integrity for enforcement pursuant to Section 130303.

(j) For purposes of this section, the following definitions shall apply:

(1) "Reported event" means all breaches included in any single report that is made pursuant to subdivision (b), regardless of the number of breach events contained in the report.

(2) "Unauthorized" means the inappropriate access, review, or viewing of patient medical information without a direct need for medical diagnosis, treatment, or other lawful use as permitted by the Confidentiality of Medical Information Act (Part 2.6 (commencing with Section 56) of Division 1 of the Civil **Code**) or any other statute or regulation governing the lawful access, use, or disclosure of medical information.

**1280.2.** (a) No deficiency cited pursuant to paragraph (2) of subdivision (b) of Section **1280** or Section **1280.1** shall be for the failure of a facility to meet the requirements of the California Building Standards **Code** if, as of January 1, 1994, the hospital building was approved under Chapter 12.5 (commencing with Section 15000) of Division 12.5, or if the hospital building was exempt from that approval under any other provision of law in effect on that date.

(b) It is the intent of the Legislature that neither the amendments made to Section **1280** by the act that added this section, nor Section **1280.1** shall be construed to require the retrofitting of hospital buildings built prior to January 1, 1994, to meet seismic standards in effect on that date.

**1280.3.** (a) Commencing on the effective date of the regulations adopted pursuant to this section, the director may assess an administrative penalty against a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 for a deficiency constituting an immediate jeopardy violation as determined by the department up to a maximum of seventy-five thousand dollars (\$75,000) for the first administrative penalty, up to one hundred thousand dollars (\$100,000) for the second subsequent administrative penalty, and up to one hundred twenty-five thousand dollars (\$125,000) for the third and every subsequent violation. An administrative penalty issued after three years from the date of the last issued immediate jeopardy violation shall be considered a first administrative penalty so long as the facility has not received additional immediate jeopardy violations and is found by the department to be in substantial compliance with all state and federal licensing laws and regulations. The department shall have full discretion to consider all factors when determining the amount of an administrative penalty pursuant to this section.

(b) Except as provided in subdivision (c), for a violation of this chapter or the rules and regulations promulgated thereunder that does not constitute a violation of subdivision (a), the department may assess an administrative penalty in an amount of up to

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twenty-five thousand dollars (\$25,000) per violation. This subdivision shall also apply to violation of regulations set forth in Article 3 (commencing with Section 127400) of Chapter 2 of Part 2 of Division 107 or the rules and regulations promulgated thereunder.

The department shall promulgate regulations establishing the criteria to assess an administrative penalty against a health facility licensed pursuant to subdivisions (a), (b), or (f) of Section 1250. The criteria shall include, but need not be limited to, the following:

- (1) The patient's physical and mental condition.
  - (2) The probability and severity of the risk that the violation presents to the patient.
  - (3) The actual financial harm to patients, if any.
  - (4) The nature, scope, and severity of the violation.
  - (5) The facility's history of compliance with related state and federal statutes and regulations.
  - (6) Factors beyond the facility's control that restrict the facility's ability to comply with this chapter or the rules and regulations promulgated thereunder.
  - (7) The demonstrated willfulness of the violation.
  - (8) The extent to which the facility detected the violation and took steps to immediately correct the violation and prevent the violation from recurring.
- (c) The department shall not assess an administrative penalty for minor violations.
- (d) The regulations shall not change the definition of immediate jeopardy as established in this section.
- (e) The regulations shall apply only to incidents occurring on or after the effective date of the regulations.
- (f) If the licensee disputes a determination by the department regarding the alleged deficiency or alleged failure to correct a deficiency, or regarding the reasonableness of the proposed deadline for correction or the amount of the penalty, the licensee may, within 10 working days, request a hearing pursuant to Section 131071. Penalties shall be paid when all appeals have been exhausted and the department's position has been upheld.
- (g) For purposes of this section, "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.
- (h) In enforcing subdivision (a) the department shall take into consideration the special circumstances of small and rural hospitals, as defined in Section 124840, in order to protect access to quality care in those hospitals.

**1280.4.** If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 fails to report an adverse event pursuant to Section 1279.1, the department may assess the licensee a civil penalty in an amount not to exceed one hundred dollars (\$100) for each day that the adverse event is not reported following the initial five-day period or 24-hour period, as applicable, pursuant to subdivision (a) of Section 1279.1. If the licensee disputes a determination by the department regarding alleged failure to report an adverse event, the licensee may, within 10 days, request a hearing pursuant to Section 100171. Penalties shall be paid when appeals pursuant to those provisions have been

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exhausted.

**1280.5.** The state department shall accept, consider, and resolve written appeals by a licensee or health facility administrator of findings made upon the inspection of a health facility.

**1280.6.** In assessing an administrative penalty pursuant to Section **1280.1** or Section **1280.3** against a licensee of a health facility licensed under subdivision (a) of Section 1250 owned by a nonprofit corporation that shares an identical board of directors with a nonprofit health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340), the director shall consider whether the deficiency arises from an incident that is the subject of investigation of, or has resulted in a fine to, the health care service plan by the Department of Managed Health Care. If the deficiency results from the same incident, the director shall limit the administrative penalty to take into consideration the penalty imposed by the Department of Managed Health Care.