

AMENDED IN ASSEMBLY AUGUST 13, 2008

AMENDED IN ASSEMBLY AUGUST 7, 2008

AMENDED IN ASSEMBLY JULY 12, 2007

AMENDED IN ASSEMBLY JUNE 18, 2007

AMENDED IN SENATE APRIL 17, 2007

AMENDED IN SENATE APRIL 9, 2007

SENATE BILL

No. 541

Introduced by Senator Alquist

February 22, 2007

An act to amend Sections 1280.1 and 1280.3 of, and to add Section 1280.15 to, the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

SB 541, as amended, Alquist. Clinics, health facilities, home health agencies, and hospices: administrative penalties and patient information.

Existing law provides for the licensure and regulation of clinics, health facilities, home health agencies, and hospices by the State Department of Public Health. A violation of these provisions is a misdemeanor.

Existing law authorizes the department to assess a licensee of a general acute care hospital, an acute psychiatric hospital, or a special hospital an administrative penalty not to exceed \$25,000 if the licensee receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction. Existing law makes these provisions applicable to incidents occurring on or after January 1, 2007.

This bill would increase this administrative penalty to \$100,000 for incidents occurring on and after January 1, 2009.

Existing law also provides that upon the adoption of specified regulations, the administrative penalty for such a violation may be up to \$50,000. If the violation does not constitute an immediate jeopardy violation, the penalty may be up to \$17,500, except that no penalty shall be assessed for a minor violation.

Under existing law, moneys collected by the department as a result of the imposition of the above penalties are required to be deposited into the Licensing and Certification Program Fund, to be expended, upon appropriation by the Legislature, to support internal departmental quality improvement activities.

This bill would increase the above administrative penalties ~~from \$25,000 to \$100,000~~, from \$50,000 to \$150,000, and from \$17,500 to \$25,000, respectively, and would apply the penalty provisions only to incidents occurring on or after January 1, 2009.

This bill would require ~~specified~~ health facilities, *clinics, hospices, and home health* agencies to prevent unlawful *or unauthorized* access to, or use; or disclosure of, a patient's medical information, as defined. The bill would authorize the department to assess an administrative penalty of \$25,000 per patient for a violation of these provisions, and \$17,500 for each subsequent accessing, use, or disclosure of that information ~~and would allow the department to refer violations to the office of Health Information Integrity for enforcement.~~

The bill would require all of the administrative penalties to be deposited into the Internal Departmental Quality Improvement Account, which would be created within the existing Special Deposit Fund, and would delete the requirement that certain of the penalties be deposited into the Licensing and Certification Program Fund. The bill would require moneys in the account to be used for *internal* quality improvement activities in the ~~Licensing and Certification Program~~ *department*.

This bill would impose specified reporting requirements on a health facility or agency with respect to unlawful *or unauthorized* access to, or use; or disclosure of, a patient's medical information, and would authorize the department to assess a penalty for the failure to report, in the amount of \$100 for each day that the *unlawful or* unauthorized access, use, or disclosure is not reported, up to a maximum of \$250,000. The bill would authorize a licensee to dispute a determination of the

department regarding a failure to make a report required by the bill, as provided.

By expanding the definition of an existing crime, this bill would impose a state-mandated local program.

~~This bill would be operative contingent on the enactment of AB 211 of the 2007–08 Regular Session on or before January 1, 2009.~~

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, if the Commission on State Mandates determines that the bill contains costs mandated by the state, reimbursement for those costs shall be made pursuant to these statutory provisions.

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 1280.1 of the Health and Safety Code is
2 amended to read:

3 1280.1. (a) ~~Prior~~ *Subject to subdivision (d), prior to the*
4 *effective date of regulations adopted to implement Section 1280.3,*
5 ~~with respect to incidents occurring on and after January 1, 2009,~~
6 *if a licensee of a health facility licensed under subdivision (a), (b),*
7 *or (f) of Section 1250 receives a notice of deficiency constituting*
8 *an immediate jeopardy to the health or safety of a patient and is*
9 *required to submit a plan of correction, the department may assess*
10 *the licensee an administrative penalty in an amount not to exceed*
11 ~~one hundred thousand dollars (\$100,000)~~ *twenty-five thousand*
12 *dollars (\$25,000) per violation.*

13 (b) If the licensee disputes a determination by the department
14 regarding the alleged deficiency or the alleged failure to correct a
15 deficiency, or regarding the reasonableness of the proposed
16 deadline for correction or the amount of the penalty, the licensee
17 may, within 10 days, request a hearing pursuant to Section 131071.
18 Penalties shall be paid when appeals have been exhausted and the
19 department’s position has been upheld.

20 (c) For purposes of this section “immediate jeopardy” means a
21 situation in which the licensee’s noncompliance with one or more

1 requirements of licensure has caused, or is likely to cause, serious
2 injury or death to the patient.

3 *(d) This section shall apply only to incidents occurring on or*
4 *after January 1, 2007. With respect to incidents occurring on or*
5 *after January 1, 2009, the amount of the administrative penalties*
6 *assessed under subdivision (a) shall not exceed one hundred*
7 *thousand dollars (\$100,000) per violation.*

8 ~~(d)~~

9 *(e) No new regulations are required or authorized for*
10 *implementation of this section.*

11 ~~(e)~~

12 *(f) This section shall become inoperative on the effective date*
13 *of regulations promulgated by the department pursuant to Section*
14 *1280.3.*

15 SEC. 2. Section 1280.15 is added to the Health and Safety
16 Code, to read:

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

37 (b) (1) A clinic, health facility, agency, or hospice to which
38 subdivision (a) applies shall report any unlawful *or unauthorized*
39 access to, or use or disclosure of, a patient's medical information
40 to the department no later than five days after the *unlawful or*

1 unauthorized access, use, or disclosure has been ~~detected~~. ~~A~~
2 *detected by the clinic, health facility, agency, or hospice.*

3 (2) A clinic, health facility, agency, or hospice shall also report
4 any unlawful *or unauthorized* access to, or use, or disclosure of,
5 a patient's medical information to the affected patient or the
6 patient's representative *at the last known address*, no later than
7 five days after the *unlawful or unauthorized* access, use, or
8 disclosure has been detected *by the clinic, health facility, agency,*
9 *or hospice.*

10 (c) If a clinic, health facility, agency, or hospice to which
11 subdivision (a) applies ~~fails to report the unlawful access to, or~~
12 ~~use or disclosure of, a patient's medical information to the~~
13 ~~department, or to the patient or the patient's representative, the~~
14 *violates subdivision (b), the department may assess the licensee a*
15 *penalty in the amount of one hundred dollars (\$100) for each day*
16 *that the unlawful or unauthorized access, use, or disclosure is not*
17 *reported, following the initial five-day period specified in*
18 *subdivision (b). However, the total combined penalty assessed by*
19 *the department under subdivision (a) and this subdivision shall*
20 *not exceed two hundred fifty thousand dollars (\$250,000) per*
21 *reported event.*

22 (d) *In enforcing subdivisions (a) and (c), the department shall*
23 *take into consideration the special circumstances of small and*
24 *rural hospitals, as defined in Section 124840, in order to protect*
25 *access to quality care in those hospitals.*

26 ~~(d)~~

27 (e) All penalties collected by the department pursuant to this
28 section, ~~Section 1280.1, and Section 1280.3~~ *Sections 1280.1,*
29 *1280.3, and 1280.4,* shall be deposited into the Internal
30 Departmental Quality Improvement Account, which is hereby
31 created within the Special Deposit Fund under Section 16370 of
32 the Government Code. Upon appropriation by the Legislature,
33 moneys in the account shall be expended for *internal* quality
34 improvement activities in the ~~Licensing and Certification Program~~
35 *department.*

36 ~~(e)~~

37 (f) If the licensee disputes a determination by the department
38 regarding a failure to prevent or failure to timely report unlawful
39 *or unauthorized* access to, or use or disclosure of, patients' medical
40 information, or the imposition of a penalty under this section, the

1 licensee may, within 10 days of receipt of the penalty assessment,
2 request a hearing pursuant to Section 131071. Penalties shall be
3 paid when appeals have been exhausted and the penalty has been
4 upheld.

5 ~~(f)~~

6 (g) In lieu of disputing the determination of the department
7 regarding a failure to prevent or failure to timely report unlawful
8 *or unauthorized* access to, or use or disclosure of, patients' medical
9 information, transmit to the department 75 percent of the total
10 amount of the administrative penalty, for each violation, within
11 30 business days of receipt of the administrative penalty.

12 ~~(g)~~

13 (h) Notwithstanding any other provision of law, the department
14 may refer violations of this section to the office of Health
15 Information Integrity for enforcement pursuant to Section 130303,
16 *except that if Assembly Bill 211 of the 2007–08 Regular Session*
17 *is not enacted, the department may refer violations to the Office*
18 *of HIPAA Implementation.*

19 (i) *For purposes of this section, the following definitions shall*
20 *apply:*

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

24 (2) *“Unauthorized” means the inappropriate access, review,*
25 *or viewing of patient medical information without a direct need*
26 *for medical treatment or other lawful use.*

27 SEC. 3. Section 1280.3 of the Health and Safety Code is
28 amended to read:

29 1280.3. (a) Commencing on the effective date of the
30 regulations adopted pursuant to this section, the director may assess
31 an administrative penalty in an amount of up to one hundred fifty
32 thousand dollars (\$150,000) per immediate jeopardy violation
33 against a licensee of a health facility licensed under subdivision
34 (a), (b), or (f) of Section 1250.

35 (b) Except as provided in subdivision (c), for a violation of this
36 chapter or the rules and regulations promulgated thereunder that
37 does not constitute a violation of subdivision (a), the department
38 may assess an administrative penalty in an amount of up to
39 twenty-five thousand dollars (\$25,000) per violation. This
40 subdivision shall also apply to violation of regulations set forth in

1 Article 3 (commencing with Section 127400) of Chapter 2 of Part
2 2 of Division 107 or the rules and regulations promulgated
3 thereunder.

4 The department shall promulgate regulations establishing the
5 criteria to assess an administrative penalty against a health facility
6 licensed pursuant to subdivisions (a), (b), or (f) of Section 1250.

7 The criteria shall include, but need not be limited to, the following:

8 (1) The patient’s physical and mental condition.

9 (2) The probability and severity of the risk that the violation
10 presents to the patient.

11 (3) The actual financial harm to patients, if any.

12 (4) The nature, scope, and severity of the violation.

13 (5) The facility’s history of compliance with related state and
14 federal statutes and regulations.

15 (6) Factors beyond the facility’s control that restrict the facility’s
16 ability to comply with this chapter or the rules and regulations
17 promulgated thereunder.

18 (7) The demonstrated willfulness of the violation.

19 (8) The extent to which the facility detected the violation and
20 took steps to immediately correct the violation and prevent the
21 violation from recurring.

22 (c) The department shall not assess an administrative penalty
23 for minor violations.

24 (d) The regulations shall not change the definition of immediate
25 jeopardy as established in this section.

26 (e) The regulations shall apply only to incidents occurring on
27 or after the effective date of the regulations.

28 (f) If the licensee disputes a determination by the department
29 regarding the alleged deficiency or alleged failure to correct a
30 deficiency, or regarding the reasonableness of the proposed
31 deadline for correction or the amount of the penalty, the licensee
32 may, within 10 working days, request a hearing pursuant to Section
33 ~~400171~~ 131071. Penalties shall be paid when all appeals have been
34 exhausted and the department’s position has been upheld.

35 (g) For purposes of this section, “immediate jeopardy” means
36 a situation in which the licensee’s noncompliance with one or more
37 requirements of licensure has caused, or is likely to cause, serious
38 injury or death to the patient.

1 ~~SEC. 4. This act shall become operative only if Assembly Bill~~
2 ~~211 of the 2007-08 Regular Session is enacted and becomes~~
3 ~~effective on or before January 1, 2009.~~

4 ~~SEC. 5.~~

5 *SEC. 4.* If the Commission on State Mandates determines that
6 this act contains costs mandated by the state, reimbursement to
7 local agencies and school districts for those costs shall be made
8 pursuant to Part 7 (commencing with Section 17500) of Division
9 4 of Title 2 of the Government Code.