Introduced by Senator Emmerson

February 22, 2013

An act to amend Sections 1248, 1248.15, 1248.35, 1248.4, and 1248.5 of the Health and Safety Code, relating to outpatient facilities.

LEGISLATIVE COUNSEL'S DIGEST

SB 701, as introduced, Emmerson. Hospital-affiliated outpatient settings.

Existing law requires the Medical Board of California to adopt standards for accreditation of outpatient settings, as defined, and, in approving accreditation agencies to perform this accreditation, to ensure that the certification program shall, at a minimum, include standards for specified aspects of the settings' operations. Existing law makes a willful violation of these and other provisions relating to outpatient settings a crime.

This bill would create entities known as hospital-affiliated outpatient settings, as defined, and would align the accreditation and reporting processes with those of the general acute care hospital with which the hospital-affiliated outpatient settings is affiliated. By expanding the definition of a crime, this bill 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.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

SB 701 -2-

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

SECTION 1. Section 1248 of the Health and Safety Code is amended to read:

- 1248. For purposes of this chapter, the following definitions shall apply:
- (a) "Accreditation agency" means a public or private organization that is approved to issue certificates of accreditation to outpatient settings by the Medical Board of California pursuant to Sections 1248.15 and 1248.4.
- (b) "Deemed accreditation agency" means a national accreditation program meeting the requirements of, and approved for, deeming authority for Medicare requirements by the United States Department of Health and Human Services, the Centers for Medicare and Medicaid Services, or any successor agency.

(a)

- (c) "Division" means the Medical Board of California. All references in this chapter to the division, the Division of Licensing of the Medical Board of California, or the Division of Medical Quality shall be deemed to refer to the Medical Board of California pursuant to Section 2002 of the Business and Professions Code.
- (d) "Hospital-affiliated outpatient setting" means a facility, clinic, unlicensed clinic, center, office, or other setting that is an outpatient setting, does not operate exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following admission, and is accredited by a deemed accreditation agency as part of a general acute care hospitals's accreditation process.

(b)

- (e) (1) "Outpatient setting" means any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility, as defined in Section 1250, and where anesthesia, except local anesthesia or peripheral nerve blocks, or both, is used in compliance with the community standard of practice, in doses that, when administered have the probability of placing a patient at risk for loss of the patient's life-preserving protective reflexes.
- (2) "Outpatient setting" also means facilities that offer in vitro fertilization, as defined in subdivision (b) of Section 1374.55.

-3- SB 701

(3) "Outpatient setting" does not include, among other settings, any setting where anxiolytics and analgesics are administered, when done so in compliance with the community standard of practice, in doses that do not have the probability of placing the patient at risk for loss of the patient's life-preserving protective reflexes.

- (e) "Accreditation agency" means a public or private organization that is approved to issue certificates of accreditation to outpatient settings by the board pursuant to Sections 1248.15 and 1248.4.
- (4) "Outpatient setting" also means a hospital-affiliated setting, except as otherwise indicated.
- SEC. 2. Section 1248.15 of the Health and Safety Code is amended to read:
- 1248.15. (a) The board shall adopt standards for accreditation and, in approving accreditation agencies to perform accreditation of outpatient settings, shall ensure that the certification program shall, at a minimum, include standards for the following aspects of the settings' operations:
- (1) Outpatient setting allied health staff shall be licensed or certified to the extent required by state or federal law.
- (2) (A) Outpatient settings shall have a system for facility safety and emergency training requirements.
- (B) There shall be onsite equipment, medication, and trained personnel to facilitate handling of services sought or provided and to facilitate handling of any medical emergency that may arise in connection with services sought or provided.
- (C) In order for procedures to be performed in an outpatient setting that is not a hospital-affiliated outpatient setting as defined in Section 1248, the outpatient setting shall do one of the following:
- (i) Have a written transfer agreement with a local accredited or licensed acute care hospital, approved by the facility's medical staff.
- (ii) Permit surgery only by a licensee who has admitting privileges at a local accredited or licensed acute care hospital, with the exception that licensees who may be precluded from having admitting privileges by their professional classification or other administrative limitations, shall have a written transfer agreement with licensees who have admitting privileges at local accredited or licensed acute care hospitals.

SB 701 —4—

1

2

3

4

5

6 7

10

11 12

13

14

15

16 17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35 36

37

38

39

40

(iii) Submit for approval by an accrediting agency a detailed procedural plan for handling medical emergencies that shall be reviewed at the time of accreditation. No reasonable plan shall be disapproved by the accrediting agency.

- (D) In addition to the requirements imposed in subparagraph (C), the outpatient setting shall submit for approval by an accreditation agency at the time of accreditation a detailed plan, standardized procedures, and protocols to be followed in the event of serious complications or side effects from surgery that would place a patient at high risk for injury or harm or to govern emergency and urgent care situations. The plan shall include, at a minimum, that if a patient is being transferred to a local accredited or licensed acute care hospital, the outpatient setting shall do all of the following:
- (i) Notify the individual designated by the patient to be notified in case of an emergency.
- (ii) Ensure that the mode of transfer is consistent with the patient's medical condition.
- (iii) Ensure that all relevant clinical information is documented and accompanies the patient at the time of transfer.
- (iv) Continue to provide appropriate care to the patient until the transfer is effectuated.
- (E) (i) All physicians and surgeons transferring patients from an outpatient setting that is not a hospital-affiliated outpatient setting shall agree to cooperate with the medical staff peer review process on the transferred case, the results of which shall be referred back to the outpatient setting, if deemed appropriate by the medical staff peer review committee. If the medical staff of the acute care facility determines that inappropriate care was delivered at the outpatient setting, the acute care facility's peer review outcome shall be reported, as appropriate, to the accrediting body or in accordance with existing law.
- (ii) All physicians and surgeons transferring patients from a hospital-affiliated outpatient setting shall agree to cooperate with the medical staff peer review process on the transferred case, the results of which shall be referred back to the general acute care facility, if deemed appropriate by the medical staff peer review committee. If the medical staff of the acute care facility determines that inappropriate care was delivered at the outpatient setting, the acute care facility's peer review outcome shall be reported,

5 SB 701

as appropriate, to the accrediting body or in accordance with existing law.

- (3) The outpatient setting shall permit surgery by a dentist acting within his or her scope of practice under Chapter 4 (commencing with Section 1600) of Division 2 of the Business and Professions Code or physician and surgeon, osteopathic physician and surgeon, or podiatrist acting within his or her scope of practice under Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code or the Osteopathic Initiative Act. The outpatient setting may, in its discretion, permit anesthesia service by a certified registered nurse anesthetist acting within his or her scope of practice under Article 7 (commencing with Section 2825) of Chapter 6 of Division 2 of the Business and Professions Code.
- (4) Outpatient settings shall have a system for maintaining clinical records.
- (5) Outpatient settings shall have a system for patient care and monitoring procedures.
- (6) (A) Outpatient settings shall have a system for quality assessment and improvement.
- (B) Members of the medical staff and other practitioners who are granted clinical privileges shall be professionally qualified and appropriately credentialed for the performance of privileges granted. The outpatient setting shall grant privileges in accordance with recommendations from qualified health professionals, and credentialing standards established by the outpatient setting.
- (C) Clinical privileges shall be periodically reappraised by the outpatient setting. The scope of procedures performed in the outpatient setting shall be periodically reviewed and amended as appropriate.
- (7) Outpatient settings regulated by this chapter that have multiple service locations shall have all of the sites inspected.
- (8) Outpatient settings shall post the certificate of accreditation in a location readily visible to patients and staff.
- (9) Outpatient settings shall post the name and telephone number of the accrediting agency with instructions on the submission of complaints in a location readily visible to patients and staff.
 - (10) Outpatient settings shall have a written discharge criteria.
- (b) Outpatient settings shall have a minimum of two staff persons on the premises, one of whom shall either be a licensed

SB 701 -6-

physician and surgeon or a licensed health care professional with current certification in advanced cardiac life support (ACLS), as long as a patient is present who has not been discharged from supervised care. Transfer to an unlicensed setting of a patient who does not meet the discharge criteria adopted pursuant to paragraph (10) of subdivision (a) shall constitute unprofessional conduct.

- (c) An accreditation agency may include additional standards in its determination to accredit outpatient settings if these are approved by the board to protect the public health and safety.
- (d) No accreditation standard adopted or approved by the board, and no standard included in any certification program of any accreditation agency approved by the board, shall serve to limit the ability of any allied health care practitioner to provide services within his or her full scope of practice. Notwithstanding this or any other provision of law, each outpatient setting may limit the privileges, or determine the privileges, within the appropriate scope of practice, that will be afforded to physicians and allied health care practitioners who practice at the facility, in accordance with credentialing standards established by the outpatient setting in compliance with this chapter. Privileges may not be arbitrarily restricted based on category of licensure.
- (e) The board shall adopt standards that it deems necessary for outpatient settings that offer in vitro fertilization.
- (f) The board may adopt regulations it deems necessary to specify procedures that should be performed in an accredited outpatient setting for facilities or clinics that are outside the definition of outpatient setting as specified in Section 1248.
- (g) As part of the accreditation process, the accrediting agency shall conduct a reasonable investigation of the prior history of the outpatient setting, including all licensed physicians and surgeons who have an ownership interest therein, to determine whether there have been any adverse accreditation decisions rendered against them. For the purposes of this section, "conducting a reasonable investigation" means querying the Medical Board of California and the Osteopathic Medical Board of California to ascertain if either the outpatient setting has, or, if its owners are licensed physicians and surgeons, if those physicians and surgeons have, been subject to an adverse accreditation decision. *This subdivision shall not apply to hospital-affiliated outpatient settings*.

7 SB 701

(h) (1) An outpatient setting shall be subject to the reporting requirements in Section 1279.1 and the penalties for failure to report specified in Section 1280.4. This paragraph shall not apply to adverse events described in subparagraph (E) of paragraph (1) of subdivision (b) of Section 1279.1 that occur in a hospital-affiliated outpatient setting.

- (2) The general acute care hospital affiliated with the hospital-affiliated outpatient setting shall report any adverse event described in subparagraph (E) of paragraph (1) of subdivision (b) of Section 1279.1 that occurs in a hospital-affiliated outpatient setting, subject to reporting requirements in Section 1279.1 and penalties for failure to report in Section 1280.4.
- SEC. 3. Section 1248.35 of the Health and Safety Code is amended to read:
- 1248.35. (a) Every outpatient setting which is accredited shall be inspected by the accreditation agency and may also be inspected by the Medical Board of California. The Medical Board of California shall ensure that accreditation agencies inspect outpatient settings.
- (b) Unless otherwise specified, the following requirements apply to inspections described in subdivision (a).
- (1) The frequency of inspection shall depend upon the type and complexity of the outpatient setting to be inspected.
- (2) Inspections shall be conducted no less often than once every three years by the accreditation agency and as often as necessary by the Medical Board of California to ensure the quality of care provided.
- (3) The Medical Board of California or the accreditation agency may enter and inspect any outpatient setting that is accredited by an accreditation agency at any reasonable time to ensure compliance with, or investigate an alleged violation of, any standard of the accreditation agency or any provision of this chapter.
- (c) If an accreditation agency determines, as a result of its inspection, that an outpatient setting is not in compliance with the standards under which it was approved, the accreditation agency may do any of the following:
- (1) Require correction of any identified deficiencies within a set timeframe. Failure to comply shall result in the accrediting

SB 701 —8—

agency issuing a reprimand or suspending or revoking the outpatient setting's accreditation.

(2) Issue a reprimand.

- (3) Place the outpatient setting on probation, during which time the setting shall successfully institute and complete a plan of correction, approved by the board or the accreditation agency, to correct the deficiencies.
- (4) Suspend or revoke the outpatient setting's certification of accreditation.
- (d) (1) (A) Except as is otherwise provided in this subdivision, before suspending or revoking a certificate of accreditation under this chapter, the accreditation agency shall provide the outpatient setting that is not a hospital-affiliated outpatient setting with notice of any deficiencies and the outpatient setting shall agree with the accreditation agency on a plan of correction that shall give the outpatient setting reasonable time to supply information demonstrating compliance with the standards of the accreditation agency in compliance with this chapter, as well as the opportunity for a hearing on the matter upon the request of the outpatient setting. During
- (B) Except as otherwise provided in this subdivision, before suspending or revoking a certificate of accreditation under this chapter, the deemed accreditation agency shall provide the hospital that is affiliated with the hospital-affiliated outpatient setting with notice of any deficiencies, which may be combined with notice of other deficiencies for the hospital's general acute care accreditation. The hospital shall agree with the accreditation agency on a plan of correction that shall give the hospital reasonable time to supply information demonstrating compliance with the standards of the accreditation agency, in compliance with this chapter, as well as the opportunity for a hearing on the matter if the hospital requests one.
- (C) During the allotted time to correct the deficiencies, the plan of correction, which includes the deficiencies, shall be conspicuously posted by the outpatient setting in a location accessible to public view. Within
- (D) Within 10 days after the adoption of the plan of correction, the accrediting agency shall send a list of deficiencies and the corrective action to be taken to the board and to the California State Board of Pharmacy if an outpatient setting is licensed

-9- SB 701

pursuant to Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of the Business and Professions Code. The If the outpatient setting is a hospital-affiliated outpatient setting, the list of deficiencies and the corrective action to be taken may be combined with the list of deficiencies and the corrective action to be taken for the hospital's general acute care accreditation that directly affect the hospital-affiliated outpatient setting.

- (E) The accreditation agency may immediately suspend the certificate of accreditation before providing notice and an opportunity to be heard, but only when failure to take the action may result in imminent danger to the health of an individual. In such cases, the accreditation agency shall provide subsequent notice and an opportunity to be heard.
- (2) If an outpatient setting does not comply with a corrective action within a timeframe specified by the accrediting agency, the accrediting agency shall issue a reprimand, and may either place the outpatient setting on probation or suspend or revoke the accreditation of the outpatient setting, and shall notify the board of its action. This section shall not be deemed to prohibit an outpatient setting that is unable to correct the deficiencies, as specified in the plan of correction, for reasons beyond its control, from voluntarily surrendering its accreditation prior to initiation of any suspension or revocation proceeding.
- (e) The accreditation agency shall, within 24 hours, report to the board if the outpatient setting has been issued a reprimand or if the outpatient setting's certification of accreditation has been suspended or revoked or if the outpatient setting has been placed on probation. If an outpatient setting has been issued a license by the California State Board of Pharmacy pursuant to Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of the Business and Professions Code, the accreditation agency shall also send this report to the California State Board of Pharmacy within 24 hours.
- (f) The accreditation agency, upon receipt of a complaint from the board that an outpatient setting poses an immediate risk to public safety, shall inspect the outpatient setting and report its findings of inspection to the board within five business days. If an accreditation agency receives any other complaint from the board, it shall investigate the outpatient setting and report its findings of investigation to the board within 30 days.

SB 701 — 10 —

1

2

3

4

5

6 7

8

10

11 12

13

14 15

16 17

18 19

20

21

22

23

2425

26

27

28

29

30

31

32

33

34

35

36 37

38

- (g) Reports on the results of any inspection shall be kept on file with the board and the accreditation agency along with the plan of correction and the comments of the outpatient setting. The inspection report for an outpatient setting that is not a hospital-affiliated outpatient setting shall include the lists of deficiencies, plans of correction or requirements for improvements and correction, and corrective action completed. The inspection report for a hospital-affiliated outpatient setting shall include a letter from the deemed accreditation agency stating the accreditation status of the hospital-affiliated outpatient setting. The inspection report may include a recommendation for reinspection. All final inspection reports for outpatient settings as defined in subdivision (e) of Section 1248, which include the lists of deficiencies, plans of correction or requirements for improvements and correction, and corrective action completed, shall be public records open to public inspection.
- (h) If one accrediting agency denies accreditation, or revokes or suspends the accreditation of an outpatient setting, this action shall apply to all other accrediting agencies. An outpatient setting that is denied accreditation is permitted to reapply for accreditation with the same accrediting agency. The outpatient setting also may apply for accreditation from another accrediting agency, but only if it discloses the full accreditation report of the accrediting agency that denied accreditation. If a deemed accreditation agency denies accreditation and the outpatient setting seeks to apply for accreditation from another accrediting agency, the outpatient setting shall also disclose the lists of deficiencies, plans of correction or requirements for improvements and correction, and corrective action completed from the deemed accreditation agency that denied accreditation. Any outpatient setting that has been denied accreditation shall disclose the accreditation report to any other accrediting agency to which it submits an application. The new accrediting agency shall ensure that all deficiencies have been corrected and conduct a new onsite inspection consistent with the standards specified in this chapter.
- (i) If an outpatient setting's certification of accreditation has been suspended or revoked, or if the accreditation has been denied, the accreditation agency shall do all of the following:
 - (1) Notify the board of the action.

-11- SB 701

(2) Send a notification letter to the outpatient setting of the action. The notification letter shall state that the setting is no longer allowed to perform procedures that require outpatient setting accreditation.

- (3) Require the outpatient setting to remove its accreditation certification and to post the notification letter in a conspicuous location, accessible to public view.
- (j) The board may take any appropriate action it deems necessary pursuant to Section 1248.7 if an outpatient setting's certification of accreditation has been suspended or revoked, or if accreditation has been denied.
- SEC. 4. Section 1248.4 of the Health and Safety Code is amended to read:
- 1248.4. (a) It is the intent of the Legislature that an accreditation agency operating on or before January 1, 1995, or a successor thereof, or an accreditation agency thereafter operating as part of a joint program granted temporary certification as an accreditation agency by the division, whether operating as part of a joint program or independently, and meeting the standards set forth in this chapter, as determined by the division, not be required to go through the entire application process with the division. Therefore, the division may grant a temporary certificate of approval to such an accreditation agency. The temporary approval issued to an accreditation agency under this subdivision shall expire on January 1, 1998. In order to continue its status as an accreditation agency, an accreditation agency approved by the division under this subdivision shall apply for renewal of approval by the division on or before January 1, 1998, and shall establish that it is in compliance with the standards set forth in this chapter and any regulations adopted pursuant thereto.
- (b) Each accreditation agency approved by the division shall, on and after January 1, 1995, promptly forward to the division a list of each outpatient setting to which it has granted a certificate of accreditation, as well as settings that have lost accreditation or were denied accreditation.
- (c) The division shall approve an accreditation agency that applies for approval on a form prescribed by the division, accompanied by payment of the fee prescribed by this chapter and evidence that the accreditation agency meets the following criteria,

SB 701 — 12 —

except that paragraph (6) shall not apply to an accreditation agency for hospital-affiliated outpatient settings:

- (1) Includes within its accreditation program, at a minimum, the standards for accreditation of outpatient settings approved by the division as well as standards for patient care and safety at the setting.
- (2) Submits its current accreditation standards to the division every three years, or upon request for continuing approval by the division.
- (3) Maintains internal quality management programs to ensure quality of the accreditation process.
- (4) Has a process by which accreditation standards can be reviewed and revised no less than every three years.
- (5) Maintains an available pool of allied health care practitioners to serve on accreditation review teams as appropriate.
- (6) Has accreditation review teams that shall do all of the following:
- (A) Consist of at least one physician and surgeon who practices in an outpatient setting; any other members shall be practicing actively in these settings.
- (B) Participate in formal educational training programs provided by the accreditation agency in evaluation of the certification standards at least every three years.
- (7) In lieu of the requirements of paragraph (6), hospital-affiliated outpatient settings shall be reviewed by physicians and surgeons or clinicians educated through formal training programs provided by a deemed accreditation organization. Members of the team shall participate in the training programs at least every three years.
- 30 (7)

3

4

5

6

7

8

9

10

11

12 13

14

15

16 17

18

19

20

21 22

23

24

25

26 27

28

29

31

32

33

35

- (8) The accreditation agency shall demonstrate that professional members of its review team have experience in conducting review activities of freestanding outpatient settings.
- 34 (8
 - (9) Standards for accreditation shall be developed with the input of the medical community and the ambulatory surgery industry.
- 37 (9)
- 38 (10) Accreditation reviewers shall be credentialed and screened 39 by the accreditation agency.
- 40 (10)

13 SB 701

(11) The accreditation agency shall not have an ownership interest in nor be involved in the operation of a freestanding outpatient setting, nor in the delivery of health care services to patients.

- (d) Notwithstanding subdivision (c) and Section 1248.15, this division shall approve any deemed accreditation agency to perform certification of any hospital-affiliated outpatient setting that applies for approval, accompanied by both of the following:
- (1) A letter by the deemed accreditation agency that it shall comply with this chapter with respect to the certification of a hospital-affiliated outpatient setting.
- (2) Evidence that the certification program includes standards for policies and procedures addressing the indication and management of sedation.

(d)

(e) Accreditation agencies approved by the division shall forward to the division copies of all certificates of accreditation and shall notify the division promptly whenever the agency denies or revokes a certificate of accreditation.

(e)

- (f) A certification of an accreditation agency by the division shall expire at midnight on the last day of a three-year term if not renewed. The division shall establish by regulation the procedure for renewal. To renew an unexpired approval, the accreditation agency shall, on or before the date upon which the certification would otherwise expire, apply for renewal on a form, and pay the renewal fee, as prescribed by the division.
- SEC. 5. Section 1248.5 of the Health and Safety Code is amended to read:
- 1248.5. The board shall evaluate the performance of an approved accreditation agency no less than every three years, or in response to complaints against an agency, or complaints against one or more outpatient settings accreditation by an agency that indicates noncompliance by the agency with the standards approved by the board. This section shall not apply to a deemed accreditation agency that is approved solely pursuant to subdivision (d) of Section 1248.4.
- SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school

SB 701 — 14 —

- 1 district will be incurred because this act creates a new crime or
- 2 infraction, eliminates a crime or infraction, or changes the penalty
- 3 for a crime or infraction, within the meaning of Section 17556 of
- 4 the Government Code, or changes the definition of a crime within
- 5 the meaning of Section 6 of Article XIIIB of the California
- 6 Constitution.