## **Introduced by Senator Hill**

February 25, 2015

An act to amend Sections 805 and 805.5 of, and to add Section 2216.5 to, the Business and Professions Code, *to amend Section 12529.7 of the Government Code*, and to amend Sections 1204, 1248.15, 1248.3, and 1248.35 of the Health and Safety Code, relating to health—and care facilities. *care*.

## LEGISLATIVE COUNSEL'S DIGEST

SB 396, as amended, Hill. Health and care facilities: care: outpatient settings and surgical—clinics: clinics: facilities: licensure and enforcement.

Existing law provides for the licensure and regulation of clinics by the State Department of Public Health. A violation of those provisions is a misdemeanor. Existing law provides that certain types of specialty clinics, including surgical clinics, as defined, are eligible for licensure. Existing law excludes from the definition of surgical clinic any place or establishment owned or leased and operated as a clinic or office by one or more physicians or dentists in individual or group practice. Existing law requires a surgical clinic that is licensed or seeking licensure to comply with federal certification standards for an ambulatory surgical clinic until the department adopts regulations relating to the provision of services by a surgical clinic.

This bill would-elarify provide that a surgical clinic that has met the federal certification standards and requirements for an ambulatory surgical clinic is eligible for licensure by the department regardless of physician, podiatrist, or dentist ownership. The bill would provide that

 $SB 396 \qquad \qquad -2-$ 

a surgical clinic is deemed to have met the licensure requirements under the chapter upon presenting documentation, within a 3-year period, that the surgical clinic has met the federal certification requirements for an ambulatory surgical clinic.

The Medical Practice Act provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. Existing law provides that it is unprofessional conduct for a physician and surgeon to perform procedures in any outpatient setting except in compliance with specified provisions. Existing law prohibits an association, corporation, firm, partnership, or person from operating, managing, conducting, or maintaining an outpatient setting in the state unless the setting is one of the specified settings, which includes, among others, an ambulatory surgical clinic that is certified to participate in the Medicare program, a surgical clinic licensed by the State Department of Public—Health Health, or an outpatient setting accredited by an accreditation agency approved by the Division of Licensing of the Medical Board of California.

Existing law provides that an outpatient setting that is accredited shall be inspected by the accreditation agency and may be inspected by the Medical Board of California. Existing law requires that the inspections be conducted no less often than once every 3 years by the accreditation agency and as often as necessary by the Medical Board of California to ensure quality of care provided. Existing law requires that certificates for accreditation issued to outpatient settings by an accreditation agency shall be valid for not more than 3 years.

This bill would require that all subsequent inspections after the initial inspection for accreditation be unannounced. This bill would require an outpatient setting accredited by the division and a facility certified to participate in the federal Medicare program as an ambulatory surgical center to pay certain fees and to comply with certain data submission requirements. The bill would also instead require that an initial certificate of accreditation by an accreditation agency be valid for not more than 2 years and that a renewal certificate be valid for not more than 3 years.

Existing law requires members of the medical staff and other practitioners who are granted clinical privileges in an outpatient setting to be professionally qualified and appropriately credentialed for the performance of privileges granted and requires the outpatient setting to grant privileges in accordance with recommendations from qualified

\_3\_ SB 396

health professionals, and credentialing standards established by the outpatient setting.

This bill would additionally require that each physician and surgeon licensee who performs procedures in an outpatient setting that requires the outpatient setting to be accredited be peer reviewed, at least every 2 years, by California licensed physicians licensees who are qualified by education and experience to perform the same types of, or similar procedures. The bill would require the findings of the peer review to be reported to the accrediting body who shall determine if the licensee continues to be professionally qualified and appropriately credentialed for the performance of privileges granted. By expanding the scope of a crime, this bill would impose a state-mandated local program.

Existing law requires specified entities, including any health care service plan or medical care foundation, to request a report from the Medical Board of California, the Board of Psychology, the Osteopathic Medical Board of California, or the Dental Board of California, prior to granting or renewing staff privileges, to determine if a certain report has been made indicating that the applying physician and surgeon, psychologist, podiatrist, or dentist has been denied staff privileges, been removed from a medical staff, or had his or her staff privileges restricted.

This bill would also require an outpatient setting and a facility certified to participate in the federal Medicare program as an ambulatory surgical center to request that report. By expanding the scope of a crime, this bill would impose a state-mandated local program.

Existing law establishes a vertical enforcement and prosecution model for cases before the Medical Board of California, and requires the board to report to the Governor and the Legislature on that model by March 1, 2015.

This bill would extend the date that report is due to March 1, 2016.

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 396 —4—

1 2

3

4

5

6

10

11

12

13

14

15

16

17

18

19

20

21 22

23

24

25

26

27

28

29

30

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

SECTION 1. Section 805 of the Business and Professions Code is amended to read:

- 805. (a) As used in this section, the following terms have the following definitions:
  - (1) (A) "Peer review" means both of the following:
- (i) A process in which a peer review body reviews the basic qualifications, staff privileges, employment, medical outcomes, or professional conduct of licentiates to make recommendations for quality improvement and education, if necessary, in order to do either or both of the following:
- (I) Determine whether a licentiate may practice or continue to practice in a health care facility, clinic, or other setting providing medical services, and, if so, to determine the parameters of that practice.
- (II) Assess and improve the quality of care rendered in a health care facility, clinic, or other setting providing medical services.
- (ii) Any other activities of a peer review body as specified in subparagraph (B).
  - (B) "Peer review body" includes:
- (i) A medical or professional staff of any health care facility or facility, of a clinic licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code, of a facility certified to participate in the federal Medicare program as an ambulatory surgical center, or of an outpatient setting accredited pursuant to Section 1248.1 of the Health and Safety Code.
- (ii) A health care service plan licensed under Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or a disability insurer that contracts with licentiates to provide services at alternative rates of payment pursuant to Section 10133 of the Insurance Code.
- 31 (iii) Any medical, psychological, marriage and family therapy, 32 social work, professional clinical counselor, dental, or podiatric 33 professional society having as members at least 25 percent of the 34 eligible licentiates in the area in which it functions (which must 35 include at least one county), which is not organized for profit and 36 which has been determined to be exempt from taxes pursuant to 37 Section 23701 of the Revenue and Taxation Code.

\_5\_ SB 396

(iv) A committee organized by any entity consisting of or employing more than 25 licentiates of the same class that functions for the purpose of reviewing the quality of professional care provided by members or employees of that entity.

- (2) "Licentiate" means a physician and surgeon, doctor of podiatric medicine, clinical psychologist, marriage and family therapist, clinical social worker, professional clinical counselor, dentist, or physician assistant. "Licentiate" also includes a person authorized to practice medicine pursuant to Section 2113 or 2168.
- (3) "Agency" means the relevant state licensing agency having regulatory jurisdiction over the licentiates listed in paragraph (2).
- (4) "Staff privileges" means any arrangement under which a licentiate is allowed to practice in or provide care for patients in a health facility. Those arrangements shall include, but are not limited to, full staff privileges, active staff privileges, limited staff privileges, auxiliary staff privileges, provisional staff privileges, temporary staff privileges, courtesy staff privileges, locum tenens arrangements, and contractual arrangements to provide professional services, including, but not limited to, arrangements to provide outpatient services.
- (5) "Denial or termination of staff privileges, membership, or employment" includes failure or refusal to renew a contract or to renew, extend, or reestablish any staff privileges, if the action is based on medical disciplinary cause or reason.
- (6) "Medical disciplinary cause or reason" means that aspect of a licentiate's competence or professional conduct that is reasonably likely to be detrimental to patient safety or to the delivery of patient care.
- (7) "805 report" means the written report required under subdivision (b).
- (b) The chief of staff of a medical or professional staff or other chief executive officer, medical director, or administrator of any peer review body and the chief executive officer or administrator of any licensed health care facility or clinic shall file an 805 report with the relevant agency within 15 days after the effective date on which any of the following occur as a result of an action of a peer review body:
- (1) A licentiate's application for staff privileges or membership is denied or rejected for a medical disciplinary cause or reason.

 $SB 396 \qquad \qquad -6-$ 

(2) A licentiate's membership, staff privileges, or employment is terminated or revoked for a medical disciplinary cause or reason.

- (3) Restrictions are imposed, or voluntarily accepted, on staff privileges, membership, or employment for a cumulative total of 30 days or more for any 12-month period, for a medical disciplinary cause or reason.
- (c) If a licentiate takes any action listed in paragraph (1), (2), or (3) after receiving notice of a pending investigation initiated for a medical disciplinary cause or reason or after receiving notice that his or her application for membership or staff privileges is denied or will be denied for a medical disciplinary cause or reason, the chief of staff of a medical or professional staff or other chief executive officer, medical director, or administrator of any peer review body and the chief executive officer or administrator of any licensed health care facility or clinic where the licentiate is employed or has staff privileges or membership or where the licentiate applied for staff privileges or membership, or sought the renewal thereof, shall file an 805 report with the relevant agency within 15 days after the licentiate takes the action.
- (1) Resigns or takes a leave of absence from membership, staff privileges, or employment.
- (2) Withdraws or abandons his or her application for staff privileges or membership.
- (3) Withdraws or abandons his or her request for renewal of staff privileges or membership.
- (d) For purposes of filing an 805 report, the signature of at least one of the individuals indicated in subdivision (b) or (c) on the completed form shall constitute compliance with the requirement to file the report.
- (e) An 805 report shall also be filed within 15 days following the imposition of summary suspension of staff privileges, membership, or employment, if the summary suspension remains in effect for a period in excess of 14 days.
- (f) A copy of the 805 report, and a notice advising the licentiate of his or her right to submit additional statements or other information, electronically or otherwise, pursuant to Section 800, shall be sent by the peer review body to the licentiate named in the report. The notice shall also advise the licentiate that information submitted electronically will be publicly disclosed to those who request the information.

\_7\_ SB 396

The information to be reported in an 805 report shall include the name and license number of the licentiate involved, a description of the facts and circumstances of the medical disciplinary cause or reason, and any other relevant information deemed appropriate by the reporter.

A supplemental report shall also be made within 30 days following the date the licentiate is deemed to have satisfied any terms, conditions, or sanctions imposed as disciplinary action by the reporting peer review body. In performing its dissemination functions required by Section 805.5, the agency shall include a copy of a supplemental report, if any, whenever it furnishes a copy of the original 805 report.

If another peer review body is required to file an 805 report, a health care service plan is not required to file a separate report with respect to action attributable to the same medical disciplinary cause or reason. If the Medical Board of California or a licensing agency of another state revokes or suspends, without a stay, the license of a physician and surgeon, a peer review body is not required to file an 805 report when it takes an action as a result of the revocation or suspension.

- (g) The reporting required by this section shall not act as a waiver of confidentiality of medical records and committee reports. The information reported or disclosed shall be kept confidential except as provided in subdivision (c) of Section 800 and Sections 803.1 and 2027, provided that a copy of the report containing the information required by this section may be disclosed as required by Section 805.5 with respect to reports received on or after January 1, 1976.
- (h) The Medical Board of California, the Osteopathic Medical Board of California, and the Dental Board of California shall disclose reports as required by Section 805.5.
- (i) An 805 report shall be maintained electronically by an agency for dissemination purposes for a period of three years after receipt.
- (j) No person shall incur any civil or criminal liability as the result of making any report required by this section.
- (k) A willful failure to file an 805 report by any person who is designated or otherwise required by law to file an 805 report is punishable by a fine not to exceed one hundred thousand dollars (\$100,000) per violation. The fine may be imposed in any civil or administrative action or proceeding brought by or on behalf of any

SB 396 —8—

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

agency having regulatory jurisdiction over the person regarding 1 2 whom the report was or should have been filed. If the person who 3 is designated or otherwise required to file an 805 report is a 4 licensed physician and surgeon, the action or proceeding shall be 5 brought by the Medical Board of California. The fine shall be paid 6 to that agency but not expended until appropriated by the 7 Legislature. A violation of this subdivision may constitute 8 unprofessional conduct by the licentiate. A person who is alleged to have violated this subdivision may assert any defense available at law. As used in this subdivision, "willful" means a voluntary 10 11 and intentional violation of a known legal duty.

(1) Except as otherwise provided in subdivision (k), any failure by the administrator of any peer review body, the chief executive officer or administrator of any health care facility, or any person who is designated or otherwise required by law to file an 805 report, shall be punishable by a fine that under no circumstances shall exceed fifty thousand dollars (\$50,000) per violation. The fine may be imposed in any civil or administrative action or proceeding brought by or on behalf of any agency having regulatory jurisdiction over the person regarding whom the report was or should have been filed. If the person who is designated or otherwise required to file an 805 report is a licensed physician and surgeon, the action or proceeding shall be brought by the Medical Board of California. The fine shall be paid to that agency but not expended until appropriated by the Legislature. The amount of the fine imposed, not exceeding fifty thousand dollars (\$50,000) per violation, shall be proportional to the severity of the failure to report and shall differ based upon written findings, including whether the failure to file caused harm to a patient or created a risk to patient safety; whether the administrator of any peer review body, the chief executive officer or administrator of any health care facility, or any person who is designated or otherwise required by law to file an 805 report exercised due diligence despite the failure to file or whether they knew or should have known that an 805 report would not be filed; and whether there has been a prior failure to file an 805 report. The amount of the fine imposed may also differ based on whether a health care facility is a small or rural hospital as defined in Section 124840 of the Health and Safety Code.

-9- SB 396

(m) A health care service plan licensed under Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or a disability insurer that negotiates and enters into a contract with licentiates to provide services at alternative rates of payment pursuant to Section 10133 of the Insurance Code, when determining participation with the plan or insurer, shall evaluate, on a case-by-case basis, licentiates who are the subject of an 805 report, and not automatically exclude or deselect these licentiates.

SEC. 2. Section 805.5 of the Business and Professions Code is amended to read:

805.5. (a) Prior to granting or renewing staff privileges for any physician and surgeon, psychologist, podiatrist, or dentist, any health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code, any health care service plan or medical care foundation, the medical staff of the institution, a facility certified to participate in the federal Medicare program as an ambulatory surgical center, or an outpatient setting accredited pursuant to Section 1248.1 of the Health and Safety Code shall request a report from the Medical Board of California, the Board of Psychology, the Osteopathic Medical Board of California, or the Dental Board of California to determine if any report has been made pursuant to Section 805 indicating that the applying physician and surgeon, psychologist, podiatrist, or dentist has been denied staff privileges, been removed from a medical staff, or had his or her staff privileges restricted as provided in Section 805. The request shall include the name and California license number of the physician and surgeon, psychologist, podiatrist, or dentist. Furnishing of a copy of the 805 report shall not cause the 805 report to be a public record.

(b) Upon a request made by, or on behalf of, an institution described in subdivision (a) or its medical staff the board shall furnish a copy of any report made pursuant to Section 805 as well as any additional exculpatory or explanatory information submitted electronically to the board by the licensee pursuant to subdivision (f) of that section. However, the board shall not send a copy of a report (1) if the denial, removal, or restriction was imposed solely because of the failure to complete medical records, (2) if the board has found the information reported is without merit, (3) if a court finds, in a final judgment, that the peer review, as defined in Section 805, resulting in the report was conducted in bad faith and

SB 396 —10—

the licensee who is the subject of the report notifies the board of 2 that finding, or (4) if a period of three years has elapsed since the 3 report was submitted. This three-year period shall be tolled during 4 any period the licentiate has obtained a judicial order precluding 5 disclosure of the report, unless the board is finally and permanently 6 precluded by judicial order from disclosing the report. If a request is received by the board while the board is subject to a judicial 8 order limiting or precluding disclosure, the board shall provide a disclosure to any qualified requesting party as soon as practicable 10 after the judicial order is no longer in force.

If the board fails to advise the institution within 30 working days following its request for a report required by this section, the institution may grant or renew staff privileges for the physician and surgeon, psychologist, podiatrist, or dentist.

- (c) Any institution described in subdivision (a) or its medical staff that violates subdivision (a) is guilty of a misdemeanor and shall be punished by a fine of not less than two hundred dollars (\$200) nor more than one thousand two hundred dollars (\$1,200).
- SEC. 3. Section 2216.5 is added to the Business and Professions Code, to read:
- 2216.5. An outpatient setting accredited pursuant to Section 1248.1 of the Health and Safety Code is and a facility certified to participate in the federal Medicare program as an ambulatory surgical center are subject to the requirements of Section—1216, 1216 of, subdivision (f) of Section—127280, 127280 of, Section 127285 of, and Section 128737-of of, the Health and Safety Code. Any fees collected pursuant to subdivision (f) of Section 127280 of the Health and Safety Code shall not exceed the reasonable costs incurred by the Office of Statewide Health Planning and Development in regulating the outpatient setting and the facility.
- 31 SEC. 4. Section 12529.7 of the Government Code is amended 32 to read:
- 33 12529.7. By March 1, 2015, 2016, the Medical Board of California, in consultation with the Department of Justice and the
- 35 Department of Consumer Affairs, shall report and make
- 36 recommendations to the Governor and the Legislature on the
- 37 vertical enforcement and prosecution model created under Section
- 38 12529.6.

11 12

13

14

15

16 17

18

19

20

21

22

23

2425

26

2728

29

-11- SB 396

SEC. 4.

1 2

*SEC. 5.* Section 1204 of the Health and Safety Code is amended to read:

- 1204. Clinics eligible for licensure pursuant to this chapter are primary care clinics and specialty clinics.
- (a) (1) Only the following defined classes of primary care clinics shall be eligible for licensure:
- (A) A "community clinic" means a clinic operated by a tax-exempt nonprofit corporation that is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a community clinic, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. No corporation other than a nonprofit corporation, exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a community clinic; provided, that the licensee of any community clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a community clinic.
- (B) A "free clinic" means a clinic operated by a tax-exempt, nonprofit corporation supported in whole or in part by voluntary donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a free clinic there shall be no charges directly to the patient for services rendered or for drugs, medicines, appliances, or apparatuses furnished. No corporation other than a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a free clinic; provided, that the licensee of any free clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a free clinic.
- (2) Nothing in this subdivision shall prohibit a community clinic or a free clinic from providing services to patients whose services are reimbursed by third-party payers, or from entering

SB 396 -12 -

into managed care contracts for services provided to private or public health plan subscribers, as long as the clinic meets the requirements identified in subparagraphs (A) and (B). For purposes of this subdivision, any payments made to a community clinic by a third-party payer, including, but not limited to, a health care service plan, shall not constitute a charge to the patient. This paragraph is a clarification of existing law.

- (b) The following types of specialty clinics shall be eligible for licensure as specialty clinics pursuant to this chapter:
- (1) (A) A "surgical clinic" means a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. A surgical clinic does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians, *podiatrists*, or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment.
- (B) A physician, podiatrist, or dentist may, at his or her option, apply for licensure. A surgical clinic shall be eligible for licensure by the department regardless of physician, podiatrist, or dentist ownership. A surgical clinic that has met the federal certification standards and requirements for an ambulatory surgical clinic, as specified in Part 416 of Title 42 of the Code of Federal Regulations, shall be eligible for licensure by the department pursuant to this chapter.
- (C) Until the department adopts regulations relating to the provision of services by a surgical clinic pursuant to Section 1225, a surgical clinic is deemed to have met the licensure requirements under this chapter upon presenting documentation, within a three-year period, that the surgical clinic has met the federal certification standards for an ambulatory surgical clinic.
- (2) A "chronic dialysis clinic" means a clinic that provides less than 24-hour care for the treatment of patients with end-stage renal disease, including renal dialysis services.
- (3) A "rehabilitation clinic" means a clinic that, in addition to providing medical services directly, also provides physical rehabilitation services for patients who remain less than 24 hours. Rehabilitation clinics shall provide at least two of the following rehabilitation services: physical therapy, occupational therapy, social, speech pathology, and audiology services. A rehabilitation

\_13\_ SB 396

1 clinic does not include the offices of a private physician in 2 individual or group practice.

(4) An "alternative birth center" means a clinic that is not part of a hospital and that provides comprehensive perinatal services and delivery care to pregnant women who remain less than 24 hours at the facility.

SEC. 5.

- SEC. 6. 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 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.
- (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.

**— 14 — SB 396** 

1

2

3

4

5

6

8

9

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

(D) 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) All physicians and surgeons transferring patients from an 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.
- (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 40 clinical records.

-15- SB 396

(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) (i) 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.
- (ii) Each—physician and surgeon licensee who performs procedures in an outpatient setting that requires the outpatient setting to be accredited shall be, at least every two years, peer reviewed, as described in subparagraph (A) of paragraph (1) of subdivision (a) of Section 805 of the Business and Professions Code, including when the outpatient setting has only-one physician and surgeon. one licensee. The peer review shall be performed by California licensed physicians licensees who are qualified by education and experience to perform the same types of, or similar procedures. The findings of the peer review shall be reported to the accrediting body who shall determine if the licensee continues to meet the requirements described in clause (i).
- (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 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

SB 396 -16-

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.

SEC. 6.

- SEC. 7. Section 1248.3 of the Health and Safety Code is amended to read:
- 1248.3. (a) An initial certificate of accreditation issued to an outpatient setting by an accreditation agency shall be valid for not

\_17\_ SB 396

more than two years, and a renewal certificate shall be valid for not more than three years.

- (b) The outpatient setting shall notify the accreditation agency within 30 days of any significant change in ownership, including, but not limited to, a merger, change in majority interest, consolidation, name change, change in scope of services, additional services, or change in locations.
- (c) Except for disclosures to the division or to the Division of Medical Quality under this chapter, an accreditation agency shall not disclose information obtained in the performance of accreditation activities under this chapter that individually identifies patients, individual medical practitioners, or outpatient settings. Neither the proceedings nor the records of an accreditation agency or the proceedings and records of an outpatient setting related to performance of quality assurance or accreditation activities under this chapter shall be subject to discovery, nor shall the records or proceedings be admissible in a court of law. The prohibition relating to discovery and admissibility of records and proceedings does not apply to any outpatient setting requesting accreditation in the event that denial or revocation of that outpatient setting's accreditation is being contested. Nothing in this section shall prohibit the accreditation agency from making discretionary disclosures of information to an outpatient setting pertaining to the accreditation of that outpatient setting.

SEC. 7.

2

3

4

5

6

7

8

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

- SEC. 8. Section 1248.35 of the Health and Safety Code is amended to read:
- 1248.35. (a) Every outpatient setting that 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

SB 396 — 18—

2

3

4

5

7

8

9

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

provided. After the initial inspection for accreditation, all subsequent inspections shall be unannounced.

- (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 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) 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 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 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 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 pursuant to Article 14 (commencing with Section 4190)

-19- SB 396

of Chapter 9 of Division 2 of the Business and Professions Code. 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.
- (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 may include a recommendation for reinspection. All final inspection reports, which include the lists of deficiencies, plans of correction or requirements for improvements and

SB 396 — 20 —

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. 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.
- (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. 8.

SEC. 9. 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 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

**— 21 — SB 396** 

- the meaning of Section 6 of Article XIII B of the California Constitution.