AMENDED IN ASSEMBLY JULY 12, 2011

AMENDED IN ASSEMBLY JUNE 23, 2011

AMENDED IN SENATE MAY 3, 2011

AMENDED IN SENATE APRIL 25, 2011

SENATE BILL No. 100

Introduced by Senator Price

January 11, 2011

An act to amend Section 2023.5 of the Business and Professions Code, and to amend Sections 1248, 1248.15, 1248.2, 1248.25, 1248.35, 1248.5, 1248.7, and 1248.85 of the Health and Safety Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 100, as amended, Price. Healing arts.

(1) Existing law provides for the licensure and regulation of various healing arts practitioners by boards under the Department of Consumer Affairs. Existing law requires the Medical Board of California, in conjunction with the Board of Registered Nursing, and in consultation with the Physician Assistant Committee and professionals in the field, to review issues and problems relating to the use of laser or intense light pulse devices for elective cosmetic procedures by their respective licensees.

This bill would require the board to adopt regulations by January 1, 2013, regarding the appropriate level of physician availability needed within clinics or other settings using certain laser or intense pulse light devices for elective cosmetic procedures.

(2) Existing law requires the Medical Board of California, as successor to the Division of Licensing of 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 include, among those specified aspects, the submission 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. This bill would, as part of the accreditation process, authorize the accrediting agency to conduct a reasonable investigation, as defined, of the prior history of the outpatient setting. The bill would also modify the definition of "outpatient setting" to include facilities that offer in vitro fertilization, as defined. By changing the definition of a crime, this bill would impose a state-mandated local program.

Existing law also requires the Medical Board of California to obtain and maintain a list of all accredited, certified, and licensed outpatient settings, and to notify the public, upon inquiry, whether a setting is accredited, certified, or licensed, or whether the setting's accreditation, certification, or license has been revoked.

This bill would, instead, require the board to obtain and maintain the list for all accredited outpatient settings, and to notify the public, by placing the information on its Internet Web site, whether the setting is accredited or the setting's accreditation has been revoked, suspended, or placed on probation, or the setting has received a reprimand by the accreditation agency.

Existing law requires accreditation of an outpatient setting to be denied if the setting does not meet specified standards. Existing law authorizes an outpatient setting to reapply for accreditation at any time after receiving notification of the denial.

This bill would require the accreditation agency to report within 3 business days to the Medical Board of California if the outpatient setting's certificate for accreditation has been denied. Because a willful violation of this requirement would be a crime, the bill would impose a state-mandated local program. The bill would also apply the denial of accreditation, or the revocation or suspension of accreditation by one accrediting agency, to all other accrediting agencies.

Existing law authorizes the Medical Board of California, as successor to the Division of Medical Quality of the Medical Board of California,

or an accreditation agency to, upon reasonable prior notice and presentation of proper identification, enter and inspect any accredited outpatient setting to ensure compliance with, or investigate an alleged violation of, any standard of the accreditation agency or any provision of the specified law.

This bill would delete the notice and identification requirements. The bill would require that every outpatient setting that is accredited be inspected by the accreditation agency, as specified, and would specify that it may also be inspected by the board and the department, as specified. The bill would require the board to ensure that accreditation agencies inspect outpatient settings.

Existing law authorizes the Medical Board of California to evaluate the performance of an approved accreditation agency no less than every 3 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 bill would make that evaluation mandatory.

Existing law authorizes the board or the local district attorney to bring an action to enjoin a violation or threatened violation of the licensing provisions for outpatient settings in the superior court in and for the county in which the violation occurred or is about to occur.

This bill would require the board to investigate all complaints concerning a violation of these provisions and, with respect to any complaints relating to a violation of a specified provision, or upon discovery that an outpatient setting is not in compliance with that specified provision, would require the board ~~or~~ *to investigate and, where appropriate, the board, through or in conjunction with* the local district attorney, to bring an action to enjoin the outpatient setting's operation, as specified.

(3) 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.

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

SECTION 1. Section 2023.5 of the Business and Professions Code is amended to read:

2023.5. (a) The board, in conjunction with the Board of Registered Nursing, and in consultation with the Physician Assistant Committee and professionals in the field, shall review issues and problems surrounding the use of laser or intense light pulse devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants. The review shall include, but need not be limited to, all of the following:

(1) The appropriate level of physician supervision needed.

(2) The appropriate level of training to ensure competency.

(3) Guidelines for standardized procedures and protocols that address, at a minimum, all of the following:

(A) Patient selection.

(B) Patient education, instruction, and informed consent.

(C) Use of topical agents.

(D) Procedures to be followed in the event of complications or side effects from the treatment.

(E) Procedures governing emergency and urgent care situations.

(b) On or before January 1, 2009, the board and the Board of Registered Nursing shall promulgate regulations to implement changes determined to be necessary with regard to the use of laser or intense pulse light devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants.

(c) On or before January 1, 2013, the board shall adopt regulations regarding the appropriate level of physician availability needed within clinics or other settings using laser or intense pulse light devices for elective cosmetic procedures. However, these regulations shall not apply to laser or intense pulse light devices approved by the federal Food and Drug Administration for over-the-counter use by a health care practitioner or by an unlicensed person on himself or herself.

(d) Nothing in this section shall be construed to modify the prohibition against the unlicensed practice of medicine.

SEC. 2. Section 1248 of the Health and Safety Code is amended to read:

1248. For purposes of this chapter, the following definitions shall apply:

(a) "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.

(b) (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) "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.

(c) "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.

SEC. 3. 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.

(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) 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 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 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.

(h) 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.

SEC. 4. Section 1248.2 of the Health and Safety Code is amended to read:

1248.2. (a) Any outpatient setting may apply to an accreditation agency for a certificate of accreditation. Accreditation shall be issued by the accreditation agency solely on the basis of compliance with its standards as approved by the board under this chapter.

(b) The board shall obtain and maintain a list of accredited outpatient settings from the information provided by the accreditation agencies approved by the board, and shall notify the public, by placing the information on its Internet Web site, whether an outpatient setting is accredited or the setting's accreditation has been revoked, suspended, or placed on probation, or the setting has received a reprimand by the accreditation agency.

(c) The list of outpatient settings shall include all of the following:

(1) Name, address, and telephone number of any owners, and their medical license numbers.

(2) Name and address of the facility.

(3) The name and telephone number of the accreditation agency.

(4) The effective and expiration dates of the accreditation.

(d) Accrediting agencies approved by the board shall notify the board and update the board on all outpatient settings that are accredited.

SEC. 5. Section 1248.25 of the Health and Safety Code is amended to read:

1248.25. If an outpatient setting does not meet the standards approved by the board, accreditation shall be denied by the accreditation agency, which shall provide the outpatient setting notification of the reasons for the denial. An outpatient setting may reapply for accreditation at any time after receiving notification of the denial. The accreditation agency shall report within three business days to the board if the outpatient setting's certificate for accreditation has been denied.

SEC. 6. 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 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. 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.

(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 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. 7. 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.

SEC. 8. Section 1248.7 of the Health and Safety Code is amended to read:

1248.7. (a) The board shall investigate all complaints concerning a violation of this chapter. With respect to any complaints relating to a violation of Section 1248.1, or upon discovery that an outpatient setting is not in compliance with Section 1248.1, the board ~~or~~ *shall investigate and, where appropriate, the board, through or in conjunction with* the local district attorney, shall bring an action to enjoin the outpatient setting's operation. The board or the local district attorney may bring an action to enjoin a violation or threatened violation of any other provision of this chapter in the superior court in and for the county in which the violation occurred or is about to occur. Any proceeding under this section shall conform to the requirements of Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure, except that the Division of Medical Quality shall not be required to allege facts necessary to show or tending to show lack of adequate remedy at law or irreparable damage or loss.

(b) With respect to any and all actions brought pursuant to this section alleging an actual or threatened violation of any requirement of this chapter, the court shall, if it finds the allegations to be true, issue an order enjoining the person or facility from continuing the violation. For purposes of Section 1248.1, if an outpatient setting is operating without a certificate of accreditation, this shall be prima facie evidence that a violation of Section 1248.1 has occurred and additional proof shall not be necessary to enjoin the outpatient setting's operation.

SEC. 9. Section 1248.85 of the Health and Safety Code is amended to read:

1248.85. This chapter shall not preclude an approved accreditation agency from adopting additional standards consistent with Section 1248.15, establishing procedures for the conduct of onsite inspections, selecting onsite inspectors to perform accreditation onsite inspections, or establishing and collecting reasonable fees for the conduct of accreditation onsite inspections.

SEC. 10. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because

the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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