

CALIFORNIA CODES
HEALTH AND **SAFETY CODE**
SECTION **1248-1248.85**

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

(a) "Division" means the Division of Licensing of the Medical Board of California.

(b) "Division of Medical Quality" means the Division of Medical Quality of the Medical Board of California.

(c) "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.

"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.

(d) "Accreditation agency" means a public or private organization that is approved to issue certificates of accreditation to outpatient settings by the division pursuant to Sections **1248.15** and **1248.4**.

1248.1. No association, corporation, firm, partnership, or person shall operate, manage, conduct, or maintain an outpatient setting in this state, unless the setting is one of the following:

(a) An ambulatory surgical center that is certified to participate in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act.

(b) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1601 of Title 25 of the United States **Code**, and located on land recognized as tribal land by the federal government.

(c) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies.

(d) Any primary care clinic licensed under subdivision (a) and any surgical clinic licensed under subdivision (b) of Section 1204.

(e) Any health facility licensed as a general acute care hospital under Chapter 2 (commencing with Section 1250).

(f) Any outpatient setting to the extent that it is used by a dentist or physician and surgeon in compliance with Article 2.7 (commencing with Section 1646) or Article 2.8 (commencing with Section 1647) of Chapter 4 of Division 2 of the Business and Professions **Code**.

(g) An outpatient setting accredited by an accreditation agency approved by the division pursuant to this chapter.

(h) A setting, including, but not limited to, a mobile van, in which equipment is used to treat patients admitted to a facility described in subdivision (a), (d), or (e), and in which the procedures performed are staffed by the medical staff of, or other healthcare practitioners with clinical privileges at, the facility and are subject to the peer review process of the facility but which setting is not a part of a facility described in subdivision (a), (d), or (e).

Nothing in this section shall relieve an association, corporation, firm, partnership, or person from complying with all other provisions of law that are otherwise applicable.

1248.15. (a) The division 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) 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, the Health Care Financing Administration, the State Department of Health Services, and the appropriate licensing authority.

(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 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 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 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 governed by the same standards may elect to have all service sites surveyed on any accreditation survey. Organizations that do not elect to have all sites surveyed shall have a sample, not to exceed 20 percent of all service sites, surveyed. The actual sample size shall be determined by the division. The accreditation agency shall determine the location of the sites to be surveyed. Outpatient settings that have five or fewer sites shall have at least one site surveyed. When an organization that elects to have a sample of sites surveyed is approved for accreditation, all of the organizations' sites shall be automatically accredited.

(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 division to protect the public health and **safety**.

(d) No accreditation standard adopted or approved by the division, and no standard included in any certification program of any accreditation agency approved by the division, 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.

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 division under this chapter.

(b) The division shall obtain and maintain a list of all accredited, certified, and licensed outpatient settings from the information provided by the accreditation, certification, and licensing agencies approved by the division, and shall 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.

1248.25. If an outpatient setting does not meet the standards approved by the division, 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.

1248.3. (a) Certificates of accreditation issued to outpatient settings by an accreditation agency 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.

1248.35. (a) The Division of Medical Quality or an accreditation agency may, upon reasonable prior notice and presentation of proper identification, 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.

(b) 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) Issue a reprimand.
(2) Place the outpatient setting on probation, during which time the setting shall successfully institute and complete a plan of correction, approved by the division or the accreditation agency, to correct the deficiencies.

(3) Suspend or revoke the outpatient setting's certification of accreditation.

(c) 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 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 center. 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.

(d) If the division determines that deficiencies found during an inspection suggests that the accreditation agency does not comply with the standards approved by the division, the division may conduct inspections, as described in this section, of other settings accredited by the accreditation agency to determine if the agency is accrediting settings in accordance with Section **1248.15**.

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:

(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) The accreditation agency shall demonstrate that professional members of its review team have experience in conducting review activities of freestanding outpatient settings.

(8) Standards for accreditation shall be developed with the input of the medical community and the ambulatory surgery industry.

(9) Accreditation reviewers shall be credentialed and screened by the accreditation agency.

(10) 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) 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) 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.

1248.5. The division may 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 division.

1248.55. (a) If the accreditation agency is not meeting the criteria set by the division, the division may terminate approval of the agency.

(b) Before terminating approval of an accreditation agency, the division shall provide the accreditation agency with notice of any deficiencies and reasonable time to supply information demonstrating compliance with the requirements of this chapter, as well as the opportunity for a hearing on the matter in compliance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(c) (1) If approval of the accreditation agency is terminated by the division, outpatient settings accredited by that agency shall be notified by the division and, except as provided in paragraph (2), shall be authorized to continue to operate for a period of 12 months in order to seek accreditation through an approved accreditation agency, unless the time is extended by the division for good cause.

(2) The division may require that an outpatient setting, that has been accredited by an accreditation agency whose approval has been terminated by the division, cease operations immediately in the event that the division is in possession of information indicating that continued operation poses an imminent risk of harm to the health of an individual. In such cases, the division shall provide the outpatient setting with notice of its action, the reason underlying it, and a subsequent opportunity for a hearing on the matter. An outpatient setting that is ordered to cease operations under this paragraph may reapply for a certificate of accreditation after six months and shall notify the division promptly of its reapplication.

1248.6. (a) The Division of Licensing shall establish by regulation a reasonable fee for an application for approval as an accreditation agency in an amount that is reasonably necessary to recover the cost of implementing and administering this chapter, and not to exceed five thousand dollars (\$5,000). The division shall establish by regulation a reasonable fee for a temporary certificate of approval, as outlined in subdivision (a) of Section **1248.4**, not to exceed two thousand dollars (\$2,000). The division shall also establish a reasonable fee for renewal. The renewal fee shall be proportionate to the number of outpatient settings accredited by the approved accrediting body seeking renewal, and shall not exceed one hundred dollars (\$100) per outpatient setting accreditation reviewed.

(b) All fees paid to and received by the division or the Medical

Board of California under this chapter shall be paid into the State Treasury and shall be credited to a special fund that is hereby created as the Outpatient Setting Fund of the Medical Board of California. Funds in the Outpatient Setting Fund of the Medical Board of California shall be expended by the board for the purpose of implementing and administering this chapter upon appropriation by the Legislature. No surplus in the fund shall be deposited in or transferred to the General Fund or any other fund.

1248.65. It shall constitute unprofessional conduct for a physician and surgeon to willfully and knowingly violate this chapter.

1248.7. The Division of Medical Quality or the local district attorney may bring an action to enjoin a violation or threatened violation 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.

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.

1248.75. (a) Except as may otherwise be provided in this section, before the Division of Medical Quality may seek an injunction as provided under Section **1248.7**, the Division of Medical Quality shall notify the outpatient setting of all deficiencies in its compliance with this chapter, and any rules and regulations adopted pursuant to this chapter, and the Division of Medical Quality and the outpatient setting shall reach an agreement upon a plan of correction that shall give the outpatient setting reasonable time to correct the deficiencies. The Division of Medical Quality shall also inform the outpatient setting that failure to reach an agreement or to correct deficiencies may lead to corrective action by the Division of Medical Quality, which may include imposition of fines under Section **1248.8**.

If at the end of the allotted time the division and the outpatient setting have failed to reach an agreement or the outpatient setting has failed to correct the deficiencies, as revealed by inspection, the Division of Medical Quality may take corrective action to include, as appropriate, seeking an injunction under Section **1248.7**, revoking or requesting that the accreditation agency revoke accreditation, or communicating with any agency that has oversight authority over the outpatient setting, such as the Department of Health Services or other appropriate licensing authority, to request that the agency take corrective action against the outpatient setting.

(b) For purposes of this section, and at the sole discretion of

the Division of Medical Quality, any notifications, inspections, and corrective action plans of the Division of Medical Quality relating to outpatient settings that have been accredited by an accreditation agency may be performed or coordinated by the accreditation agency rather than by the Division of Medical Quality.

(c) If the Division of Medical Quality determines that an outpatient setting poses an immediate and substantial hazard to the health or **safety** of the patient, that may not reasonably be corrected through a plan of correction, the Division of Medical Quality may immediately institute injunction proceedings pursuant to Section **1248.7**.

1248.8. (a) Any person or entity that willfully violates this chapter or any rule or regulation adopted under this chapter shall be guilty of a misdemeanor and subject to a fine not to exceed one thousand dollars (\$1,000) per day of violation.

(b) In determining the punishment to be imposed under this section, the court shall consider all relevant facts, including, but not limited to, the following:

(1) Whether the violation exposed a patient or other individual to the risk of death or serious physical harm.

(2) Whether the violation had a direct or immediate relationship to health, **safety**, or security of a patient or other individual.

(3) Evidence, if any, of willfulness in the violation.

(4) The presence or absence of good faith efforts by the outpatient setting to prevent the violation.

(c) For purposes of this section, "willfully" or "willful" means that the person doing an act or omitting to do an act intends the act or omission, and knows the relevant circumstances connected with the act or omission.

(d) The district attorney of every county shall, upon application by the Division of Medical Quality or its authorized representative, institute and conduct the prosecution of any action or violation within the county of any provisions of this chapter.

1248.85. Nothing in this chapter shall preclude an approved accreditation agency from adopting additional standards consistent with Section **1248.15**, establishing procedures for the conduct of surveys, selecting surveyors to perform accreditation surveys, or establishing and collecting reasonable fees for the conduct of accreditation surveys.