

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: April 15, 2015  
ATTENTION: Members, Medical Board of California  
SUBJECT: Outpatient Surgery Setting Accreditation Agency Standards  
Regulation Amendment  
STAFF CONTACT: Curtis J. Worden, Chief of Licensing

REQUESTED ACTION:

After review and consideration of the attached amended accreditation agency standards regulatory language, make a motion to direct staff to notice the proposed regulatory language and hold a hearing to add Title 16, Division 13, Chapter 1, Article 3.5, California Code of Regulations (CCR), section 1313.4.

BACKGROUND AND ANALYSIS:

Upon staffs' review of recent amendments to Health and Safety Code (HSC) sections 1248.15 and 1248.35 staff identified the need to amend the language in CCR section 1313.4 to make it consistent with HSC sections 12448.15 and 1248.35.

HSC section 1248.15 states the Board shall adopt standards for accreditation and that outpatient settings regulated by this chapter with multiple locations shall have all of the sites inspected. CCR section 1313.4 currently says the actual sample size shall be determined by the accreditation agency. This is in conflict with HSC section 1248.15(a)(7) and must be deleted.

HSC section 1248.35 states an accreditation agency shall, within 24 hours, report to the Board when it has issued a reprimand, suspended, placed on probation, or revoked any outpatient setting. Currently CCR section 1314.4 only specifies that denials and revocations must be reported to the Board. Therefore, reports of reprimands, placement on probation and suspensions must be added.

STAFF RECOMMENDATION:

Staff recommends the Board authorize staff to proceed with preparing the necessary regulatory documents to amend CCR section 1313.4 and hold a regulatory hearing. The proposed amended language for CCR section 1313.4 is attached (Attachment A). The suggested language is identified with underlined text for new language and ~~striketrough text~~ for deleted language. HSC sections 1248.15 and 1248.35 is also attached (Attachment B) for reference.

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Attachment A

**PROPOSED REGULATION LANGUAGE:**

California Code of Regulations  
 Title 16, Division 13, Chapter 1, Article 3.5

**§ 1313.4. Standards.**

(a) An accreditation agency shall meet the standards set forth in sections 1248.15, 1248.35 and 1248.4 of the Health and Safety Code.

(1) With respect to section 1248.15(a)(2)(C)(i), a written transfer agreement shall include a mechanism for patient transport; a plan for transfer of the patient's records; policies defining the role of each person in handling an emergency; and a plan for continuity of the patient's care upon transfer of that care.

(2) With respect to section 1248.15(a)(6), the required system for quality assessment and improvement shall include, in addition to chart review, actions that utilize information derived through quality assessment to improve systems to maximize patient protection.

~~(3) With respect to section 1248.15(a)(7), the actual sample size shall be determined by the accreditation agency.~~

(b) An accreditation agency shall send to the division any change in its accreditation standards within 30 calendar days after making the change.

(c) An accreditation agency shall, within fourteen calendar days after issuance, provide to the ~~division~~ board a copy of any certificates of accreditation it issues, and, within 24 hours, a copy of any reprimand, placement on probation, suspension, denial or revocation of a certificate of accreditation. For each setting whose accreditation it reprimands, places on probation, suspends, denies or revokes, the accreditation agency shall also provide to the ~~division~~ board in writing the reasons for its action.

Note: Authority cited: Sections 2018 and 2217, Business and Professions Code; and Section 1248.15, Health and Safety Code. Reference: Sections 1248.15, 1248.35 and 1248.4, Health and Safety Code.

**HISTORY**

1. New section filed 1-18-96; operative 2-17-96 (Register 96, No. 3).

2. New subsection (a)(1), subsection renumbering, amendment of subsection (c) and amendment of Note filed 12-5-2000; operative 1-4-2001 (Register 2000, No. 49).

This database is current through 3/27/15 Register 2015, No. 13

16 CCR § 1313.4, 16 CA ADC § 1313.4

***HEALTH AND SAFETY CODE - HSC***

***DIVISION 2. LICENSING PROVISIONS [1200 - 1796.63]***

*( Division 2 enacted by Stats. 1939, Ch. 60. )*

**CHAPTER 1.3. Outpatient Settings [1248 - 1248.85]**

*( Chapter 1.3 added by Stats. 1994, Ch. 1276, Sec. 2. )*

**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.

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(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.

*(Amended by Stats. 2013, Ch. 515, Sec. 36. Effective January 1, 2014.)*

**HEALTH AND SAFETY CODE - HSC**

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*( Division 2 enacted by Stats. 1939, Ch. 60. )*

**CHAPTER 1.3. Outpatient Settings [1248 - 1248.85]**

*( Chapter 1.3 added by Stats. 1994, Ch. 1276, Sec. 2. )*

**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 and to the California State Board of Pharmacy if an outpatient setting is licensed pursuant to Article 14 (commencing with Section 4190) 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 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.

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(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.

*(Amended by Stats. 2012, Ch. 454, Sec. 5. Effective January 1, 2013.)*