

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: January 29, 2014
ATTENTION: Members, Medical Board of California
SUBJECT: Outpatient Surgery Settings Task Force
STAFF CONTACT: Curtis J. Worden, Chief of Licensing

REQUESTED ACTION:

Review and approve the proposed amendment to Health and Safety Code (HSC) Section 1248.15(a)(6)(B)(i) regarding peer review requirements for physicians in Outpatient Surgery Settings (OSS). Direct staff to seek legislation for this proposed amendment.

BACKGROUND:

On January 22, 2014, the OSS Task Force held an interested parties meeting regarding proposed amendments to the OSS statutes and regulations.

The OSS Task Force meeting was held at the Medical Board of California (MBC) Headquarters in Sacramento and was video conferenced to three MBC District Offices located in Cerritos, San Jose, and San Diego. The OSS Task Force provided the interested parties with the language and reasons for the recommended changes to the statutes and regulations, and requested input on these changes.

At the October 2013 Board Meeting, the OSS Task Force was authorized to move forward with its recommended changes after receiving and considering input from the interested parties at the January 22, 2014 meeting. Based upon the comments from the interested parties on January 22, 2014, the OSS Task Force determined three legislative changes could move forward. Therefore, the language for these changes was provided to the Senate Business, Professions, and Economic Development Committee Staff, as Senator Lieu will be authoring a bill for these changes.

Specifically, the OSS Task Force recommended changes to:

- 1) HSC Section 1248.15(a)(2)(D) – providing some clean up language;
- 2) HSC Sections 1248.3(a) – requiring initial certifications of accreditation to be valid for only two years, instead of three; and
- 3) HSC Section 1248.35(b)(2) – requiring inspections, after the initial inspection, to be unannounced.

See **Attachment 1** for the specific language.

In addition to the above statutory changes, the OSS Task Force determined the Board needed to make some conforming changes to the regulations based upon recent legislative changes. Specifically, changes needed to be made to Section 1314.4 of the California Code of Regulations, Title 16. No comments requiring modification to these suggested changes were received at the interested parties meeting. Therefore, staff will begin the regulatory process to make these conforming changes. See **Attachment 2** for the specific regulatory changes.

At the interested parties meeting, there were two of the suggested amendments that received a significant amount of comments. The first amendment, which received extensive comments, was the deletion of HSC Section 1248.15(a)(2)(C)(iii). This recommended deletion would have removed one of the methods whereby an OSS can be accredited. Based upon the comments received, the OSS Task Force has determined that more discussion is needed.

The other amendment that received some significant input was the change to HSC Section 1248.15(a)(6)(B)(i), which requires peer review for all physicians in an OSS even if there is only one physician performing procedures in the OSS. The interested parties requested the Board provide more clarification and also provide a definition for peer review. The OSS Task Force has discussed the comments received by the interested parties and has modified the proposed section based upon these comments.

The OSS Task Force is requesting the Board Members review and approve the newly revised amendment to this section prior to providing the language to Legislative Staff for inclusion into a bill. The recommended change is found on page BRD 27-4.

The changes are identified below in ~~strike through~~ – indicating a recommendation to delete the section/word, and underline – indicating an addition to the section. After each deletion/addition is a highlighted section indicating the reason for the recommended change.

HEALTH AND SAFETY CODE

Section 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.~~

The above pathway does not adequately provide consumer protection.

~~(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:

The above language should be stricken because an outpatient surgery setting must comply with each of the subsections, and it does not have to start with "in addition to..."

- (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.

(i) All physicians who perform procedures for which accreditation is required in the outpatient setting are required to have peer review evaluations as defined in Business and Professions Code Section 805 (a)(1)(A), including outpatient settings that only have one physician. For purposes of this section, a peer review body consists of California licensed physicians who are qualified by education and experience in performing the same types of procedures, who may or may not have privileges at the outpatient setting.

The above additional language is needed to enhance consumer protection since a physician who owns his or her own outpatient setting may choose not to have peer

review of his or her practice. This will also help ensure all physicians who are

(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.)

Section 1248.3.

(a) Initial certificates of accreditation shall be valid for not more than two years and renewal 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.

(Added by Stats. 1994, Ch. 1276, Sec. 2. Effective January 1, 1995.)

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

The above revision will enhance consumer protection since the inspections will be unannounced. The outpatient surgery setting will be more likely to consistently maintain compliance with the minimum standards for accreditation, since the

outpatient surgery setting will not know when the accreditation agency inspection

(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.

(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.)

California Code of Regulations (CCR)

Title 16. Professional and Vocational Regulations

Division 13. Medical Board of California

Chapter 1. ~~Division of Licensing~~

There is no longer a Division of Licensing within the Board

Section 1313.4. Standards.

(a) An accreditation agency shall meet the standards set forth in sections 1248.15 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.~~

CCR § 1314.4 (3) is no longer applicable since statute now requires all locations to

(b) An accreditation agency shall send to the ~~division~~ *board* 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 a copy of any certificates of accreditation it issues and any denial or revocation of a certificate of accreditation. For each setting whose accreditation it denies or revokes, the accreditation agency shall also provide to the division 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 and 1248.4, Health and Safety Code.