

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: April 16, 2013
ATTENTION: Board Members
SUBJECT: Outpatient Surgery Settings
STAFF CONTACT: Curtis J. Worden, Chief of Licensing

PURPOSE:

To provide the Board members with more detailed information to supplement the: April 25 2013, PowerPoint Presentations on Outpatient Surgery Settings.

BACKGROUND:

California Business and Professions Code (B&P) Sections 2215, 2216 and 2217 were added to statutes in 1994 and became effective January 1, 1995. B&P Sections 2216.1 and 2216.2 were added to statutes in 1999 (AB271) and became effective January 1, 2000. These statutes (B&P Sections 2215-2217) identify surgery in certain outpatient settings, restrictions on use of anesthesia, minimum staffing and security requirements (Attachment 1- B&P Sections 2215 - 2217).

California Health and Safety Code (H&S) Sections 1248 – 1248.85 were added to statutes in 1994 (AB595) and became effective January 1, 1995. H&S Section 1248.4 was amended in 1997 (AB219) and became effective October 8, 1997. H&S Section 1248.15 was amended in 1999 (AB271) and became effective January 1, 2000. H&S Sections 1248, 1248.15, 1248.2, 1248.25, 1248.35, 1248.5, 1248.7, and 1248.85 were amended in 2011 (SB100) and became effective in January 2012. H&S Section 1248.35 was amended in 2012 (SB1095) and became effective January 1, 2013 (Attachment 2 – H&S Sections 1248 – 1248.85)

The Board authored language for the California Code of Regulations regarding Outpatient Surgery Settings and the Office of Administrative Law approved the following: California Code of Regulations, Title 16, Division 1, (CCR) Sections 1313.2 – 1313.6, that became operative February 17, 1996 (Attachment 3 – CCR Sections 1313.2 – 1313.6). These regulations further define statutes regarding Outpatient Surgery Setting Accreditation Agencies.

SUMMARY:

On January 1, 1995 the Board received statutory authority to approve Outpatient Surgery Setting Accreditation Agencies. In order to implement new statutes created by the passage of AB595, the Board drafted the language for CCR Sections 1313.2 - 1313.6, held hearings regarding the language, voted to approve the language and submitted the language for approval by the Office of Administrative Law. The Office of Administrative Law approved the proposed regulations and the regulations became operative on February 17, 1996.

The above referenced statutes and regulations define the specific authority for the Medical Board of California (Board), and the California Department of Public Health regarding Outpatient Surgery Settings. In addition, the above referenced statutes and regulations specify the following Outpatient Surgery Setting and Accreditation Agency requirements, and define:

- What is an Outpatient Surgery Setting
- Who may own an Outpatient Surgery Setting
- Accreditation Agency minimum requirements
- Exemptions from requiring an accreditation from an Accreditation Agency
- Minimum requirements to receive accreditation by an Accreditation Agency
- Levels of anesthesia used in an Outpatient Surgery Setting requiring accreditation

This report will focus on the Board's responsibilities.

Business and Professions Code Sections 2215 – 2217:

B&P Section 2215 states the Legislative findings and declarations, and intent regarding certain Outpatient Surgery Settings, effective on January 1, 1995.

B&P Section 2216 restricts the use of anesthesia in certain Outpatient Surgery Settings.

B&P Section 2216.1 “On or after July 1, 2001, it is unprofessional conduct for a physician and surgeon to perform procedures in any outpatient setting except in compliance with Section 2216, unless the setting has a minimum of two staff persons on the premises...”

B&P Section 2216.2 (a) “It is unprofessional conduct for a physician and surgeon to fail to provide adequate security by liability insurance, or by participation in an interindemnity trust, for claims by patients arising out of surgical procedures performed outside of a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code...”

B&P Section 2217 The Division of Licensing of the Medical Board of California may adopt regulations to implement this article and Chapter 1.3 (commencing with Section 1248) of Division 2 of the Health and Safety Code.

Note: Please see Attachment 1 for copies of B&P Sections 2215 - 2217

Health and Safety Code Sections 1248 – 1248.85:

H&S Section 1248 defines for the Board what an Outpatient Surgery Setting is and what is an Accreditation Agency.

What is an Outpatient Surgery Setting?

H&S Section 1248(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.

H&S Section 1248(b)(2) “Outpatient setting” also means facilities that offer in vitro fertilization, as defined in subdivision (b) of Section 1374.55.

What is not an Outpatient Surgery Setting?

H&S Section 1248(b)(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.

What is an Accreditation Agency?

H&S Section 1248(b)(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.

Who can own an Outpatient Surgery Setting?

H&S Section 1248. identifies the following acceptable owners:

- An Association
- Corporation
- Firm
- Partnership
- Individual Person

When is an Outpatient Surgery Setting exempt from accreditation?

H&S Section 1248.1 (a) - (f) and (h) identifies the following exemptions from accreditation requirements:

- An ambulatory surgical center that is certified to participate in Medicare program...
- Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization...
- Any clinic directly conducted, maintained or operated by the United States...
- Any primary care clinic or surgical clinic licensed under section 1204
- Any health facility licensed as a general acute care hospital
- Outpatient surgical setting where anxiolytics and analgesics are administered 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 life preserving protective reflexes
- 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).

H&S Section 1248.15 defines minimum standards for accreditation of Outpatient Surgery Settings and approving accreditation agencies. The following are some of the accreditation standards:

- Outpatient setting allied health staff shall be licensed or certified ...
- Outpatient settings shall have a system for facility safety and emergency training...
- Onsite equipment, medication, and trained personnel to handle services sought or provided and to facilitate handling of any medical emergency....
- Have a written transfer agreement with a local accredited or licensed acute care hospital...
- 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...
- Submit for approval by an accrediting agency a detailed procedural plan for handling medical emergencies...
- Submit for approval by an accrediting agency a detailed plan, standardized procedures, and protocols to be followed in the event of serious complications...
- Plan shall include at a minimum:
 - Notify individual designated by the patient in case of an emergency
 - Ensure that the mode of transfer is consistent with the patient's medical condition
 - Ensure all relevant clinical information is documented and accompanies the patient
 - Continue to provide appropriate care to the patient until the transfer is effectuated
- All physicians and surgeons transferring patients from an outpatient setting shall agree to cooperate with medical staff peer review process on the transfer case...
- Outpatient setting shall permit surgery by a dentist, physician and surgeon, an osteopathic physician and surgeon or podiatrist acting within his or her scope of practice...
- Outpatient setting may, in its discretion, permit anesthesia service by a certified registered nurse anesthetist acting within his or her scope of practice...
- Outpatient setting shall have a system for:
 - Maintaining clinical records
 - Patient care and monitoring procedures
 - Quality assessment
- Members of medical staff and other practitioners who are granted clinical privileges shall be professionally qualified and appropriately credentialed
- Outpatient setting shall grant privileges in accordance with recommendations from qualified health professionals, and credentialing standards established by the outpatient setting
- Clinical privileges shall be periodically reappraised...
- Outpatient settings that have multiple service locations shall have all of the sites inspected
- Outpatient settings shall post the certificate of accreditation in a location readily visible to patients ...
- Outpatient settings shall post the name and telephone number of the accrediting agency with instructions on submission of complaints in a location readily visible to patients...
- Outpatient settings shall have a written discharge criteria

- 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)...
- Transfer to an unlicensed setting of a patient who does not meet the written discharge criteria shall constitute unprofessional conduct
- An accreditation agency may include additional standards in its determination to accredit outpatient settings...
- 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...
- Privileges may not be arbitrarily restricted based on category of licensure
- The Board shall adopt regulations that it deems necessary for outpatient settings that offer in vitro fertilization
- 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 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...
- 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

H&S Section 1248.2 specifies certificate of accreditation requirements. The following are some of the requirements:

- Any outpatient setting may apply to an accreditation agency for a certificate of accreditation...
- 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
- The list of outpatient settings shall include:
 - Name, address, and telephone number of any owners, and their medical license numbers.
 - Name and address of the facility.
 - The name and telephone number of the accreditation agency.
 - The effective and expiration dates of the accreditation.
- Accrediting agencies shall notify the board and update the board on all outpatient settings that are accredited.

H&S Section 1248.25 specifies the criteria for denial of accreditation.

H&S Section 1248.3 specifies the terms of certificates; Notification of change of ownership; Disclosure of information by agency. The following are some of the requirements:

- Certificates of accreditation shall be valid for not more than three years
- The outpatient setting shall notify the accreditation agency within 30 days of any significant change in ownership...
- The outpatient setting shall notify the accreditation agency within 30 days of any significant change in change in scope of services, additional services, or change in locations
- 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... shall prohibit the accreditation agency from making discretionary disclosures of information to an outpatient setting pertaining to the accreditation of that outpatient setting

H&S Section 1248.35 identifies inspections by agency or the Board. The following are some of the requirements:

- 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.
- The frequency of inspection shall depend upon the type and complexity of the outpatient setting to be inspected.
- 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...
- 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...
- 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:
 - 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
 - Place the outpatient setting on probation...
 - Suspend or revoke the outpatient setting's certification of accreditation

- 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...
- 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...
- 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...
- 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...
- 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. ..
- 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.
- 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...
- 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
- 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...

H&S Section 1248.4 identifies accreditation agency approval and requirements. The following are some of requirements:

- 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...

- Submit an application, supporting documentation and fees to apply for approval by the Board.
- The division shall approve an accreditation agency that applies for approval if the accreditation agency meets the following:
 - Includes within its accreditation program, at a minimum, the standards for accreditation of outpatient settings approved by the Board
 - Submits its current accreditation standards to the division every three years, or upon request for continuing approval by the Board
 - Maintains internal quality management programs to ensure quality of the accreditation process.
 - Has a process by which accreditation standards can be reviewed and revised no less than every three years.
 - Maintains an available pool of allied health care practitioners to serve on accreditation review teams as appropriate
 - Has accreditation review teams...
 - Review teams consist of at least one physician and surgeon who practices in an outpatient setting; any other members shall be practicing actively in these settings
 - Participate in formal educational training programs provided by the accreditation agency in evaluation of the certification standards...
 - The accreditation agency shall demonstrate that professional members of its review team have experience ...
 - Standards for accreditation shall be developed with the input of the medical community...
 - Accreditation reviewers shall be credentialed and screened by the accreditation agency
 - 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.

H&S Section 1248.5 is regarding the evaluation of approved accreditation agencies.

H&S Section 1248.55 is regarding the termination of approval of an approved accreditation agency. The following are some of the requirements:

- The Board shall notify the accreditation agency with a notice of deficiencies and a reasonable time to supply the information....
- If approval of an accreditation agency is terminated, outpatient settings accredited by the that agency shall be notified by the Board...
- This may require an outpatient setting that has been accredited by an accreditation agency whose approval has been terminated to cease operations immediately...

H&S Section 1248.6 identifies the fees for application of approval by the Board

H&S Section 1248.65 identifies unprofessional conduct by a physician and surgeon regarding outpatient settings.

H&S Section 1248.7 is regarding complaints against an outpatient setting. The following are some of the requirements:

- The board shall investigate all complaints concerning a violation of this chapter...

H&S Section 1248.75 is regarding notice of deficiencies.

H&S Section 1248.8 is regarding violations of this chapter as a misdemeanor.

H&S Section 1248.85 is regarding the adoption of additional standards by an approved accreditation agency.

Note: Please see Attachment 2 for copies of H&S Code Sections 1248 - 1248.85

The California Code of Regulations, Title 16, Division 13, Sections 1313.2 – 1313.6 further define some of the above statutes, specifically:

CCR Section 1313.2 relates to H&S Section 1248

CCR Section 1313.3 relates to H&S Sections 1248.15 and 1248.4

CCR Section 1313.4 relates to H&S Sections 1248.15 and 1248.4

CCR Section 1313.5 relates to H&S Section 1248.4

CCR Section 1313.6 relates to H&S Section 1248.6

Note: Please see Attachment 3 for copies of CCR Sections 1313.2 - 1313.6

The Board is authorized by statute to accept applications from Accreditation Agencies that are requesting the Board's approval to accredit an outpatient surgery setting. The Board currently has four approved Accreditation Agencies:

- American Association for Accreditation of Ambulatory Surgery Facilities Inc. (AAAASF)
- Accreditation Association for Ambulatory Health Care (AAAHC)
- Institute for Medical Quality (IMQ)
- The Joint Commission (JC)

ATTACHMENTS:

1. California Business and Professions Code Sections: 2215 – 2217
2. California Health and Safety Code Sections: 1248 – 1248.85
3. California Code of Regulations, Title 16, Division 13, Sections: 1313.2 – 1313.6

ATTACHMENT - 1

Business and Professions Code - BPC

DIVISION 2. HEALING ARTS [500. - 4999.129.]

(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 5. Medicine [2000. - 2521.]

(Chapter 5 repealed and added by Stats. 1980, Ch. 1313, Sec. 2.)

ARTICLE 11.5. Surgery in Certain Outpatient Settings [2215. - 2217.]

(Article 11.5 added by Stats. 1994, Ch. 1276, Sec. 1.)

2215.

The Legislature finds and declares that in this state, significant surgeries are being performed in unregulated out-of-hospital settings. The Legislature further finds and declares that without appropriate oversight, some of these settings may be operating in a manner which is injurious to the public health, welfare, and safety. Although the health professionals delivering health care services in these settings are licensed, further quality assurance is needed to ensure that health care services are safely and effectively performed in these settings. The Legislature further recognizes that there is a wide range of surgical procedures safely performed in a myriad of outpatient settings, and the degree of patient risk varies greatly. It is the intent of the Legislature to create regulations that directly impact patient safety. It is not the intent of the Legislature to require standards in excess of those requirements in Section 1248.15, or to require physical modifications to facilities unless the modifications or standards directly impact patient safety and are cost-effective. The cost effectiveness of any modifications shall be taken into consideration by the Division of Licensing of the Medical Board of California, and shall ensure that the least costly and effective method of achieving patient safety is required.

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

Business and Professions Code - BPC

DIVISION 2. HEALING ARTS [500. - 4999.129.]

(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 5. Medicine [2000. - 2521.]

(Chapter 5 repealed and added by Stats. 1980, Ch. 1313, Sec. 2.)

ARTICLE 11.5. Surgery in Certain Outpatient Settings [2215. - 2217.]

(Article 11.5 added by Stats. 1994, Ch. 1276, Sec. 1.)

2216.

On or after July 1, 1996, no physician and surgeon shall perform procedures in an outpatient setting using anesthesia, except local anesthesia or peripheral nerve blocks, or both, complying 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, unless the setting is specified in Section 1248.1. Outpatient settings where anxiolytics and analgesics are administered are excluded when administered, 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.

The definition of "outpatient settings" contained in subdivision (c) of Section 1248 shall apply to this section.

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

Business and Professions Code - BPC

DIVISION 2. HEALING ARTS [500. - 4999.129.]

(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 5. Medicine [2000. - 2521.]

(Chapter 5 repealed and added by Stats. 1980, Ch. 1313, Sec. 2.)

ARTICLE 11.5. Surgery in Certain Outpatient Settings [2215. - 2217.]

(Article 11.5 added by Stats. 1994, Ch. 1276, Sec. 1.)

2216.1.

On and after July 1, 2000, it is unprofessional conduct for a physician and surgeon to perform procedures in any outpatient setting except in compliance with Section 2216, unless the setting has 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.

(Added by Stats. 1999, Ch. 944, Sec. 2. Effective January 1, 2000.)

Business and Professions Code - BPC

DIVISION 2. HEALING ARTS [500. - 4999.129.]

(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 5. Medicine [2000. - 2521.]

(Chapter 5 repealed and added by Stats. 1980, Ch. 1313, Sec. 2.)

ARTICLE 11.5. Surgery in Certain Outpatient Settings [2215. - 2217.]

(Article 11.5 added by Stats. 1994, Ch. 1276, Sec. 1.)

2216.2.

(a) It is unprofessional conduct for a physician and surgeon to fail to provide adequate security by liability insurance, or by participation in an interindemnity trust, for claims by patients arising out of surgical procedures performed outside of a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

(b) For purposes of this section, the board shall determine what constitutes adequate security.

(c) Nothing in this section shall require an insurer admitted to transact liability insurance in this state to provide coverage to a physician and surgeon.

(d) The security required by this section shall be acceptable only if provided by any one of the following:

(1) An insurer admitted pursuant to Section 700 of the Insurance Code to transact liability insurance in this state.

(2) An insurer that is eligible pursuant to Section 1765.1 of the Insurance Code.

(3) A cooperative corporation authorized by Section 1280.7 of the Insurance Code.

(4) An insurer licensed to transact liability insurance in at least one state of the United States. (Amended by Stats. 2011, Ch. 83, Sec. 1. Effective July 15, 2011. Operative July 21, 2011, by Sec. 34 of Stats. 2011, Ch. 83.)

Business and Professions Code - BPC

DIVISION 2. HEALING ARTS [500. - 4999.129.]

(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 5. Medicine [2000. - 2521.]

(Chapter 5 repealed and added by Stats. 1980, Ch. 1313, Sec. 2.)

ARTICLE 11.5. Surgery in Certain Outpatient Settings [2215. - 2217.]

(Article 11.5 added by Stats. 1994, Ch. 1276, Sec. 1.)

2217.

The Division of Licensing of the Medical Board of California may adopt regulations to implement this article and Chapter 1.3 (commencing with Section 1248) of Division 2 of the Health and Safety Code.

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

ATTACHMENT - 2

Health and Safety Code - HSC

DIVISION 2. LICENSING PROVISIONS [1200. - 1795.]

(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.)

HSC § 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.

(Amended by Stats. 2011, Ch. 645, Sec. 2. Effective January 1, 2012.)

HSC § 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.

Outpatient Surgery Centers - Agenda Item 4, Attachment B: H&S Codes 1248 – 1248.85

- (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.

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

HSC § 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.

Outpatient Surgery Centers - Agenda Item 4, Attachment B: H&S Codes 1248 – 1248.85

(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.

(Amended by Stats. 2011, Ch. 645, Sec. 3. Effective January 1, 2012.)

HSC § 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.

(Amended by Stats. 2011, Ch. 645, Sec. 4. Effective January 1, 2012.)

HSC § 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.

(Amended by Stats. 2011, Ch. 645, Sec. 5. Effective January 1, 2012.)

HSC § 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.

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

HSC § 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.)

HSC § 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.

Outpatient Surgery Centers - Agenda Item 4, Attachment B: H&S Codes 1248 – 1248.85

- (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.

(Amended by Stats. 1997, Ch. 769, Sec. 1. Effective October 8, 1997.)

HSC § 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.

(Amended by Stats. 2011, Ch. 645, Sec. 7. Effective January 1, 2012.)

HSC § 1248.55.

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

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(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.

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

HSC § 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.

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

HSC § 1248.65.

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

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

HSC § 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 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.

(Amended by Stats. 2011, Ch. 645, Sec. 8. Effective January 1, 2012.)

HSC § 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.

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

HSC § 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.

(Amended by Stats. 2011, Ch. 645, Sec. 9. Effective January 1, 2012.)

ATTACHMENT - 3

16 CCR § 1313.2

Cal. Admin. Code tit. 16, § 1313.2

Barclays Official California Code of Regulations Currentness

Title 16. Professional and Vocational Regulations

Division 13. Medical Board of California [FNA1]

Chapter 1. Division of Licensing

Article 3.5. Outpatient Setting Accreditation Agencies (Refs & Annos)

[FNA1] For disposition of former Sections 1370-1375.45, see Table of Parallel Reference, Chapter 13.2, Title 16, California Code of Regulations.

§ 1313.2. Definitions.

(a) “Accredited” shall include, for purposes of section 1248.1(g) of the Health and Safety Code, not only full accreditation but also provisional accreditation granted by an accreditation agency to an outpatient setting, provided that (1) the outpatient setting is in substantial compliance with the accreditation agency's standards; (2) the deficiencies in compliance do not affect the quality of patient care; and (3) the deficiencies will be corrected within six months of the date on which the outpatient setting was granted provisional accreditation.

(b) “Accreditation agency” has the meaning given to it in section 1248(d) of the Health and Safety Code.

Note: Authority cited: Sections 2018 and 2217, Business and Professions Code. Reference: Section 1248, Health and Safety Code.

HISTORY

1. New Article 3.5 and section filed 1-18-96; operative 2-17-96 (Register 96, No. 3).

16 CCR § 1313.2, 16 CA ADC § 1313.2

This database is current through 3/8/13 Register 2013, No. 10

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16 CCR § 1313.3

Cal. Admin. Code tit. 16, § 1313.3

Barclays Official California Code of Regulations Currentness

Title 16. Professional and Vocational Regulations

Division 13. Medical Board of California [FNA1]

Chapter 1. Division of Licensing

Article 3.5. Outpatient Setting Accreditation Agencies (Refs & Annos)

[FNA1] For disposition of former Sections 1370-1375.45, see Table of Parallel Reference, Chapter 13.2, Title 16, California Code of Regulations.

§ 1313.3. Applications; Processing Times.

(a) An application for approval as an accreditation agency shall be filed with the division at its principal office and shall be accompanied by the fee prescribed by this article.

(b) An application shall include the following information and documents:

(1) Name and address of applicant;

(2) Date applicant began to operate as an accreditation agency;

(3) Copy of applicant's current accreditation standards;

(4) A list of all outpatient settings accredited or certified by applicant;

(5) Information to establish the applicant's compliance with sections 1248.15 and 1248.4 of the Health and Safety Code and section 1313.4.

(c) The division shall inform an applicant for approval as an accreditation agency in writing within 30 days of receipt of an application whether the application is complete and accepted for filing or is deficient and what specific information or documentation is required to complete the application.

(d) The division shall inform an applicant as an accreditation agency within 120 days after completion of the application of its decision whether the applicant meets the requirements for approval. An application is considered complete if it is in compliance with the requirements of sections 1248.15 and 1248.4 of the Health and Safety Code and section 1313.4.

Note: Authority cited: Sections 2018 and 2217, Business and Professions Code; and Section 15376, Government Code. Reference: Sections 1248.15 and 1248.4, Health and Safety Code; and Section 15376, Government Code.

HISTORY

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

16 CCR § 1313.3, 16 CA ADC § 1313.3

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16 CCR § 1313.4

Cal. Admin. Code tit. 16, § 1313.4

Barclays Official California Code of Regulations Currentness

Title 16. Professional and Vocational Regulations

Division 13. Medical Board of California [FNA1]

Chapter 1. Division of Licensing

Article 3.5. Outpatient Setting Accreditation Agencies (Refs & Annos)

[FNA1] For disposition of former Sections 1370-1375.45, see Table of Parallel Reference, Chapter 13.2, Title 16, California Code of Regulations.

§ 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.

(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 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.

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).

16 CCR § 1313.4, 16 CA ADC § 1313.4

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16 CCR § 1313.5

Cal. Admin. Code tit. 16, § 1313.5

Barclays Official California Code of Regulations Currentness

Title 16. Professional and Vocational Regulations

Division 13. Medical Board of California [FNA1]

Chapter 1. Division of Licensing

Article 3.5. Outpatient Setting Accreditation Agencies (Refs & Annos)

[FNA1] For disposition of former Sections 1370-1375.45, see Table of Parallel Reference, Chapter 13.2, Title 16, California Code of Regulations.

§ 1313.5. Renewal.

An application for renewal of approval shall be filed with the division at its principal office prior to expiration of the approval. It shall include all of the information required by section 1313.3(b) and shall be accompanied by the renewal fee prescribed by this article.

Note: Authority cited: Sections 2018 and 2217, Business and Professions Code; and Section 1248.4(e), Health and Safety Code. Reference: Section 1248.4, Health and Safety Code.

HISTORY

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

16 CCR § 1313.5, 16 CA ADC § 1313.5

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END OF DOCUMENT

16 CCR § 1313.6

Cal. Admin. Code tit. 16, § 1313.6

Barclays Official California Code of Regulations Currentness

Title 16. Professional and Vocational Regulations

Division 13. Medical Board of California [FNA1]

Chapter 1. Division of Licensing

Article 3.5. Outpatient Setting Accreditation Agencies (Refs & Annos)

[FNA1] For disposition of former Sections 1370-1375.45, see Table of Parallel Reference, Chapter 13.2, Title 16, California Code of Regulations.

§ 1313.6. Fees.

(a) The fee for temporary approval as an accreditation agency is \$2,000.

(b) The fee for approval as an accreditation agency is \$5,000.

(c) The fee for renewal of approval is \$100 for each outpatient setting accredited or reaccredited during the three years immediately preceding the filing of the renewal application.

Note: Authority cited: Sections 2018 and 2217, Business and Professions Code; and Section 1248.6, Health and Safety Code. Reference: Section 1248.6, Health and Safety Code.

HISTORY

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

16 CCR § 1313.6, 16 CA ADC § 1313.6

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MEDICAL BOARD OF CALIFORNIA

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

April 25, 2013

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

Business and Professions Code Section 2215

“The Legislature finds and declares that in this state, significant surgeries are being performed in unregulated out-of-hospital settings. The Legislature further finds and declares that without appropriate oversight, some of these settings may be operating in a manner which is injurious to the public health, welfare and safety...”

(Added Stats. 1994, ch. 1276, § 1 (AB 595.)

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

Business and Professions Code Section 2216

“On or After July 1, 1996, no physician and surgeon shall perform procedures in an outpatient setting using anesthesia, except local anesthesia or peripheral nerve blocks, or both, complying 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, unless the setting is specified in Section 1248.1...”

(Added Stats. 1994, ch. 1276, § 1 (AB 595.)

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

Health and Safety Code Section 1248

(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...

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

Required Settings

Health and Safety Code Section 1248.1 specifies them as:

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

* * *

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

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

Outpatient Surgery Settings are “authorized” in the following ways :

- 1) Licensed by California Department of Public Health;
- 2) Accredited by an agency approved by the Medical Board of California; or
- 3) Fit another statutory classification.

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

- A court decision (*Capen v. Shewry*) altered the landscape relating to the operation of these settings.
- After *Capen*, the Department of Public Health will not license Outpatient Surgery Settings that are owned in whole or part by physicians
- If these sites don't fit within a statutory classification, they need to be accredited

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

- To implement these laws, MBC has adopted regulations specifying approval and renewal criteria for Accreditation Agencies
- These criteria may be found at California Code of Regulations, Title 16, Division 13, Sections 1313.2 – 1313.6

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

Important Concept

- An Outpatient Surgery Setting is a place
- A fixed location with an address
- If we had a vehicle with a GPS device, we could drive there

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

Contrast A Personal License

- ▣ Physician's and Surgeon's Certificate
- ▣ Law License
- ▣ These licenses follow you around

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

Q. Does the Medical Board of California License Outpatient Surgery Settings?

A. No. The Medical Board of California indirectly oversees Outpatient Surgery Settings

Q. How does it do that?

A. The Board approves the agencies that accredit Outpatient Surgery Settings

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

Who can operate, manage, conduct or maintain an Outpatient Surgery Setting?

- ▣ An Association
- ▣ Corporation
- ▣ Firm
- ▣ Partnership
- ▣ Individual Person

(Health and & Safety Code, § 1248.1)

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

Exemptions from accreditation:

An ambulatory surgical center that is certified to participate in Medicare program...

Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization,...

Any clinic directly conducted, maintained or operated by the United States...

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

Any primary care clinic or surgical clinic licensed under section 1204

Any health facility licensed as a general acute care hospital

Outpatient surgical setting where anxiolytics and analgesics are administered 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 life preserving protective reflexes

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

Powers of the Board

The Board Approves Accreditation Agencies

The Board may inspect outpatient settings and shall investigate complaints

The Board shall evaluate approved accreditation agencies not less than every three years

The Board may terminate the approval of an accrediting agency

The Board, under certain circumstances, may seek injunctive relief

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

The Board grants approval to an Accreditation Agency upon the Accreditation Agency submitting the application and necessary fee, the required supporting documentation, and the Board determining that the materials submitted indicate the Accreditation Agency meets the minimum requirements set forth in the relevant sections of the California Health and Safety Code and the California Code of Regulations.

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

Outpatient Surgery Setting Accreditation Requirements

Outpatient Surgery Settings must meet the minimum requirements pursuant to Health and Safety Code Section 1248.15 and California Code of Regulations Section 1313.4 to be eligible for accreditation by a Medical Board of California approved Accreditation Agency.

OUTPATIENT SURGERY SETTING INFORMATIONAL PRESENTATION

The Medical Board of California currently has approved four Accreditation Agencies:

American Association for Accreditation of Ambulatory Surgery Facilities Inc. (AAAASF)

Accreditation Association for Ambulatory Health Care (AAAHC)

Institute for Medical Quality (IMQ)

The Joint Commission (JC)