

## **TITLE 16. MEDICAL BOARD OF CALIFORNIA**

**NOTICE IS HEREBY GIVEN** that the Medical Board of California (Board) is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at San Francisco Airport Marriott Waterfront, 1800 Old Bayshore Hwy, Burlingame, CA 94010, at 9:05 a.m., on July 31, 2015

Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board at its office no later than 5:00 p.m. on July 20, 2015, or must be received at the hearing. The Board, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Section 2018 of the Business and Professions Code, and to implement, interpret or make specific sections 1248.15 and 1248.35 of Health and Safety Code, the Board is considering changes to Division 13 of Title 16 of the California Code of Regulations as follows:

### INFORMATIVE DIGEST

#### A. Informative Digest

Current Health and Safety Code (HSC) section 1248.15 requires that an outpatient surgery setting regulated by the Board with multiple locations must have all of its sites inspected.

In regards to the site inspections, the Board's current regulations allow the actual sample size to be determined by the accreditation agency.

The Board is amending its regulations by deleting 16 CCR 1313.4(a)(3), thereby allowing the statute to dictate that all sites must be inspected.

In addition, HSC section 1248.35 now requires an accreditation agency to report to the Board additional violations issued against outpatient surgery settings and requires the accreditation agency to report some violations to the Board within 24 hours.

At present, 1313.4(c) specifies that denials and revocations must be reported to the Board.

The Board is amending that section to add reprimands, probations, and

suspension as additional events that have to be reported, in order to be consistent with statutes.

B. Policy Statement Overview/Anticipated Benefits of Proposal

This proposed rulemaking would benefit public health and safety by the increased scope of inspections on outpatient surgery settings, as well as the additional reporting requirements and the requirement that some of the violations must be reported to the Board within 24 hours.

In addition, the rulemaking is being proposed in order to maintain consistency in language between HSC section 1248.15 and 1248.35 and CCR section 1313.4. The consistency will eliminate conflicts within the HSC and CCR sections.

C. Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the Board has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations. The amendments proposed in this rulemaking will make the Board's regulations consistent with HSC 1248.15 and 1248.35.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 - 17630 Require Reimbursement: None

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Cost Impact on Representative Private Person or Business:

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs:

None

EFFECT ON SMALL BUSINESS

The Board has determined that the proposed regulations would affect small businesses.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/Businesses:

The Board has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Benefits of Regulation:

The Board has determined that this regulatory proposal will benefit the health and welfare of California residents, worker safety, and state's environment by ensuring that outpatient settings with multiple locations shall have all sites inspected. Further, an accreditation agency shall, within 24 hours, report to the Board when it has issued a reprimand, suspended, placed on probation, or revoked any outpatient setting.

CONSIDERATION OF ALTERNATIVES

The Board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board has prepared an initial statement of reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of the initial statement of reasons, and all of the

information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the person designated in the Notice under Contact Person, below, or by accessing the Board's website at [http://www.mbc.ca.gov/About\\_Us/Laws/Proposed\\_Regulations](http://www.mbc.ca.gov/About_Us/Laws/Proposed_Regulations).

#### AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

#### CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Curtis Worden  
Address: Medical Board of California  
2005 Evergreen St., Ste. 1200  
Sacramento, CA 95815  
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Fax No.: (916) 263-2387  
E-Mail Address: [regulations@mbc.ca.gov](mailto:regulations@mbc.ca.gov)

The backup contact person is:

Name: Kevin A Schunke, Regulations Manager  
Address: Medical Board of California  
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Sacramento, CA 95815  
Telephone No.: (916) 263-2368  
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Website Access Materials regarding this proposal can be found at [http://www.mbc.ca.gov/About\\_Us/Laws/Proposed\\_Regulations](http://www.mbc.ca.gov/About_Us/Laws/Proposed_Regulations).

## **MEDICAL BOARD OF BOARD INITIAL STATEMENT OF REASONS**

**Hearing Date:** July 31, 2015

**Subject Matter of Proposed Regulations:**

To amend regulations for Outpatient Surgery Setting Accreditation Agency Standards.

**Section(s) Affected:**

Title 16, Division 13, Chapter 1, Article 3.5, California Code of Regulations (CCR) section 1313.4.

**Specific Purpose of each adoption, amendment, or repeal:**

1. Problem being addressed:

Due to recent amendments to Health and Safety Code (HSC) sections 1248.15 and 1248.35, staff has identified the need to amend the language in CCR section 1313.4 to make it consistent with HSC sections 1248.15 and 1248.35.

2. Anticipated benefits from this regulatory action:

The rulemaking is being proposed in order to maintain consistency in language between HSC section 1248.15 and 1248.35 and CCR section 1313.4. The consistency will eliminate conflicts within the HSC and CCR sections.

3. Specific Purpose of Each Amendment:

One the of the amendments will require outpatient settings regulated by this chapter with multiple locations to have all of the sites inspected.

The second amendment requires an accreditation agency, within 24 hours, to report to the Board when it has issued a reprimand, suspended, placed on probation, or revoked any outpatient setting.

**Factual Basis/Rationale**

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

HSC section 1248.35 states an accreditation agency shall, within 24 hours, report to the Board when it has issued a reprimand, suspended, placed on probation, or revoked any

outpatient setting. Currently CCR section 1314.4 only specifies that denials and revocations must be reported to the Board. Therefore, reports of reprimands, placement on probation and suspensions must be added.

### **Underlying Data**

Staff prepared a report for the May 8, 2015, Medical Board of California meeting (agenda item 28) regarding the need for the amendment to CCR section 1313.4. A copy of the staff report is included in this rulemaking file.

At the same meeting, the Board adopted a motion directing staff to begin the regulatory process to amend CCR section 1313.4 to be consistent with HSC sections 1248.15 and 1248.5.

### **Business Impact**

The amendment to CCR section 1313.4 will not have a significant adverse economic impact on businesses. This initial determination is based on the following facts or evidence/documents/testimony: the proposed amendments are necessary to make CCR section 1313.4 consistent with HSC sections 1248.15 and 1248.35.

### **Economic Impact Assessment**

This regulatory proposal will have the following effects:

- It will not create or eliminate jobs within the State of California because the only amendments to CCR section 1313.4 are already required pursuant to HSC sections 1248.15 and 1248.35, and these amendments will make CCR section 1313.4 consistent with HSC sections 1248.15 and 1248.35.
- It will not create new business or eliminate existing businesses within the State of California because the only amendments to CCR section 1313.4 are already required pursuant to HSC sections 1248.15 and 1248.35, and these amendments will make CCR section 1313.4 consistent with HSC sections 1248.15 and 1248.35.
- It will not affect the expansion of businesses currently doing business within the State of California because the only amendments to CCR section 1313.4 are already required pursuant to HSC sections 1248.15 and 1248.35, and these amendments will make CCR section 1313.4 consistent with HSC sections 1248.15 and 1248.35.
- This regulatory proposal benefits the health and welfare of California residents because the amendments to CCR section 1313.4 will make this section consistent with HSC sections 1248.15 and 1248.35.

- This regulatory proposal benefits does not affect worker safety because the only amendments to CCR section 1313.4 are already required pursuant to HSC sections 1248.15 and 1248.35, and these amendments will make CCR section 1313.4 consistent with HSC sections 1248.15 and 1248.35.
- This regulatory proposal does not affect the state's environment because the only amendments to CCR section 1313.4 are already required pursuant to HSC sections 1248.15 and 1248.35 and these amendments will make CCR section 1313.4 consistent with HSC sections 1248.5 and 1248.35.

### **Specific Technologies or Equipment**

This regulation does not mandate the use of specific technologies or equipment.

### **Consideration of Alternatives**

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

1. Do not seek a change. This alternative was rejected because language in CCR 1313.4 would remain inconsistent with HSC sections 1248.15 and 1248.35.
2. Adopt the proposed regulatory amendments. This alternative was determined to be the most appropriate since these amendments will make CCR section 1313.4 consistent with HSC sections 1248.15 and 1248.35.

**MEDICAL BOARD OF CALIFORNIA  
OUTPATIENT SURGERY SETTING ACCREDITATION AGENCY STANDARDS  
Specific Language of Proposed Changes**

Legend

<u>Underlined</u>	Indicates proposed amendments or additions to the existing regulation
<del>Strikeout</del>	Indicates proposed deletions to the existing regulation

Amend Section 1313.4 in Article 3.5, of Chapter 1, Division 13, of Title 16 of the California Code of Regulations to read as follows:

**§1313.4. Standards.**

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

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

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

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

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

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



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

#### HISTORY

1. New section filed on 1-18-1996; operative 2-17-1996 (Register 96, No.3).
2. New subsection (a)(1), subsection renumbering, amendment of subsection (c) and amendment of Note filed 12-5-2000; operative 1-4-2001 (Register 2000, No.49).

This database is current through 3-27-2105 Register 2015, No. 13.

16 CCR § 1313.4, 16 CA ADC § 1313.4