



Agenda Item 8d – Senate Bill 100 (Price)
Task Force on Outpatient Surgery Settings

Bullet 1 – Website

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Outpatient Surgery Settings

WHO MUST BE ACCREDITED OR LICENSED?

California law prohibits physicians from performing some outpatient surgery, unless it is performed in an accredited or licensed setting.

Section 2216 of the Business and Professions Code (B&P) specifies that 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 Health and Safety Code 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 Health and Safety Code Section 1248 shall apply.

ACCREDITED OUTPATIENT SURGERY SETTINGS:

Pursuant to the enactment of SB 100, effective January 1, 2012, **Health and Safety Code (H&S) Section 1248.2 (b), (c), and (d)** now provides that the Board shall obtain and maintain a list of accredited outpatient settings from the information provided by the accreditation agencies approved by the Board. The Board 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information on its Internet Web site, whether an outpatient setting is accredited or the setting's accreditation has been revoked, suspended, or placed on probation, or the setting has received a reprimand by the accreditation agency.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 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

Disclaimer

The information contained in the Outpatient Surgery Setting Database has been received from an approved accreditation agency in accordance with the provisions of Section 1248.2 of the H&S Code and, pursuant to that section, is displayed on the Board's Internet site. The Board cannot guarantee the accuracy of the information provided. Upon receipt of updated information from an accreditation agency, the information will be made available in the database.

Search for an
**Outpatient Surgery
Setting**

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Surgery Settings
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Complaint Form](#)

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agency.

4. The effective and expiration dates of the accreditation.

Accrediting agencies approved by the Board shall notify the Board and update the Board on all outpatient settings that are accredited.

As outlined in **Health and Safety Code (H&S) Section 1248.1** certain outpatient surgery settings are excluded from the accreditation requirement, such as ambulatory surgical centers certified to participate in the Medicare program under Title XVIII, health facilities licensed as general acute care hospitals, federally operated clinics, facilities on recognized tribal reservations, and facilities used by dentists or physicians in compliance with Article 2.7 or Article 2.8 of Chapter 4 of Division 2 of the B&P Code.

For further information concerning this law, or for assistance in determining accreditation or licensure of an outpatient surgery setting, please contact Susan Morrish, Licensing Program Analyst, at (916) 263-2393 or susan.morrish@mbc.ca.gov.

The Board currently approves the following Accreditation Agencies:

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

5101 Washington Street,
Suite 2F, Gurnee, IL 60031
Telephone #:
(847) 775-1970
Fax #: (847) 775-1985
www.aaaasf.org

**Accreditation
Association for
Ambulatory Health
Care (AAAHc)**

5200 Old Orchard Road,
Suite 200, Skokie, IL
60077
Telephone #:
(847) 853-6063 or
(847) 853-6060
Fax #:
(847) 853-9028
www.aaahc.org

The Joint Commission

One Renaissance Boulevard
Oakbrook Terrace, IL 60181
Telephone #:
(630) 792-5261
Fax #: (630) 792-5005
www.jointcommission.org

**Institute for Medical
Quality (IMQ)**

221 Main Street, suite
210, San Francisco, CA
94105
Telephone #:
(415) 882-5173
Fax #:
(415) 882-5149
www.imq.org

(Spanish)

→ Types of Settings
Not Required on
List

Note: When completing
the complaint form,
please put the name of
the outpatient setting in
the "Other" box

LICENSED OUTPATIENT SURGERY SETTINGS:

To find out if an outpatient surgery setting is licensed by the California Department of Public Health, click [HERE](#).

CENTERS FOR MEDICAL & MEDICAID SERVICES (CMS):

- [CMS - Acronyms](#)
- [CMS - Glossary](#)
- [CMS - Approved Accreditation Organization Contact Information](#)
- [CMS – Accrediting Organization Complaint Contacts](#)

DRAFT

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Agenda Item 8d – Senate Bill 100 (Price)
Task Force on Outpatient Surgery Settings

Bullet 2 - Complaint Process

Pages 4-10

SB 100 – Outpatient Surgery Settings

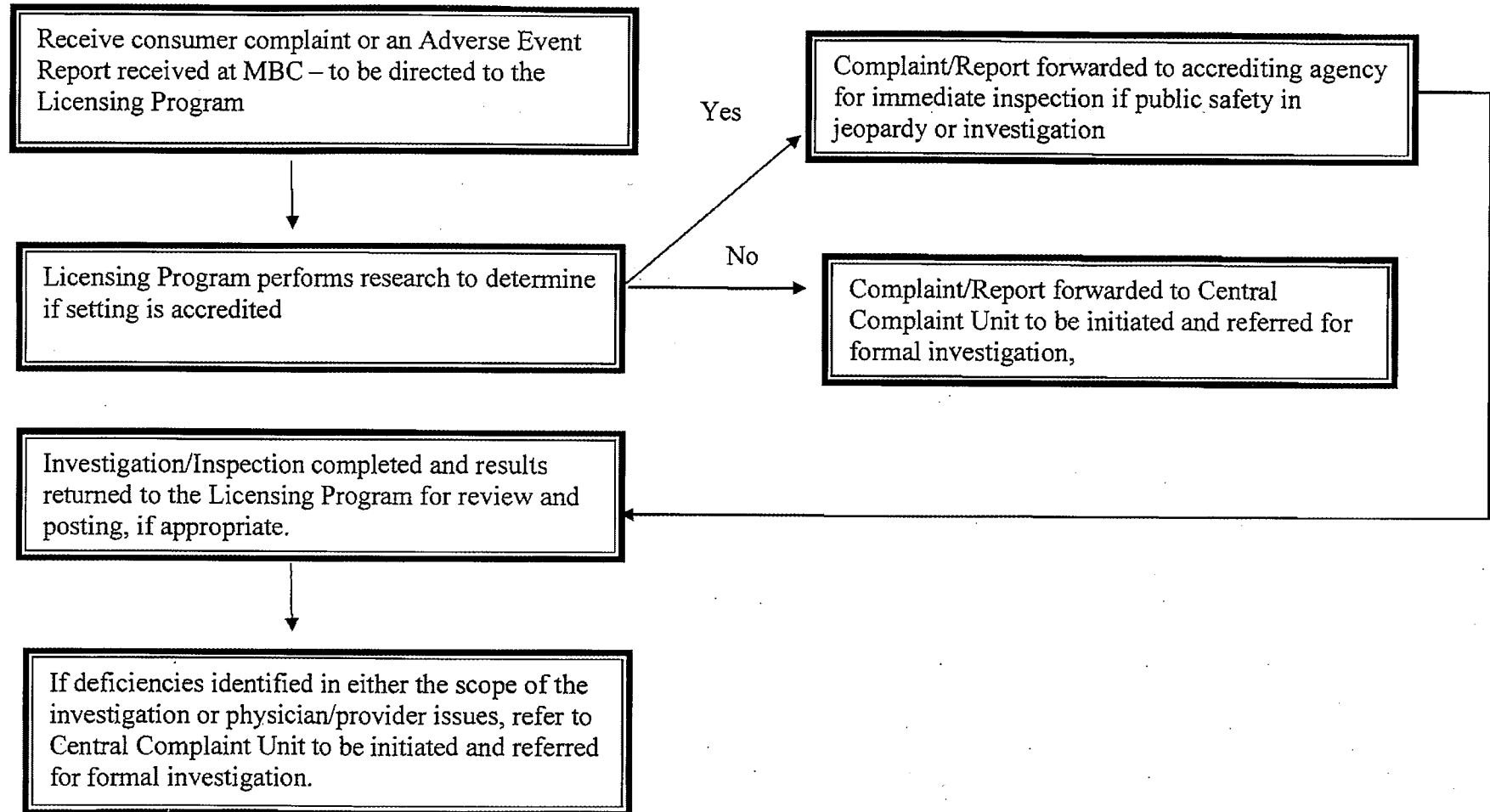
The bill requires MBC to maintain and publish a list of all accredited outpatient settings and provide information regarding the status of their accreditation. This portion of the statutory requirements is assigned to the Licensing Program and the status of implementation was reported directly to the Licensing Committee.

SB 100 also required the Medical Board to investigate complaints related to a violation of Health and Safety Code Section 1248 and, upon discovery that an outpatient setting is not in compliance with a specific provision, bring an action through or in conjunction with a district attorney to enjoin the outpatient setting's operation. In addition, SB 100 made outpatient settings subject to the adverse event reporting requirements currently required for licensing health facilities. Adverse events are reported to the Department of Public Health and the setting can be subject to penalties by Public Health for failing to report adverse events.

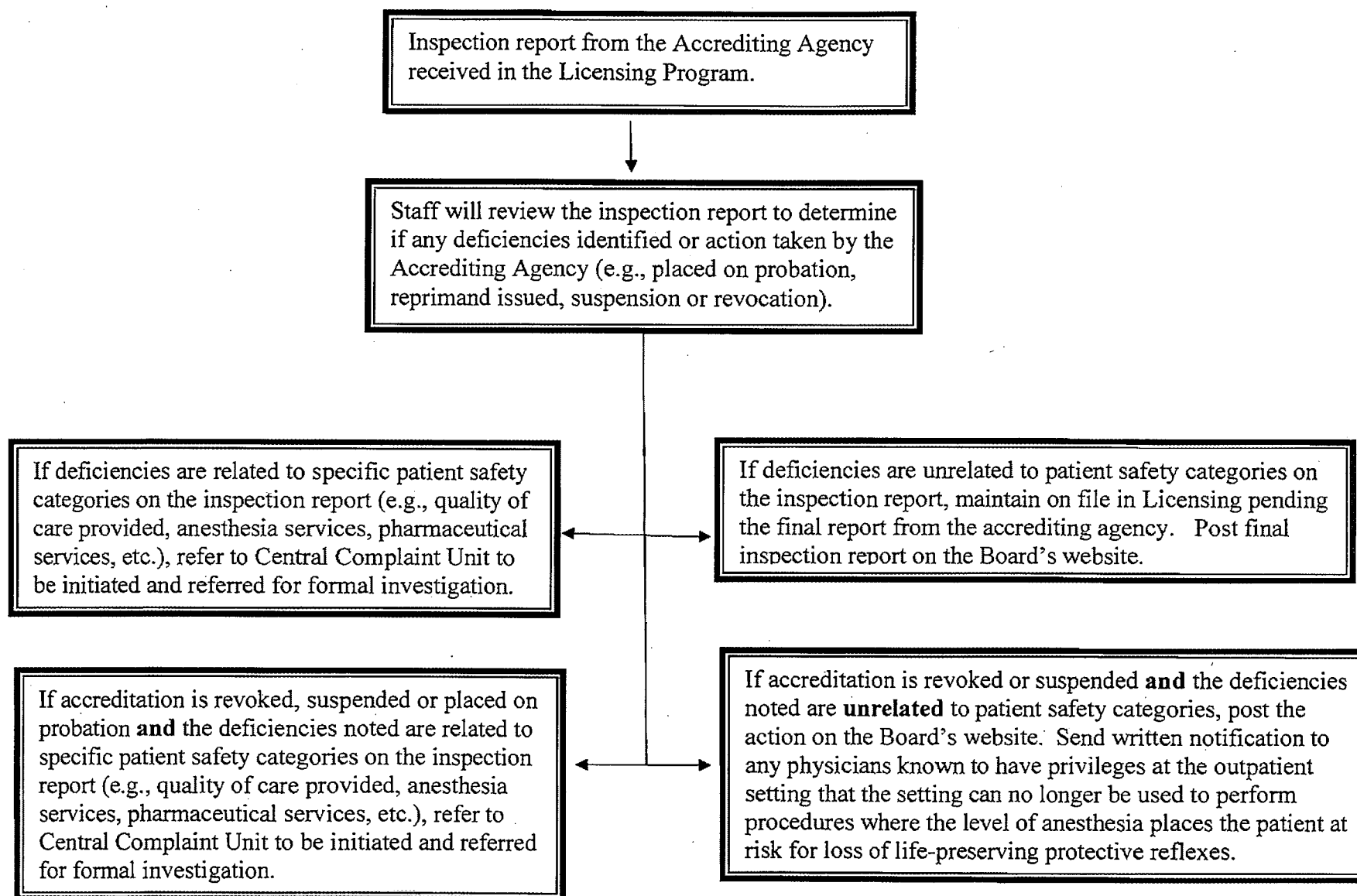
The following identifies the responsibilities assigned in statute to pertinent entities as it relates to oversight and response to patient care concerns:

H & S Section	Accrediting Agency	Medical Board
1248.35	Every outpatient setting shall be inspected no less often than 3 years.	May inspect the setting as often as necessary and shall ensure the accrediting agency conducts the required inspection
	If the results of the inspection conclude that the setting is out of compliance, they must issue a deficiency report and may 1) require correction, 2) issue a reprimand; 3) place the setting on probation; or 4) suspend or revoke the accreditation.	The accrediting agency must report within 24 hours if the setting has been issued a reprimand, been placed on probation or had the accreditation suspended or revoked.
	Shall inspect the setting within 24 hours upon receipt of a complaint from the Board that the setting poses an immediate risk to the public	Shall receive the findings of the inspection within five business days
	Shall investigate any complaint received from the Board within 30 days	Shall receive the findings of the investigation within 30 days
		Reports on the results of any inspection shall be maintained on file and final inspection reports shall be public record open to public inspection.
1248.7		Shall investigate all complaints concerning a violation of this chapter and, where appropriate, through or in conjunction with a DA may bring action to enjoin the setting's operation.

Complaint Process



Enforcement Response to Action taken by an Accrediting Agency





MEDICAL BOARD OF CALIFORNIA
Executive Office



December 11, 2012

Ron Chapman, MD, MPH, Director
California Department of Public Health
PO Box 997377, MS 0500
Sacramento, CA 95899-7377

Re: Adverse Outcome Reports

Dear Director Chapman:

As Executive Director of the Medical Board of California (Board), I write to request the assistance of the California Department of Public Health (CDPH) regarding the implementation of Senate Bill 100 (Ch. 645, Stats. 2011). As you are aware, key provisions of SB 100 require outpatient surgery settings to report adverse events to CDPH.


This reporting requirement has created some challenges because CDPH, following the *Capen* decision, may not have jurisdiction over an outpatient setting for which it receives an adverse report, as that setting may be accredited by an accrediting agency approved by the Board.

It is the Board's understanding that CDPH has received several adverse event reports for accredited (but not CDPH – licensed) settings, but has not yet transmitted those reports to the Medical Board. This is due to the lack of an executed Memorandum of Understanding (MOU) between the two agencies, that CDPH believes is necessary. CDPH has advised the Board that it has MOU's drafted for other agencies and will provide the Board with an MOU for the Board's review. Please be advised that the Board is committed to reviewing the CDPH MOU promptly to execute this agreement.

While the MOU is being completed, it would seem that public policy and consumer protection would best be served by having CDPH promptly dispatch those reports to the Board, since current statute already allows government agencies to share information. The Board and CDPH have been sharing information in the past without an MOU. Accordingly, the Board hereby requests that CDPH transmit to the Board for review and assessment any of these adverse events reports that it has found to be non-jurisdictional to CDPH. The Board, as a health oversight agency, will treat the reports as confidential to the extent permitted by law.

I thank you for your attention to this request. Please have your staff contact Curtis (Curt) Worden, Chief of Licensing at (916) 274-2986 or by email Curt.Worden@mbc.ca.gov or Susan Cady, Manager, Enforcement Program, Central Complaint Unit (916) 263-2644 or by email Susan.Cady@mbc.ca.gov or you may contact me directly if you have any questions on this matter.

Sincerely,



Linda K. Whitney
Executive Director

cc: Curtis Worden, Chief of Licensing
A. Renee Threadgill, Chief of Enforcement
Susan Cady, Manager, Enforcement Program, Central Compliant Unit



RON CHAPMAN, MD, MPH
Director & State Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

April 15, 2013

Ms. Linda K. Whitney
Executive Director
Medical Board of California
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815

Dear Ms. Whitney:

Thank you for your letter to the California Department of Public Health (CDPH) concerning the reporting of adverse events of accredited outpatient surgery settings. I apologize for the delay in responding to your inquiry.

As requested in your letter, you are seeking to have CDPH transmit to the Medical Board of California (Board), any reportable adverse event reports that have been received from accredited, but not CDPH licensed, outpatient surgery settings. In response to your request, CDPH's Licensing and Certification (L&C) Program has researched their database and identified six (6) adverse events in outpatient surgery centers that meet this request; these will be referred to the Board.

We have determined that L&C can provide adverse event incident information to the Board without the need for a Data Use Agreement (DUA) between the Board and the Centers for Medicare and Medicaid Services (CMS), as long as the information provided does not include specific patient identifier information. A representative from our Systems Technology and Research (STAR) Branch will be in contact with information on applying for a DUA with CMS should you be interested in details that include patient identifiers.

The Board must determine if an Inter-Agency Agreement (IAA) is necessary to notify L&C of enforcement actions the Board may take or if the Board becomes aware of failures to report an adverse event to L&C. Please contact our Office of Legal Services if an IAA must be developed.

-Continued on next page-

If you have additional questions regarding this matter, please contact Scott Vivona,
Chief of Field Operations of L&C, at (916) 440-7377.

Sincerely,

A handwritten signature in dark ink, appearing to read "Debby Rogers", with a stylized flourish at the end.

Debby Rogers, RN, MS, FAEN
Deputy Director



Agenda Item 8d – Senate Bill 100 (Price)
Task Force on Outpatient Surgery Settings

Bullet 3 – Accreditation Standards

Pages 11-16

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: May 23, 2013
ATTENTION: Board Members
SUBJECT: Outpatient Surgery Settings; Accreditation Standards

STAFF CONTACT: Curtis J. Worden, Chief of Licensing

PURPOSE:

To provide the Board members with information regarding the standards established in law and regulation for the accreditation of outpatient settings at which a certain level of anesthesia is administered to patients. The Board's Outpatient Setting Task Force will be reviewing these standards in the future to make a recommendation to the Board members regarding the need for possible revisions to existing statute or new regulations.

BACKGROUND:

The Medical Board of California (Board) is the state agency charged with the responsibility of licensing and disciplining physicians and surgeons. Additionally, the Board is charged with the responsibility of adopting standards for the accreditation of outpatient settings, and these standards are to be used by accreditation agencies. The Board currently has four approved accreditation agencies.

SUMMARY:

State law requires the Board to adopt standards for accreditation of outpatient surgery settings, and the outpatient surgery settings standards can be found in Health and Safety Code (H&S) §1248.15 (Attachment 1).

Please note that the outpatient surgery setting standards are minimum standards and the Board may adopt regulations that clarify/define the accreditation criteria [Attachment 1, H&S § 1248.15(a)]. Each accreditation agency approved by the Board must use these standards as minimum criteria for accreditation but may utilize more comprehensive criteria.

Accreditation agencies may have additional standards that an outpatient surgery setting must meet to receive accreditation by that specific accreditation agency, that is in addition to the minimum standards pursuant to H&S § 1248.15.

Note: An outpatient surgery setting may elect to be accredited by more than one accreditation agency.

The Board also has the authority to adopt regulations on outpatient surgery settings that offer in vitro fertilization services and may also adopt regulations regarding procedures that should be performed in licensed or accredited outpatient surgery setting [Attachment 1, H&S § 1248.15 (e) and (f)].

Due to time constraints, Board staff has not had the time to research and prepare a side-by-side comparison of each of the approved accreditation agencies' additional standards. Staff will be working on obtaining that information if it is available to the Board's staff for the July meeting.

Staff recommends obtaining input from the approved accreditation agencies to determine what the accreditation agencies may have identified as additional minimum standards that they use that the Board may wish to consider for possible development of additional regulations for consumer protection.

ATTACHMENT 1

HEALTH AND SAFETY CODE

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.

(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.)