

# Outpatient Surgery Settings Program





# Medical Board of California

## Evolution of the Program



- ▶ 1995 – Program Enacted
  - Board approved four accreditation agencies
- ▶ 2000 – Mandatory Reporting



BUSINESS, CONSUMER SERVICE, AND HOUSING AGENCY *Department of Consumer Affairs*
EDMUND G. BROWN, JR., Governor

**MEDICAL BOARD OF CALIFORNIA**  
 Central Complaint Unit

**OUTPATIENT SURGERY – PATIENT DEATH REPORTING FORM**

State law (Section 22863) of the California Business and Professions Code requires that whenever a patient death results from a medical procedure performed by a health care provider, the provider must file a report with the Medical Board of California. This report must be filed within 30 days of the patient's death. The report must be filed with the Medical Board of California, 2000 Corporate Center, Sacramento, CA 95833, or the Central Complaint Unit.

1. Patient Name			
Last	First	Middle	

- ## ► 2007 – Capen v Shewry

## Evolution of the Program



- ▶ 2011 – Significant legislation to improve oversight
- ▶ For Medical Board:
  - Database
  - Public postings
  - Investigations
- ▶ For OSSs:
  - Posting information
  - Disclosure
  - Adverse Event Reporting to CDPH
  - All Sites to be Inspected



## Evolution of the Program



- ▶ For AAs:
  - Prior history review
  - Inspections every three years
  - Time requirements upon receipt of complaint
  - Provide OSS information to the Board
  - Notify Board when action taken
  - OSS notification



## Evolution of the Program



- ▶ 2013 – More Improvements
  - Board established a Task Force
    - Recommended improvements to Program
    - Recommended legislation



- ▶ 2014 – Legislation passed requiring Adverse Event Reports to be submitted to the Board



## Evolution of the Program




- ▶ 2016 – SB 396
  - OSSs to obtain 805 information
  - Unannounced inspections
  - Required peer review every 2 years
- ▶ 2018 – SB 798
  - Amended adverse event reporting criteria





# Outpatient Surgery Setting Database





The Medical Board of California

## Outpatient Surgery Setting Database

Enter name or keyword here . . .


Search by Settings

Searches can be performed by:

Setting Name

Owner Name

To perform a search of an Outpatient Setting enter the name or keyword of the setting, or the name of an Owner. Search results will return any settings with keywords matching the search criteria.


A green check mark  will indicate which Accreditation Agency a setting is accredited by. To review additional information available regarding a setting or owner, select the green check mark . If a setting is accredited by multiple Accreditation Agencies, select each green check mark  to view the individual Accreditation Agencies information.


Please enter the name or keywords you are searching for in the search box above.

If you have any questions or require assistance, please contact the Board's Consumer Information Unit at (916) 263-2382@.

**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.

# Outpatient Surgery Setting Database







The Medical Board of California

## Outpatient Surgery Setting Database

Search by Settings

Setting Name	Address	City	State	AAAASF	AAAHG	IMQ	JC
Plastic Surgery Center		Roseville	CA				

1

\*To review additional information available regarding a setting or owner, select the green check mark 

IMQ

Institute for Medical Quality  
221 Main Street, Suite 210 | San Francisco, CA 94105 | (415) 882-5151

Plastic Surgery Center

Street Address:

City:

Roseville

State:

CA

Zip:

95678

County:

Placer

Phone:

Setting Type:

Office-Based Surgery Center

CMS Approved:

No

Initial Accreditation:

8/10/2000

Accreditation Status

Effective Date

Expiration Date

Term

Accreditation Renewed

8/8/2013

8/7/2016

3 Years

Doing Business As Name:

Plastic and Laser Center

Specialties:

Facial Plastic and Reconstructive Surgery  
Cosmetic Surgery

Owners:

Accreditation History

Effective Date

Expiration Date

Term

Accreditation Renewed

8/8/2010

8/7/2013

3 Years

Inspection Date

Report

Deficiencies

Corrective Action Plan

Outcome

Outcome Report

None\*

Requirements Met

None\*

STATE OF CALIFORNIA  
DEPARTMENT OF CONSUMER AFFAIRS  
MEDICAL BOARD OF CALIFORNIA  
EST. 1876

IMQ

Institute for Medical Quality  
180 Howard Street • Suite 210 • San Francisco • CA 94105  
T: 415.882.5151 F: 415.882.5149 W: imq.org

ACCREDITATION REPORT AND CORRECTIVE ACTION PLAN

July 12, 2013

Roseville, CA 95678

DATE OF SURVEY

July 02, 2013

ACCREDITATION DECISION

Accreditation 3 Years with Interim Reports  
August 08, 2013 - August 07, 2016

Important Notice

When reviewing this document, please reference the enclosed cover letter. The cover letter details other important requirements of your accreditation.

The IMQ Accreditation Standards for Ambulatory Facilities were met with the exception of the following standards where corrective action is required. Please note that CONSULTATIVE COMMENTS are suggested options for your consideration in meeting the standard.

CHAPTER TWO-PERSONNEL AND CREDENTIALING

2.1.3 Employee policies and procedures address: a) Hiring and dismissal of staff;b) Performance expectations and competency; c) Training; d) Expected working hours;  
e) Sexual harassment prohibition;f) Patient privacy and confidentiality; and g) Management of the impaired practitioner.

PARTIALLY MET

FINDING: No policy found for G)

CORRECTIVE ACTION REQUIRED: Submit policy and procedure for impaired practitioner (G).  
Due 8/12/2013 interim report.

TITLE OF PERSON RESPONSIBLE:

STATE OF CALIFORNIA  
DEPARTMENT OF CONSUMER AFFAIRS  
MEDICAL BOARD OF CALIFORNIA  
EST. 1876

# Roles and Responsibilities

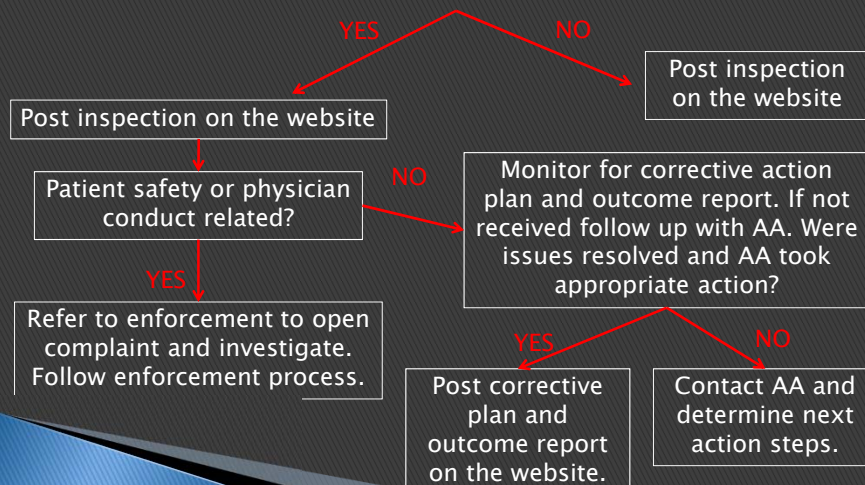


Accrediting Agency	Medical Board of California
Every outpatient setting shall be inspected no less often than three years	May inspect the setting as often as necessary and shall ensure the accrediting agency conducts the required inspection
If the results of the inspection conclude that the setting is 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
	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

# After an Inspection



## Deficiencies?



## Adverse Event Reports



- ▶ Outpatient Surgery Setting has to report adverse events:
  - Within 5 days after detection, or
  - If event is urgent or threat to patient welfare and safety within 24 hours

## Adverse Event Reports



- 1) Surgical or other invasive procedure event
  - Surgery or other invasive procedure on wrong body part
  - Surgery or other invasive procedure on wrong patient
  - Wrong surgery or other invasive procedure performed on a patient
  - Retention of foreign object
  - Death of a patient during or up to 24 hours after admittance
  - Transfer of a patient to a hospital or emergency center for medical treatment for a period exceeding 24 hours following procedure



## Adverse Event Reports



### 2) Product/device event

- Patient death/serious disability associated with a contaminated drug or device
- Patient death/serious disability associated with the use or function of a device
- Patient death/serious disability associated with intravascular air embolism

### 3) Patient protection event

- Minor discharged to wrong person
- Patient suicide/attempted suicide

## Adverse Event Reports



### 4) Care management event

- Patient death/serious disability associated with medication error
- Patient death/serious disability associated with hemolytic reaction due to administration of ABO-incompatible blood
- Patient death/serious disability directly related to hypoglycemia
- Patient death/serious disability due to spinal manipulative therapy



## Adverse Event Reports



### 5) Environmental event

- Patient death/serious disability associated with an electric shock
- Any incident in which a line contains the wrong gas or is contaminated
- Patient death/serious disability associated a burn
- Patient death associated with a fall
- Patient death/serious disability associated with the use of restraints or bed rails

## Adverse Event Reports



### 6) Criminal event

- Care ordered or provided by someone impersonating a health care provider
- Abduction of a patient
- Sexual assault on a patient
- Death or significant injury of a patient or staff member from physical assault

### 7) An adverse event or series of events that cause the death or serious disability of a patient, personnel, or visitor

## Adverse Event Report Review Process



- Event occurs as listed in Health and Safety Code section 1279.1 and requires reporting to the Board pursuant to Business and Professions Code section 2216.3



Medical Board of California  
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ADVERSE EVENT REPORTING FORM FOR ACCREDITED OUTPATIENT SURGERY SETTINGS

Business and Professions Code (BPC) section 2216.3 requires accredited outpatient surgery settings subject to adverse event reporting requirements to follow:

- If facilities shall report an adverse event no later than five days after the adverse event has been identified, or
- If that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, no later than 24 hours after the adverse event has been detected.

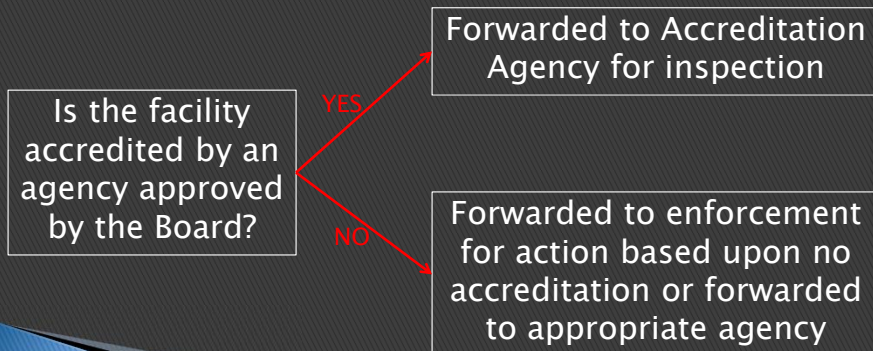
Facility Information	
Facility Name:	
Facility Address:	
Contact Person:	
Emergency Contact:	
Contact Phone:	
Facility Fax:	
Facility Information	
Name of Facility:	
Facility Type:	
License Number:	
Patient Information	
Patient's Name:	
(Last, First, Middle)	
Patient's Address:	
(Street, City, State, Zip)	
Patient's DOB:	
Patient's Phone Number:	
Medical Record Number:	
Patient's Next of Kin or Legal Representative (if applicable):	
Patient Deceased?	
Yes	No

Note: Under the Federal Health Insurance Portability and Accountability Act ("HIPAA"), the Medical Board of California is deemed a "health oversight agency" under 45 CFR 161.101. The disclosure of patient identification information is required for official use, including investigation and possible administrative proceedings regarding any violations of the laws of the State of California.

## Adverse Event Report Review Process **for the Setting**



- Adverse Event Report is received at the Board and given to the Licensing Program



## Adverse Event Report Review Process **for the Setting**



- ▶ After Inspection Survey results are received
  - Reviewed to ensure appropriate action is taken
  - Posted on website
  - If necessary, ensure corrective action plan is provided and outcome report posted
- ▶ If information indicates a physician departed from standard of care – refer to

**IMQ Institute for Medical Quality**  
221 Main Street, Suite 210 | San Francisco, CA 94108 | (415) 882-0181

**Plastic Surgery Center**

Street Address: [Redacted]  
City: Roseville  
State: CA  
Zip: 95678  
County: Placer  
Phone: [Redacted]  
Setting Type: Office-Based Surgery Center  
CMS Approved: No  
Initial Accreditation: 8/10/2000  
Accreditation Status: Effective Date: 8/8/2013 Expiration Date: 8/7/2016 Term: 3 Years  
Accreditation Renewed: [Redacted]  
Doing Business As Name: [Redacted] Plastic and Laser Center  
Specialties: Facial Plastic and Reconstructive Surgery  
Cosmetic Surgery  
Owners: [Redacted]  
Accreditation History: Effective Date: 8/8/2010 Expiration Date: 8/7/2013 Term: 3 Years  
Accreditation Renewed: [Redacted]

Inspection Date	Report	Deficiencies	Corrective Action Plan	Outcome	Outcome Report
7/1/2010	None*	No	None*		None*
7/2/2013	[Redacted]	Yes	[Redacted]	Requirements Met	[Redacted]

\* Report not required before 6/1/2012

## Adverse Event Report Review Process **for the Setting**



- ▶ Adverse Event Report is confidential
- ▶ Inspection Survey results are posted on the website

**IMQ Institute for Medical Quality**  
221 Main Street, Suite 210 | San Francisco, CA 94108 | (415) 882-0181

**Plastic Surgery Center**

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Inspection Date	Report	Deficiencies	Corrective Action Plan	Outcome	Outcome Report
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## Adverse Event Report Review Process **for the Physician**



- ▶ The adverse event report and any inspection report are used as “a report of a possible violation”
- ▶ Matter referred to the Complaint Unit and the enforcement process begins

## Adverse Event Reports



- ▶ FY 13/14 – 50 reports (partial year)
- ▶ FY 14/15 – 104 reports
- ▶ FY 15/16 – 111 reports
- ▶ FY 16/17 – 118 reports
- ▶ FY 17/18 – 165 reports (included transfers)



California Health and Safety Code (HSC)	Medical Board of California - Outpatient Settings
HSC 1248.15(a)(1)	Outpatient setting allied health staff must be licensed or certified to the extent required by state or federal law.
HSC 1248.15(a)(2)(A)	Outpatient settings must have a system for facility safety and emergency training requirements.
HSC 1248.15(a)(2)(B)	Must have available equipment, medication, and trained personnel to facilitate handling of services sought or provided and to facilitate handling of any medical emergency.
HSC 1248.15(a)(2)(C)(i)	Must have an approved written transfer agreement with a local accredited or licensed acute care hospital.
HSC 1248.15(a)(2)(C)(ii)	Allow surgery to be conducted by a licensee who has admitting privileges at a local accredited or licensed acute care hospital, with the exception that licensees who may have a written transfer agreement with licensees who have admitting privileges at local accredited or licensed acute care hospitals.
HSC 1248.15(a)(2)(C)(iii)	A detailed procedural plan for handling medical emergencies must be submitted by an accrediting agency for approval and review. No reasonable plan shall be disapproved by the accrediting agency.
HSC 1248.15(a)(2)(D)	A detailed plan, standardized procedures, and protocols for 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 must be submitted by an accrediting agency for approval. The plan must include, at a minimum, all of the following if a patient is being transferred to a local accredited or licensed acute care hospital:
HSC 1248.15(a)(2)(D)(i)	Notify the individual designated by the patient to be notified in case of an emergency.
HSC 1248.15(a)(2)(D)(ii)	The mode of transfer is consistent with the patient's medical condition.
HSC 1248.15(a)(2)(D)(iii)	All relevant clinical information is documented and accompanies the patient at the time of transfer.
HSC 1248.15(a)(2)(D)(iv)	Continue to provide appropriate care to the patient until the transfer is effectuated.



California Health and Safety Code (HSC)	Medical Board of California - Outpatient Settings
HSC 1248.15(a)(2)(E)	All physicians and surgeons transferring patients from an outpatient setting must agree to cooperate with the medical staff peer review process; if deemed appropriate, the results must be referred back to the outpatient setting 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 must be reported to the accrediting body or in accordance with existing law.
HSC 1248.15(a)(3)	The outpatient setting must permit surgery by a dentist, physician and surgeon, osteopathic physician and surgeon, or podiatrist acting within his or her scope of practice. The outpatient setting may, in its discretion, permit anesthesia service by a certified registered nurse anesthetist acting within his or her scope of practice.
HSC 1248.15(a)(4)	Outpatient settings shall have a system for maintaining clinical records.
HSC 1248.15(a)(5)	Outpatient settings shall have a system for patient care and monitoring procedures.
HSC 1248.15(a)(6)(A)	Outpatient settings shall have a system for quality assessment and improvement.
HSC 1248.15(a)(6)(B)(i)	Medical staff and other practitioners granted clinical privileges must be qualified and credentialed. The outpatient setting must grant privileges with recommendations from qualified health professionals and credentialing standards established by the outpatient setting.
HSC 1248.15(a)(6)(B)(ii)	Each licensee who performs procedures must be peer reviewed every two years on the basic qualifications, staff privileges, employment, medical outcomes, or professional conduct of a licensee for recommendations for quality improvement and education, including when there is only one licensee. The peer review must be performed by licensees who are qualified by education and experience. The findings of the peer review must be reported to the governing body to determine if the licensee continues to meet the requirements in clause (i). The results of the peer review must be reviewed by the accrediting agency at the next survey to determine if accreditation standards are being met .

California Health and Safety Code (HSC)	Medical Board of California - Outpatient Settings
HSC 1248.15(a)(6)(C)	On a periodically basis, clinical privileges must be reappraised by the outpatient setting. The scope of procedures performed must be periodically reviewed and amended as appropriate.
HSC 1248.15(a)(7)	Outpatient settings that have multiple service locations must have all of the sites inspected.
HSC 1248.15(a)(8)	The certificate of accreditation must be posted in a location that is visible to patients and staff.
HSC 1248.15(a)(9)	The name and telephone number of the accrediting agency with instructions on the submission of complaints must be posted in a location visible to patients and staff .
HSC 1248.15(a)(10)	Outpatient settings shall have a written discharge criteria.
HSC 1248.15(b)	A minimum of two staff persons must be on the premises, one should 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. Transfer of a patient to an unlicensed setting who does not meet the discharge criteria constitutes unprofessional conduct.
HSC 1248.15(c)	An accreditation agency may include additional standards to accredit outpatient settings if approved by the board.
HSC 1248.15(d)	No accreditation standard adopted or approved by the board, and no standard included in any certification program of any accreditation agency, should 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 by the outpatient setting. Privileges may not be arbitrarily restricted based on category of licensure.

California Health and Safety Code (HSC)	Medical Board of California - Outpatient Settings
HSC 1248.15(g)	<p>As part of the accreditation process, the accrediting agency must conduct a reasonable investigation of the prior history of the outpatient setting, including all licensed physicians and surgeons who have an ownership interest, to determine whether there have been any adverse accreditation decisions. 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 determine if 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.</p>