AGENDA ITEM 26

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED:	July 11, 2013
ATTENTION:	Medical Board of California
SUBJECT:	Review and Consideration of Request for Approval as an Outpatient Surgery Setting Accreditation Agency; American Osteopathic Association / Healthcare Facilities Accreditation Program
STAFF CONTACT:	Curtis J. Worden, Chief of Licensing

REQUESTED ACTION AND RECOMMENDATION:

The Medical Board of California (Board) Members approve the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) as a Board approved Outpatient Surgery Setting Accreditation Agency.

AOA/HFAP APPLICATION REVIEW ANALYSIS:

AOA/HFAP submitted an "Application for Approval as an Outpatient Surgery Setting Accreditation Agency" (Attachment 1- Application) with supporting documentation to the Board in late December 2012.

AOA/HFAP has been providing medical facilities with an objective, standards-based review of their services since 1945. In 2003, AOA/HFAP was granted "Deeming Authority" by the Center for Medicare and Medicaid Services (CMS) to conduct accreditation surveys of Ambulatory Surgical Centers, (Outpatient Surgery Settings) for CMS. In addition, AOA/HFAP is a CMS "Deeming Authority" to survey Acute Care Hospitals, Critical Care Hospitals, and hospital and facility laboratories.

Board Staff performed a preliminary review of the AOA/HFAP application and supporting documents for compliance with the criteria established in the Board's statutes and regulations. Board Staff then submitted the AOA/HFAP application and supporting documents, along with Staff's findings for executive level review. Following that review, additional information was requested from AOA/HFAP (Attachment 2).

On July 10, 2013, the Board received AOA/HFAP's response to the Board's request for clarification and additional information (Attachment 3). This new information was reviewed, and as part of that review process, the attached comparison chart (Attachment 4) was prepared substantiating AOA/HFAP's compliance with the established criteria.

STATUTORY/REGULATORY BACKGROUND:

Accreditation Agencies may submit to the Board an "Application for Approval as an Outpatient Surgery Setting Accreditation Agency" to be a Board approved Outpatient Surgery Setting Accreditation Agency with the appropriate application fee. Accreditation Agencies that apply for the Board's approval shall meet the criteria established pursuant to California Health and Safety Code section 1248.15.

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.

California Health and Safety Code (HSC) sections 1248 – 1248.85 were added to statutes in 1994 (AB595) and became effective January 1, 1995. HSC section 1248.4 was amended in 1997 (AB219) and became effective October 8, 1997. HSC section 1248.15 was amended in 1999 (AB271) and became effective January 1, 2000. HSC 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. HSC section 1248.35 was amended in 2012 (SB1095) and became effective January 1, 2013.

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 interpret statutes regarding Outpatient Surgery Setting Accreditation Agencies.

FISCAL CONSIDERATIONS:

AOA/HFAP submitted the applicable "Approved Outpatient Surgery Setting Accreditation Agency" application fee. If the Board grants approval to AOA/HFAP, it would be subject to the applicable renewal requirements.

If you have any questions concerning this memorandum, please contact me at (916) 263-2389.

ATTACHMENTS:

1. AOA/HFAP – Redacted Copy of "Application for Approval as an Outpatient Surgery Setting Accreditation Agency," Supporting Documentation Not Included

2. Board Correspondence to AOA/HFAP Requesting Clarification and Additional Information Dated July 1, 2013

3. AOA/HFAP's Response to the Board's Request for Clarification and Additional Information Received July 10, 2013

4. HSC §1248.15 and AOA/HFAP Responses Comparison Chart

MEDICAL BOARD OF CALIFORNIA
LICENSING PROGRAM
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815
(916) 263-2382 Fax: (916) 263-2487
www.mbc.ca.gov

APPLICATION FOR APPROVAL AS AN OUTPATIENT SURGERY SETTING ACCREDITATION AGENCY

$5000.00 Fee
Please print or type.
All illegible applications will be returned.

FOR OFFICE USE ONLY

Fee Pd _____ Rcpt. No. _____

Date Filed _____ RC No. _____

Date Approved _____

Date Denied _____

Name of Organization applying for approval as Outpatient Surgery Setting Accreditation Agency	American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)	
Address of Organization applying for approval as Outpatient Surgery Setting Accreditation Agency	142 East Ontario Street, Chicago, Illinois 60611	
Telephone and Fax Numbers:	Telephone 312.202.8258	Fax 312.202.8361
Date Organization began to operate as an Accreditation Agency:	1945	
The Organization is a(n): (Check ✓ one box only)	☐ Individual (Sole Proprietor) ☐ Partnership	☐ Group of Individuals ☑ Corporation
Contact Person's Full Name and Title	Joseph L. Cappiello, Chief Operating Officer	
Applicants Social Security Number or Federal Employer ID Number	Federal Employer ID	
Telephone and Fax Numbers: (Contact Person)	Telephone	Fax

Please answer each question listed below by checking either "Yes" or "No". Attach an explanation for any question answered "No". Documentation may be required upon request by the Licensing Program.

Question	Yes	No	Documentation To Be Made Available Upon Request
Does your Organization have accreditation standards for outpatient settings as well as the standards for patient care and safety at the setting?	☑	☐	2 Sets of accreditation standards.
Are your Organization's standards for accreditation developed with the input of the medical community and the ambulatory surgery industry?	☑	☐	2 copies of the Development Process.
Does your Organization have a process by which its accreditation standards are reviewed and revised no less than every three years?	☑	☐	2 copies of the Review Process.
Does your Organization maintain internal management programs to ensure the quality of its outpatient setting accreditation process?	☑	☐	2 copies of the Quality Control Program(s) process.
Does your Organization require outpatient settings that it accredits, to notify it of certain changes (e.g., operation, services, ownership, etc.) with respect to the setting?	☑	☐	2 copies of the Notification Requirements.
Does the Organization maintain an available pool of allied health care practitioners to serve on accreditation review (survey) teams in California?	☑	☐	
Are reviewers (Surveyors) screened and credentialed by your Organization?	☑	☐	2 copies of the Screening and Credentialing Processes.
Does your Organization provide formal education training programs in the evaluation of certification standards that each reviewer (Surveyor) must attend at least every three years?	☑	☐	2 Sets of current Evaluation Training Manuals, and Training Schedule.
Does the composition of each of your Organizations review (survey) team(s) consist of at least one physician and surgeon who practices in an outpatient setting?	☑	☐	2 copies of the Physician & Surgeon Surveyors' Roster (Must include each physician's name, license number, telephone number, field of medical practice, the number of on-site inspections completed, and the date each last attended surveyor training.)

Question	Yes	No	Documentation To Be Made Available Upon Request
Does the composition of your Organization's review (survey) team(s) consist of other allied health care practitioners actively practicing in outpatient setting?	☑	☐	2 copies of the Allied Health Care Practitioners' Roster (must include each individual's name, license number (if applicable), telephone number, field of medical practice, the number of on-site inspections completed, and the date each last attended surveyor training.)
Does your Organization provide its reviewers (surveyors) with printed material to use in the on-site inspection of an outpatient surgery setting?	☑	☐	2 Sets of the Surveyor inspection material, and surveyor instructions for completing an on-site inspection.
Does your Organization issue any type of accreditation certificate to an outpatient surgery setting that passes its on-site inspection and meets with your Organization standards?	☑	☐	2 copies of each type accreditation certificate issued, and accreditation decision process.

California state law precludes an accreditation agency from having an ownership interest in or being involved in the operation of a freestanding outpatient setting or in the delivery of health care services to patients.

1. Does your Organization have an ownership interest in any freestanding outpatient setting?		Yes	x	No
2. Is your Organization involved in the operation of any freestanding outpatient setting?		Yes	x	No
3. Is your Organization involved the delivery of any health care services to patients?		Yes	x	No

If you answered "YES" to questions 1, 2, or 3, please attach an explanation

The applying accreditation agency must agree, as part of the approval, to submit the following items with the application per Health and Safety Code section 1248.4(b): 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.

DECLARATION

I hereby declare under the penalty of perjury under the laws of the State of California that all information contained in this application, and all attachments thereto, submitted to the Medical Board of California in support of this application are true and correct to the best of my knowledge, and that I have the legal authority to sign this application on behalf of the applicant.

Executed at Chicago (City), Illinois (State), this 20th day of December, 2012

By: Joseph L. Cappiello
Type or Print Full Name

Chief Operating Officer
Type or Print Title


Signature

Submit the completed application with fee and requested documentation to:

Medical Board of California, Licensing Program
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815

Questions regarding the completion of this application may be directed to the Outpatient Surgery Settings Unit at the aforementioned address or by telephone at (916) 263-2393.

The Information Practices Act, Section 1798.17 Civil Code, requires the following information be provided when collecting information from individuals. Agency Name: Medical Board of California, Licensing Program, 2005 Evergreen Street, Suite 1200, Sacramento, CA 95815; Telephone: (916) 263-2382. The official responsible for information maintenance is the Program Manager. The authority which authorizes the maintenance of this information is Business and Professions Code. Public Law 94-455(42 U.S.C.A. 405(c)(2)(C)) authorizes collection of your Social Security Number (SSN) and/or federal employer identification number (FEIN). Your SSN and/or FEIN will be used exclusively for tax enforcement purposes and for purposes of compliance with any judgment or order for family support in accordance with Section 11350.6 of the Welfare & Institutions Code. If you fail to disclose your SSN or FEIN, you will be reported to the Franchise Tax Board, which may assess a $100 penalty against you. Failure to provide all or any part of the requested information will result in this form being rejected as incomplete. The principal purpose(s) for which the information is to be used is to determine your eligibility. Any known or foreseeable interagency or intergovernmental transfer which may be made of the information, when necessary, is to other federal, state and local law enforcement agencies. Each individual has the right to review the files or records maintained on them by the agency, except for information exempt from disclosure, pursuant to Section 6254 of the government Code or Section 1798.40 of the Civil Code.

CERTIFICATION PROGRAM – HEALTH AND SAFETY CODE §1248.15			
		To be completed by accreditation agency	To be completed by Medical Board Staff
H & S Code Section	Summary of Requirement	List agency standard that applies and where applicable standards is located.	Does agency meet requirements?
Part 1 – Staff Privileges			
1248.15(2)(C)(ii)	An outpatient setting may 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.	**06.00.02 Medical Staff Membership & Clinical Privileges.** Members of the Medical Staff must be legally and professionally qualified for the positions to which they are appointed and for performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel. **06.00.04 Other Practitioners** If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities. Allied Health Practitioners (AHP) privileges must be consistent with federal and state regulations applicable to their specific profession. **01.00.04 Hospitalization** The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. This hospital must be a local, Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under 482.2 of 42 Code of Federal Regulation. **01.00.05 Transfer Agreement** The ASC must satisfy one of the following: Have a written transfer agreement with a hospital that meets the requirements of Federal Regulation. Ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements of paragraph (b)(2).	
1248.15(6)(B)	Medical staff and other practitioners granted clinical privileges shall be professionally qualified and appropriately credentialed for the	**06.00.02 Medical Staff Membership & Clinical Privileges.** Members of the Medical Staff must be legally and professionally qualified for the positions to which	

	privileges granted. Additionally, an outpatient setting shall grant privileges in accordance with recommendations from qualified health professionals, and credentialing standards established by the outpatient setting.	they are appointed and for performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel. **06.00.04 Other Practitioners** If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities. Allied Health Practitioners (AHP) privileges must be consistent with federal and state regulations applicable to their specific profession.	
1248.15(a)(1)	An outpatient setting's allied health staff shall be appropriately licensed or certified.	**06.00.04 Other Practitioners** If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities. Allied Health Practitioners (AHP) privileges must be consistent with federal and state regulations applicable to their specific profession.	
1248.15(10)(b)	Outpatient settings shall 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 shall constitute unprofessional conduct.	**07.00.02 Organization & Staffing** Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC. **05.01.08 Emergency Personnel** Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.	
Part 2 – Medical Services			
1248.15(0)(3)	An outpatient setting shall permit surgery by a dentist, physician and surgeon, or podiatrist acting within his or her scope of practice pursuant to the governing the licensee. Additionally, at the discretion of the outpatient setting, a certified registered nurse anesthesia may be permitted to provide anesthesia services within his or her scope of practice pursuant to the laws governing the licensee.	**03.05.01 Anesthesia** Administrator's Qualifications Only physicians, dentists or podiatrists who are qualified by education, training and licensure to administer moderate sedation (conscious sedation) should supervise the administration of moderate sedation (conscious sedation). **03.00.05 Administration of Anesthesia** Anesthetics must be administered by only: 1. A qualified anesthesiologist 2. A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined 410.69(b) of 42 Code of Federal Regulation, or a supervised trainee in an approved educational program. In	

		those cases in which a nonphysician administers the anesthesia, unless exempted in accordance with paragraph [(c)} of 42 Code of Federal Regulation, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist. **03.00.06 State Exemption** An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of 42 Code of Federal Regulation, if the state in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the state and has concluded that it is in the best interests of the state's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with state law.	
1248.15(2)(B)	An outpatient setting shall have onsite equipment, medication, and trained personnel to facilitate handling the services sought or provided, and any medical emergency that may arise in the connection with those services.	**05.00.01 Environment** The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients. **05.00.03 Operating Room Design** Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area. **05.00.04 Recovery Room & Waiting Area** The ASC must have a separate recovery room and waiting area. **05.01.01 Safety from Fire** Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Centers of the 2000 edition of the Life Safety Code of the National Fire Protection Association, regardless of the number of patients served. **05.01.05 Emergency Lighting** An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006. **05.01.07 Emergency Equipment**	

		The ASC medical staff and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room. The equipment must meet the following requirements: (1) Be immediately available for use during emergency situations; (2) Be appropriate for the facility's patient population; (3) Be maintained by appropriate personnel. **05.01.08 Emergency Personnel** Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC. **07.00.01 Nursing Services** The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met. **07.00.02 Organization & Staffing** Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. These must be a registered nurse available for emergency treatment whenever there is a patient in the ASC. **09.00.01 Pharmaceuticals** The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice and under the direction of the individual responsible for pharmaceutical services. **09.00.02 Administration of Drugs** Drugs must be prepared and administered according to established policies and acceptable standards of practice. **09.00.03 Adverse Reactions** Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.	
Part 3 – Patient Care			
1248.15(2)(C)(i)	An outpatient setting must have a written transfer agreement with a local accredited or licensed acute care hospital, approved by the facility's medical staff. A written transfer agreement shall include a – mechanism for patient transport; a	**01.00.04 Hospitalization** The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. This hospital must be a local, Medicare-participating	

	plan for transfer of the patient's records; policies defining the role of each person handling an emergency; and a plan for continuity of the patient's care upon transfer of that care.	hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under 482.2 of 42 Code of Federal Regulation.	
1248.15(D)	All physicians and surgeons transferring patients from an outpatient setting shall agree to cooperate with the medical staff peer review process in those transferred cases.	**01.00.02 Governing Body & Management** The ASC must have a Governing Body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan. Any quality related issues will be forwarded to the QAPI committee, the CEO and the Governing Body (this can include transfers, burns, falls, deaths, SSI). **01.02.02 Medical Staff Appointments** The Governing Body must appoint and reappoint the medical staff. The ASC establishes criteria for initial and reappointment to staff membership which includes current supporting documents of: a. License (including narcotics registration, if applicable) b. Training/education c. Current competence including current peer evaluation **01.02.03 Information for Medical Staff Applications.** In addition to the completed application and current supporting documentation, the Governing Body and competent authority must use additional available information when taking action on applications for appointment and reappointment and in awarding current privileges, including: a. Documentation of relevant continuing education. b. Current information obtained from the National Practitioner Data Bank. c. Documentation of changes in board eligibility or certification status. d. ASC quality information and peer review evaluations. e. Voluntary or involuntary reductions or limitations in privileges or membership at any hospital, or the ASC. f. Procedure logs from other ASC(s) to support	

		privilege requests for procedures not attested to in the past.	
8.15(2)(C)(iii)	An outpatient setting is required to submit for approval to the accrediting agency, a detailed procedural plan for handling medical emergencies.	**01.00.03 Governing Body & Management** The ASC must have a Governing Body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan. **01.00.06 Disaster Preparedness Plan** The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC.	
1248.15(10)	Outpatient settings shall have written a discharge criteria.	**03.00.01 Evaluation for Anesthesia Recovery** Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at 410.69(b) of 42 Code of Federal Regulation, in accordance with applicable state health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery. An evaluation of the patient's recovery from anesthesia, to determine whether the patient is recovering appropriately, must be completed and documented before the patient is discharged from the ASC. American Society of Anesthesiology (ASA) guidelines do not define moderate or conscious sedation as anesthesia. While current practice dictates that the patient receiving conscious sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, a postanesthesia evaluation is not required. The evaluation must be completed and documented by a physician or anesthetist, as defined at 42 CFR 410.69(b), i.e., a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant. See the discussion of §416.42(b) for more discussion of CRNA and anesthesiologist's assistant requirements. ASCs would be well advised in developing their policies and procedures for postanesthesia care to consult recognized guidelines. For example, Practice	

		Guidelines for Postanesthetic Care, Anesthesiology, Vol 96, No 3, March, 2002, provides the recommendations of the American Society of Anesthesiologists for routine postanesthesia assessment and monitoring, including monitoring/assessment of: o Respiratory function, including respiratory rate, airway patency, and oxygen saturation o Cardiovascular function, including pulse rate and blood pressure o Mental status o Temperature o Pain o Nausea and vomiting o Postoperative hydration Depending on the specific surgery or procedure performed, additional types of monitoring and assessment may be necessary. **03.13.01 Discharge** The ASC Must: 1. Provide each patient with written discharge instructions. 2. Ensure the patient has a safe transition to home and that the post surgical needs are met. 3. Ensure each patient has a discharge order, signed by a physician or the qualified practitioner who performed the surgery or procedure unless otherwise specified by state law. The discharge order must indicate that the patient has been evaluated for proper anesthesia and medical recovery. • Postoperative assessment **03.13.02 Discharge Assessment** Assessment and evaluation for discharge must be documented by a physician. Rules and regulations approve by the Governing body, define the discharge criteria from PACU. These, if used in lieu of a practitioner assessment/order, are consistently applied whenever postanesthesia recovery occurs. Even when the above rules are used. **03.13.03 Discharge & Transportation** All patients are discharged in the company of a responsible adult, except those exempted by the attending physician. **03.13.04 Discharge Instructions** Ambulatory surgery patients and their families - companions as appropriate, are provided with instructions regarding post procedure management in language that the patient or accompanying responsible person can understand.	

		06.01.10 Discharge Criteria The Medical Staff periodically reviews and makes recommendations to the Governing Body, on discharge criteria, if any, for discharge from post-anesthesia observation. **08.05.01 Discharge Planning** Prior to discharge from the current session of care, the physician must determine the advisability and safety of the patient's discharge destination make arrangements for follow-up care and provide for appropriate transportation to their home. **08.05.02 Evaluation of Patient's Condition** All ASC(s) must have a process for evaluating and re-evaluating the patient's condition upon arrival and throughout their stay.	
1248.15(D)(5)	An outpatient setting shall have a system for patient care and monitoring procedures.	**03.01.01 Invasive Procedures Performed in Appropriate Environment.** ASC invasive procedures must be performed in an operating room. The Governing Body, based upon recommendation of competent medical authority, must define for each location where invasive procedures are performed: 1. The type of procedure(s) that may be performed in that location. **03.02.04 Monitoring Patients under Moderate Sedation (Conscious Sedation)** When only moderate sedation (conscious sedation) is implemented, a RN or other provider licensed by the state must monitor the patient. Check the state law requirements. **03.04.01 Adequate Instrumentation in Operating Rooms** Instruments, supplies and equipment must be in sufficient quantity and located so that movement is minimized during cases. Processed instruments are protected from surface/airborne contamination. **06.01.08 Patient Monitoring Frequency** The Medical Staff periodically reviews and makes recommendations to the Governing Body on the minimum frequency of monitoring and recording of critical physiological measures of patients before, during and after permitted procedures. **03.05.03 Intra-operative/Procedural Anesthesia (Time-Based Record of Events)** When a topical anesthetic or local block is used: Immediately prior to initiation of the topical anesthetic or local block, the patient will be assessed.	

After initial administration and prior to initiation of the laser/surgical procedure or treatment, determination of the effectiveness of the topical anesthetic or local block.

When moderate sedation (conscious sedation) through general anesthesia is used:
There is an anesthesia event which reflects the management of the patient during the anesthetic administration including the following parameters:

A. Immediate review prior to initiation of anesthetic procedures:
   - Patient re-evaluation
   - Check of equipment, drugs and gas supply
B. Monitoring of the patient** (e.g., recording of vital signs).
C. Amounts of drugs and agents used, and times of administration.
D. The type and amounts of intravenous fluids administered if administered, including blood and blood products, and times of administration.
E. The techniques(s) used.
F. Unusual events during the administration of anesthesia.
G. The status of the patient at the conclusion of anesthesia.

03.05.04 Post-anesthesia Evaluation
When a topical anesthetic or local block is used:

A. Patient assessment for pain and range of motion if appropriate.

When moderate sedation (conscious sedation) through general anesthesia is used:

A. Patient evaluation on admission and discharge from the postanesthesia care unit.
B. A time-based record of vital signs and level of consciousness.
C. A time-based record of drugs administered their dosage and route of administration.
D. Type and amounts of intravenous fluids administered, if administered, including blood and blood products.
E. Any unusual events including post anesthesia or post procedural complications.
F. Postanesthesia visits.

07.00.01 Nursing Services
The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

07.00.02 Organization & Staffing
Patient care responsibilities must be delineated for

		all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. These must be a registered nurse available for emergency treatment whenever there is a patient in the ASC. **07.01.04 Administration of Medications** Medications must be administered only by individuals licensed to do so or under the direct supervision of a licensed provider. The ASC shall have policies and procedures to administer medications that are current.	
1248.15(D)(4)	An outpatient setting shall have a system for maintaining clinical records.	**08.00.01 Medical Record for Each Patient** The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care. **08.00.02 Organization** The ASC must develop and maintain a system for the proper collection, storage, and use of patient records. **08.00.03 Form & Content of Record** The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following: 1. Patient identification 2. Significant medical history and results of physical examination 3. Preoperative diagnostic studies (entered before surgery), if performed 4. Findings and techniques of the operation including a pathologist's report on all tissues removed during surgery, except those exempted by the Governing Body 5. Any allergies and abnormal drug reactions 6. Entries related to anesthesia administration 7. Documentation of properly executed informed patient consent 8. Discharge diagnosis **08.01.02 Record Storage** Clinical records must be stored in secure locations, away from access by unauthorized individuals and secure from destruction by fire or disaster. **08.02.03 Medical Record Distinct Identifier** Each medical record must have a distinct identifier, unique for each patient, and documentation on each patient must be consolidated into one clinical record. Each page within the record will contain patient identification. **08.02.04 Medical Records Accurate, Organized &**	

		Accessible All ASC medical records must be arranged in a consistent manner, appropriate to the scope and complexity of services offered. The medical records must be accurate, readily accessible and systematically organized. **08.03.01 Medical Record Content** The medical record must also include: 1. A record of all medications, treatments, advice, or evaluations ordered or provided. 2. A legible, chronological record of care given, which must be authenticated by the provider of that care, with the date care was provided and the time care was provided when appropriate. 3. As appropriate, each visit will include the Subjective complaint, the Objective findings, an Analysis and a Treatment Plan with follow-up instructions. **08.03.02 Medical Record Content (cont'd)** For patients seen more than once, the clinical record must contain a list of chronic conditions, including chronic medications, and an updated list of appropriate preventive medicine evaluations and treatments. **08.03.03 Time Frame for Completion of Physical Examination** The ASC, in conjunction with the professional staff, must define the scope and time for completion of any physical examination (PE) required based upon the care to be provided or procedure to be performed. **08.03.04 Scope of Medical Record Defined** The ASC must define the scope of the medical, dental, family, work, drug or alcohol use, psychosocial history(s) to be obtained and documented and the time frame when the history(s) must be completed. **08.03.05 Documentation Requirements Defined** The ASC must establish or implement evaluation and documentation requirements for specific conditions or care in accordance with professional recommendations and standards. **08.03.06 Medical Record – Drugs** Medical records entries for prescribed drugs must include at least: a. Drug name b. Dosage c. Amount prescribed d. Directions for taking or using e. Frequency of usage	

		f. Patient's name g. Patient's number	
Part 4 – Additional Standards			
1248.15(b)(c)	An accreditation agency may include additional standards in its determination to accredit outpatient settings, if these are approved by the division to protect the public health and safety. An accreditation agency shall send to the division any change in its accreditation standards within 30 calendar days after making the change. (16 CCR 113.4 (b)) An accreditation agency shall, within fourteen calendar says 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 agency it denies or revokes, the accreditation agency shall also provide to the division in writing the reasons for its action. (16 CCR 1313.4 (c))	See attached accreditation manual: **Accreditation Requirements for Ambulatory Surgical Centers.**	
Part 5 – Safety and Emergency Training			
1248.15 (2)(A)	An outpatient setting shall have a system for facility safety and emergency training requirements.	**08.04.04 Required Emergency Training** The ASC in conjunction with the medical director must determine the level of initial and recurrent emergency training required for each level of staff. **01.00.06 Disaster Preparedness Plan** The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC. **02.01.14 ASC Provides OSHA Training as Appropriate** The ASC must comply with training requirements and documentation as required by the Occupational Health and Safety Administration (OSHA) for all personnel whose duties involve occupational exposure to	

		Bloodborne Pathogens. **02.01.15 ASC Provides HAZMAT Training as Appropriate** All personnel, whose workplace exposure requires it, must have documented initial and periodic Hazardous materials (HAZMAT) training. Material Safety Data Sheets (MSDS) for each hazardous material/chemical will be maintained in each workplace. **05.01.08 Emergency Personnel** Personnel trained in the use of emergency equipment and in Cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.	
Part 6 – Quality Control			
1248.15(6)(A)	An outpatient setting shall have a system for quality assessment and improvement. The required system for quality assessment and improvement shall include, in addition to chart review, actins that utilize information derived through quality assessment to improve systems to maximize patient protection. (16 CCR 1314(a)(2))	**01.00.02 Governing Body & Management** The ASC must have a Governing Body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan. **02.00.08 CEO & Executive Team Serve as QAPI Committee** The CEO and/or selected members of the executive team, or the group as a whole serve on the Quality Assessment Performance Improvement (QAPI) committee. **04.00.01 Quality Assessment Performance Improvement.** The ASC must develop, implement and maintain an ongoing, data-driven Quality Assessment Performance Improvement (QAPI) program. **04.00.03 Track Quality Indicators** The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that	

		includes care and services furnished in the ASC.	
Part 7- Periodic Review			
1248.15(6)(C)	An outpatient setting shall periodically reappraise its clinical privileges, and review and amend as appropriate, the scope of procedures it performs.	**06.00.03 Reappraisals** Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate. The medical staff, as a body or as a committee, will review and make recommendations to the governing body on all applications for reappointment to the professional staff. The ASC must have a policy on this function. **06.00.04 Other Practitioners** If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities. Allied Health Practitioners (AHP) privileges must be consistent with federal and state regulations applicable to their specific profession. **06.00.03 Reappraisals** Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate. The medical staff, as a body or as a committee, will review and make recommendations to the governing body on all applications for reappointment to the professional staff. The ASC must have a policy on this function.	
Part 8 – Posting of Accreditation Agency Information			
1248.15(8)	Outpatient settings shall post the certificate of accreditation readily visible to patients and staff.	See Section II. The Bureau of Healthcare Facilities Accreditation (page ix) A. Bureau Authority and Procedure - Health Care Facilities 1. The Bureau has been delegated authority by the American	

		Osteopathic Association Board of Trustees: a. To conduct accreditation surveys of health care facilities. b. To evaluate the survey reports, and on the basis of the survey findings, to grant, deny, or withdraw accreditation to those health care facilities seeking accreditation. 2. Accreditation actions that may be taken for health care facilities are: a. Preliminary Accreditation – The organization demonstrates compliance with selected standards in surveys conducted under the Early Option Survey Policy. b. Accredited – indicates that a healthcare facility meets the HFAP accreditation requirements and, based on the decision of the Executive Committee, accreditation may be granted for one, two, or three years. c. Interim Accreditation – (not applicable for organizations seeking initial accreditation) indicates that a facility generally meets the standards, but that certain areas have been identified which require additional work to be compliant. The facility is required to complete the additional work within a specified period of time, as defined by the Executive Committee that will not exceed twelve months, in order to remain accredited. d. Denial of Accreditation – indicates that a healthcare facility has been denied accreditation because it does not meet HFAP requirements. 3. A random sample of five (5) percent of accredited ASCs will receive a mid-cycle review in order to demonstrate that facilities maintain their compliance with the HFAP requirements throughout the three-year accreditation period. 4. A health care facility that has been granted accreditation is provided with an HFAP Certificate	

		of Accreditation. 5. The Bureau may alter the accreditation status of a health care facility for just cause. Just cause includes, but is not limited to, failure to maintain compliance with HFAP accreditation requirements.	
1248.15(9)	Outpatient settings shall post the name and telephone numbers of the accrediting agency with instructions on the submission of complaints in a location readily visible to patients and staff.	**11.00.05 Notice of Rights** The ASC must, prior to the start of the surgical procedure, provide the patient, the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the patient's representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Website for the Office of the Medicare Beneficiary Ombudsman.	
rt 9 – Certificates of Approval			
1248.15(7)	Outpatient settings regulated by Chapter 1.3 – Outpatient Settings that have multiple service locations governed by the same standards may elect to have all service sites surveyed on any (one) accreditation (agency) survey. An organization that elects not to have all its service sites surveyed shall have at a maximum no more than 20 percent of the sites surveyed. The actual sample size shall be determined by the accreditation agency. The accreditation agency shall determine the location of the sites to be surveyed. Outpatient settings that have 5 or fewer sites shall have at least 1 site surveyed. An organization that elects to have a sample of its sites surveyed and is approved for accreditation, all of the organization's sites shall be automatically accredited.	See HFAP Surveyor Handbook under TEAM COMPOSITION, beginning at page (7).	

CERTIFICATES OF ACCREDITATION – HEALTH & SAFETY CODE 1248.3			
10 – Certificates of Approval			
1248.3(a)	Certificates of accreditation issued to outpatient settings by an accreditation agency shall be valid for not more than three years.	A health care facility that has been granted accreditation by the Healthcare Facilities Accreditation Program is awarded a Certificate of Accreditation for a three year period. **See page ix of the Accreditation Requirements of Ambulatory Surgical Centers.** D. Survey Procedures 1. Health care facility surveys will be unannounced and conducted on a three-year cycle by a combination of the following approved surveyor categories: physician, health care facility administrator, registered nurse, and a life safety code specialist. The number of surveyors, the combination of surveyors, and the survey days will vary based on the size and complexity of the health care facility. The fee for each survey will take into account the complement of the survey, i.e., the length of the survey and the number of surveyors assigned to the survey. **See page x of the Accreditation Requirements for Ambulatory Surgical Centers.** **II. The Bureau of Healthcare Facilities Accreditation** A. Bureau Authority and Procedure - Health Care Facilities 1. The Bureau has been delegated authority by the American Osteopathic Association Board of Trustees: a. To conduct accreditation surveys of health care facilities. b. To evaluate the survey reports, and on the basis of the survey findings, to grant, deny, or withdraw accreditation to those health care facilities seeking accreditation. 2. Accreditation actions that may be taken for health care facilities are: **a. Preliminary Accreditation** – The organization demonstrates compliance with selected	

		standards in surveys conducted under the Early Option Survey Policy. **b. Accredited** – indicates that a healthcare facility meets the HFAP accreditation requirements and, based on the decision of the Executive Committee, accreditation may be granted for one, two, or three years.	
ACCREDITATION PROGRAM – HEALTH & SAFETY CODE 1248.4 (C)			
Part 11 – Agency Standards			
1248.4(c)(1)	An accreditation program, at a minimum, must include the standards for accreditation of outpatient settings approved by the division as well as standards for patient care and safety at the outpatient setting.	See BUREAU OF HEALTHCARE FACILITIES ACCREDITATION (BHFA) (see pages (3) & (4) of Surveyor Handbook. The AOA Bureau of Healthcare facilities Accreditation (BHFA) is the body, which makes accreditation decisions. The committee provides a wide-spread representation of healthcare professionals, including: •Surgery •Obstetrics •Gynecology •Medical education •Medical administration •Osteopathic manipulation •Internal medicine •Family practice •Pathology •Hospital administration pharmacy •Nursing The BHFA meets three times per year to review accreditation policy issues, and proposed additions, changes, and deletions to accreditation requirements. The BHFA takes accreditation actions based on the results of the accreditation surveys and the corrective actions taken by the health care facility, in response to any cited deficiencies. When called, the BHFA's Executive Committee convenes monthly to review policies, procedures, additions to standards, deletions of standards, updates to standards, and make accreditation decisions.	

1248.4(c)(2)	An accreditation agency must submit its current accreditation standards to the division every three years, or upon request for continuing approval by the division.	See Current HFAP Accreditation ASC Manual for 2013.	
1248.4(c)(4)	An accreditation agency must have a process by which accreditation standards can be reviewed and revised no less than every three years.	The HFAP accreditation standards are reviewed annually – Please see 2013 ASC HFAP manual.	
1248.4(c)(8)	Standards for accreditation shall be developed with the input of the medical community and the ambulatory surgery industry.	Please refer to HFAP references such as CMS/ CfC/ NQF/ AORN/ APIC & CDC. Ambulatory also participates in the ASC Quality Collaboration regarding quality outcome measurements. Standards are reviewed by the Bureau specialty disciplines for current content and best practices.	
Part 12 – Review Teams			
1248.4(c)(5) & 1248.4(c)(6)	An accreditation agency must maintain an available pool of allied health care practitioners to serve on accreditation review teams as appropriate. The accreditation review teams shall do all of the following:	See application requirements	
1248.4(c)(6)(A)	Accreditation review teams must consist of at least one physician and surgeon who practices in an outpatient setting; any other members shall be practicing actively in these settings.	See application requirements	
1248.4(c)(6)(B)	Accreditation review teams must participate in formal education training programs provided by the accreditation agency in evaluation of the certification standards at least every three years.	See application requirements	
1248.4(c)(7)	An accreditation agency shall demonstrate that professional members of its review team have experience in conducting review activities of freestanding outpatient settings.	See application requirements	
1248.4(c)(9)	Accreditation reviewers shall be credentialed and screened by the accreditation agency.	See application requirements	
Part 13 – Quality Control			
1248.4(c)(3)	An accreditation agency must maintain internal quality management programs to ensure quality of the accreditation	See attached HFAP policy. "The Quality Management Program"	

	process.		
14 – Conflict of Interest			
1248.4(c)(10)	An 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.	NA- HFAP does not participate in this type of practice or ownership.	
Part 15 - Comments			

MEDICAL BOARD OF CALIFORNIA
Licensing Program

July 1, 2013

Sent Via Email: JCappiello@HFAP.org

Joseph L. Cappiello
Chief Operating Officer
American Osteopathic Association /
Healthcare Facilities Accreditation Program
142 East Ontario Street
Chicago, IL 60611

RE: APPLICATION FOR APPROVAL AS AN OUTPATIENT SURGERY SETTING ACCREDITATION AGENCY

Dear Mr. Cappiello:

The Medical Board of California (Board) has reviewed the information you have provided in your "Application for Approval as an Outpatient Surgery Setting Accreditation Agency" and request additional information or clarification on the following items:

Questions one through four are also being asked of all approved Accreditation Agencies and as part of your request for approval. The additional questions are regarding AOA/HFAP's request for approval by the Board:

1) California Business and Professions Code §2216.2 requires a physician and surgeon 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 §2216.2(d) further requires that 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.

    a. Title 16 of the California Code of Regulations §1304 defines "adequate security" to mean that a physician has coverage of the type prescribed in Section 2216.2 of the code in the amount of not less than one million dollars per incident and not less than three million dollars per year.

b. Please provide information on AOA/HFAP's standards regarding liability insurance for physicians and surgeons performing surgery outside of general acute care hospitals. Please indicate how these standards are evaluated by AOA/HFAP.

2) California Health and Safety Code §1248.15(a)(2)(b) requires that there shall be on-site 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.

   a. Please provide information on AOA/HFAP's standards regarding on-site equipment, medication, and trained personnel to facilitate handling of service provided and medical emergencies.

3) California Health and Safety Code §128.15(a)(6)(B) requires that members of the medical staff and other practitioners who are granted clinical privileges shall be professionally qualified and appropriately credentialed for the performance of the privileges granted. Members of the Medical Board's Outpatient Surgery Setting Task Force have requested additional information on how this provision is implemented by accreditation agencies.

   a. Please provide information on the safeguards within the credentialing process to prevent an untrained and/or limited trained physician from performing procedures they are not qualified to perform.

4) California Health and Safety Code §1248.15(c) allows an accreditation agency to include additional standards in its determination to accredit outpatient settings if these are approved by the board to protect the public health and safety.

   a. Please provide a complete list of any and all standards required by AOA/HFAP that are not specifically required by California law. This information will be presented to the members of the Medical Board of California at an upcoming quarterly Board meeting as a "side-by-side" comparison of the additional standards required by each of the accreditation agencies that have been approved by the Board.

   b. Please provide the answers to following questions and/or request for additional information:

5) When is the first site visit for the Outpatient Surgery Setting facility that is currently applying for accreditation?

6) The Board has asked each of the approved Accreditation Agencies to provide information regarding the Outpatient Surgery Settings that they have certified for CMS as Medicare facilities. Will AOA/HFAP also provide the Board with these CMS certified facilities for includion on the Board's Web site in our efforts to assist California consumers?

7) Has AOA/HFAP formally adopted all of the draft Policy/Procedures that were initially provided to the Board at the time of application for approval as a Board-approved Accreditation Agency?

8) Page 3 of 4 of the Quality Management Plan states …."No disclosure of any reports…". Will these reports be provided to the Board?

9) Does AOA/HFAP use the Medicare/Medicaid standards to accredit non-CMS certified Outpatient Surgery Settings?

10) Are Non-CMS certified Outpatient Surgery Settings required to have a formal and posted transfer plan to a hospital that accepts Medicare?

11) Does HFAP require peer review processes for physician & surgeons? This information is not referenced in the Governing Body & Management section, 0100.02. California regulation code 1248.15 (D) references physicians and surgeons who transfer patients from an Outpatient Surgery Setting shall agree to cooperate with the medical staff peer review process in those transferred cases.

12) HFAP performs on-site inspections within 120 days of expiration dates for re-accreditation. How often do Outpatient Surgery Settings undergo regular and routine on-site inspections? Are on-site inspections performed for initial and/or renewal accreditations?

13) Are Outpatient Surgery Settings required to post the certificate of accreditation to be readily visible and accessible to patients and staff at the facility?

14) Inspection teams must comply with the following criteria:
- Accreditation reviewers must be credentialed and screened by the accreditation agency.
- Professional members of the accreditation review team must have experience in conducting review activities of free-standing outpatient settings.
- Participation in formal education training programs provided by the accreditation agency.

Please provide information identifying where these requirements are specifically addressed in the HFAP manual.

15) The Board is required to post the following information to the Board's Web site pursuant to California Health and Safety Code (HSC) Section 1248.2:
- Whether an outpatient setting is accredited; or whether the setting's accreditation has been revoked, suspended, or placed on probation; or whether the setting has received a reprimand by the Accreditation Agency.
- The list of outpatient settings shall include all of the following:
  - Name, address, and telephone number of any owners, and their corresponding medical license numbers.
  - Facility ownership percentage for each owner.

- Name and address of the facility.
- The name and telephone number of the accreditation agency.
- The approval 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.

16) Is AOA/HFAP planning to provide the Board with the above information for the Outpatient Surgery Settings accredited by your organization?

Pursuant to HSC Section 1248.15(7), Outpatient Surgery Settings regulated by this chapter with multiple service locations shall have all of the sites inspected. Each and all facility locations are to be identified and must undergo individual separate on-site reviews.

17) Does the HFAP require on-site reviews for each facility seeking initial accreditation or reaccreditation?

18) Please identify where this information is located in your manual.

Pursuant to HSC Section 148.35, approved Accreditation Agencies are required to submit documents to the Board within specific timeframes. These documents include, but are not limited to electronic copies of inspection reports and corrective action reports with specific timeframes identified to correct all facility deficiencies.

19) Will AOA/HFAP provide the required documents to the Board within the specified timeframes?

Please provide AOA/HFAP's response to each of the above items in *both a paper and electronic format* by July 5, 2013. The Board also requests an electronic copy of AOA/HFAP's initial submission of the table comparing AOA/HFAP's standards and policies to those required in California law.

Thank you for your assistance in this matter.

Sincerely,

Curtis J. Worden
Chief of Licensing

Medical Board of California Licensing Program Response
ASC Application for Approval

1) California Business and Professions Code 2216.2 requires a physician and surgeon to provide adequate security by liability insurance, or by participation in an inter-indemnity 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 2216.2(d) further requires that 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.
    a. Title 16 of the California Code of Regulations 1304 defines "adequate security" to mean that a physician has coverage of the type prescribed in Section 2216.2 of the code in the amount of not less than one million dollars per incident and not less than three million dollars per year.
    b. Please provide information on AOA/HFAP's standards regarding liability insurance for physicians and surgeons performing surgery outside of general acute care hospitals. Please indicate how these standards are evaluated by AOA/HFAP.

HFAP Standard: 01.00.01 *Compliance with state licensure law. The ASC must comply with state licensure requirements (416.40). ASC must also conform to state, local and accreditation laws, regulations and/or standards.*

Explanation: *The standard addresses the requirements to conform to all state licensure requirements that may include adequate security for liability insurance or participation in an inter-indemnity trust, as specified within the state-specific licensure law. Facilities must outline in their administrative policies of their intent to conform to laws and standards and take appropriate, expeditious, remedial actions when noncompliance is noted. Failure of the facility to meet state licensure law may be cited when the authority having jurisdiction (AHJ) has made a determination of noncompliance and has also taken a final adverse action as a result. If the surveyor identifies a situation that indicates the provider may not be in compliance with state licensure law, the information may be referred to the AHJ for follow-up.*

2) California Health and Safety Code 1248.15(a)(2)(b) requires that there shall be on-site 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.

a. Please provide information on AOA/HFAP's standards regarding on-site equipment, medication, and trained personnel to facilitate handling of service provided and medical emergencies.

HFAP Standards: 05.01.07 *Emergency equipment. The ASC medical staff and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room. The equipment must meet the following requirements: (1) Be immediately available for use during emergency situations; (2) Be appropriate for the facility's patient population; and (3) Be maintained by appropriate personnel.* ***05.01.08*** *Emergency personnel. Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC (416.44(d)).* ***09.02.01*** *Emergency drugs storage. When provided, emergency drugs maintained in patient care areas must be securely stored and are in quantities as established by the medical staff. Storage units must not be locked to facilitate access in case of emergency; however, security must be such that violation of that security is readily evident.*

Explanation: *The facility must meet the current acceptable standards of practice, and incorporate the identified emergency equipment, supplies and medications that are most suitable for the potential emergencies associated with the procedures performed in the ASC, and the population the ASC serves. Personnel should be current in CPR and depending on the type and extent of surgery current in ACLS. Personnel who are CPR trained should be free of other duties.*

3) California Health and Safety Code 128.15(a)(6)(B) requires that members of the medical staff and other practitioners who are granted clinical privileges shall be professionally qualified and appropriately credentialed for the performance of the privileges granted. Members of the Medical Board's Outpatient Surgery Setting Task Force have requested additional information on how this provision is implemented by accreditation agencies.
    a. Provide information on the safeguards within the credentialing process to prevent an untrained/limited trained physician from performing procedures they are not qualified to perform.

HFAP Standards: 06.00.02 *Medical staff membership & clinical privileges. Members of the Medical Staff must be legally and professionally qualified for the positions to which they are appointed and for performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel (416.45(a)).* ***06.00.03*** *Reappraisals. Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate (416.45(b)).*

Explanation*: The ASC's governing body must have a process for granting clinical privileges that would safeguard prevention of untrained/limited trained physicians from performing procedures that they are not qualified to perform. The credentialing process must also include reappraisal every 24 months and documentation of reappraisals being performed in a timely manner. Granting of privileges must*

be supported by recommendations. The medical staff personnel file should contain records of personnel qualifications, privileges granted, and other appropriate records/documents.

4) California Health and Safety Code 1248.15(c) allows an accreditation agency to include additional standards in its determination to accredit outpatient settings if these are approved by the board to protect the public health and safety.
    a. Please provide a complete list of any and all standards required by AOA/HFAP that are not specifically required by California law. This information will be presented to the members of the Medical Board of California at an upcoming quarterly Board meeting as a "side-by-side" comparison of the additional standards required by each of the accreditation agencies that have been approved by the Board.

HFAP Response: *You may download the link below to the ASC standards manual.*

Download Link:
https://www.dropbox.com/s/y7yzougliihg2ny/Accreditation%20Requirements%20for%20Ambulatory%20Surgical%20Centers%202012-2013.pdf

    b. Please provide the answers to following questions and/or request for additional information:

5) When is the first site visit for the Outpatient Surgery Setting facility that is currently applying for accreditation?

HFAP Response: *Currently, there are no new (initial) ASC facilities in California scheduled for a site visit. Two currently accredited facilities will have site visits scheduled before the end of 2013.*

6) The Board has asked each of the approved Accreditation Agencies to provide information regarding the Outpatient Surgery Settings that they have certified for CMS as Medicare facilities. Will AOA/HFAP also provide the Board with these CMS certified facilities for inclusion on the Board's website in our efforts to assist California consumers?

HFAP Response: *The following ASCs are certified for CMS as Medicare facilities.*

	Facility Name	***Facility ID***	***Expiration Date/Status***
1	*Prescott Eye Car & Surgery Center*	*327737*	*11/28/14*
2	*Pain MDS*	*195764*	*07/12/16*
3	*Newport Bay Surgery Center, LLC*	*181507*	*11/26/13*
4	*Evansville Surgery Center-Deaconess Campus*	*188632*	*06/13/14*
5	*Evansville Surgery Center Associates, LLC*	*181668*	*06/13/14*
6	*Mooresville Endoscopy Center, LLC*	*189867*	*12/16/15*
7	*St Francis Mooresville Surgery Center, LLC*	*189742*	*01/18/16*
8	*Hammond Community Ambulatory Care Center*	*189290*	*06/19/16*

9	*Epic Surgery Center, LLC*	*191225*	*11/02/15*
10	*Coastal Eye Surgery Center*	*182440*	*07/07/14*
11	*Mackinaw Surgery Center, LLC*	*175480*	*10/15/15*
12	*Chu Surgery Center, LLC*	*188733*	*04/07/15*
13	*Murphy Watson Burr Surgery Center*	*199609*	*12/10/13*
14	*Freeman Surgical Center*	*196683*	*07/20/16*
15	*Eltra LLC*	*181339*	*01/21/14*
16	*Delphos ASC*	*164119*	*03/10/12 (withdrawal)*
17	*Meridian Center for Surgical Excellence, LLC*	*182576*	*07/30/14*
18	*Guaynabo Ambulatory Surgical Group, Inc.*	*188610*	*04/28/15*
19	*Babcock Surgical Center, LLC*	*328562*	*08/29/14*
20	*Eye Surgery of Edmonds*	*189166*	*06/30/15*
21	*Spokane Valley Ambulatory Surgery Center*	*191933*	*03/09/16*
22	*Seattle Spine Institute*	*195463*	*03/12/16*
23	*The Retina Surgery Center*	*196689*	*06/09/14*
24	*Tri-State Surgical Center*	*163330*	*04/07/14*

7) Has AOA/HFAP formally adopted all of the draft Policy/Procedures that were initially provided to the Board at the time of application for approval as a Board-approved Accreditation Agency?

HFAP Response: *Yes. All draft policies/procedures have been submitted to our Executive Committee and were approved on January 23, 2013.*

8) Page 3 of 4 of the Quality Management Plan states…."No disclosure of any reports…". Will these reports be provided to the Board?

HFAP Response*: The statement states "No disclosure of any reports, records, statements, memoranda, findings, or data shall be made without the authorization of the Quality Improvement Committee." Once the Board approves our application, that will provide the basis for us to authorize release of reports required under the regulations.*

9) Does AOA/HFAP use the Medicare/Medicaid standards to accredit non-CMS certified Outpatient Surgery Settings?

HFAP Response: *The Medicare/Medicaid standards apply to those who choose to be CMS certified as Ambulatory Surgery Centers (ASC). Outpatient Surgery Settings, such as Office Based Surgery (OBS), that are not seeking deemed status is not required to be surveyed under the Medicare/Medicaid standards.*

10) Are non-CMS certified Outpatient Surgery Settings required to have a formal and posted transfer plan to a hospital that accepts Medicare?

HFAP Response: *Currently, non-CMS certified Outpatient Surgery Settings are not required to have a formal and posted transfer plan to a hospital that accepts Medicare.*

11) Does HFAP require peer review processes for physician & surgeons? This information is not referenced in the Governing Body & Management chapter, **01.00.02**. California regulation code 1248.15(D) references physicians and surgeons who transfer patients from an Outpatient Surgery Setting shall agree to cooperate with the medical staff peer review process in those transferred cases.

HFAP Standards: 01.00.02 *Governing Body & Management. The ASC must have a Governing Body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.*

01.00.05 *Transfer agreement. The ASC must satisfy one of the following: Have a written transfer agreement with a hospital that meets the requirements of paragraph (b)(2) of 42 Code of Federal Regulation (416.41(b)(3)(i)); or, ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements of paragraph (b)(2) (416.41(b)(3)(ii)).*

Explanation: *HFAP's standard does not explicitly require participation in peer review processes for physicians & surgeons who transfer patients from an Outpatient Surgery Setting. The requirement is implicit in the requirement that the physician have admitting privileges. Generally, transfer agreements establish the respective responsibilities of each party to the agreement. If the ASC does not have a transfer agreement, then it must maintain documentation of the current admitting privileges of all physicians who perform surgery at the ASC at local hospitals that satisfy the regulatory requirements in 416.41(b)(2).*

12) HFAP performs on-site inspections within 120 days of expiration dates for re-accreditation. How often do Outpatient Surgery Settings undergo regular and routine on-site inspections? Are on-site inspections performed for initial and/or renewal accreditations?

HFAP Response: *Onsite inspections are performed for initials and/or renewal accreditations. HFAP's accreditation cycle is three (3) years for Outpatient Surgery Settings. At mid-cycle (18 months), 5% of facilities will undergo a random unannounced validation survey. Facilities that are due for renewal, the inspection will occur within 120 days before the expiration date. Accreditation award for renewals is three (3) years from prior expiration date and not based on last survey date.*

13) Are Outpatient Surgery Settings required to post the certificate of accreditation to be readily visible and accessible to patients and staff at the facility?

HFAP Response: *The facility is not required to post the certificate of accreditation. However, it may choose to do so as a statement of their accomplishment to the public. What is suggested is that the facility may notify the public of their upcoming accreditation survey; and if any members of the public*

have any quality-of-care or safety concerns, they are to notify HFAP of the complaint process by one of two methods: 1) Completion of the Complaint Form online at www.hfap.org; or 2) Contact HFAP's Quality Specialist by phone at 312-202-8067.

14) Inspection teams must comply with the following criteria:
    a. Accreditation reviewers must be credentialed and screened by the accreditation agency.
    b. Professional members of the accreditation review team must have experience in conducting review activities of free-standing outpatient settings.
    c. Participation in formal education training programs provided by the accreditation agency.

HFAP Response: *HFAP's policies require all surveyors to be credentialed and screened prior to seeking approval from the Executive Committee. Surveyors' performances are also evaluated and presented to the Executive Committee for appointment and re-appointment each year. Professional members of the surveyor cadre are appropriately selected for the type of setting(s) based on their education and experiences. Regular training is provided to all surveyors on an ongoing basis, and at least annually.*

Please provide information identifying where these requirements are specifically addressed in the HFAP manual.

15) The Board is required to post the following information to the Board's website pursuant to California Health and Safety Code (HSC) Section 1248.2:
    a. Whether an outpatient setting is accredited; or whether the setting's accreditation has been revoked, suspended, or placed on probation; or whether the setting has received a reprimand by the Accreditation Agency.
    b. The list of outpatient settings shall include all of the following:
        i. Name, address, and telephone number of any owners and their corresponding medical license numbers.
        ii. Facility ownership percentage for each owner.
        iii. Name and address of the facility
        iv. The name and telephone number of the accreditation agency
        v. The approval and expiration dates of the accreditation
        vi. Accrediting agencies approved by the board shall notify the board and update the board on all outpatient settings that are accredited.

HFAP Standard: 01.00.01 *Compliance with state licensure law. The ASC must comply with state licensure requirements (416.40). ASC must also conform to state, local and accreditation laws, regulations and/or standards.*

HFAP Response*: The ASC's compliance to the accreditation standard will also involve compliance with state-specific licensure requirements. Therefore, the applicant facility (ASC) as well as the approved accreditor (HFAP) will be required to report any necessary information in accordance with the California Health and Safety Code (HSC) Section 1248.2 as part of the application agreement.*

16) Is AOA/HFAP planning to provide the Board with the above information for the Outpatient Surgery Settings accredited by your organization?

HFAP Response: *If permitted and required, HFAP will comply with providing the necessary information for the Outpatient Surgery Settings, in the state of California, that are accredited by HFAP to the Board.*

Pursuant to HSC Section 1248.15(7), Outpatient Surgery Settings regulated by this chapter with multiple service locations shall have all of the sites inspected. Each and all facility locations are to be identified and must undergo individual separate on-site reviews.

17) Does the HFAP require on-site reviews for each facility seeking initial accreditation or reaccreditation?

HFAP Response: *Yes. All ASC facilities will undergo an on-site inspection whether seeking initial accreditation or re-accreditation. In cases where an applicant is seeking accreditation under one application with multiple sites, all ASC sites will be visited at 100%.*

18) Please identify where this information is located in your manual.

Pursuant to HSC Section 148.35, approved Accreditation Agencies are required to submit documents to the Board within specific timeframes. These documents include, but are not limited to electronic copies of inspection reports and corrective action report with specific timeframes identified to correct all facility deficiencies.

HFAP Response: *State-specific requirements are not specified within the accreditation manual. The requirement between the state, the ASC, and approved accreditation agency (HFAP) may be outlined in an agreement between the specified parties or, absent an agreement, part of the HFAP standard operating procedures.*

19) Will AOA/HFAP provide the required documents to the Board within the specified timeframes?

HFAP Response: *HFAP will comply with providing the necessary information for the Outpatient Surgery Settings that are accredited by HFAP within the specified timeframes to the Board.*

ATTACHMENT 4

CA - STATUTORY REQUIREMENT	ACCREDITATION CRITERIA	INITIAL MEETS REQUIREMENT Y/N/?	FOLLOW-UP MEETS REQUIREMENT Y/N/?	COMMENTS
HSC 1248.15(a)(1)	Outpatient setting allied health staff shall be licensed or certified to the extent required by state or federal law.	Y		
HSC 1248.15(a)(2)(A)	Outpatient settings shall have a system for facility safety and emergency training requirements.	Y		
HSC 1248.15(a)(2)(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.	?	Y	Sent AOA/HFAP request for clarification. AOA/HFAP submitted clarification substaniating compliance. HFAP Standard 05.01.07
HSC 1248.15(a)(2)(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:			
HSC 1248.15(a)(2)(C) (i)	Have a written transfer agreement with a local accredited or licensed acute care hospital, approved by the facility's medical staff	Y		
HSC 1248.15(a)(2)(C) (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.	Y		
HSC 1248.15(a)(2)(C) (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.	?	Y	Sent AOA/HFAP request for clarification. AOA/HFAP submitted clarification substaniating compliance. HFAP Standard 01.00.05

CA - STATUTORY REQUIREMENT	ACCREDITATION CRITERIA	INITIAL MEETS REQUIREMENT Y/N/?	FOLLOW-UP MEETS REQUIREMENT Y/N/?	COMMENTS
HSC 1248.15(a)(2)(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:	?	Y	Sent AOA/HFAP request for clarification. AOA/HFAP submitted clarification substaniating compliance. HFAP Standard 01.00.05
HSC 1248.15(a)(2)(D) (i)	Notify the individual designated by the patient to be notified in case of an emergency.	Y		
HSC 1248.15(a)(2)(D) (ii)	Ensure that the mode of transfer is consistent with the patient's medical condition.	Y		
HSC 1248.15(a)(2)(D) (iii)	Ensure that all relevant clinical information is documented and accompanies the patient at the time of transfer.	Y		
HSC 1248.15(a)(2)(D) (iv)	Continue to provide appropriate care to the patient until the transfer is effectuated	Y		
HSC 1248.15(a)(2)(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.	?	Y	Sent AOA/HFAP request for clarification. AOA/HFAP submitted clarification substaniating compliance. HFAP Standard 01.00.05
HSC 1248.15(a)(4)	Outpatient settings shall have a system for maintaining clinical records.	Y		

CA - STATUTORY REQUIREMENT	ACCREDITATION CRITERIA	INITIAL MEETS REQUIREMENT Y/N/?	FOLLOW-UP MEETS REQUIREMENT Y/N/?	COMMENTS
HSC 1248.15(a)(5)	Outpatient settings shall have a system for patient care and monitoring procedures.	**Y**		
HSC 1248.15(a)(6)(A)	Outpatient settings shall have a system for quality assessment and improvement.	**Y**		
HSC 1248.15(a)(6)(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.	**?**	**Y**	Sent AOA/HFAP request for clarification. AOA/HFAP submitted clarification substaniating compliance. HFAP Standard 06.00.02
HSC 1248.15(a)(6)(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.	**Y**		
HSC 1248.15(a)(7)	Outpatient settings regulated by this chapter that have multiple service locations shall have all of the sites inspected.	**Y**		
HSC 1248.15(a)(8)	Outpatient settings shall post the certificate of accreditation in a location readily visible to patients and staff.	**Y**		
HSC 1248.15(a)(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.	**Y**		
HSC 1248.15(a)(10)	Outpatient settings shall have a written discharge criteria.	**Y**		

CA - STATUTORY REQUIREMENT	ACCREDITATION CRITERIA	INITIAL MEETS REQUIREMENT Y/N/?	FOLLOW-UP MEETS REQUIREMENT Y/N/?	COMMENTS
HSC 1248.15(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.	**Y**		
HSC 1248.15(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.	**?**	**Y**	Sent AOA/HFAP request for clarification. AOA/HFAP submitted clarification substaniating compliance.
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 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.	**Y**		

CA - STATUTORY REQUIREMENT	ACCREDITATION CRITERIA	INITIAL MEETS REQUIREMENT Y/N/?	FOLLOW-UP MEETS REQUIREMENT Y/N/?	COMMENTS
HSC 1248.15(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.	**Y**		
HSC 1248.3(a)	Certificates of accreditation issued to outpatient settings by an accreditation agency shall be valid for not more than three years.	**Y**		
HSC 1248.3(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.	**Y**		

CA - STATUTORY REQUIREMENT	ACCREDITATION CRITERIA	INITIAL MEETS REQUIREMENT Y/N/?	FOLLOW-UP MEETS REQUIREMENT Y/N/?	COMMENTS
HSC 1248.3(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.	**Y**		
HSC 1248.4(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:	**Y**		
HSC 1248.4(c)(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.	**Y**		
HSC 1248.4(c)(2)	Submits its current accreditation standards to the division every three years, or upon request for continuing approval by the division.	**Y**		
HSC 1248.4(c)(3)	Maintains internal quality management programs to ensure quality of the accreditation process.	**Y**		

CA - STATUTORY REQUIREMENT	ACCREDITATION CRITERIA	INITIAL MEETS REQUIREMENT Y/N/?	FOLLOW-UP MEETS REQUIREMENT Y/N/?	COMMENTS
HSC 1248.4(c)(4)	Has a process by which accreditation standards can be reviewed and revised no less than every three years.	Y		
HSC 1248.(c)(5)	Maintains an available pool of allied health care practitioners to serve on accreditation review teams as appropriate.	Y		
HSC 1248.4(c)(6)	Has accreditation review teams that shall do all of the following:	Y		
HSC 1248.4(c)(6)(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.	Y		
HSC 1248.4(c)(6)(B)	Participate in formal educational training programs provided by the accreditation agency in evaluation of the certification standards at least every three years.	Y		
HSC 1248.4(c)(7)	The accreditation agency shall demonstrate that professional members of its review team have experience in conducting review activities of freestanding outpatient settings.	Y		
HSC 1248.4(c)(8)	Standards for accreditation shall be developed with the input of the medical community and the ambulatory surgery industry.	Y		
HSC 1248.4(c)(9)	Accreditation reviewers shall be credentialed and screened by the accreditation agency.	Y		
HSC 1248.4(c)(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.	Y		
HSC 1248.4(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.	Y		