CHAPTER ONE – ADMINISTRATION

SECTION 1 - GOVERNANCE

1.1.1 The ownership of the facility is clearly defined in appropriate documents.

The facility is licensed by the state or by the federal government, if required for the services offered. The scope of services for a facility owned by a podiatrist is limited to podiatry.

1.1.2 The patient is informed when the referring physician has a financial interest in a facility to which the patient is referred; such information is available in patient handouts or posted in the facility.

For facilities requesting CMS deemed status option:
Facility provides written disclosure of financial interest to the patient.

1.1.3 The physician owner(s)/Medical Director/Governing Body, administrators, employees, and staff of the facility abide by applicable Federal, state, or local laws and regulations.

For facilities requesting CMS deemed status option:
The facility is a distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization. Patient stay does not exceed 24 hours.

The facility has an agreement with CMS to participate in Medicare as an ASC.

Facility meets the conditions set forth in subparts B and C of 42 CFR 416.

1.1.4 Licensed medical personnel on staff (e.g., MD, DO, DDS, NP, PA, CNM, CRNA, RN, and LVN- titles used may vary by state) follow state board probation restrictions regarding their activities at the facility. The facility has a process that ensures that the provider does not violate the terms of probation in any activities carried out at, or on behalf of, the facility.

Facility administrative oversight of such restrictions is reflected in written policies.

1.1.5 The facility reports to IMQ, within 10 days of the action, any adverse action taken against it by other entities, such as state departments of public health or other state agencies, the Centers for Medicare & Medicaid Services or other federal entities, or other non-governmental accreditation entities. This is reflected in written policies. Such adverse actions include, but are not limited to:

a) Suspension, restriction or revocation of the facility's certification to participate in the Medicare or Medicaid program;
b) Any suspension, restriction or revocation of a facility's surgical clinic license certificate, permit or other authorization required by law for the facility to operate as a surgical facility; and
c) Any restriction, probation, suspension, termination or denial of accreditation imposed by a private accrediting entity including, but not limited to, The Joint Commission, Accreditation Association for Ambulatory Health Care (AAAHC), American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) and the Healthcare Facilities Accreditation Program.

For facilities requesting CMS deemed status option:
Facility informs IMQ when it is subject to a validation survey and provides IMQ with a copy of any Form CMS 2567 related to the survey.

1.1.6 The physician owner(s)/Medical Director in a solo/small group (SSG) model has full legal responsibility and accountability -for the facility's total operation, including:

a) Oversight and accountability for the quality assessment and performance improvement program;
b) Development, implementation, and monitoring of the facility's policies and programs, so as to provide quality healthcare in a safe environment;
c) Development and maintenance of a disaster preparedness plan; and
d) The provision of safe and effective clinical services provided through contract with outside resources.

In the organized medical staff (OMS) model, this responsibility falls to the governing body.

For facilities requesting CMS deemed status option:
The physician owner(s)/Medical Director/Governing Body implements a formal process for complying with all medical staff regulatory requirements.

SECTION 2 - PRACTICE MANAGEMENT

1.2.1 The written job description for the Medical Director, if not the physician owner, outlines his/her responsibilities.

1.2.2 There is a written job description for the person(s) responsible for the day-to-day operations, e.g., administrative, medical, and personnel.

1.2.3 The scope of procedures is approved by the physician owner(s)/Medical Director/Governing Body. It is complete and amended as new procedures are introduced or procedures no longer performed are removed. There is documentation of yearly review.

1.2.4 **For facilities requesting CMS deemed status option:**
The facility's space is used exclusively for the ASC. If the physician's office or clinic is in the same building, it is separated physically by, at a minimum, semi-permanent walls and doors. If the ASC and the physician's practice share the facility, the two practices are temporally distinct. There are separate and exclusive schedules for use of shared spaces. Operating rooms and recovery areas are used exclusively for surgical procedures. Facility staff and record keeping also are separate and exclusive.

See Appendix J for resources and information regarding CMS (Medicare) deemed status option.

1.2.5 Standardized clinical procedures for registered nurses, when permitted by the state, and protocols for physician's assistants are developed in consultation with, and signed by, the physician owner(s)/Medical Director/Governing Body, and reviewed at least every three years, or sooner if necessary, to ensure alignment with accepted practice standards.

For facilities requesting CMS deemed status option:
The governing body approves written policies and procedures that establish a system for oversight and evaluation of the quality of the services provided by licensed practitioners to provide clinical care other than nursing care.

Nursing services are provided in accordance with recognized standards of practice.

1.2.6 Each site posts a notice with the name, phone number, and web site of the state medical board that regulates the doctor's office, if required by the state medical board, in one of three ways:

a) Prominently places the notice in documents given to patients or their representatives;
b) Includes the information in a written statement that is signed and dated by patients or their representatives; or
c) Posts a sign in an area of the medical office that is clearly visible to patients.

A sample Notice to Consumers for California facilities is provided in Appendix H2.

1.2.7 The facility accreditation certificate is posted in a location readily visible to patients and staff.

1.2.8 The name and phone number of the accrediting agency, with instructions for the submission of complaints, is posted in a location readily visible to patients and staff.

1.2.9 The "IMQ Notification of Accreditation Survey" is posted in a readily visible location.

1.2.10 Marketing materials (brochures, the facility's website, and advertisements) related to physician qualifications and procedures offered are current and accurate. These are reviewed at least every three years, or when significant changes take place at the facility. Such review is documented.

Information regarding physician advertising is found in Appendix H6.

SECTION 3 - PATIENT RIGHTS

1.3.1 Patient rights and responsibilities are honored and respected. Patient rights and responsibilities are posted in a location readily visible to patients or are provided to each patient, in writing, prior to the start of the surgical procedure. Clinical and support staff treat patients with respect and dignity.

For facilities requesting CMS deemed status option:
The facility gives patients, the patient's representative or surrogate verbal and written notice of the patient's rights. The facility posts the written notice of patient's rights and responsibilities in a location readily visible to patients.
The notice of rights includes the address and phone number of the entity to which patients may report complaints, as well as the website for the Office of the Medicare Beneficiary Ombudsman.
The facility's patients' rights policies and procedures indicate that the facility does not engage in reprisals or discriminatory behavior, that the patient has the right to voice grievances.
The facility's patients' rights policies state that the patient is free from all forms of abuse or harassment.
The facility has a policy that addresses the exercise of rights on behalf of a patient judged legally incompetent.
The facility has a policy addressing the delegation by a patient of the exercise of rights to a representative.

A sample of Patient Rights and Responsibilities is provided in Appendix C.

1.3.2 The facility has an advanced directives policy. The policy informs the patient of the patient's right to make informed decisions regarding the patient's care. The policy states whether the facility will honor advance directives. If the facility does NOT honor "Do Not Resuscitate" (DNR) directives, the patient is informed of the policy. This is documented in the medical record. Also documented is whether or not the patient has executed an advance directive.

For facilities requesting CMS deemed status option:
The facility provides the patient or, as appropriate, the patient's representative with written information concerning its policy on advance directives, including a description of applicable State health and safety laws

and, if requested, official State advance directive forms.

1.3.3 There is a written procedure for handling patient's grievances.

a) Grievances include perceived patient problems or complaints. Specific personnel are designated to address and respond to patient grievances.

b) All alleged grievances relating to, but not limited to, mistreatment, neglect, verbal, mental, sexual or physical abuse, are fully documented as part of the risk management function.

c) The grievance procedure specifies timeframes for review of the grievance and provisions for a response. The facility, in responding to the grievance, investigates all allegations made by a patient or the patient's representative regarding treatment or care that is (or fails to be) provided.

d) The facility documents how the grievance is addressed, as well as provides the patient with written notice of its decision. The decision includes the name of a contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process is completed.

For facilities requesting CMS deemed status option:
All allegations are immediately reported to a person in authority.

The facility reports to the State or local authority, or both, substantiated allegations.

1.3.4 The facility makes every effort to have an interpreter (use of publicly available language interpreter services, trained facility staff, adult family member, or friends) available to ensure appropriate communication between physician and patient, if there is language or other communication barriers.

The facility has language appropriate translations of "vital documents" for Limited English Proficiency (LEP) patient group that comprise 5% or more of the facility's patient population, as required by Federal law when facilities receive Medicare or Medicaid funding.

(See Appendix J for available resources.)

SECTION 4 - OFFICE POLICIES

1.4.1 Scheduling and prioritizing of appointments is based upon the clinical needs of the patient (e.g., emergency, urgent, post-operative or routine/preventive). A clinician is available to the scheduling staff for consultation.

(See standard 5.2.1 for generally accepted benchmarks for accessibility.)

1.4.2 Scheduling and prioritizing of patient messages/follow-up is based upon the clinical needs of the patient.

1.4.3 There is 24-hour clinical coverage of the physician's practice.

1.4.4 There is follow-up on cancelled or missed appointments based on clinical need. This is documented in the medical record.

SECTION 5 - OFFICE SYSTEMS

1.5.1 There are uniform systems and trained personnel to ensure accurate and timely patient billing. There are established written procedures to monitor submitted bills to verify accuracy.

1.5.2 There are personnel responsible for ensuring that patients understand the fees charged, co-pays, deductibles, and other costs, as well as the types of payments accepted. There is a process for authorization of services, if required.

Chapter Two – Personnel and Credentialing

SECTION 1 - ADMINISTRATION

2.1.1 The facility staff are appropriately trained and supervised by qualified personnel. They are provided an initial orientation appropriate to their job, including:

a) All duties as outlined in their written job description;
b) Confidentiality of patient information (HIPAA);
c) Fire and life safety equipment and emergency drills;
d) OSHA Blood-Borne Pathogen Standards; and
e) Maintenance and operation of equipment within their scope of practice.

This standard also applies to part-time and per diem personnel.

For facilities requesting CMS deemed status option:
Nursing services are provided in accordance with recognized standards of practice. Nursing services is under the leadership of a Registered Nurse. There is documentation that the ASC has designated an RN to direct nursing services.

See Appendix H8 for information regarding HIPAA privacy rules.

2.1.2 Staff development (in-service education) is provided at least once a year and is based on issues that impact patient care and satisfaction. Staff is made aware of the strategies adopted for prevention of adverse events. Documentation of completed in-services is kept on file.

2.1.3 Written employee policies and procedures address:

a) Hiring and dismissal of staff;
b) Performance expectations and competency;
c) Employment training and orientation;
d) Expected working hours;
e) Sexual harassment prohibitions; and
f) Patient privacy and confidentiality.

See Appendix H11 for information regarding sexual harassment of patients

and employees.

2.1.4 Deleted.

2.1.5 Licensed health care personnel wear nametags (in 18-point type) that include the practitioners' licensure. Nametags with titles are recommended for other staff members.

2.1.6 Written job descriptions are documented in the employee file, are consistent with applicable state regulations, and are within the employee's scope of practice. Education, licensure/certification, and experience requirements are included in the job descriptions.

Employee's performance is reviewed within 90 - 180 days of hire and then annually. Job descriptions are reviewed in conjunction with personnel evaluations to ensure the job descriptions match the scope of practice and work assignment of the staff member.

For facilities requesting CMS deemed status option:
Patient care responsibilities are delineated in job descriptions for all nursing services personnel.

2.1.7 Employees, including contracted personnel, have personnel files that include job descriptions, documentation of education and training, initial orientation to job duties, performance reviews, and signed confidentiality statements.

2.1.8 Personnel files for staff with direct clinical patient contact include all items enumerated in standard 2.1.7, as well as, copy of current professional state licensure, registration, and/or certification, evidence of Hepatitis-B immunization or declination, and TB assessment.

2.1.9 Organizations using registry nurses or technicians:

a) Confirm identity with a picture ID and file a copy of the clinical license and picture ID verification, and
b) Ensure that primary source verification of licensure, credentials, and competency is performed by the registry company. This is included in the contract with the registry. "Self-assessment" is not acceptable as a

means to determine competency.

SECTION 2 - PHYSICIAN CREDENTIALS FILES

2.2.1 Deleted.

2.2.2 Credentials files for each licensed independent practitioner's (LIP) (e.g., MD, DO, DPM, DDS, and CRNA) are accessible on-site, in either paper or electronic format. Access is restricted to defined personnel. Licensed independent practitioner files include:

a) State licensure*;
b) DEA*;
c) Verification of education and training;
d) Board eligibility or certification*, if applicable;
e) Proof of current professional liability insurance or other coverage;
f) List of privileges granted by the facility;
g) Proctoring assessments of privileges initially granted; and
h) Two peer references or evidence of current membership on the medical staff of an accredited facility not owned or operated by the practitioner.

* State licensure, DEA, and board eligibility are primary source verified by the facility. The facility may contract verification tasks with a Credentials Verification Organization (CVO) under terms that guarantee primary source verification is performed and evidence is provided to the facility.

(For information on verification, please see Appendix D).

California facilities only:
Facility will determine if any report has been made pursuant to Section 805 indicating that the applying LIP has been denied staff privileges, been removed from a medical staff, or had his or her staff privileges restricted as provided in 13 Section 805.

2.2.3 Physicians have current, adequate security for professional liability in a minimum amount determined by the state medical board. The security is provided by liability insurance, participation in an interindemnity trust, an

escrow account, or letter of credit that will enable the physician to pay claims and costs.

CRNA's have professional liability insurance or other coverage with minimum coverage equal to that of anesthesiologists in the facility.

SECTION 3 - SOLO/SMALL GROUP (SSG) PRIVILEGES

2.3.1 The facility has a process for documenting and granting initial privileges.

Except for CMS deemed status facilities, the facility may grant initial privileges based on documentation of similar current privileges granted at another accredited facility. A copy of the other accredited facility's privileges is on file, as well as, a specific list of privileges appropriate to, and granted by, the facility. The practitioner is not an owner or operator of the other accredited facility.

Practitioners are professionally qualified and appropriately credentialed for the performance of privileges granted.

For facilities requesting CMS deemed status option:
Privileges are granted by the governing body of the facility in accordance with approved policies and procedures that include the facility performing the complete process of granting privileges.

The type and complexity of procedures for which the practitioner administers anesthesia, or supervises another practitioner administering anesthesia, are specified in the privileges granted to the individual practitioner.

Written policies explicitly provide for operating physicians supervising CRNAs administering anesthesia, unless there exists a State exemption.

2.3.2 The physician owner(s)/Medical Director/Governing Body reviews, approves, and documents the granting of clinical privileges to practitioners.

2.3.3 The practitioner is subject to a period of on-site proctoring when privileges are not granted based on another accredited facility's privileges.

Proctoring policy establishes, at a minimum, evidence of relevant training, the number of cases to be reviewed, the evaluation process for patient selection, and review of surgical knowledge and technique. Documentation of proctoring assessments is in the credential and privileging file.

2.3.4 Clinical privileges are periodically re-appraised by the facility.

Re-appraisal is at least every three years, is accessible on-site, either in paper or electronic format, and includes an assessment of:

a) Practitioner's past performance, and
b) Peer Review.

For facilities requesting CMS deemed status option:
Reappraisal is at least every 24 months.

2.3.5 Deleted.

SECTION 4 - ORGANIZED MEDICAL STAFF (OMS) – BYLAWS & PRIVILEGES

2.4.1 An organized medical staff has written bylaws or policies.

For facilities requesting CMS deemed status option:
Medical staff is accountable to the governing body.

2.4.2 Members of the medical staff establish the criteria and standards for admission to, and continuing membership of, the organized medical staff.

Credentialing information is verified according to clearly defined policies and procedures.

The following criteria is included in the organized medical staff bylaws:

a) Provisions are made for the expeditious processing and verification of applications to the medical staff, and
b) All initial applicants are required to provide evidence of the following:
    1) State licensure*;
    2) DEA*;

3) Verification of education and training;
4) Board eligibility or certification*, if applicable;
5) Proof of current professional liability insurance or other coverage;
6) List of privileges granted by the facility;
7) Proctoring assessments of privileges initially granted; and
8) Two peer references or evidence of current membership on the medical staff of an accredited facility not owned or operated by the practitioner.

* State licensure, DEA, and board eligibility are primary source verified by the facility. The facility may contract verification tasks with a Central Verification Organization (CVO) under terms that guarantee primary source verification is performed and evidence is provided to the facility.

(For information on verification, please see Appendix D).

2.4.3 Deleted.

2.4.4 The frequencies for re-appointment to the staff and re-appraisal of privileges are defined in the bylaws/policies. Review is periodic and takes place at least every three years.

For facilities requesting CMS deemed status option:
Reappraisal is at least every 24 months.

2.4.5 Assessment of peer review activity is included in the credentialing and privileging file.

2.4.6 The facility has a process for documenting and granting initial privileges.

Except for CMS deemed status facilities, the facility may grant initial privileges based on documentation of similar current privileges granted at another accredited facility. A copy of the other accredited facility's privileges is on file, as well as, a specific list of privileges appropriate to, and granted by, the facility. The practitioner is not an owner or operator of the other accredited facility.

Practitioners are professionally qualified and appropriately credentialed for the performance of privileges granted.

For facilities requesting CMS deemed status option:
Privileges are granted by the governing body of the facility in accordance with approved policies and procedures.

2.4.7 The governing body reviews, approves, and documents clinical privileges granted. The organized medical staff maintains documentation of clinical privileges granted.

If there are multiple sites, documentation is accessible at each site, either on paper or electronically. **(Not applicable to CMS deemed status facilities.)**

2.4.8 Deleted.

2.4.9 The practitioner is subject to a period of on-site proctoring when privileges are not granted based on another accredited facility's privileges or when the practitioner seeks to perform procedures outside his/her current scope of privileges granted.

Proctoring policy establishes, at a minimum, evidence of relevant training, the number of cases to be reviewed, the evaluation process for patient selection, and review of surgical knowledge and technique. Documentation of proctoring assessments is in the credential and privileging file.

2.4.10 Clinical privileges of licensed independent health care practitioners are granted, restricted, and terminated based on criteria developed by members of the medical staff.

2.4.11 Clinical privileges are periodically re-appraised by the facility.

Re-appraisal is at least every three years, is accessible on-site, either in paper or electronic format, and includes an assessment of:

a) Practitioner's past performance, and
b) Peer Review.

For facilities requesting CMS deemed status option:
Reappraisal is at least every 24 months.

2.4.12 Deleted.

CHAPTER THREE – QUALITY PROGRAMS AND PEER REVIEW

SECTION 1 - GENERAL REQUIREMENTS

3.1.1 The facility has a formal system for quality assessment and improvement and takes a proactive, comprehensive, and ongoing approach to improving the quality and safety of the services delivered to maximize patient protection.

The system for quality assessment and improvement has the active participation of the medical staff. It includes, but is not limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes. It uses quality indicators or performance measures associated with improved health outcomes to improve patient safety. It identifies and reduces medical errors. It includes chart review and utilizes information derived from other data sources, such as patient satisfaction surveys and incident reports.

The facility measures, analyzes, and tracks quality indicators, adverse patient events, infection control, and other aspects of performance relating to care and services provided.

Quality improvement projects are documented. Such documentation includes the reason for implementing the project and the results obtained.

For facilities requesting CMS deemed status option:
The number and scope of distinct improvement projects conducted annually reflect the scope and complexity of the ASC's services and operations.

(*See Appendix H for QI Study template*)

3.1.2 The Quality Management's priorities are reviewed, modified as necessary, and approved, at least annually, by the physician owner(s)/Medical Director/Governing Body. Such review is documented. Documentation can be in minutes, on a face sheet, or by initialing and dating the bottom of the original document.

3.1.3 The facility sets and implements priorities for its performance improvement activities that:

a) Focus on high risk, high volume, and problem-prone areas;
b) Consider incidence, prevalence, and severity of problems in those areas;
c) Affect health outcomes, patient safety, and quality of care;
d) Monitor the effectiveness and safety of services provided and the quality of the care; and
e) Identify opportunities that lead to improvements and changes in patient care.

The activities track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.

The facility implements preventive strategies throughout the facility targeting adverse patient events and ensures that all staff is familiar with these strategies.

3.1.4 The physician owner(s)/Medical Director/Governing Body and administration support the medical staff in efforts to improve the quality of care within the facility.

For facilities requesting CMS deemed status option:
The governing body ensures that a Quality Assessment and Improvement Program:

a) Is defined implemented and maintained;
b) Addresses the facility's priorities and ensure improvements are evaluated for effectiveness;
c) Specifies data collection methods, frequency, and details;
d) Clearly establishes the expectations for safety; and
e) Allocates resources for staff, time, information systems, and training to implement the system.

3.1.5 A Quality Management program oversees:

a) Safety of patients and staff;
b) Infection prevention and control
    i. Monitoring rates of post-operative infections,
    ii. Assessing the cause of such infections,
    iii. Taking actions based upon the findings of the assessment, and
    iv. Conducting a follow-up evaluation to determine whether the corrective course of action was successful:

c) Clinical outcomes;
d) Risk management
    i. Capturing, tracking, analyzing causes of unanticipated events, implementing improvements, ensuring improvements are sustained over time, and reporting unanticipated events and
    ii. Identifying and managing the impaired practitioner;
e) Monitoring of equipment, if applicable;
f) Quality improvement and analysis independent of review of identified problems. (This element applies to larger organizations); and
g) All contracted services to ensure provision of service is safe and effective.

For facilities requesting CMS deemed status option:
The infection control and prevention program includes documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.

3.1.6 The Quality Management program has an on-going, organized, integrated, and data-driven plan that addresses administrative and clinical outcomes, is documented in a standardized manner, and is reported to the governing body at least annually.

(See suggested format for documenting quality improvement studies in Appendix G)

3.1.7 The facility actively assesses patient satisfaction, at least annually.

3.1.8 Deleted.

3.1.9 Deleted.

SECTION 2 - SOLO/SMALL GROUP PEER REVIEW

3.2.1 Peer review determines the appropriateness of clinical decision-making and performance of procedures specific to each practitioner's specialty or scope of practice and/or clinical privileges.

Frequency: Peer review occurs at least yearly, with the exception of significant events. There is an expedited peer review (within 7 days) of all unanticipated events (deaths, unplanned transfers to acute facilities, significant complications).

Number: Peer review covers the full scope of privileges granted to each practitioner. A minimum of 10 cases per practitioner per year will be reviewed or all cases if less than ten per provider per year.

Internal or external: For one and two-physician practices, peer review is external. When there are three or more physicians in the same specialty or with the same scope of practice and/or clinical privileges, internal review is appropriate. The qualifications of the external peer reviewers are defined and require individuals who are free from all conflicts of interest and are not professional associates of the providers being reviewed. A credential file is maintained on-site for all external peer reviewers. At a minimum, the file contains a CV, verification of current licensure, and a confidentiality statement for the peer reviewer.

On-site or off-site: Facilities that choose to use paper records and choose off-site peer review ensure that every step of the process meets HIPAA and legal confidentiality requirements. Electronic records can be reviewed off-site if both the EMR and the results of peer review are appropriately secured.

Confidentiality: Peer review activities are confidential. Records are secure with access restricted to clearly defined personnel. Records of peer review activity are clearly labeled as "confidential and privileged" to maintain state protection from legal disclosure of peer review documents, if applicable.

3.2.2 Peer review, at a minimum, evaluates the following elements:

a) Clinical decision making,
b) Procedural or surgical technique through review of documentation, when applicable, and
c) The area of deficiency, if identified, is clearly defined and leads to a plan of correction and evidence of implementation.

(See Appendix F for sample Peer Review forms.)

3.2.3 Deleted.

3.2.4 Deleted.

3.2.5 The results of individual peer reviews, as well as potential trends in peer review, are considered in the credentialing and privileging process.

SECTION 3 - ORGANIZED MEDICAL STAFF (OMS) PEER REVIEW

3.3.1 Peer review determines the appropriateness of clinical decision-making and performance of procedures specific to each practitioner's specialty or scope of practice and/or clinical privileges. Medical staff bylaws establish standards for peer review prior to conducting the review.

Frequency: The peer review body meets on a regular basis, at least quarterly, and distributes peer review findings to the appropriate physicians and committees. There is an expedited peer review (within 7 days) of all unanticipated events (deaths, unplanned transfers to acute facilities, significant complications).

Number: Peer review covers the full scope of privileges granted to each practitioner. A minimum of 10 cases per practitioner per year will be reviewed or all cases if less than ten per provider per year.

Internal or external: When there are three or more physicians in the same specialty or with the same scope of practice and/or clinical privileges, internal review is appropriate. For specialties with one or two physicians, peer review is external. The qualifications of the external peer reviewers are defined and require individuals who are free from all conflicts of interest and are not professional associates of the providers being reviewed. A credential file is maintained on-site for all outside peer reviewers. At a minimum, the file contains a CV, verification of current licensure, and a confidentiality statement for the peer reviewer.

On-site or off-site: Facilities that choose to use paper records and choose off-site peer review ensure that every step of the process meets HIPAA and legal confidentiality requirements. Electronic records can be reviewed off-site if both the EMR and the results of peer review are appropriately secured.

Confidentiality: Peer review activities are confidential. Records are secure with access restricted to clearly defined personnel. Records of peer review activity are clearly labeled as "confidential and privileged" to maintain current state protection from legal disclosure of peer review documents.

3.3.2 Deleted.

3.3.3 Peer review, at a minimum, evaluates the following elements:

a) Clinical decision making,
b) Procedural or surgical technique through review of documentation, when applicable, and
d) The area of deficiency, if identified, is clearly defined and leads to a plan of correction and evidence of implementation.

(See Appendix F for sample Peer Review forms.)

3.3.4 Deleted.

3.3.5 Reports are filed with the state medical board and the National Practitioner Data Bank when required by state and federal law.

3.3.6 The results of individual peer reviews, as well as potential trends in peer review, are considered in the credentialing and privileging process.

CHAPTER FOUR – MEDICAL RECORDS

SECTION 1 - GENERAL REQUIREMENTS

4.1.1 The facility has a system for maintaining clinical records that are complete, comprehensive, and accurate, to ensure adequate patient care.

For facilities requesting CMS deemed status option:
The facility has a written medical records policy and procedure.

Information regarding medical records is found in Appendix H10.

4.1.2 The medical record is legible, complete, and organized in a consistent format.

There is a patient identifier (name or ID number) on each side of every page of the record. This is applicable to all pages printed from an EMR.

4.1.3 The medical record of the individuals receiving care is readily accessible to the health care professionals and includes the following:

a) Patient's name;
b) Date of birth;
c) Current address;
d) Home and work phone numbers;
e) Contact information for the person designated to be called in an emergency;
f) The patient's billing and/or insurance information;
g) Employer (if relevant); and
h) Notation of special circumstances for notification (e.g., hearing impaired).

4.1.4 Deleted.

4.1.5 Additions and corrections to the medical record are clearly indicated with reason for the change and are dated, timed, and initialed/signed. For paper records, deletions are shown with a single line through the entry. EMR entries

are never deleted.

4.1.6 Clinical records are completed within 30 days from the date services were provided.

4.1.7 The retention of medical records complies with applicable regulations and statutes.

Medical records are retained for at least seven years after the last patient encounter. The retention time for children's records is seven years after age 18. Off-site storage is in a secured facility experienced in confidential record storage.

4.1.8 The non-surgical medical record includes information needed to appropriately and safely treat patients, including, but not limited to:

a) A notation on allergies/adverse reactions or the absence thereof, documented in a prominent and consistent location;
b) Relevant history and physical exam including vital signs and pain assessment, if indicated;
c) Patient's immunization information, if indicated;
d) All pertinent findings, diagnoses, treatments, and documentation of physician's review, including follow-up instructions and appointments;
e) Results of pertinent laboratory, x-ray, and diagnostic studies and outside consultations, operative reports, etc., reviewed and initialed by the provider;
f) A problem list;
g) Individualized treatment plan;
h) Current medication lists;
i) Reports in chronological order;
j) Phone consultations when clinically relevant, including the date, time, and by whom;
k) Prescription and refills records with the drug name, dose, amount, date, and provider;
l) Informed consent documentation;
m) Notation as to whether the patient has an advance directive and copies of advance directive forms, if available;
n) Notes regarding patient refusal of care, non-compliance with treatments ordered, clinical appointments missed, etc.;
o) Documented preventative care, if indicated;
p) Patient education regarding diagnosis, treatment, and preventive

measures; and

q) The medical record is signed and dated.

This standard is not applicable to facilities requesting CMS deemed status option. The expected documentation of all medical records for facilities requiring CMS deemed status follow Standard 4.2.1.

4.1.9 Deleted.

SECTION 2 - SURGERY AND INVASIVE DIAGNOSTIC RECORDS

4.2.1 Facilities performing surgery or invasive diagnostic procedures have documentation in each patient's medical record, including:

a) A current comprehensive medical history and physical examination, including a problem list and current medication list, performed within 30 calendar days of the procedure, completed and placed in the patient's chart prior to surgery, with an assessment and plan that includes indications for surgery and the planned operation;
b) Updated H&P on the day of surgery performed by a physician to include assessment of heart, lungs, and airway and to assess risk of anesthesia and procedure;
c) A notation on allergies/adverse reactions or the absence thereof, documented in a prominent and consistent location;
d) Results of preoperative diagnostic studies, if performed;
e) A pre-operative anesthesia evaluation performed by a physician to assess anesthetic risk and options;
f) Written, signed consents for surgery and anesthesia;
g) An operative or invasive procedure note, written in the chart immediately after the surgery or procedure, with documentation that includes:
    i. The pre-operative or pre-procedure diagnosis and/or indications for surgery or procedure;
    ii. The operation/procedure performed;
    iii. The name of the surgeon, assistant surgeon, and provider of anesthesia;
    iv. The type of anesthesia administered;
    v. Post-operative or post-procedure diagnosis;
    vi. The details of operation or procedure including all findings;

vii. Any complications or adverse outcomes; and
viii. The patient's condition and prognosis after surgery or procedure;

h) An anesthesia record or means of documenting all patient monitoring, (physiologic monitoring and documentation should include, at a minimum, blood pressure, pulse rate, respiratory rate, continuous pulse oximetry, continuous electro-cardiogram monitoring, and, if intubated or LMA, End Tidal CO2);
i) Post-anesthetic note written after the patient has fully recovered from the effect of the anesthetic and documenting the presence or absence of any anesthesia related complications;
j) An order form or means of documenting all medications before, during, and after the surgery or procedure;
k) A recovery room record with documentation of monitoring and, at a minimum, an assessment of pain on entry and exit;
l) A pathology report authenticated by the physician, if indicated;
m) Copies of written pre-procedure and post-procedure patient instructions, including diet, activities, and when the patient should return for follow-up appointments;
n) Documentation that a post op call, when indicated, occurred within 24 hours. There is a policy that clearly defines what procedures require a post-op;
o) Dictated notes include the dates of dictation, transcription, and date of signature;
p) Notation as to whether the patient has an advance directive and copies of advance directive forms, if available; and
q) The medical record is signed, dated, and timed.

Except for CMS deemed status facilities, documentation for procedures that are minimally invasive, incisional or laser surgery - not including liposuction, performed under local or topical anesthesia, follow the requirements in Standard 4.2.2.

4.2.2 Facilities performing minimally invasive incisional or laser surgery (not including liposuction) under local or topical anesthesia have documentation in each patient's medical record, including:

a) A current focused medical history and relevant physical examination performed within one month of the procedure, completed and placed in the patient's chart prior to surgery, with an assessment and plan that includes indications for surgery and the planned operation;
b) Written, signed consents for surgery and local anesthesia;

c) Assessment of pain;
d) An operative or invasive procedure note, written in the chart immediately after the surgery or procedure, with documentation that includes:
    i. The pre-operative or pre-procedure diagnosis and/or indications for surgery or procedure;
    ii. The operation/procedure performed;
    iii. The name of the surgeon;
    iv. The type of anesthesia administered;
    v. Post-operative or post-procedure diagnosis;
    vi. The details of operation or procedure including all findings;
    vii. Any complications or adverse outcomes; and
    viii. A pathology report authenticated by the physician, if applicable;
e) Brief post procedure note including condition prior to discharge;
f) Documentation that patient post procedure instructions were given including when the patient should return for follow-up appointments;
g) Dictated notes include the dates of dictation, transcription, and date of signature; and
h) The medical record is signed, dated, and timed.

All procedures that fall under standard 4.2.2 are specifically listed in a written policy and procedure (otherwise, the expected documentation follows standard 4.2.1).

This standard is not applicable to facilities requesting CMS deemed status option. The expected documentation of all medical records for facilities requiring CMS deemed status follow Standard 4.2.1.

SECTION 3 - HIPAA AND CONFIDENTIALITY OF MEDICAL RECORDS

4.3.1 The facility ensures strict confidentiality of all patient information that includes, but is not limited to, medical records, patient sign-in lists, computer screen visibility, and patient-related conversations (including phone conversations).

See Appendix H8 for information regarding HIPAA privacy rules.

4.3.2 The facility has a compliance program that is consistent with the HIPAA Privacy Rules, to the extent the facility is a HIPAA covered entity, which complies with confidentiality requirements under state law.

See Appendix H8 for information regarding HIPAA privacy rules.

4.3.3 There is documentation that patients are given the HIPAA Notice of Privacy Practices.

A Policy and Procedure documenting how the Notice of Privacy Practices is distributed to the patient meets this requirement.

4.3.4 The Notice of Privacy Practices is posted in the office and, if the practice has a website, is available on the website.

4.3.5 Medical records are:

a) Accessible only to authorized individuals as defined by the facility in writing;
b) Stored in a secure area, readily accessible to appropriate health care providers, and inaccessible to the public; and
c) Stored in a secure place in which all reasonable efforts have been made to protect records from fire or other natural disasters.

Security for EMR also includes the following:

a) EMR screen sections are restricted in access by position and information limited based on the user's "need to know";
b) In patient care areas, terminals have screen protection and timed log-off.

4.3.6 The release of medical, mental health, and other patient information complies with applicable regulations and statutes.

See Appendix H8 for information regarding HIPAA privacy rules.

CHAPTER FIVE – CARE AND TREATMENT

SECTION 1 - CONSENT FOR CARE

5.1.1 Informed consent is a discussion with the patient and/or the patient's representative of the risks, benefits, and alternatives to a procedure, including not to treat, and is:

a) Obtained prior to any medical, psychiatric, invasive diagnostic or surgical procedure, except those simple and common procedures involving risks which are commonly understood to be remote, in which case a notation of verbal consent in the chart is sufficient;
b) Documented in the medical record;
c) Obtained prior to inclusion in any research or experimental protocol in accordance with the law and standards of the medical profession; and
d) Obtained prior to giving immunizations if required by laws or regulations.

5.1.2 Provisions are made to inform, as appropriate, the patient's representative of the patient's right to make informed decisions regarding the patient's care and include family members and significant others in the discussion and consent process, if requested by the patient.

SECTION 2 - CONTINUITY OF CARE

5.2.1 There is adequate staff for the volume of patients.

There is access to care commensurate with the clinical needs of the patient.

Generally accepted benchmarks for primary care accessibility (**not applicable to facilities requesting CMS deemed status option**) are:

a) Within twenty-four (24) hours for urgent appointments;
b) Within fourteen (14) days for specialist consultation appointments; and
c) Within thirty (30) days for physical examinations.

5.2.2 Continuity of care is provided.

There is evidence demonstrating that:

a) The facility has a process to assure that the responsible physician is aware of findings of diagnostic studies;
b) Patients are contacted in a timely manner, consistent with the patient's clinical status, with results from diagnostic testing;
c) Physician requests for consultation include the reason for the consultation and the information necessary for the formation of a properly founded opinion, e.g., information to which the consultant does not otherwise have access and that is important to assure appropriate medical care by the consultant;
d) Consultation reports are reviewed by the responsible physician in a timely fashion;
e) Patients are promptly contacted to discuss any significant consultation or pathology result; and
f) There are summary reports of other consultations and hospitalizations if the information is not already available to the treating physician.

5.2.3 Second opinions and referrals to consultants/specialists are timely and are appropriate to the patient's clinical condition.

5.2.4 Appropriate medical information and orders are provided to outside services when a patient is referred, to ensure appropriate care (e.g., home health, physical therapy).

5.2.5 Transfer of the patient's care to another provider (whether prompted by physician specialty, patient choice, insurance plan requirements or other reasons) is done in a professional manner with appropriate documentation forwarded to the new provider to ensure continuity of care.

5.2.6 Deleted.

SECTION 3 - DIAGNOSTIC TESTING

5.3.1 Testing performed is necessary and appropriate to the care being delivered.

5.3.2 There is follow-up by the facility to ensure that the tests are completed and the results are available for review by the medical staff. Abnormal results are acted upon in a timely manner and such action is documented in the medical record.

5.3.3 Patients are given the option of obtaining diagnostic services at a site of their choosing, when they must pay separately for recommended services. If a facility refers patients to a specific outside facility, it is an appropriately licensed facility.

5.3.4 Deleted.

SECTION 4 - MANAGEMENT OF MEDICATIONS

5.4.1 There is a written policy for the reduction of medication errors.

5.4.2 There is a consistent system for documenting and maintaining patients' prescriptions and renewal information.

Physicians document:

a) Patient's health conditions to avoid adverse drug/disease interactions;
b) Patient's medication allergies to avoid adverse drug/allergy interactions;
c) Medications the patient is taking, including medications from other prescribers; non-prescription medications including vitamins, herbals, and other supplements/remedies; and any substances used for recreational purposes, to avoid adverse drug/drug interactions and unintended drug duplications; and
d) That appropriate information regarding any prescribed medication was clearly explained to the patient.

5.4.3 There are policies and procedures for appropriate storage, administration, and dispensing of medications and biologic agents, to ensure that;

a) Drugs are prepared and administered according to established and acceptable standards of practice;
b) Medication and biological agents are inaccessible to patients;
c) Refrigerators used for storage of medication and biological agents are not used for any other purpose and are locked or located in a locked room;
d) Daily temperature log of refrigerators are maintained and out of norm notations are addressed; and
e) The lot number is logged for each patient when medication is dispensed and/or biologic agent is administered.

5.4.4 Syringes and basins containing medication or other solutions must be labeled with the name and concentration of the drug/combination of drugs, date, and time.

5.4.5 Adverse reactions must be reported promptly to the physician responsible for the patient and must be documented in the medical record.

5.4.6 Verbal orders for drugs and biologicals are followed by a written order and signed by the prescribing provider as soon as possible (the next time the physician enters the medical record, but within 24 hours). Policies and procedures for verbal orders include read-back and verification processes.

For facilities requesting CMS deemed status option:
Verbal orders followed by a written order are signed by a physician.

5.4.7 Prescription pads are stored in a secure area inaccessible to patients and non-authorized office staff. Prescription pads are signed by the prescribing provider at the time it is issued to the patient.

5.4.8 When the facility dispenses medications:
a) Applicable state laws regarding labeling of medications, including samples, are followed and
b) Patients are given the opportunity to fill the prescription at a pharmacy of their choice, if the facility imposes a fee for dispensing.

5.4.9 Outdated medications are destroyed in compliance with policy and regulation, to ensure that:

a) Medications intended for single use or medications without a preservative are discarded after single use is completed and
b) Multiple use vials:
    i. Are dated and initialed upon initial opening and
    ii. Are discarded within 28 days of initial opening except for vaccines that can be kept until the manufacturer's expiration date.

5.4.10 Scheduled drugs (parenteral and/or oral) are logged and accounted for.

There are policies and procedures to ensure the security of all scheduled drugs, and include:

a) Storage of medications is in a double-locked area;
b) Access (and both sets of keys) is limited to licensed individuals*;
c) Wastage of narcotics/controlled substances is witnessed and documented by two licensed individuals*;
d) At the beginning of any day when narcotics/controlled substances are accessed, two licensed individuals* independently count and document all narcotics/controlled substances; and
e) At the end of any day that narcotics/controlled substances were accessed, two licensed individuals* independently count and document all narcotics/controlled substances, as well as notation of any discrepancies.

*__Note__: If state law permits, a medical assistance with special training, and with this responsibility clearly defined in the job description, may substitute for one licensed individual.

5.4.11 **For facilities requesting CMS deemed status option**:
The facility designates a specific licensed healthcare professional to provide direction to the pharmaceutical services.

CHAPTER SIX – FACILITY AND ENVIRONMENTAL SAFETY

SECTION 1 - INFECTION CONTROL

6.1.1 There is a written infection control program detailing a plan for preventing, identifying, and managing infections and communicable diseases, and for immediately implementing corrective and preventive measures that result in improvement. The program requires:

a) Proper training of personnel and
b) Compliance with OSHA Blood-Borne Pathogen requirements.

The program is under the direction of a designated and qualified professional who has training in infection control.

The program is an integral part of the facility's quality assessment and performance improvement program.

For facilities requesting CMS deemed status option:
Facility follows Infection Control guidelines chosen from one of the nationally recognized infection control organizations. This is documented in Governing Body meeting minutes or in the Infection Control Policies and Procedures.

6.1.2 The facility provides a safe and sanitary environment for the provision of surgical/invasive procedures. The environment is maintained to protect the health and safety of patients. Facility adheres to acceptable national standards of practice. This includes, but is not limited to:

a) Adherence to universal precautions;
b) Adherence to aseptic techniques;
c) Handling (packaging, storing, and labeling) and sterilization of reusable medical instruments and supplies according to manufacturer's specifications;
d) Routine systematic cleaning of all environmental surfaces, use of cleaning agents, and cleaning between surgical/invasive procedures;
e) Handling of infected or contaminated patients and those with communicable diseases;

f) Procedures to limit the spread of infections among patients, health care providers, and through families;
g) Separate disposal of infectious waste in labeled bags/containers and a contract with a licensed service provider organization;
h) Disposal of needles and other hazardous objects in secure containers;
i) Care of surgical specimens;
j) Techniques for food sanitation, if employee food storage and eating areas are provided;
k) Techniques for pest control; and
l) Clear separation of clean and dirty laundry areas.

6.1.3 Access to the operating room is limited to designated personnel in proper surgical attire.

Doors to the operating room are labeled. A red line on floor delineates limited access areas.

6.1.4 Deleted.

6.1.5 Alcohol based hand rub dispensers are installed in a manner that adequately protects against inappropriate access and fire safety.

For facilities requesting CMS deemed status option
The facility meets the provisions applicable to the Ambulatory Health Care Occupancy (AHCO) Chapters of the 2012 NFPA 101 edition of the Life Safety Code (LSC) including Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4, the applicable chapters of NFPA 99 – Healthcare Facilities Code of the National Fire Protection Association (NFPA), and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6.

SECTION 2 - FIRE SAFETY

6.2.1 The facility complies with locally required fire inspections and regulations.

A yearly fire inspection certificate or documentation from the Fire Marshall

that a yearly inspection is not required, is available.

6.2.2 Lighted exit signs, that operate when power fails, and simple maps are posted, to ensure that patients and staff members can rapidly determine fire evacuation routes. Dead end halls are clearly marked "no exit". Doors leading to exits are unlocked during business hours.

Facility conducts and documents functional tests of battery powered lights once a year.

For facilities requesting CMS deemed status option:
The facility meets the provisions applicable to the Ambulatory Health Care Occupancy (AHCO) Chapters of the 2012 NFPA 101 edition of the Life Safety Code (LSC) including Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4, the applicable chapters of NFPA 99 – Healthcare Facilities Code of the National Fire Protection Association (NFPA), and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6.

6.2.3 Fire drills are conducted at least twice a year. Dates of drills, names of participants, and evaluation are documented. Availability of part-time staff is considered when scheduling drills. All new staff is oriented to fire safety. A new facility conducts a fire drill prior to the date of their initial survey.

For facilities requesting CMS deemed status option:
The facility meets the provisions applicable to the Ambulatory Health Care Occupancy (AHCO) Chapters of the 2012 NFPA 101 edition of the Life Safety Code (LSC) including Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4, the applicable chapters of NFPA 99 – Healthcare Facilities Code of the National Fire Protection Association (NFPA), and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6.

6.2.4 If fire extinguishers are required by the local jurisdiction, they are:

a) Visible;
b) Conveniently located;
c) Serviced on a regular basis; and
d) Staff is trained in their use.

Fire extinguisher maintenance is not a substitute for a fire inspection as

required in 6.2.1.

For facilities requesting CMS deemed status option:
The facility meets the provisions applicable to the Ambulatory Health Care Occupancy (AHCO) Chapters of the 2012 NFPA 101 edition of the Life Safety Code (LSC) including Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4, the applicable chapters of NFPA 99 – Healthcare Facilities Code of the National Fire Protection Association (NFPA), and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6.

6.2.5 There is training in fire and emergency procedures in oxygen-enriched environments, where applicable, that includes, understanding and limiting risk of fire when using alcohol-based skin cleaner and electro-cautery devices.

6.2.6 Emergency lighting of exit paths is available.

For facilities requesting CMS deemed status option:
The facility meets the provisions applicable to the Ambulatory Health Care Occupancy (AHCO) Chapters of the 2012 NFPA 101 edition of the Life Safety Code (LSC) including Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4, the applicable chapters of NFPA 99 – Healthcare Facilities Code of the National Fire Protection Association (NFPA), and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6.

SECTION 3 - PREPARATION FOR EMERGENCIES

6.3.1 There are written policies and procedures for emergency preparedness (responding to non-medical emergencies) that include staff roles and responsibilities, including the evacuation of incapacitated patients.

Non-medical emergencies can include fire, natural disasters (earthquakes, floods), equipment failure, or other unexpected events such as bomb threats, violent patients, etc.

For facilities requesting CMS deemed status option:

The facility develops an emergency preparedness program that complies with all Federal, State, and local emergency preparedness requirements and includes the following elements:

a) Develop, maintain, document, and annually review and update an emergency preparedness plan that includes:
    1. A facility and community-based risk assessment that utilizes an all-hazards approach.
    2. The plan includes the strategies for addressing the events identified.
    3. The plan addresses the facility's patient population, the types of services that could be provided for continuity of operations to include delegation of authority and succession plans.
    4. A process for cooperation and collaboration with all relevant authorities*. The facility documents all efforts to contact officials and, when applicable, document its participation in collaborative and cooperative planning efforts.

b) Develop, implement, and annually review and update policies and procedures that align with the hazards identified in the risk assessment and addresses:
    1. A system to track the location of on-duty staff and patients, as well as the name and location of the facility receiving relocated patients.
    2. Means for safe evacuation, including consideration of care and treatment needs of evacuees, staff responsibilities and transportation, identification of evacuation locations(s), and primary and alternate means of communication with external sources of assistance.
    3. Plan for shelter in place,
    4. System -of medical documentation that preserves patient information, protects confidentiality of medical information, and secures and maintains availability of records,
    5. Use of volunteers in an emergency and other staffing strategies, including the process and role for integration of State and Federally designated health care professionals to addresses patient surge, and
    6. Facility's role under a waiver declared by the Secretary, in accordance with sections 1135 of the Act, in providing care and treatment at an alternate care site identified by emergency management officials.

c) Develop, maintain, and annually review and update a communication plan that addresses coordination within the facility, across healthcare

providers, and relevant authorities* and includes:

1. Names and contact information for:
   - Staff,
   - Entities providing services under agreements,
   - Patients' physicians, and
   - Volunteers.
2. Contact information for relevant authorities and other sources of assistance,
3. Primary and alternate means to communicate with facility staff and relevant authorities,
4. A method for sharing information and medical documentation for patients under the ASC's care, as necessary, with other health care providers to maintain continuity of care,
5. A means to release patient information as permitted under 45 CFR 164.510(b)(1)(ii), if evacuation is required,
6. A means for providing information regarding the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4), and
7. Means of providing information regarding the facility's needs and ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

d) Develop, maintain, and annually review and update an emergency preparedness training and testing program based on the facility's emergency plan that includes the risk assessment, the policies and procedures, and the communication plan.
   1. Training includes education and instruction to all staff. The facility must do all of the following:
      i. Initial training in all policies and procedures to all staff, individual providing on-site services under agreement, and volunteers, consistent with their expected roles,
      ii. Train annually,
      iii. Maintain documentation of all training, and
      iv. Demonstrate staff knowledge.
   2. Testing is operationalizing the plan, i.e., conducting drills. The facility must conduct exercises to test the plan at least annually and must do all of the following:
      i. Participate in a community-based full-scale exercise, or, if not accessible, an individual, facility-based one,
      ii. Conduct an additional exercise, that may be:
         A. A second full-scale exercise, or
         B. A tabletop exercise that includes a group discussion led by

a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

iii. Analyze the facility's response and maintain documentation of all drills, tabletop, and emergency events, and revise the plan as needed.

e) If the facility is part of a healthcare system consisting of multiple separately certified facilities that elects to have a unified and integrated emergency preparedness program, the ASC may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:
   1. Demonstrate that each separately certified facility within the system actively participates in the development of the integrated plan,
   2. Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patients, and services offered,
   3. Demonstrate that each separately certified facility is capable of actively using the unified and integrated program and is in compliance,
   4. The unified and integrated emergency plan must be based on and include:
      i. An all-hazards community-based approach, and
      ii. Document the individual entity-based all-hazards risk assessment for each separately certified facility within the system, and
   5. Include integrated policies and procedures and meet the requirements of a communication plan and a training and testing program.

* Relevant authorities include local, tribal, regional, State, and Federal emergency preparedness officials, and emergency management agencies.

(See Appendix J for available resources)

6.3.2 Deleted.

6.3.3 The facility's medical staff and governing body coordinates, develops, and

revises, policies and procedures to specify the types of emergency equipment and emergency medications required in the operating room. Emergency equipment is immediately available for use during emergency situations and is commensurate with the types of services provided.

Facilities that administer anesthesia are suitably equipped and have ACLS-certified staff members available to respond to an emergency.

Emergency equipment and medications meet current standards of practice and take into consideration the patient population served at the facility and the scope of procedures performed, at a minimum includes:

a) Emergency call system (for large facilities);
b) Oxygen;
c) Mechanical ventilator assistance equipment, including airways, manual breathing bag, and/or ventilator;
d) Cardiac defibrillator;
e) Cardiac monitoring equipment;
f) Laryngoscope and endotracheal tubes;
g) Suction equipment; and
h) Lights and back-up power to equipment used in surgery.

Appropriate emergency equipment is available for pediatric patients, if applicable.

For facilities requesting CMS deemed status option:
The facility has supplies of medications required to treat malignant hyperthermia when the facility uses anesthetics that carry MH risk.

6.3.4 The facility has emergency power sources with:

a) The capability to start immediately upon cessation of power;
b) The ability to power all equipment, including lighting and physiologic monitors, necessary to ensure patient safety and complete or safely terminate a procedure in progress;
c) Documented functional tests as per manufacturer's recommendation; and
d) Evidence of scheduled maintenance.

For facilities requesting CMS deemed status option:
The facility meets the provisions applicable to the Ambulatory Health Care Occupancy (AHCO) Chapters of the 2012 NFPA 101 edition of the Life Safety Code (LSC) including Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4, the applicable chapters of NFPA 99 –

Healthcare Facilities Code of the National Fire Protection Association (NFPA), and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6.

6.3.5 There are written policies and procedures for responding to medical emergencies. Staff members are aware of their roles and responsibilities.

6.3.6 Deleted.

6.3.7 There is a written plan for the safe management of the patient in the event that the physician and/or anesthesia provider becomes physically incapacitated during the procedure.

6.3.8 Disaster drills are conducted annually. Dates of drills, names of participants, and evaluation are documented. Availability of part-time staff is considered when scheduling drills.

6.3.9 There is a written policy for transferring a patient to a hospital in an emergency, that includes the following:

a) The physician transferring the patient notifies the receiving facility;
b) The mode of transfer is consistent with the patient's clinical condition and acuity, e.g., ambulance;
c) The individual designated in the record as a contact in case of emergency is notified;
d) Pertinent clinical information is documented and sent with the patient;
e) If the physician does not have privileges at the facility to which the patient is being transferred, arrangements are made for medical care to be provided by physicians who do have privileges, and
f) The facility continues to provide care until the transfer is complete.

For facilities requesting CMS deemed status option:
The policy includes all the aforementioned elements. Element (e), above requires that, if the physician does not have privileges at the facility to which the patient is being transferred, the facility must transfer the patient to the hospital with which it holds a transfer agreement.

The policy identifies both the circumstances that warrant emergency transfers and the person that makes the transfer decision.

(See Chapter 7, Section 9 for information regarding reporting requirements for emergency transfers.)

SECTION 4 - FACILITY EQUIPMENT

6.4.1 Laboratory, medical, surgical, and anesthesia equipment is:

a) Operated by qualified personnel and
b) Properly maintained, tested, and calibrated by qualified personnel according to manufacturer's specifications. A log documenting this activity is maintained.

For facilities requesting CMS deemed status option:
The facility meets the provisions applicable to the Ambulatory Health Care Occupancy (AHCO) Chapters of the 2012 NFPA 101 edition of the Life Safety Code (LSC) including Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4, the applicable chapters of NFPA 99 – Healthcare Facilities Code of the National Fire Protection Association (NFPA), and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6.

6.4.2 Radiology and imaging equipment complies with state regulations.

The facility ensures that:

a) The radiologic services are free from hazards for patients and personnel;
b) Proper safety precautions are maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials;
c) Periodic inspection and maintenance of equipment is completed;
d) Staff use exposure meters or badges to measure radiation exposure;
e) Radiologic services are provided only on the order of practitioners with clinical privileges;
f) A qualified full-time, part-time, or consulting radiologist or other qualified practitioner* supervises the radiology services;
g) Tests are interpreted by a radiologist or other practitioner*, and
h) The radiologist or other practitioner* who performs radiology

services signs reports of his or her interpretations.

*As required by the state.

Records of radiologic services must be maintained.

See Appendix H for California specific requirements.

For facilities requesting CMS deemed status option:
The facility only provides radiological services as an integral part of the surgical procedures it performs.

The scope and complexity of radiological services provided within the ASC, either directly or under arrangement, as an integral part of the ASC's surgical services must be specified in writing and approved by the physician owner(s)/Medical Director/Governing Body.

6.4.3 The facility has functioning, well maintained, and appropriate equipment for the perioperative care of patients for the scope of procedures.

SECTION 5 - FACILITY DESIGN AND ACCESS

6.5.1 The facility is clean and well maintained.

Hazards that might lead to physical injury of patients or staff members are removed.

6.5.2 The facility provides sufficient seating in the patient waiting area.

6.5.3 Visual and auditory privacy is provided for health encounters. There is privacy for dressing and undressing.

6.5.4 There are a sufficient number of patient examination rooms.

6.5.5 The facility and restrooms are accessible to those with disabilities.

6.5.6 There is adequate parking available for patients. There is handicap designated parking.

CHAPTER SEVEN – SURGERY, ANESTHESIA, AND INVASIVE DIAGNOSTIC PROCEDURES

SECTION 1 - SURGERY AND ANESTHESIA SERVICES

7.1.1 The facility's surgical procedure list is developed by the physician owner(s)/Medical Director/Governing Body based on the training and experience of the providers at the facility performing the procedures, and is appropriate to the providers' scope of practice.

(Also, see standard 1.2.3)

7.1.2 The facility, equipment, and medications are adequate and appropriate for the types of procedures being performed.

7.1.3 The medical staff (including the individuals administering anesthesia) are licensed, legally and professionally qualified, and working within their scope of practice. Written documentation defines the qualifications of such personnel and a mechanism for peer review.

For facilities requesting CMS deemed status option:
Anesthetics are administered by a physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempt, 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.

NOTE: State Exemption
An ASC may be exempted from the requirement for physician supervision of CRNAs, (CFR 416.42.(b)(2)), 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.

The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and is effective upon submission.

7.1.4 Written documentation addresses the administration of anesthesia and includes:

a) Evaluation of each patient's anesthetic risk category prior to their receiving anesthesia, to be done by the licensed practitioner whose scope of practice permits;
b) Assignment of a risk category* for each patient receiving anesthesia;
c) Documentation that the pre-anesthesia assessment and discussion of risks with the patient is done prior to a scheduled procedure; and
d) Assignment of oral airway access designation (e.g., Mallampati) for conscious/deep sedation and general anesthesia patients.

*Risk category refers to the standard risk categories of the American Society of Anesthesiology (ASA). If another system is used, the facility defines the categories.

For facilities requesting CMS deemed status option:
Written policies and procedures determine the criteria used for conducting the risk assessment and to ensure the assessment of anesthesia-related risk is completed just prior to surgical procedure.

7.1.5 There is a surgical pause (**TIME OUT)** before starting the procedure/surgery/laser treatment to ensure that the following is correct and confirmed:

a) Patient;
b) Site;
c) Procedure;
d) Required documents; and
e) Equipment and supplies.

The above is documented in the medical record.

7.1.6 There is a signed consent for anesthesia following discussion with the provider. If the consent form is combined with the surgery consent, it is signed after the conversation with the provider.

Combined consents require a signature for each section - anesthesia and surgery/procedure.

7.1.7 There are two persons present in the room during all procedures, one of whom is a licensed physician or a licensed health care professional with certification in ACLS (advanced cardiac life support).

SECTION 2 - INTRA-OPERATIVE MONITORING

7.2.1 Written policies and procedures require physiologic monitoring during any procedure where conscious/moderate or deep sedation or general anesthesia is used. Documentation in the medical record will reflect policy.

Regular periodic assessment of the patient's vital signs (temperature, pulse, blood pressure, respiratory rate, and pulse oximetry) is performed by a clinician functioning within the permitted "scope of practice", with the interval based on the patient's underlying health condition and the nature of the procedure as outlined in the policy.

SECTION 3 - OPERATING ROOMS

7.3.1 Operating/procedure rooms are of sufficient size and are appropriately equipped for the type of surgeries/procedures performed. The design takes into account the physical safety of both patients and staff.

7.3.2 The operating room(s) is constructed and equipped to meet state and local building and fire codes.

The norms for air exchange rate are 12-20 times per hour and 20-60%

humidification. Air exchange rates apply to operating room(s) and procedure room(s).

For facilities requesting CMS deemed status option:
Facility maintains temperature and humidity logs for the operating room(s). Appropriate levels are maintained. When levels are not within acceptable parameters, corrective actions are performed in a timely manner, and documented.

The facility maintains humidity levels in operating rooms in accordance with nationally accepted guidelines and follows current manufacturers' instructions for use (IFU) regarding humidity levels of supplies and equipment used in their operating rooms.

The facility meets the provisions applicable to the Ambulatory Health Care Occupancy (AHCO) Chapters of the 2012 NFPA 99 ASHRAE 170 requirements per 2012 NFPA 99.

7.3.3 Only non-flammable anesthetic agents are present in the operating room.

7.3.4 A surgical or procedure log is maintained and includes:

a) Name, age, and gender of patient;
b) Date of operation/procedure;
c) Name of surgeon, assistant surgeon, if applicable, and anesthesia provider;
d) Surgical or invasive procedure performed;
e) Complications, if any, of the surgery or procedure; and
f) Specimens, if any.

SECTION 4 – RECOVERY

7.4.1 There are no less than two people on-site, one of whom is a physician or a licensed health care professional with certification in ACLS (advanced cardiac life support, which includes the use of emergency equipment and CPR), until all patients are clinically discharged.

For facilities requesting CMS deemed status option:

The facility has a registered nurse available for emergency treatment whenever there is a patient in the ASC.

7.4.2 All patients are evaluated as they enter the recovery phase. This is reflected in written policies and procedures.

Physiologic monitoring is extended into the post-operative (recovery) period depending upon the level of anesthesia and the needs of the patient. Monitoring includes at a minimum blood pressure, pulse, respiratory rate, and continuous pulse oximetry and is reflected in the policy.

Monitoring is documented in the medical record. (See 4.2.1)

For facilities requesting CMS deemed status option:
Policies and procedures for post-anesthesia care include assessment and monitoring of respiratory function (rate, airway patency, and O2 saturation), cardiovascular function (pulse rate and blood pressure), mental status, temperature, pain, nausea and vomiting, and postoperative hydration.

7.4.3 The recovery area is staffed by an adequate number of trained and qualified personnel.

The staffing ratio in the recovery area is consistent with national standards and applicable state regulations.

For California facilities: The minimum number required to staff the recovery area is one licensed nurse to every two patients. If an LVN is staffing the recovery room, an RN or MD is immediately available.

7.4.4 There is appropriate physical space and equipment for the safe recovery of a patient.

For facilities requesting CMS deemed status option:
Facility has a room, separate from other areas of the ASC, where patients recover. This room may also be used for preoperative preparation. The facility also has a waiting area that is separate from other areas of the ASC.

SECTION 5 - PATIENT DISCHARGE

7.5.1 There are written criteria for discharge.

7.5.2 All patients are evaluated prior to clinical discharge.

a) This evaluation is done by a LIP or if standardized protocols are allowed in the state in which the facility operates, an RN/PA working according to standardized protocol may conduct the evaluation, and
b) The documentation of the evaluation matches the criteria for discharge.

For facilities requesting CMS deemed status option:
Each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

Each patient is evaluated by a physician or by an anesthetist, for proper anesthesia recovery.

7.5.3 The physician or anesthesia provider who performed the procedure is immediately available until the patient has been clinically discharged.

7.5.4 All patients who receive sedation or anesthesia leave the facility in the company of a responsible adult, except those patients exempted by the attending physician.

7.5.5 Patients receive clear, appropriate, verbal and written post-operative instructions, and overnight supplies, including:

a) How to obtain 24-hour assistance and
b) When and where to go for follow-up care with the provider.

It is recommended that the individual who will be caring for the patient also sign the discharge instructions.

7.5.6 Physicians performing surgery continue patient care throughout the post-

operative period - after discharge from the facility (e.g., follow-up appointments). If the physician is not personally available, appropriate arrangements are made with a qualified, licensed physician.

SECTION 6 - STANDARDS FOR LASERS

7.6.1 Providers using lasers may do so only within their scope of practice, and must have documented training and experience with lasers to qualify for privileges in the facility.

See Appendix H7 for information regarding cosmetic procedures including use of lasers.

7.6.2 Use of laser technology requires proctoring or evidence of privileges at another accredited facility.

7.6.3 Patients are evaluated by an appropriate practitioner before treatment to determine if they qualify for laser therapy.

7.6.4 Informed consent for laser procedures is based on physician communication regarding the procedure and the potential complications. Manufacturer information (for the laser device) is available upon patient request.

Consent is documented in the medical record.

7.6.5 Lasers meet FDA Mandatory Performance Standards and are inspected periodically according to manufacturers' instructions.

7.6.6 Policies and procedures for laser use ensure the safety of patients and staff.

The following safety procedures are included:

a) Prominent signage on entry doors that states lasers are in use;
b) Protection of eyes and exposed areas for all people exposed to the laser using appropriate devices for the intended laser;

c) Utilization of smoke evacuators, appropriate devises to control tissue debris or high filtration masks and/or wall suction with filters to minimize laser plume inhalation;
d) Compliance with state and local environmental regulations and recommendations for the use of lasers;
e) Documentation logs of all inspection and maintenance of equipment;
f) Operation and maintenance of the laser and other equipment within the guidelines of the manufacturer; and
g) Precautions against chemical and fire hazards.

7.6.7 Deleted.

SECTION 7 – LIPOSUCTION

7.7.1
The following standard applies to any liposuction procedure performed in the outpatient setting:

Less than 2,000 ml total aspirate	**More than 2,000 ml total aspirate**
1. Intravenous Access and Emergency Plan	
Intravenous access is optional with supplies available if needed.	Intravenous access is **required**
2. Anesthesia	
The physician who is performing the procedure is not also administering or maintaining the anesthesia or sedation unless a licensed person certified in advanced cardiac life support (ACLS) is present and is monitoring the patient.	
3. Monitoring	
Monitoring is available if needed.	Monitoring is **required**.
i. Pulse oximeter; ii. Blood pressure (by manual or automatic means); iii. Fluid loss and replacement monitoring and recording; and iv. Electrocardiogram.	
4. Records	
Records are maintained in the manner necessary to meet the standard of practice and include sufficient information to determine the quantities of drugs and fluids infused and the volume of fat, fluid, and supernatant extracted, and the nature and duration of any other surgical procedures performed during the same session as the liposuction procedure.	

See Appendix H9 for information regarding liposuction.

SECTION 8 - LABORATORY AND PATHOLOGY SERVICES

7.8.1 Ambulatory surgery centers providing clinical laboratory services, including pathology services, have a valid CLIA certificate and if

applicable, a valid state license.

If the ambulatory surgery center refers patient specimens to a reference laboratory, the reference laboratory is CLIA certified and, if applicable, state licensed.

See Appendix H for California laboratory registration requirement information.

7.8.2 Biological specimens are placed in a secured location or container until transported.

7.8.3 There are policies and procedures for access to blood and blood products, if the procedure warrants it, that address:

a) Personnel responsible for the administration of the products. Only physicians and registered nurses administer blood and blood products;
b) Timely access to the products;
c) Appropriate means for storage of the blood until administered; and
d) Obtaining the blood from an approved qualified source.

SECTION 9 - PATIENT TRANSFER

7.9.1 All facilities performing surgical procedures comply with one of the following:

a) Have a written transfer agreement with a local accredited or licensed acute care hospital that is approved by that hospital's medical staff. (The transfer agreement shall include a mechanism for patient transport; a plan for transfer of patient's records; policies defining the role of each person in handling the emergency; and a plan for continuity of the patient's care upon transfer of that care.)
b) Permit surgery only by licensed practitioners who have admitting privileges at a local accredited or licensed acute-care hospital. (Practitioners who are precluded from having admitting privileges by their professional classification, have a written transfer agreement with practitioners with appropriate expertise who have admitting privileges at a local accredited or licensed hospital.)
c) Submit a detailed procedural plan for handling medical emergencies

and the transfer and admission of patients to an acute-care facility when necessary.

A local hospital is defined as one at a reasonable distance from the surgery center, especially in a metropolitan area.

For facilities requesting CMS deemed status option:
Facility transfers patients to the nearest Medicare-participating hospital, or non-participating hospital that meets the requirements for payment for emergency services (CFR 482.2).
Option C, above, is not permitted for Medicare deemed status ASCs.

7.9.2 All physicians with privileges at the facility agree to cooperate with the receiving hospital's medical staff peer review process involving the transfer of any patient to that hospital.

7.9.3 FOR CA FACILITIES ONLY In the event of a patient transfer to a hospital, if the hospital's medical staff determines that inappropriate care was delivered by the outpatient setting, all of the following must be met:

a) The hospital shall report these findings in a confidential communication to all of the following agencies: IMQ, CMS, DHS, and the state medical board or appropriate licensing agency);
b) The outpatient setting must perform a thorough peer review of the incident and take appropriate corrective action; and
c) If the hospital medical staff imposes any restrictions on the physician's privilege status on the hospital medical staff, this must be reported to the IMQ by the outpatient setting.

7.9.4 A written report by the physician is filed with the state medical board or appropriate entity within 5 days of occurrence of an adverse event within seven days of a procedure performed at the surgery center, when required by the state.

See Appendix H2 for adverse event reporting forms for California.

7.9.5 A written report by the physician is filed with the appropriate state agency within 15 days of occurrence of a transfer to a hospital or emergency center, or the patient goes by him/herself, for medical treatment that exceeds 24

hours within seven days of a procedure performed at the surgery center.

See Appendix H2 for adverse event reporting forms for California.

7.9.6 The physician must report to IMQ within 5 days any unanticipated event (transfer to a hospital or emergency center for medical treatment that exceeds 24 hours, any admission to the hospital, and any occurrence of a death, or adverse event) within seven days of a procedure performed at the surgery center.

See Appendix H2 for adverse event reporting forms for California.