STANDARDS FOR ACCREDITATION OF OFFICE BASED SURGERY OR DIAGNOSTIC PROCEDURES REQUIRING CONSCIOUS SEDATION, MAJOR NERVE BLOCK OR GENERAL ANESTHESIA

PREAMBLE: The Oregon Medical Association, in an effort to continue its pursuit of the highest quality and safest medical care possible for the citizens and guests of the state of Oregon, sets forth herein standards for the conduct of office-based surgery or diagnostic procedures and sedation and anesthesia. The purpose of the document is to provide clarity and standardization to medical practitioners performing office procedures that would otherwise result in an unacceptable level of discomfort to patients, and in order to secure a safe environment for those patients undergoing such procedures. Three levels of sedation have been recognized and defined by the American Society of Anesthesiology: Mild Sedation (or Anxiolysis), Moderate Sedation (Conscious Sedation), and Deep Sedation, with a fourth and subsequent level being General Anesthesia.

Beginning with Mild Sedation, each of these levels may pass into the next level achieving deeper sedation than was initially intended, which requires an increased vigilance, observation, monitoring, and skills to avoid untoward side effects or complications such as cardiac or respiratory depression, leading to hypoxia, hypercarbia, acidosis, cardiac arrhythmias and possibly death. Patient selection should be limited to individuals who are generally healthy or who have stable medical conditions as ascertained through appropriate medical history and physical examination and deemed to have a remote possibility of exacerbation or deterioration of their medical condition requiring transfer to a hospital. Offices shall be accredited in accordance with their ability to care for patients under the categories: Class A, Class B, and Class C facilities. The terminology surrounding the use of analgesics, sedatives and anesthetic agents as well as levels of the descriptive continuum of mental states from unaltered, alert consciousness to general anesthesia are delineated in following DEFINITIONS.

DEFINITIONS:

1. Advanced Cardiac Life Support (ACLS) trained-means that a licensee has successfully completed and requalified periodically an advanced cardiac life support course offered by a recognized accrediting organization appropriate to the licensee's field of practice. For example, for those licensees treating adult patients, training in advanced cardiac life support (ACLS) is appropriate; for those treating children, training in pediatric advanced life support (PALS) or advanced pediatric life support (APLS) is appropriate.

2. Basic Life Support (BLS) – Noninvasive assessments and interventions used to treat victims of respiratory and/or cardiovascular emergencies and stroke. This term has become synonymous with cardiopulmonary resuscitation (CPR) insofar as it employs the “A, B, Cs” of resuscitation management including: A - initial assessment and airway maintenance; B - ventilation via rescue breathing; and C - chest compressions for temporary support of circulation. “D” - defibrillation is also considered as a part of BLS where an Automatic External Defibrillator (AED) can be used. BLS requires periodic re-certification.
3. **Anesthesiologist**—means a physician who has successfully complete a residency program in anesthesiology approved by the Accreditation Council of Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA), or who is currently a diplomat of either the American Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982.

4. **Anesthetizing location**—means any location in an office where anesthetic agents are administered to a patient.

5. **Certified registered nurse anesthetist (CRNA)**—means a registered nurse who successfully completed an advanced, organized formal educational program in nurse anesthesia accredited by the national certifying organization of such specialty which is recognized by the Oregon Board of Nursing; and is certified by a board approved national certifying organization, and who demonstrates advanced knowledge and skills in the delivery of anesthesia services. The Certified Registered Nurse Anesthetist must practice in accordance with approved written guidelines developed under the supervision of a licensed physician or dentist or approved by the medical staff within the facility where practice privileges have been granted.

6. **Complications**—means an untoward event occurring at any time within 48 hours of any surgery, special procedure or the administration of anesthesia in an office setting including, but not limited to, any of the following: paralysis, nerve injury, malignant hyperthermia, seizures, myocardial infarction, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, unintended hospitalization for more than 24 hours, or death.

7. **Credentialed**—means that a practitioner or physician has been granted and continues to maintain, the privilege by a facility licensed in the jurisdiction in which it is located to provide specified services, such as surgery or the administration or supervision of the administration of one or more types of anesthetic agents or procedures, or can show adequate documentation of training experience in specified services such as surgery that is performed more often in an office or outpatient setting.

8. **Deep Sedation**—a drug induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

9. **General Anesthesia**—means a drug induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

10. **Health care personnel**—means personnel licensed by or registered by the Oregon Board of Medical Examiners or the Oregon Board of Nursing to perform medical therapeutic or diagnostic procedures, to provide nursing services or to administer anesthesia.
11. *Hospital* - means a facility licensed as such by the Oregon State Health Division.

12. *Local Anesthetic* - means the administration of an agent that produces a transient and reversible loss of sensation in a circumscribed portion of the body.

13. *Major Surgery* - means surgery that requires deep sedation, general anesthesia or major conduction blockade for patient comfort.

14. *Major conduction blockade* - means the injection of a local anesthetic agent in close proximity to a specific nerve or nerves to stop or prevent a painful sensation in a region of the body. Major conduction blocks include, but are not limited to, all blocks and approaches to the brachial plexus, spinal blocks, epidural and caudal blocks.

15. *Minimal sedation* - (Anxiolysis) - is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

16. *Moderate sedation (Conscious Sedation)* - is a drug induced depression of consciousness during which patients respond purposefully* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

   * Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

17. *Minor Surgery* - means surgery that can be safely and comfortably performed on a patient who has received local or topical anesthesia, pre-operative medication or moderate intraoperative sedation and where the likelihood of complications is remote.

18. *Minor Conduction Block* - means the injection of a local anesthetic to stop or prevent a painful sensation in a circumscribed area of the body (that is, infiltration or local nerve block), or the block of a nerve by direct pressure or refrigeration. Minor nerve blocks include but are not limited to, intercostals, retrobulbar, paravertebral, peribulbar, pudendal, sciatic nerve, and ankle blocks.

19. *Monitoring* - means continuous visual observation of a patient and regular observation of the patient as deemed appropriate by the level of sedation or recovery using instruments to measure, display, and record physiologic values such as heart rate, blood pressure, respiration and oxygen saturation.

20. *Office* - means a location at which medical or surgical services are rendered and which is not subject to the jurisdiction of and licensing by the Oregon Health Division.

21. *Office-based surgery* - means the performance of any surgical or other invasive procedure requiring anesthesia, analgesia, or sedation, including cryosurgery and laser surgery, which results in a necessary patient stay of less than twenty-four consecutive hours and is performed by a practitioner in a location other than a hospital, free-standing surgery center, or a diagnostic treatment center licensed as defined in No. 20 above.
22. Operating room- means that location in the office dedicated to the performance of surgery or special procedures.

23. Physical status classification- means a description of a patient used in determining if an office procedure is appropriate. The American Society of Anesthesiologists enumerates classification: I - Normal, Healthy patient; II - a patient with mild systemic disease; III - a patient with severe systemic disease limiting activity but not incapacitating; IV - a patient with incapacitating systemic disease that is a constant threat to life; and V - Moribund, patients not expected to live 24 hours with or without an operation.

24. Recovery area- means a room or limited access area of an office dedicated to providing medical services to patients recovering from surgery or anesthesia.

25. Special Procedure- means patient care which requires entering the body with instruments in a potentially painful manner, or which require the patient to be immobile, for a diagnostic or therapeutic procedure requiring anesthesia services; e.g. diagnostic or therapeutic endoscopy; invasive radiologic procedures, pediatric magnetic resonance imaging; manipulation under anesthesia.

26. Surgery- means any operative or manual procedure, including the use of lasers, performed for the purpose of preserving health, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life or relieving suffering, or any elective procedure for aesthetic or cosmetic purposes. This includes but is not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or an organ; extraction of tissue from the uterus; insertion of natural or artificial implants; closed or open fracture reduction; or an endoscopic examination with use of local or general anesthesia.

27. Topical Anesthesia- means an anesthetic agent applied directly or by spray to the skin or mucous membranes, intended to produce a transient and reversible loss of sensation to a circumscribed area.
1. **CASE SELECTION FOR OFFICE BASED PROCEDURES SHALL BE APPROPRIATE TO THE CONDITION OF THE PATIENT, THE PROCEDURE UNDERTAKEN AND THE NATURE OF SEDATION.**

(A) Class A accreditation shall be limited to office facilities where tumescent liposuction is performed. Patient selection should be appropriate in order to render the chance of complication requiring hospitalization remote. The maximum total dosage of lidocaine and supernatant fat removal for a patient during one procedure shall not exceed the current consensus clinical guidelines of the American Academy of Dermatology. Patients undergoing tumescent liposuction in a Class A facility shall be continually visually observed and periodically monitored for vital signs and with pulse oximetry by the surgeon or appropriately trained personnel. Both the surgeon and any other designated attendant shall be currently BLS trained.

Non-parenteral anxiolytics and/or narcotics are permitted in Class A facilities. Small doses of subcutaneous or intramuscular anxiolytics and/or narcotics are permitted in Class A facilities if the patient is appropriately monitored. Whenever such drugs are administered an RN or similarly qualified individual shall perform monitoring with documented competence in monitoring patients under the influence of subcutaneous and intramuscular anxiolytics and narcotics. Physicians performing tumescent liposuction may perform the procedure in a Class A facility providing they are in compliance with Accreditation Standard No. 2.

(B) Class B accreditation shall be limited to office facilities where procedures requiring conscious sedation are performed. Surgical procedures are limited to those where there is little risk of surgical or anesthetic complications and therefore hospitalization of these complications is unlikely. Either the surgeon or another qualified practitioner participating in the patient’s care must be currently trained in Advanced Cardiac Life Support (ACLS) and the surgeon must be currently trained in Basic Life Support (BLS). Sedation shall be administered only by a qualified practitioner (surgeon, anesthesiologist, CRNA or RN). When the surgeon administers the sedation, another qualified person shall monitor the patient. Registered Nurses administering and/or monitoring sedation must do so under the direct supervision of the surgeon, have documented competence in administering/monitoring parenteral sedatives and be currently ACLS trained. Practitioners performing therapeutic or diagnostic procedures in a Class B facility must be in compliance with Accreditation Standard No. 2.

(C) Class C accreditation shall be limited to offices where surgical procedures requiring general anesthesia or major nerve blocks such as epidural or subarachnoid blocks are performed. Surgical and anesthetic complications are, by definition, known to exist for services performed in a Class C facility. Anesthesia shall only be administered by an anesthesiologist or a CRNA, who is currently ACLS trained. At least two currently ACLS trained practitioners shall be on the premises at all times when procedures are performed at a Class C facility. Practitioners performing therapeutic, diagnostic and anesthetic procedures in a Class C facility must be in compliance with Accreditation Standard No. 2.

(D) Surgeons using Class A, B or C accredited facilities who do not have admitting privileges but are otherwise in compliance with Standard 2 herein, shall have a written agreement with a physician with admitting privileges at a nearby hospital to admit and care for patients requiring acute inpatient care.
(E) The condition of the patient, specific co-morbidities complicating conduct of operative and anesthetic management, and the intrinsic risk of the procedure shall be considered in selecting patients for accredited office based procedure facilities.

(F) Only those procedures where there is reasonable expectation of discharge from that facility shall be performed in accredited office based facilities.

(G) Exempt facilities - The Oregon Medical Association does not propose or intend that exempt office facilities where routine medical procedures are performed under topical or local anesthesia be accredited. Minor peripheral nerve blocks are also permitted. Non-parenteral anxiolytics and/or narcotics are permitted in exempt facilities. Small doses of subcutaneous or intramuscular anxiolytics and/or narcotics can be administered in facilities if the patient is appropriately monitored. An RN or similarly qualified individual should perform monitoring with documented competence in monitoring patients under the influence of subcutaneous and intramuscular anxiolytics and narcotics. It is suggested that a BLS certified individual be present whenever systemic injectable medication is administered, surgeons performing procedures in exempt facilities also be currently BLS certified, and that oxygen and suction be readily available. Except as indicated in this section, no drug-induced alteration of consciousness other than non-parenteral anxiolytics should be administered in exempt facilities. Patient selection should be appropriate in order to render remote the chance of complication requiring hospitalization.

2. THE PRACTITIONER(S) PERFORMING PROCEDURES IN THE FACILITY SHALL BE QUALIFIED TO PERFORM THEM

(A) All practitioners using the office facility to perform procedures requiring conscious sedation or anesthesia shall be licensed by the Oregon licensing agency appropriate to their discipline.

(B) Except with respect to practitioners functioning in Class A facilities and provided the practitioners can demonstrate professional liability insurance for the procedures requested, all practitioners using the office facility to perform procedures requiring conscious sedation or anesthesia and/or providing sedation or anesthesia services shall have privileges to admit patients to an accredited institution licensed by the Oregon Health Division and to perform the same procedures and/or anesthetic techniques as are performed in the office facility.

3. PRACTITIONER(S) USING THE OFFICE FACILITY SHALL MAINTAIN APPROPRIATE RECORDS AND OTHER DOCUMENTATION CONCERNING EACH PROCEDURE PERFORMED

(A) The medical record for each patient undergoing a procedure in an office facility shall document that informed consent has been obtained consistent with Oregon Revised Statutes.

(B) The medical record for each patient undergoing a procedure in an office facility utilizing conscious sedation techniques shall contain documentation consistent with the complexity of the procedure including an operative note, medications and anesthetic agents and their doses and the patient’s condition at discharge. Any unusual events and/or complications shall be documented. Policies and procedures must be in place and observed so as to assure patient confidentiality.
For procedures involving an anesthesiologist or nurse anesthetist a separate anesthetic record that contains documentation of anesthetic provider, procedure and technique employed utilizing such forms as are provided in the application materials for accreditation shall be maintained. Vital signs, patient positioning, monitors used, type and dose of medications used, fluids administered, type and dosage of anesthetic agents, level of consciousness, patient weight, estimated blood loss, and duration of procedure shall be recorded. Any unusual events and/or complications shall be documented.

For procedures involving an anesthesiologist or nurse anesthetist documentation shall be made that: (1) preoperatively a physical examination and a medical history was reviewed by the anesthesia provider pertinent to issues regarding the anesthesia; (2) the anesthetic, alternatives and risks were discussed; and (3) informed consent to the planned anesthetic was obtained from the patient.

For procedures involving an anesthesiologist or nurse anesthetist an appropriate nursing record of preoperative condition, including vital signs, mental status, ambulatory status, and appropriate NPO status, and medication shall be made. Appropriate nursing staff shall maintain a post-anesthesia record of observation during recovery from anesthesia.

(C) The medical record for each patient undergoing a procedure in an office facility shall document instructions for post-operative pain management, sedation and post-operative management. Guidelines shall be in place defining suitable criteria for discharge of patients having undergone sedation, major nerve block or general anesthesia. Patients shall receive verbal and written discharge instructions including pain management, complications and how to contact the provider or obtain assistance for post-operative emergency or complication.

For procedures involving an anesthesiologist or nurse anesthetist, the provider shall remain on the premises until the patient is ready for discharge or the surgical provider agrees to take responsibility for post-operative management of the patient at the facility. Patients shall be given information regarding potential side effects and complications of the anesthetic employed, treatment, and how to contact the anesthesia provider.

(D) Excepting trivial tissues, such as teeth, epidermal inclusion cysts and nails, the medical record for each patient undergoing a procedure in an office facility shall document that tissues and other specimens have been submitted for histopathologic diagnosis.

(E) For all complications a separate record or chart identification system shall be maintained and available for inspection. Upon accreditation the applicant shall report to the Oregon Medical Association within ten (10) days of the occurrence any complication associated with a procedure in the accredited facility.

(F) Provision for continuity of post-operative care shall be documented in each patient’s medical record.

(G) NPO instructions and recorded documentation shall be consistent with Current American Society of Anesthesiology guidelines ("Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures," Anesthesiology 1999, 90:896-905.)
The medical records of each patient undergoing a procedure in an office facility shall otherwise comply with the generally accepted standards for ambulatory medical records.

4. **THE OFFICE FACILITY SHALL HAVE EQUIPMENT AND POLICIES IN PLACE TO ASSURE A SAFE AND SECURE ENVIRONMENT FOR THE PATIENT.**

(A) The office facility shall document specific and current arrangements are in place for obtaining laboratory, radiological, pathologic and other ancillary services as may be required to support the procedures undertaken. Monitoring and resuscitation equipment consistent with the level and complexity of procedures and conscious sedation undertaken shall be in place.

(B) Class A facilities shall have a blood pressure apparatus, airways automatic external defibrillator, oxygen, suction apparatus, pulse oximeter with an audible alarm, and bag mask respirator, and appropriate resuscitation drugs.

In addition to monitoring and resuscitation equipment required of Class A facilities, Class B facilities shall have appropriate airway management equipment. Additional monitoring equipment appropriate to procedures performed, their duration and complexity, depth or degree of anesthesia and sedation, and patient age and comorbidities shall also be available. Such equipment might include but not be limited to electrocardiogram, defibrillator and automatic blood pressure apparatus with alarm. All equipment shall have current records documenting appropriate calibration and/or preventive maintenance.

In addition to monitoring and resuscitation equipment required of Class A and Class B facilities, Class C facilities shall have capnography, temperature monitoring for procedures lasting longer than 30 minutes, at least 12 ampoules of dantrolene sodium, and appropriate resuscitation medications and equipment required in ACLS protocols.

(C) Intravenous fluids and administration equipment appropriate to the procedures undertaken shall be available.

(D) The facility shall demonstrate that appropriate standards of cleanliness and sterility are maintained. Sterilization and high-level disinfection methods, including quality control, for use during procedures shall be in place. With the exception of procedures that do not entail an incision, there shall be a separate area from the procedure room for instrument cleaning, preparation and sterilization.

(E) The office procedures facility shall be of adequate size to accommodate the procedures undertaken. With the exception of endoscopy rooms, there shall be at least one room that is used exclusively for all procedures requiring conscious sedation that are undertaken. Procedure tables and surgical lighting suitable for all procedures undertaken shall be present. Operating room dimensions, ventilation, electrical safety, and backup oxygen delivery systems shall meet Oregon Health Division requirements – OAR 333. (76).

(F) There shall be adequate space, equipment and trained personnel available to assure aseptic conditions and to prevent cross-contamination among patients. All personnel directly involved in procedures shall be trained in basic aseptic techniques.

(G) If recovery is done in other than the procedures rooms, there shall be an adequate patient recovery area with an appropriate number of stretchers. A protocol shall be in place to
demonstrate that appropriate post-sedation and procedure recovery monitoring and shall be available for inspection. All office procedures facilities shall have wheelchairs in adequate number to accommodate all patients.

Class C facilities shall have adequate number of stretchers to transport all anesthetized patients or recovering patients as well as adequate staff, facilities and procedures to facilitate evacuation. The operating room, recovery areas, ingress and egress to the facility must meet code for transport of a patient on a stretcher. The operating room and recovery area shall have appropriate oxygen delivery, suction system and patient monitoring devices. Recovery shall be supervised by appropriately trained medical personnel, who shall be currently BLS trained. At least two currently ACLS trained practitioners shall be on the premises when anesthesia is delivered or patients are recovering from anesthesia.

(H) Personnel directly involved in office-based procedures shall be currently licensed in their respective disciplines or, if unlicensed, shall be under the direct supervision of a licensed physician or registered nurse. Except as specifically provided in Standard 1, sedation medication administration and patient monitoring shall be done by appropriately licensed and trained personnel other than the surgeon. In cases where the surgeon administers sedation medication, the patient must be monitored by another appropriately licensed person or an appropriately trained person functioning under the direct supervision of the surgeon.

Anesthesia involving major nerve block or general anesthesia shall be provided by a CRNA consistent with current state statutes and Federal Medicare Guidelines, as they may apply to Medicare patients in the State of Oregon or by an anesthesiologist. There shall be written standards regarding the services to be performed by the anesthesia provider in facilities where major nerve block or general anesthesia is provided. The anesthesia provider shall not function in any other capacity during the procedure.

(I) The operating practitioner shall be competent to manage both procedural and anesthetic emergencies such as anaphylaxis and cardiopulmonary arrest. For Class C facilities the operating surgeon shall provide supervision of CRNA-administered anesthetics as required by state law. The anesthesia provider shall remain on the premises until all patients undergoing major nerve block or general anesthesia have been evaluated and deemed ready for discharge.

(J) Discharge of the patient is the responsibility of the operating practitioner and shall occur only when a patient is adequately recovered to function independently. When sedation has been used or if the patient has significant symptoms such as vaso-vagal syncope, a responsible adult must accompany the patient, provide for the patient's transportation and be instructed with regard to the patient's care. The medical record shall document such instruction has occurred and written instructions shall be given to the patient or to the responsible adult.

Criteria for discharge of all patients who have received anesthesia or sedation should include the following: (1) confirmation of stable vital signs; (2) stable oxygen saturation levels; (3) return to pre-procedure mental status; (4) adequate pain control; minimal bleeding, nausea and vomiting; resolving neural blockade or resolved neuraxial blockade; and discharge in the company of a competent adult.

(K) There shall be evidence that all operating personnel wear attire suitable to the procedures undertaken.
(L) At least one person among the operating team shall be currently trained in basic life support. For Class B facilities the surgeon shall be currently BLS or ACLS trained. In the former instance, another person on the operating team shall be currently ACLS trained. For Class C anesthesia two providers on the premises must be currently ACLS trained and readily available.

(M) Practitioners administering anesthesia shall document in the medical record they are familiar with relevant aspects of the patient's medical history and physical and laboratory findings. The record shall also document that a contemporaneous focused physical examination of the cardiorespiratory system was performed.

(N) The facility must have adequate patient and family waiting areas, examining rooms and storage areas for supplies and equipment used in the performance of procedures performed.

(O) Facilities using neuraxial blockade or general anesthesia shall have equipment including but not limited to an anesthetic machine with documentation and protocols in place to demonstrate periodic maintenance including: capability for mechanical ventilation; end tidal capnography; in-circuit oxygen analyzer; respirometer/volumeter; oxygen failure protection (fail-safe device); vaporizer exclusion (interlock) system; pressure compensated anesthesia vaporizers, not placed downstream of the oxygen flush valve, preventing oxygen mixtures of less than 21 percent from being administered; alarm systems for high, low, and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; gas evacuation (scavenging) system; backup generator or battery for emergency electrical power; and an operating table capable of Trendelenberg and other positions necessary to facilitate the surgical procedure.

5. **THE OFFICE PROCEDURES FACILITY SHALL DOCUMENT OR OTHERWISE DEMONSTRATE IT IS IN COMPLIANCE WITH ALL FEDERAL AND STATE REGULATIONS INCLUDING THE OCCUPATIONAL SAFETY AND HEALTH ACT, HAZARD AND BLOOD-BORNE PATHOGENS STANDARDS AND THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988.**

6. **THE OFFICE PROCEDURES FACILITY SHALL DOCUMENT OR OTHERWISE DEMONSTRATE THAT IT IS IN COMPLIANCE WITH THE AMERICANS WITH DISABILITIES ACT.**