

OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 76

AMBULATORY SURGICAL CENTERS (ASC)

333-076-0101

Definitions

As used in OAR chapter 333, division 76 unless the context requires otherwise, the following definitions apply:

- (1) "Ambulatory Surgical Center" (ASC) means:
 - (a) A facility or portion of a facility that operates exclusively for the purpose of providing surgical services to patients who do not require hospitalization and for whom the expected duration of services does not exceed 24 hours following admission.
 - (b) Ambulatory surgical center does not mean:
 - (A) Individual or group practice offices of private physicians or dentists that do not contain a distinct area used for outpatient surgical treatment on a regular and organized basis, or that only provide surgery routinely provided in a physician's or dentist's office using local anesthesia or conscious sedation; or
 - (B) A portion of a licensed hospital designated for outpatient surgical treatment.
- (2) "Authentication" means verification that an entry in the patient medical record is genuine.
- (3) "CMS" means Centers for Medicare and Medicaid Services.
- (4) "Certified ambulatory surgical center" means a facility that is licensed by the Division and is certified by the CMS as meeting the conditions for coverage for ambulatory surgical services, 42 CFR 416, Subpart C.
- (5) "Certified Nurse Anesthetist" (CRNA) means a registered nurse certified by the Council on Certification of Nurse Anesthetists and licensed by the Oregon State Board of Nursing (OSBN).
- (6) "Certified Nursing Assistant" (CNA) means a person who is certified by the Oregon State Board of Nursing (OSBN) to assist licensed nursing staff in the provision of nursing care.
- (7) "Conditions for Coverage" mean the applicable federal regulations that ASCs are required to comply with in order to participate in the federal Medicare and Medicaid programs.
- (8) "Conscious sedation" has the same meaning as "moderate sedation."
- (9) "Deemed" means a health care facility that has been inspected by an approved accrediting organization and has been approved by the CMS as meeting CMS Conditions of Participation.
- (10) "Deep sedation" means an induced controlled state of depressed consciousness in which the patient experiences a partial loss of protective reflexes, as evidenced by the inability to respond purposefully either to physical stimulation or to verbal command and the patient's ability to independently and continuously maintain an airway may be impaired.
- (11) "Direct ownership" has the meaning given the term 'ownership interest' in 42 CFR 420.201.
- (12) "Division" means the Public Health Division of the Oregon Health Authority.
- (13) "Financial interest" means a five percent or greater direct or indirect ownership interest.
- (14) "General anesthesia" means an induced controlled state of unconsciousness in which the patient experiences complete loss of protective reflexes, as evidenced by the inability to

independently maintain an airway, the inability to respond purposefully to physical stimulation, or the inability to respond purposefully to verbal command.

(15) "Governing body" means the body or person legally responsible for the direction and control of the operation of the facility.

(16) "Health Care Facility" (HCF) has the meaning given the term in ORS 442.015.

(17) "Health Care Facility Licensing Law" means ORS 441.015-441.990 and rules thereunder.

(18) "High complexity non-certified" means a facility that is licensed by the Division, is not CMS certified, and performs surgical procedures involving deep sedation or general anesthesia.

(19) "Hospital" has the meaning given that term in ORS 442.015.

(20) "Indirect ownership" has the meaning given the term 'indirect ownership interest' in 42 CFR 420.201.

(21) "Licensed" means that the person or facility to whom the term is applied is currently licensed, certified or registered by the proper authority to follow his or her profession or vocation within the State of Oregon, and when applied to a health care facility means that the facility is currently and has been duly and regularly licensed by the Division.

(22) "Licensed Nurse" means a Registered Nurse (RN) or a Licensed Practical Nurse (LPN).

(23) "Licensed Practical Nurse" (LPN) means a person licensed under ORS chapter 678 to practice practical nursing.

(24) "Local anesthesia" means the administration of an agent that produces a transient and reversible loss of sensation in a circumscribed portion of the body.

(25) "Moderate complexity non-certified" means a facility licensed by the Division, is not CMS certified, and performs procedures requiring not more than conscious sedation.

(26) "Moderate sedation" means an induced controlled state of minimally depressed consciousness in which the patient retains the ability to independently and continuously maintain an airway and to respond purposefully to physical stimulation and to verbal command. Formerly referred to as conscious sedation.

(27) "New construction" means a new building or an addition to an existing building.

(28) "NFPA" means National Fire Protection Association.

(29) "Nursing staff" means a person licensed by the OSBN as a registered nurse (RN), licensed practical nurse (LPN) or certified as a nursing assistant (CNA).

(30) "Patient audit" means review of the medical record or physical inspection of a patient.

(31) "Person" means an individual, a trust or estate, or a partnership or corporation (including associations, joint stock companies and insurance companies, a state or a political subdivision or instrumentality including a municipal corporation).

(32) "Physician" means a person licensed under ORS chapter 677 to practice medicine by the Oregon Medical Board.

(33) "Podiatrist" means a person licensed under ORS chapter 677 to practice podiatry.

(34) "Podiatry" means the diagnosis or the medical, physical or surgical treatment of ailments of the human foot, except treatment involving the use of a general or spinal anesthetic unless the treatment is performed in a hospital certified in the manner described in subsection (2) of ORS 441.055 and is under the supervision of or in collaboration with a physician licensed to practice medicine by the Oregon Medical Board. "Podiatry" does not include the administration of general or spinal anesthetics or the amputation of the foot.

(35) "Registered Nurse" (RN) means a person licensed as a Registered Nurse under ORS chapter 678.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.015-ORS 441.065, 441.098, & 442.015

333-076-0106

Issuance of License and Fees

- (1) As used in this rule, the term "deemed status" means an ASC that has been inspected by a CMS-approved national accrediting organization, has been found to meet or exceed all applicable Medicare conditions, and CMS finds the ASC to be in compliance.
- (2) Application for a license to operate an ASC shall be in writing on a form provided by the Division, including demographic, ownership and administrative information. The form shall specify such information required by the Division.
- (3) For purposes of determining the correct license fee required under ORS 441.020 and this rule:
 - (a) "Procedure room" means a room where surgery or invasive procedures are performed; and
 - (b) "Invasive procedure" means a procedure requiring insertion of an instrument or device into the body through the skin or a body orifice for diagnosis or treatment, and operative procedures in which skin or mucous membranes and connective tissue are incised, or an instrument is introduced through a natural body orifice.
- (4) Upon receipt of an application and the license fee as described in ORS 441.020, the Division shall review the application and conduct an on-site inspection of the ASC.
- (5) In lieu of an onsite inspection required under section (3) of this rule, the Division may accept:
 - (a) CMS certification by a federal agency or accrediting organization; or
 - (b) A survey conducted within the previous three years by an accrediting organization approved by the Division, if:
 - (A) The certification or accreditation is recognized by the Division as addressing the standards and conditions for coverage requirements of the CMS and other standards set by the Division and an ASC provides the Division with a letter from CMS indicating its deemed status;
 - (B) The ASC notifies the Division of any exit interview conducted by the federal agency or accrediting body and permits the Division to participate; and
 - (C) The ASC provides copies of all documentation concerning the certification or accreditation requested by the Division.
- (6) If the deemed status of an ASC changes, the ASC administrator must notify the Division.
- (7) No person or ASC licensed pursuant to the provisions of ORS chapter 441, shall in any manner or by any means assert, represent, offer, provide or imply that such person or facility is or may render care or services other than that which is permitted by or which is within the scope of the license issued to such person or facility by the Division nor shall any service be offered or provided which is not authorized within the scope of the license issued to such person or facility.
- (8) The Division shall issue a license to an ASC that:
 - (a) Submits a completed application as described in section (1) of this rule;
 - (b) Submits the license fee as described in ORS 441.020;
 - (c) Successfully completes the survey requirements established in this rule or provides documentation acceptable to the Division under section (4) of this rule; and
 - (d) Is found by the Division to be in compliance with applicable statutes and these rules.
- (9) In determining whether to license an ASC pursuant to ORS 441.025, the Division shall consider only factors relating to the health and safety of individuals to be cared for therein and the ability of the operator of the ASC to safely operate the facility, and shall not consider

whether the ASC is or will be a governmental, charitable, or other nonprofit institution or whether it is or will be an institution for profit.

(10) The license shall be conspicuously posted in the area where patients are admitted.

(11) A facility license that has been suspended or revoked may be reissued after the Division determines that compliance with HCF laws has been achieved satisfactorily.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.020, 441.022, 441.025 and 441.062

333-076-0137

Surgery Services

(1) For purposes of this rule:

(a) "Circulating nurse" means a registered nurse who is responsible for coordinating the nursing care and safety needs of the patient in the operating room and who also meets the needs of the operating room team members during surgery.

(b) "Rural or medically underserved community" means a geographic area of Oregon that is 10 or more miles from the geographic center of a population center of 40,000 or more individuals.

(c) "Surgical technology" means intraoperative surgical patient care that involves:

(A) Preparing an operating room for surgical procedures by ensuring that surgical equipment is functioning properly and safely;

(B) Preparing an operating room and the sterile field for surgical procedures by preparing sterile supplies, instruments and equipment using sterile techniques;

(C) Anticipating the needs of a surgical team based on knowledge of human anatomy and pathophysiology and how those fields relate to the surgical patient and the patient's surgical procedure; and

(D) Performing tasks as directed in an operating room, including:

(i) Passing instruments, equipment or supplies;

(ii) Sponging or suctioning of an operative site;

(iii) Preparing and cutting suture material;

(iv) Transferring fluids or drugs;

(v) Handling specimens;

(vi) Holding retractors and other equipment;

(vii) Applying electrocautery to clamps on bleeders;

(viii) Connecting drains to suction apparatus;

(ix) Applying dressings to closed wounds; and

(x) Assisting in counting supplies and instruments, including sponges and needles.

(2) An ASC, regardless of classification, shall comply with this rule.

(3) An ASC shall have operating rooms that conform to the applicable requirements in OAR 333-076-0185.

(4) An ASC's operating rooms must be supervised by an experienced registered nurse or doctor of medicine or osteopathy.

(5) The duties of a circulating nurse performed in an operating room of an ASC shall be performed by a registered nurse licensed under ORS 678.010 through 678.410. In all cases requiring general anesthesia, a circulating nurse shall be assigned to, and present in, an operating room for the duration of the surgical procedure unless it becomes necessary for the circulating nurse to leave the operating room as part of the surgical procedure. While assigned to a surgical procedure, a circulating nurse may not be assigned to any other patient or procedure.

- (6) Nothing in section (5) precludes a circulating nurse from being relieved during a surgical procedure by another circulating nurse assigned to continue the surgical procedure.
- (7) In order for a person to practice surgical technology at an ASC, the ASC governing body shall ensure that the following provisions are met by the individual:
- (a) Documentation showing that the person has completed a training program for surgical technologists in a branch of the armed forces of the United States or in the United States Public Health Service Commissioned Corp and completes 16 hours of continuing education as described in section (11) of this rule every two years; or
 - (b) Completion of a surgical technology education program accredited by the Commission on Accreditation of Allied Health Education Program (CAAHEP) or the Accrediting Bureau of Health Education Schools (ABHES) and certification as a surgical technologist issued by the National Board of Surgical Technology and Surgical Assisting (NBSTSA); or
 - (c) Documentation that a person has practiced surgical technology at least two years between January 1, 2014 and January 1, 2017 in a hospital, ambulatory surgical center or as an employee of a federal government agency or institution and completes 16 hours of continuing education as described in section (11) of this rule every two years.
- (8) Notwithstanding subsection (7)(b), an ASC may allow a person who is not certified by the NBSTSA to practice surgical technology at the hospital for 12 months after the person completes an educational program accredited by the CAAHEP or ABHES.
- (9) An ASC located in a rural or medically underserved community may allow a person to practice surgical technology at the ASC who does not meet the requirements specified in section (7) of this rule until July 1, 2017. After July 1, 2017, a person not meeting the requirements specified in section (7) of this rule, may work at an ASC in a rural or medically underserved community while the person is attending an educational program accredited by the CAAHEP or ABHES. Such persons are exempt from the educational requirements for three years from the date on which the person began practicing at the ASC.
- (10) These rules do not prohibit a licensed practitioner from performing surgical technology if the practitioner is acting within the scope of the practitioner's license and an ASC allows the practitioner to perform such duties.
- (11)(a) The continuing education requirements described in subsections (7)(a) and (7)(c) shall:
- (A) Consist of 16 hours every two years;
 - (B) Be tracked by the surgical technologist and is subject to audit by the ASC in which the person is practicing; and
 - (C) Be relevant to the medical-surgical practice of surgical technology.
- (b) Continuing education may include but is not limited to:
- (A) Continuing education credits approved by the Association for Surgical Technologist;
 - (B) Healthcare sponsored conferences, forums, seminars, symposiums or workshops;
 - (C) Online distance learning courses;
 - (D) Live lectures at national conferences; or
 - (E) College courses.
- (12) An ASC shall conduct a random audit of a representative sample of the surgical technologists employed by the ASC every two years to verify compliance with educational requirements.
- (13) The requirements identified in sections (7), (8), and (10) through (12) of this rule become effective on July 1, 2016.

Stat. Auth.: ORS 441.025 & ORS 676.890

Stats. Implemented: ORS 441.025, 676.870 – 676.890 & 678.362

333-076-0165

Medical Records

- (1) A medical record shall be maintained for every patient admitted for care.
- (2) A legible reproducible medical record shall include at least the following (if applicable):
 - (a) Admitting identification data including date of admission;
 - (b) Chief complaint;
 - (c) Pertinent family and personal history;
 - (d) History and physical. This history and physical shall be completed no more than 30 days prior to the initiation of any procedure. Sufficient time shall be allowed between examination and the initiation of any procedure, to permit review of tests;
 - (e) Clinical laboratory reports as well as reports on any special examinations. (The original report shall be authenticated and recorded in the patient's medical record.);
 - (f) X-ray reports shall be recorded in the medical record and shall bear the identification (authentication) of the originator of the interpretation;
 - (g) Signed or authenticated report of consultant when such services have been obtained;
 - (h) All entries in patient's medical record must be dated, timed, and authenticated:
 - (A) Verification of an entry requires use of a unique identifier, i.e., signature, code, thumbprint, voice print or other means, which allows identification of the individual responsible for the entry;
 - (B) Verbal orders may be accepted by those individuals authorized by law and by medical staff rules and regulations and shall be countersigned or authenticated within two business days by the ordering health care practitioner or another health care practitioner who is responsible for the care of the patient;
 - (C) A single signature or authentication of the physician, dentist, podiatrist or other individual authorized within the scope of his or her professional license on the medical record does not suffice to cover the entire content of the record.
 - (i) Records of assessment and intervention, including but not limited to preprocedure vital sign records, graphic charts, medication records and appropriate personnel notes;
 - (j) Anesthesia record including records of anesthesia, analgesia and medications given in the course of the operation and postanesthetic condition, signed or authenticated by the person making the entry;
 - (k) A record of operation dictated or written immediately following surgery and including a complete description of the operation procedures and findings, postoperative diagnostic impression, and a description of the tissues and appliances, if any, removed;
 - (l) Postanesthesia Recovery (PAR) progress notes including but not limited to vital sign records and other appropriate clinical notes;
 - (m) Pathology report on tissues and appliances, if any, removed at the operation. The following tissues and appliances may be exempted from pathology exam:
 - (A) Specimens that, by their nature or condition, do not permit fruitful examination, including but not limited to a cataract, orthopedic appliance, foreign body, or portion of rib removed only to enhance operative exposure;
 - (B) Therapeutic radioactive sources, the removal of which shall be guided by radiation safety monitoring requirements;

- (C) Traumatically injured members that have been amputated and for which examination for either medical or legal reasons is not considered necessary;
- (D) Specimens known to rarely, if ever, show pathological change, and the removal of which is highly visible postoperatively, including but not limited to the foreskin from circumcision of a newborn infant;
- (E) Placentas that are grossly normal and have been removed in the course of operative and nonoperative obstetrics;
- (F) Teeth, provided that the number, including fragments, is recorded in the medical record.
- (n) Summary including final diagnosis;
- (o) Date of discharge and discharge note;
- (p) Autopsy report if applicable;
- (q) Informed consent forms that document:
 - (A) The name of the ASC where the procedure or treatment was undertaken;
 - (B) The specific procedure or treatment for which consent was given;
 - (C) The name of the health care practitioner performing the procedure or administering the treatment;
 - (D) That the procedure or treatment, including the anticipated benefits, material risks, and alternatives was explained to the patient or the patient's representative or why it would have been materially detrimental to the patient to do so, giving due consideration to the appropriate standards of practice of reasonable health care practitioners in the same or a similar community under the same or similar circumstances;
 - (E) The manner in which care will be provided in the event that complications occur that require health services beyond what the ASC has the capability to provide. If the ASC has entered into agreements with more than one hospital, the patient must be provided with the most likely possible option, but that the transfer hospital may be dependent on the type of problem encountered.
 - (F) The signature of the patient or the patient's legal representative; and
 - (G) The date and time the informed consent was signed by the patient or the patient's legal representative;
- (r) Documentation of the disclosures required in ORS 441.098;
- (s) Such signed documents as may be required by law.
- (3) The completion of the medical record shall be the responsibility of the attending physician:
 - (a) Medical records shall be completed by the physician, dentist, podiatrist or other individual authorized within the scope of his or her professional license within four weeks following the patient's discharge;
 - (b) If a patient is transferred to another health care facility, transfer information shall accompany the patient. Transfer information shall include but not be limited to facility from which transferred, name of physician to assume care, date and time of discharge, current medical findings, current nursing assessment, current history and physical, diagnosis, orders from a physician for immediate care of the patient, operative report, if applicable; TB test, if applicable; other information germane to patient's condition. If discharge summary is not available at time of transfer, it shall be transmitted as soon as available.
- (4) Diagnoses and operations shall be expressed in standard terminology.
- (5) The medical records shall be filed in a manner which renders them easily retrievable. Medical records shall be protected against unauthorized access, fire, water and theft.

(6) Medical records are the property of the ASC. The medical record, either in original, electronic or microfilm form, shall not be removed from the institution except where necessary for a judicial or administrative proceeding. Authorized personnel of the Division shall be permitted to review medical records. When an ASC uses off-site storage for medical records, arrangements must be made for delivery of these records to the health care facility when needed for patient care or other health care facility activities. Precautions must be taken to protect patient confidentiality.

(7) All medical records shall be kept for a period of at least 10 years after the date of last discharge. Original medical records may be retained on paper, microfilm, electronic or other media.

(8) If an ASC changes ownership all medical records in original, electronic or microfilm form shall remain in the ASC or related institution, and it shall be the responsibility of the new owner to protect and maintain these records.

(9) If any ASC shall be finally closed, its medical records may be delivered and turned over to any other health care facility in the vicinity willing to accept and retain the same as provided in section (7) of this rule.

(10) All original clinical records or photographic or electronic facsimile thereof, not otherwise incorporated in the medical record, such as x-rays, electrocardiograms, electroencephalograms, and radiological isotope scans shall be retained for seven years after patient's last discharge if professional interpretations of such graphics are included in the medical records.

(11) A current written policy on the release of medical record information including patient access to his/her medical record shall be maintained in the facility.

(12) The Division may require the facility to obtain periodic and at least annual consultation from a qualified medical records consultant, RHIA/RHIT. The visits of the medical records consultant shall be of sufficient duration and frequency to review medical record systems and assure quality records of the patients. Contract for such services shall be available to the Division upon request.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.025

333-076-0250

Violations

In addition to non-compliance with any health care facility licensing law or conditions for coverage, it is a violation to:

(1) Refuse to cooperate with an investigation or survey, including but not limited to failure to permit Division staff access to the ASC, its documents or records;

(2) Fail to implement an approved plan of correction;

(3) Fail to comply with all applicable laws, lawful ordinances and rules relating to safety from fire;

(4) Refuse or fail to comply with an order issued by the Division;

(5) Refuse or fail to pay a civil penalty; or

(6) Fail to comply with rules governing the storage of medical records following the closure of an ASC.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.015, 441.025 & 441.030

333-076-0255

Informal Enforcement

- (1) If, during an investigation or survey Division staff document violations of health care facility licensing laws or conditions for coverage, the Division may issue a statement of deficiencies that cites the law alleged to have been violated and the facts supporting the allegation.
- (2) A signed plan of correction must be received by the Division within 10 business days from the date the statement of deficiencies was mailed to the ASC. A signed plan of correction will not be used by the Division as an admission of the violations alleged in the statement of deficiencies.
- (3) An ASC shall correct all deficiencies within 60 days from the date of the exit conference, unless an extension of time is requested from the Division. A request for such an extension shall be submitted in writing and must accompany the plan of correction.
- (4) The Division shall determine if a written plan of correction is acceptable. If the plan of correction is not acceptable to the Division, the Division shall notify the ASC administrator in writing and request that the plan of correction be modified and resubmitted no later than 10 working days from the date the letter of non-acceptance was mailed to the administrator.
- (5) If the ASC does not come into compliance by the date of correction reflected on the plan of correction or 60 days from date of the exit conference, whichever is sooner, the Division may propose to deny, suspend, or revoke the ASC license, or impose civil penalties.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.015 & 441.025

333-076-0260

Formal Enforcement

- (1) If, during an investigation or survey Division staff document substantial failure to comply with health care facility licensing laws, conditions for coverage or if an ASC fails to pay a civil penalty imposed under ORS 441.170, the Division may issue a Notice of Proposed Suspension or Notice of Proposed Revocation in accordance with ORS 183.411 through 183.470.
- (2) The Division may issue a Notice of Imposition of Civil Penalty for violations of health care facility licensing laws.
- (3) At any time the Division may issue a Notice of Emergency License Suspension under ORS 183.430(2).
- (4) If the Division revokes an ASC license, the order shall specify when, if ever, the ASC may reapply for a license.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.015, 441.025, 441.030 & 441.037

333-076-0270

Approval of Accrediting Organizations

- (1) An accrediting organization must request approval by the Division to ensure that ASCs meet state licensing standards.
- (2) An accrediting organization shall request approval in writing and shall provide, at a minimum:
 - (a) Evidence that it is a nationally recognized Medicare accreditation program approved by CMS; or

(b) If the accrediting organization is not approved by CMS, provide:

(A) Documentation of program policies and procedures that its accreditation process meets state licensing standards;

(B) Accreditation history; and

(C) References from a minimum of two health care facilities currently receiving services from the organization.

(3) If the Division finds that an accrediting organization has the necessary qualifications to certify that state licensing standards have been met, the Division will enter into an agreement with the accrediting organization permitting it to accredit ASCs in Oregon.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.062