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Medicare Conditions for Coverage Oregon State Licensure Requirements Crosswalk

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	Code of Federal Regulations **Title 42. Public Health** **Chapter IV** **Centers for Medicare & Medicaid Services,** **Department of Health and Human Services** **Subchapter B. Medicare Program** **Part 416. Ambulatory Surgical Services** **Subpart A – General Provisions and Definitions** **Subpart C – Specific Conditions for Coverage**	**Oregon Health Authority** **Public Health Division** **Division 76** **Special Health Care Facilities** **Ambulatory Surgical Centers**
Basis and Scope	**42 C.F.R. § 416.1** The Social Security Act provides for Medicare Part B coverage of facility services furnished in connection with surgical procedures specified by the Secretary of the Department of Health and Human Services. 42 C.F.R. § 416 sets forth the conditions that an ambulatory surgical center must meet in order to participate in the Medicare program.	
Definitions *The term "ambulatory surgical center" for purposes of Medicare certification has a different meaning from the term "ambulatory surgical facility" for purposes of state licensure.*	**42 C.F.R. § 416.2** Ambulatory surgical center or ASC means "any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC, and must meet the conditions set forth in subparts B and C of this part."	**OAR § 333-076-0101** (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.
Compliance with Federal, State and Local Law	**42 C.F.R. § 416.40** The ASC must comply with State licensure requirements.	

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Governing Body and Management *These provisions establish the responsibilities of the governing body. For responsibilities of the governing body related to quality assurance and performance improvement, see the "Quality Assessment and Performance Improvement" section below.*	**42 C.F.R. § 416.41** The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.	**OAR § 333-076-0115** The governing body of each ASC shall be responsible for the operation of the facility, the selection of the medical staff and the quality of care rendered in the facility. The governing body shall: (1) Insure that all health care personnel for whom state licenses or registration are required are currently licensed or registered; (2) Insure that physicians admitted to practice in the facility are granted privileges consistent with their individual training, experience and other qualifications; (3) Insure that procedures for granting, restricting and terminating privileges exist and that such procedures are regularly reviewed to assure their conformity to applicable law; (4) Insure that physicians admitted to practice in the facility are organized into a medical staff insofar as applicable in such a manner as to effectively review the professional practices of the facility for the purposes of reducing morbidity and mortality and for the improvement of patient care; and (5) Insure that a physician is not denied medical staff membership or privileges at the facility solely on the basis that the physician holds medical staff membership or privileges at another ASC. **OAR § 333-076-0130** The governing body shall have a formal organizational plan with written policies, procedures and by-laws that are enforced and that clearly set forth the organizational plan with written responsibilities, accountability and relationships of professional and other personnel including volunteers. (1) The clinical services of each ASC shall be under the supervision of a manager who shall be an RN or a physician. (2) The following are written policies and procedures that the ASC shall develop and implement: (a) Types of procedures that may be performed in the facility; (b) Types of anesthesia that may be used including storage procedures. Where inhalation anesthetics and medical gases are used there shall be procedures to assure safety in storage and use; (c) Criteria for evaluating patient before admission and before discharge or transfer; (d) Nursing service activities; (e) Infection control; (f) Visitor's conduct and control; (g) Criteria and procedures for admission of physicians, dentists, or other

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		individuals within the scope of his or her license, to the staff; (h) Content and form of medical records; (i) Procedures for storage and dispensing of clean and sterile supplies and equipment and the processing and sterilizing of all supplies, instruments and equipment used in procedures unless disposable sterile packs are used; (j) Procedures for the disposal of pathological and other potentially infectious waste and contaminated supplies. Guidelines established by the Division shall be used in developing these procedures; (k) Procedures for the procurement, storage and dispensing of drugs; (l) If the program calls for the serving of snacks or other foods procedures shall be written covering space, equipment and supplies. Arrangements may be made for outside services. All food services shall meet the requirements of the Food Sanitation Rules, OAR 333-150-0000; (m) Procedures for the cleaning, storage and handling of soiled linen and the storage and handling of clean linen; (n) Policies and procedures relating to routine laboratory testing; (o) A policy and procedure which assures at least annual training in emergency procedures, including, but not limited to: (A) Procedures for fire and other disaster; (B) Infection control measures; and (C) For staff involved in direct patient care, procedures for life threatening situations including, but not limited to, cardiopulmonary resuscitation and the life saving techniques for choking; (p) Policies and procedures for essential life saving measures and stabilization of a patient and arrangements for transfer to an appropriate facility; (q) Procedures for notifying patients orally and in writing of any financial interest as required by ORS 441.098; (r) Requirements for informed consent signed by the patient or legal representative of the patient for diagnostic and treatment procedures; such policies and procedures shall address informed consent of minors in accordance with provisions in ORS 109.610, 109.640, 109.670, and 109.675; and (s) Requirements for identifying persons responsible for obtaining informed consent and other appropriate disclosures and ensuring that the information provided is accurate.

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These provisions set forth requirements related to the transfer of patients requiring emergency medical care.	**42 C.F.R. § 416.41(b)** (b) Standard: Hospitalization. (1) The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. (2) This hospital must be a local, Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under § 482.2 of this chapter. (3) The ASC must— (i) Have a written transfer agreement with a hospital that meets the requirements of paragraph (b)(2) of this section; or (ii) Ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements of paragraph (b)(2) of this section.	**OAR § 333-076-0150** The facility shall provide services, equipment and staff necessary to implement emergency medical care protocols.
These provisions set forth requirements related to disaster preparedness plans.	**42 C.F.R. § 416.41(c)** (c) Standard: Disaster preparedness plan. (1) The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC. (2) The ASC coordinates the plan with State and local authorities, as appropriate. (3) The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.	**OAR § 333-076-0190** (1) The ASC shall develop, maintain, update, train and exercise an emergency plan for the protection of all individuals in the event of an emergency, in accordance with the regulations as specified in Oregon Fire Code (Oregon Administrative Rules chapter 837, division 40). (a) The ASC shall conduct at least two drills every year that document and demonstrate that employees have practiced their specific duties and assignments, as outlined in the emergency preparedness plan. (2) The emergency plan shall include the contact information for local emergency management. Each facility shall have documentation that the local emergency management office has been contacted and that the facility has a list of local hazards identified in the county hazard vulnerability analysis. (3) The summary of the emergency plan shall be sent to the Division within one year of the filing of this rule. New facilities that have submitted licensing documents to the state before this provision goes into effect will have one year from the date of license application to submit their plan. All other new facilities shall have a plan prior to licensing. The Division shall request updated plans as needed. (4) The emergency plan shall address all local hazards that have been identified by local emergency management that may include, but is not limited to, the following: (a) Chemical emergencies; (b) Dam failure;

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		(c) Earthquake; (d) Fire; (e) Flood; (f) Hazardous material; (g) Heat; (h) Hurricane; (i) Landslide; (j) Nuclear power plant emergency; (k) Pandemic; (l) Terrorism; or (m) Thunderstorms. (5) The emergency plan shall address the availability of sufficient supplies for staff and patients to shelter in place or at an agreed upon alternative location for a minimum of two days, in coordination with local emergency management, under the following conditions: (a) Extended power outage; (b) No running water; (c) Replacement of food or supplies is unavailable; (d) Staff members do not report to work as scheduled; and (e) The patient is unable to return to the pre-treatment shelter. (6) The emergency plan shall address evacuation, including: (a) Identification of individual positions' duties while vacating the building, transporting, and housing residents; (b) Method and source of transportation; (c) Planned relocation sites; (d) Method by which each patient will be identified by name and facility of origin by people unknown to them; (e) Method for tracking and reporting the physical location of specific patients until a different entity resumes responsibility for the patient; and (f) Notification to the Division about the status of the evacuation. (7) The emergency plan shall address the clinical and medical needs of the patients, including provisions to provide: (a) Storage of and continued access to medical records necessary to obtain care and treatment of patients, and the use of paper forms to be used for the transfer of care or to maintain care on-site when electronic systems are not available. (b) Continued access to pharmaceuticals, medical supplies and equipment, even during and after an evacuation; and (c) Alternative staffing plans to meet the needs of the patients when scheduled staff members are unavailable. Alternative staffing plans may include, but is not limited to, on-call staff, the use of travelers, the use of management staff, or the use of other emergency personnel.

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		(8) The emergency plan shall be made available as requested by the Division and during licensing and certification surveys. Each plan will be re-evaluated and revised as necessary or when there is a significant change in the facility or population of the ASC.
Surgical Services *These provisions set forth requirements related to anesthetic risk and assessment, administration of anesthesia, and the performance of surgical procedures in a safe manner.*	**42 C.F.R. § 416.42** Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC. (a) Standard: Anesthetic risk and evaluation. (1) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. (2) Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at § 410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery. (b) Standard: Administration of anesthesia. Anesthetics must be administered by only— (1) A qualified anesthesiologist; or (2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in § 410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a nonphysician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, 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. (c) Standard: State exemption. (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, 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	**OAR § 333-076-0140** (1) General or spinal anesthesia shall be administered only by a physician or a certified nurse anesthetist. Either the physician or the CRNA shall be present for the administration of general or spinal anesthetics, during anesthesia, and the recovery of the patients when any general or spinal anesthesia is used. (2) In all areas where flammable anesthetics are used, such rooms shall be equipped and maintained in compliance with provisions of the current issue of NFPA 99, Standard for Health Care Facilities, unless the governing body's written policy forbids the use or storage of flammable anesthetics in the facility.

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	requirement, and that the opt-out is consistent with State law. (2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.	
Quality Assessment and Performance Improvement *These provisions set forth quality assessment and performance improvement requirements and requirements related to maintenance of coordinated quality improvement programs under state law.*	**42 C.F.R. § 416.43** The ASC must develop, implement and maintain an ongoing, data driven quality assessment and performance improvement (QAPI) program. (a) Standard: Program scope. (1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors. (2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC. (b) Standard: Program data. (1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC. (2) The ASC must use the data collected to— (i) Monitor the effectiveness and safety of its services, and quality of its care. (ii) Identify opportunities that could lead to improvements and changes in its patient care. (c) Standard: Program activities. (1) The ASC must set priorities for its performance improvement activities that— (i) Focus on high risk, high volume, and problem-prone areas. (ii) Consider incidence, prevalence, and severity of problems in those areas. (iii) Affect health outcomes, patient safety, and quality of care. (2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time. (3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies. (d) Standard: Performance improvement projects.	**OAR § 333-076-0170** (1) The governing body of an ASC must ensure that there is an effective, facility-wide quality assessment and performance improvement program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors. (2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC. Written documentation of quality assessment and performance improvement activities shall be recorded at least quarterly. (3) After an analysis of the causes for adverse events, the ASC must develop and implement facility-wide preventive strategies and ensure that staff are trained in and familiar with these strategies. (4) The ASC must set 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; and (c) Affect health outcomes, patient safety and quality of care. (5) An ASC already in operation and not certified by CMS on December 15, 2010 must be in compliance with this section by June 15, 2011.

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	(1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations. (2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results. (e) Standard: Governing body responsibilities. The governing body must ensure that the QAPI program— (1) Is defined, implemented, and maintained by the ASC. (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness. (3) Specifies data collection methods, frequency, and details. (4) Clearly establishes its expectations for safety. (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.	
Medical Staff *These provisions set forth requirements related to medical staff membership and clinical privileges, including reappraisal, and oversight and evaluation of practitioners other than physicians.* *The state law provisions also set forth requirements mandating reports of unprofessional conduct.*	**42 C.F.R. § 416.45** The medical staff of the ASC must be accountable to the governing body. (a) Standard: Membership and clinical privileges. Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel. (b) Standard: Reappraisals. Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate. (c) Standard: Other practitioners. If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.	**OAR § 333-076-0120** (1) The physicians organized into a medical staff pursuant to OAR 333-076-0115 shall propose medical staff bylaws to govern the medical staff. The bylaws shall include, but not be limited to the following: (a) Procedures for physicians admitted to practice in the facility to organize into a medical staff; (b) Procedures for insuring that physicians admitted to practice in the facility are granted privileges consistent with their individual training, experience and other qualifications; (c) Provisions establishing a framework for the medical staff to nominate, elect, appoint or remove officers and other persons to carry out medical staff activities with accountability to the governing body; (d) Procedures for insuring that physicians admitted to practice in the facility are currently licensed by the Oregon Medical Board; (e) Procedures for insuring that the facility's procedures for granting, restricting and terminating privileges are followed and that such procedures are regularly reviewed to assure their conformity to applicable law; and (f) Procedures for insuring that physicians provide services within the scope of the privileges granted by the governing body. (2) Amendments to medical staff bylaws shall be accomplished through a cooperative process involving both the medical staff and the governing body. Medical staff bylaws shall be adopted, repealed or amended when approved by the medical staff and the governing body. Approval shall not be unreasonably withheld by either. Neither the medical staff nor the governing

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		body shall withhold approval if such repeal, amendment or adoption is mandated by law, statute or regulation or is necessary to obtain or maintain accreditation or to comply with fiduciary responsibilities or if the failure to approve would subvert the stated moral or ethical purposes of this institution.
Nursing Services *These provisions set forth requirements related to the provision of nursing services, including staffing levels.*	**42 C.F.R. § 416.46** The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met. (a) Standard: Organization and staffing. Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.	**OAR § 333-076-0135** (1) An RN shall be responsible for the nursing care provided to the patients. (2) The number and types of nursing personnel, including RNs, LPNs and nursing and surgical assistants shall be based on the needs of the patients and the types of services performed. (3) At least one RN and one other nursing staff member shall be on duty at all times patients are present. (4)(a) For purposes of this rule, "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 operating room team members during surgery. (b) The duties of a circulating nurse performed in an operating room of a certified or high complexity non-certified ambulatory surgical center shall be performed by a registered nurse licensed under ORS 678.010-678.410. (c) In any case requiring anesthesia or conscious sedation, 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. (d) Nothing in this rule precludes a circulating nurse from being relieved during a surgical procedure by another circulating nurse assigned to continue the surgical procedure. (5) Nurses who supervise the recovery area shall have current training in resuscitation techniques and other emergency procedures. **OAR § 333-076-0180** (1) Each year the inservice training agenda for nurses shall include at least the following: (a) Infection control measures; (b) Emergency procedures including, but not limited to, procedures for fire and other disaster; (c) Procedures for life-threatening situations including, but not limited to, cardiopulmonary resuscitation and the life-saving techniques for choking victims; and

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		(d) Other special needs of the patient population. (2) The facility shall assure that each licensed/certified employee is knowledgeable of the laws/rules governing his/her performance and that employees function within those performance standards. (3) Documentation of such training shall include the date, content, duration and names of attendees.
Medical Records *These provisions set forth requirements related to the form and content of medical records as well as their collection, storage and use.* *In addition, these provisions set forth requirements related to the confidentiality, security and integrity of patient information.*	**42 C.F.R. § 416.47** The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care. (a) Standard: Organization. The ASC must develop and maintain a system for the proper collection, storage, and use of patient records. (b) Standard: Form and content of record. The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following: (1) Patient identification. (2) Significant medical history and results of physical examination. (3) Pre-operative diagnostic studies (entered before surgery), if performed. (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body. (5) Any allergies and abnormal drug reactions. (6) Entries related to anesthesia administration. (7) Documentation of properly executed informed patient consent. (8) Discharge diagnosis.	**OAR § 333-076-0165** (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

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		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 deemed 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;

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		(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

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		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.
Personnel *These state law provisions set forth requirements related to personnel. There is no similar federal provision.*		**OAR § 333-076-0125** (1) As used in this rule, "person" means any: (a) ASC employee; (b) ASC contractor; (c) Health care practitioner granted privileges by the ASC; or (d) ASC volunteer or student. (2) The facility shall maintain a sufficient number of qualified personnel to provide effective patient care and all other related services. (3) There shall be written personnel policies and procedures which shall be made available to personnel. (4) Provisions shall be made for orientation. (5) Provisions shall be made for an annual continuing education plan. (6) There shall be a job description for each position which delineates the qualifications, duties, authority and responsibilities inherent in each position. (7) There shall be an annual work performance evaluation for each employee with appropriate records maintained. (8) There shall be an employee health screening program for the purpose of protecting patients and employees from communicable diseases, including but not limited to requiring tuberculosis testing for employees in accordance with section (10) of this rule. (9) An ASC shall restrict the work of employees with restrictable diseases in

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		accordance with OAR 333-019-0010. (10) Each ASC shall formally assess the risk of tuberculosis transmission among ASC employees, contractors, health care practitioners granted privileges by the ASC, volunteers or students, and shall comply with the "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings," published by the Centers for Disease Control and Prevention (Morbidity and Mortality Weekly Report, vol. 54, number RR-17, December 30, 2005 or by following recommendations otherwise approved by the Division. (11) An ASC shall obtain documentation that tuberculosis (TB) testing has been conducted in a manner consistent with the CDC guidelines for any person who enters an ASC and who has contact with patients, enters rooms that patients may enter, or who handles clinical specimens or other material from patients or their rooms. (a) An ASC shall require documentation of baseline TB screening conducted in accordance with the CDC Guidelines, within six weeks of the date of hire, date of executed contract or date of being granted ASC credentials. (b) For persons hired, contracted with or granted ASC privileges prior to December 15, 2010, an ASC shall obtain documentation of compliance with CDC Guidelines by February 1, 2011. (12) An ASC that is classified as "potential ongoing transmission" under CDC Guidelines shall consult with the Oregon TB control program within the Division, for guidance on the extent of TB testing required. (13) If an ASC learns that a person or a patient at the hospital is diagnosed with communicable TB, the ASC shall notify the local public health authority and conduct an investigation to identify contacts. If the Division or local public health authority conducts its own investigation, an ASC shall cooperate with that investigation and provide the Division or local public health authority with any information necessary for it to conduct its investigation. (14) An ASC shall notify the local public health administrator of its intent to discharge a patient known to have active TB disease. (15) The actions taken under this rule and all results thereof shall be fully documented for each employee. Such documentation is subject to review by authorized representatives of the Division.

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Pharmaceutical Services *These provisions set forth requirements for the administration of pharmaceuticals. In addition, the state law provisions require designation of pharmaceutical consultants and set forth the consultants' responsibilities.*	**42 C.F.R. § 416.48** The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services. (a) Standard: Administration of drugs. Drugs must be prepared and administered according to established policies and acceptable standards of practice. (1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record. (2) Blood and blood products must be administered by only physicians or registered nurses. (3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.	**OAR § 333-076-0145** (1) In an ASC that does not have a pharmacy on the premises, stock quantities of prescription drugs, including local anesthetics shall be stored on the premises only when such drugs have been obtained for dispensation or administration to his/her respective patients by a physician, dentist, podiatrist or other person authorized within the scope of his/her license to so dispense or administer such drugs. Prescribed drugs already prepared for patients in the ASC may also be stored on the premises. (2) Old medications, including special prescriptions for patients who have left the facility, shall be disposed of by incineration or other equally effective method, except narcotics and other drugs under the drug abuse law, which shall be handled in the manner prescribed by the Drug Enforcement Administration of the United States Department of Justice. (3) Drugs shall not be administered to patients unless ordered by a physician, dentist, podiatrist or individual authorized within the scope of his or her professional license to prescribe drugs; and such order shall be in writing over the physician's or other authorized individual's signature or authentication. (4) Prescription drugs dispensed by a physician shall be personally dispensed by the physician. Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by the physician. (5) The dispensing physician shall label prescription drugs with the following information: (a) Name of patient; (b) The name and address of the dispensing physician; (c) Date of dispensing; (d) The name of the drug. If the dispensed drug does not have a brand name, the prescription label shall indicate the generic name of the drug dispensed along with the name of the drug distributor or manufacturer, its quantity per unit and the directions for its use stated in the prescription. However, if the drug is a compound, the quantity per unit need not be stated; (e) Cautionary statements, if any, as required by law; and (f) When applicable, and as determined by the Oregon Board of Pharmacy, an expiration date after which the patient should not use the drug. (6) Prescription drugs shall be dispensed in containers complying with the federal Poison Prevention Packaging Act unless the patient requests a noncomplying container. (7) Pharmacist and pharmacy personnel providing services to the ASC are subject to ORS chapter 689 and the rules thereunder.

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Laboratory and Radiologic Services *These provisions set forth requirements related to laboratory services. In addition, the federal provisions set forth requirements regarding radiologic services.*	**42 C.F.R. § 416.49** (a) Standard: Laboratory services. If the ASC performs laboratory services, it must meet the requirements of Part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of Part 493 of this chapter. (b) Standard: Radiologic services. (1) The ASC must have procedures for obtaining radiological services from a Medicare approved facility to meet the needs of patients. (2) Radiologic services must meet the hospital conditions of participation for radiologic services specified in § 482.26 of this chapter.	**OAR § 333-076-0155** (1) Laboratory services shall be available for every patient either through the use of a licensed clinical laboratory in the facility or a written contract with a licensed clinical laboratory. (2) Any tissue removed during surgery except those exempted under OAR 333-076-0165, shall be submitted for histological examination by a pathologist. A written report of findings shall be filed in the patient's record in accordance with 333-076-0165. (3) OAR 333-024-0005 through 333-024-0350 shall also apply.
Patient Rights *These provisions address patient rights and notice to patients of their rights and set forth requirements for complaint resolution processes. In addition, the federal provisions set forth specific requirements related to advance directives.*	**42 C.F.R. § 416.50** The ASC must inform the patient or the patient's representative of the patient's rights, and must protect and promote the exercise of such rights. (a) Standard: Notice of rights. (1) The ASC must provide the patient or the patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative understands. In addition, the ASC must— (i) Post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representative, if applicable) waiting for treatment. The ASC's notice of rights must include the name, address, and telephone number of a representative in the State agency to whom patients can report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman. (ii) The ASC must also disclose, where applicable, physician financial interests or ownership in the ASC facility in accordance with the intent of Part 420 of this subchapter. Disclosure of information must be in writing and furnished to the patient in advance of the date of the procedure. (2) Standard: Advance directives. The ASC must comply with the following requirements: (i) Provide the patient or, as appropriate, the patient's representative in	

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	advance of the date of the procedure, with information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms. (ii) Inform the patient or, as appropriate, the patient's representative of the patient's right to make informed decisions regarding the patient's care. (iii) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive. (3) Standard: Submission and investigation of grievances. (i) The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. (ii) All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented. (iii) All allegations must be immediately reported to a person in authority in the ASC. (iv) Only substantiated allegations must be reported to the State authority or the local authority, or both. (v) The grievance process must specify timeframes for review of the grievance and the provisions of a response. (vi) The ASC, in responding to the grievance, must investigate all grievances made by a patient or the patient's representative regarding treatment or care that is (or fails to be) furnished. (vii) The ASC must document how the grievance was addressed, as well as provide the patient with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed. (b) Standard: Exercise of rights and respect for property and person. (1) The patient has the right to— (i) Exercise his or her rights without being subjected to discrimination or reprisal. (ii) Voice grievances regarding treatment or care that is (or fails to be) furnished. (iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed. (2) If a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.	

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	(3) If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law. (c) Standard: Privacy and safety. The patient has the right to— (1) Personal privacy. (2) Receive care in a safe setting. (3) Be free from all forms of abuse or harassment. (d) Standard: Confidentiality of clinical records. The ASC must comply with the Department's rules for the privacy and security of individually identifiable health information, as specified at 45 CFR parts 160 and 164.	
Infection Control *These provisions set forth requirements for maintaining a sanitary environment, for establishing an infection control program and designation of infection control personnel.*	**42 C.F.R. § 416.51** The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases. (a) Standard: Sanitary environment. The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. (b) Standard: Infection control program. The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. The program is— (1) Under the direction of a designated and qualified professional who has training in infection control; (2) An integral part of the ASC's quality assessment and performance improvement program; and (3) Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.	**OAR § 333-076-0175** (1) Each ASC shall establish and maintain an active facility wide infection control program for the control and prevention of infection. The program shall be managed by a qualified individual and overseen by a multi-disciplinary committee which shall be responsible for investigating, controlling and preventing infections in the facility. (2) Each ASC shall be responsible for developing written policies and for annual review of such policies, relating to at least the following: (a) Identification of existing or potential infections in patients, employees, medical staff, and health care practitioners with ASC privileges; (b) Control of factors affecting the transmission of infections and communicable diseases; (c) Provisions for orienting and educating all employees, medical staff, health care practitioners with ASC privileges and volunteers on the cause, transmission, and prevention of infections; (d) Collection, analysis, and use of data relating to infections in the ASC. (3) Each ASC shall be responsible for the development, implementation and annual review of policies under section (2) of this rule. (4) An ASC shall comply with all rules of the Division for the control of communicable diseases. (5) Written isolation procedures in accordance with current Universal Precautions for Prevention of Transmission of HIV and Other Bloodborne Infections shall be established and followed by all ASC personnel for control and prevention of cross-infection. Guidelines can be obtained from U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, GA 30333. Any guidelines published and distributed by the Division shall also be taken into consideration.

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Patient Admission, Assessment and Discharge *These provisions set forth requirements for patient admission, presurgical assessment, postsurgical assessment and discharge.*	**42 C.F.R. § 416.52** The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed. (a) Standard: Admission and pre-surgical assessment. (1) Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy. (2) Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the patient's condition since completion of the most recently documented medical history and physical assessment, including documentation of any allergies to drugs and biologicals. (3) The patient's medical history and physical assessment must be placed in the patient's medical record prior to the surgical procedure. (b) Standard: Post-surgical assessment. (1) The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy. (2) Post-surgical needs must be addressed and included in discharge notes. (c) Standard: Discharge. The ASC must— (1) Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a follow-up appointment with the physician, and ensure that all patients are informed, either in advance of their surgical procedure or prior to leaving the ASC, of their prescriptions, post-operative instructions and physician contact information for follow-up care. (2) Ensure 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. (3) Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.	**OAR § 333-076-0160** (1) Each patient shall be evaluated for all risk factors before a surgical procedure may be performed in accordance with 42 CFR 416.42 and 416.52. (2) Each patient shall be observed for post-operative complications under the direct supervision of a licensed registered nurse. Patients shall be observed for post-procedure complications until their conditions are stable. (3) No medications or treatments shall be given without the order of a physician or other individual authorized within the scope of his/her license. (4) At the time of discharge from the ASC, each patient must be evaluated by a physician, or by an anesthetist as defined by 45 CFR 410.69(b) for proper anesthesia recovery. (5) Written instruction shall be given to patients on discharge covering signs and symptoms of complications as well as any necessary follow-up instructions for routine and/or emergency care. (6) Each facility shall adopt and observe written patient care policies. (7) Patient care policies shall be evaluated annually and rewritten as needed. Documentation of the evaluation is required.