Medicare Conditions for Coverage
Washington State Licensure Requirements
Crosswalk

By Emily R. Studebaker
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| Basis and Scope | Code of Federal Regulations  
|---|---|
| **42 C.F.R. § 416.1** | **Chapter 70.230 RCW  
| Ambulatory Surgical Facilities** |
| 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. | The Washington State Department of Health adopted chapter 246-330 WAC to implement chapter 70.230 RCW (commonly referred to as the “ambulatory surgical facility licensure law”) and to establish minimum health and safety requirements for the licensing, inspection, operation, maintenance, and construction of ambulatory surgical facilities. |

<table>
<thead>
<tr>
<th>Definitions</th>
<th><strong>42 C.F.R. § 416.2</strong></th>
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<tr>
<td><strong>42 C.F.R. § 416.2</strong></td>
<td><strong>WAC § 246-330-010</strong></td>
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<td>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.”</td>
<td>Ambulatory surgical facility or ASF means “any distinct entity that operates for the primary purpose of providing specialty or multispecialty outpatient surgical services in which patients are admitted to and discharged from the facility within twenty-four hours and do not require inpatient hospitalization, whether or not the facility is certified under Title XVIII of the federal Social Security Act. Excluded from this definition are a dental office, an ambulatory surgical facility licensed as part of a hospital under chapter 70.41 RCW or a practitioner’s office where surgical procedures are conducted without general anesthesia.”</td>
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<table>
<thead>
<tr>
<th>Compliance with Federal, State and Local Law</th>
<th><strong>42 C.F.R. § 416.40</strong></th>
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<tr>
<td><strong>42 C.F.R. § 416.40</strong></td>
<td><strong>WAC § 246-330-010(1)</strong></td>
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<tr>
<td>The ASC must comply with State licensure requirements.</td>
<td>Compliance with chapter 246-330 WAC does not constitute release from the requirements of applicable federal, state and local codes and</td>
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<tr>
<td>Ambulatory Surgical Center Medicare Conditions for Coverage</td>
<td>Ambulatory Surgical Facility Licensure Requirements</td>
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<tr>
<td>ordinances. Where regulations in chapter 246-330 WAC exceed other codes and ordinances, the regulations in chapter 246-330 WAC will apply.</td>
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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.

<table>
<thead>
<tr>
<th>42 C.F.R. § 416.41</th>
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<tr>
<td>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.</td>
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<tr>
<th>WAC § 246-330-115</th>
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<tr>
<td>An ambulatory surgical facility must have a governing authority that is responsible for determining, implementing, monitoring and revising policies and procedures covering the operation of the facility that includes:</td>
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<tr>
<td>1) Selecting and periodically evaluating a chief executive officer or administrator;</td>
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<tr>
<td>2) Appointing and periodically reviewing a medical staff;</td>
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<td>3) Approving the medical staff bylaws;</td>
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<tr>
<td>4) Reporting practitioners according to RCW 70.230.120iii;</td>
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<td>5) Informing patients of any unanticipated outcomes according to RCW 70.230.150vi;</td>
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<tr>
<td>6) Establishing and approving a coordinated quality performance improvement plan according to RCW 70.230.080v;</td>
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<tr>
<td>7) Establishing and approving a facility safety and emergency training program according to RCW 70.230.060vi;</td>
</tr>
<tr>
<td>8) Reporting adverse events and conducting root cause analyses according to RCW 70.56.020vi;</td>
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<tr>
<td>9) Providing a patient and family grievance process including a time frame for resolving each grievance according to RCW 70.230.080(1)(d)vi;</td>
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<tr>
<td>10) Defining who can give and receive patient care orders that are consistent with professional licensing laws; and</td>
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<tr>
<td>11) Defining who can authenticate written or electronic orders for all drugs, intravenous solutions, blood, and medical treatments that are consistent with professional licensing laws.</td>
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The federal provisions set forth requirements related to contract services. There is no similar state licensure provision.

<table>
<thead>
<tr>
<th>42 C.F.R. § 416.41(a)</th>
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<tbody>
<tr>
<td>(a) <strong>Standard: Contract services.</strong> When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner.</td>
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<tr>
<td>Ambulatory Surgical Center Medicare Conditions for Coverage</td>
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<tr>
<td>These provisions set forth requirements related to the transfer of patients requiring emergency medical care.</td>
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<tr>
<td>42 C.F.R. § 416.41(b)</td>
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<tr>
<td>(b) Standard: Hospitalization.</td>
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<td>(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.</td>
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<tr>
<td>(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.</td>
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<tr>
<td>(3) The ASC must—</td>
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<tr>
<td>(i) Have a written transfer agreement with a hospital that meets the requirements of paragraph (b)(2) of this section; or</td>
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<tr>
<td>(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.</td>
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<tr>
<th>WAC § 246-330-230</th>
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<td>(2) An ambulatory surgical facility must assure the environment of care management plan contains the following items:</td>
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<tr>
<td>(d) Emergency preparedness:</td>
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<tr>
<td>(i) Establish, implement and periodically review a disaster plan for internal and external disasters that is specific to the facility and community;</td>
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<tr>
<td>(ii) Process to educate and train staff on the disaster plan;</td>
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<tr>
<td>(iii) Process to periodically conduct drills to test the plan.</td>
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These provisions set forth requirements related to disaster preparedness plans. | 42 C.F.R. § 416.41(c) |
| (c) Standard: Disaster preparedness plan. | (d) Establish, implement and periodically review a disaster plan for internal and external disasters that is specific to the facility and community; |
| (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. | (ii) Process to educate and train staff on the disaster plan; |
| (2) The ASC coordinates the plan with State and local authorities, as appropriate. | (iii) Process to periodically conduct drills to test the plan. |
| (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. | |
| **Ambulatory Surgical Center**  
| Medicare Conditions for Coverage | **Ambulatory Surgical Facility**  
| Licensure Requirements |

**WAC § 246-330-210**

An ambulatory surgical facility must:

1. Adopt and implement policies and procedures that:
   a. Identify areas where surgery and invasive procedures may be performed;
   b. Define staff access to areas where surgery and invasive procedures are performed;
   c. Identify practitioner and advanced registered nurse practitioner’s privileges for operating room staff; and
   d. Define staff qualifications and oversight.

2. Use facility policies and procedures which define standards of care;

3. Implement a system to identify and indicate the correct surgical site prior to beginning a surgical procedure;

4. Provide emergency equipment, supplies, and services to surgical and invasive areas;

5. Provide separate refrigerated storage equipment with temperature alarms, when blood is stored in the surgical department; and

6. Assure a registered nurse qualified by training and experience functions as the circulating nurse in every operating room whenever deep sedation or general anesthesia are used during surgical procedures.

**WAC § 246-330-215**

An ambulatory surgical facility must:

1. Adopt and implement policies and procedures that:
   a. Identify the types of anesthesia and sedation that may be used;
   b. Identify areas where each type of anesthesia and sedation may be used; and
   c. Define the staff qualifications and oversight for administering each type of anesthesia and sedation used in the facility.

2. Use facility policies and procedures which define standards of care; and

3. Assure emergency equipment, supplies and services are immediately available in all areas where anesthesia is used.

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**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 non-physician 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 requirement, and that the opt-out is consistent with State law.
### Ambulatory Surgical Center Medicare Conditions for Coverage

(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.

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<th>42 C.F.R. § 416.43</th>
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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

### Ambulatory Surgical Facility Licensure Requirements

WAC § 246-330-155

An ambulatory surgical facility must:

1. Have a facility-wide approach to process design and performance measurement, assessment, and improving patient care services according to RCW 70.230.080 including, but not limited to:

   (a) A written performance improvement plan that is periodically evaluated;

   (b) Performance improvement activities that are interdisciplinary and include at least one member of the governing authority;

   (c) Prioritize performance improvement activities;

   (d) Implement and monitor actions taken to improve performance;

   (e) Education programs dealing with performance improvement, patient safety, medication errors, injury prevention; and

   (f) Review serious or unanticipated patient outcomes in a timely manner.

2. Systematically collect, measure and assess data on processes and outcomes related to patient care and organization functions;

3. Collect, measure and assess data including, but not limited to:

   (a) Operative, other invasive, and noninvasive procedures that place patients at risk;

   (b) Infection rates, pathogen distributions and antimicrobial susceptibility profiles;

   (c) Death;

   (d) Medication management or administration related to wrong medication, wrong dose, wrong time, near misses and any other medication errors and incidents;

   (e) Injuries, falls, restraint use, negative health outcomes and incidents injurious to patients in the ambulatory surgical facility;

   (f) Adverse drug reactions (as defined by the ambulatory surgical facility);

   (g) Discrepancies or patterns between preoperative and postoperative (including pathologic) diagnosis, including pathologic review of specimens removed during surgical or invasive procedures;

   (h) Adverse events according to chapter 70.56 RCW;

   (i) Confirmed transfusion reactions;

   (j) Patient grievances, needs, expectations, and satisfaction; and
facility targeting adverse patient events and ensure that all staff are familiar with these strategies.

(d) **Standard: Performance improvement projects.**
   (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.

(k) Quality control and risk management activities.

| Environment |
|-------------------|-------------------|
| **These provisions set forth requirements related to the physical environment of an ASC or ASF, including safety from fire and the maintenance of emergency equipment and trained emergency personnel.** | **42 C.F.R. § 416.44** |

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

(a) **Standard: Physical environment.** The ASC must provide a functional and sanitary environment for the provision of surgical services.
   (1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.
   (2) The ASC must have a separate recovery room and waiting area.
   (3) The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

(b) **Standard: Safety from fire.**
   (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Centers of the

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<th>Ambulatory Surgical Facility License Requirements</th>
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<td>(k) Quality control and risk management activities.</td>
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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. | *(k) Quality control and risk management activities.* |

WAC § 246-330-230

(1) An ambulatory surgical facility must create and follow an environment of care management plan that addresses safety, security, hazardous materials and waste, emergency preparedness, fire safety, medical equipment, utility systems and physical environment.
   (2) An ambulatory surgical facility must assure the environment of care management plan contains the following items:
      (a) Safety:
         (i) Policies and procedures on safety-related issues such as but not limited to physical hazards and injury prevention;
         (ii) Method to educate and periodically review with staff the safety policies and procedures;
         (iii) Process to investigate, correct and report safety-related incidents; and
         (iv) Process to keep the physical environment free of hazards.
      (b) Security:
         (i) Policies and procedures to protect patients, visitors, and staff while in the facility including preventing patient abduction;
         (ii) Method to educate and periodically review security policies and
2000 edition of the Life Safety Code of the National Fire Protection Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

(4) An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006.

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, an ASC may place alcohol-based hand rub dispensers in its facility if—
   (i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;
   (ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;
   (iii) The dispensers are installed in a manner that adequately protects against inappropriate access;
   (iv) The dispensers are installed in accordance with the following provisions:
      (A) Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m);
(B) The maximum individual dispenser fluid capacity shall be:
   (1) 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.
   (2) 0.5 gallons (2.0 liters) for dispensers in suites of rooms.
   (C) The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other;
   (D) Not more than an aggregate 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet;
   (E) Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, Flammable and Combustible Liquids Code;
   (F) The dispensers shall not be installed over or directly adjacent to an ignition source;
   (G) In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments; and
   (v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

(c) Standard: Emergency equipment. Emergency equipment available to the operating rooms must include at least the following:
   (1) Emergency call system.
   (2) Oxygen.
   (3) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator.
   (4) Cardiac defibrillator.
   (5) Cardiac monitoring equipment.
   (6) Tracheostomy set.
   (7) Laryngoscopes and endotracheal tubes.
   (8) Suction equipment.
   (9) Emergency medical equipment and supplies specified by the medical staff.

(d) Standard: Emergency personnel. Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.
| **Medical Staff** | **Ambulatory Surgical Center**  
**Medicare Conditions for Coverage** | **Ambulatory Surgical Facility**  
**Licensure Requirements** |
|------------------|---------------------------------|---------------------------------|
| These provisions set forth requirements related to medical staff membership and clinical privileges, including reappraisal, and oversight and evaluation of practitioners other than physicians. | **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. | **WAC § 246-330-145**  
The medical staff must:  
(1) Be accountable to the governing body;  
(2) Adopt bylaws, rules, regulations, and organizational structure including an appointment and reappointment process;  
(3) Be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges in accordance with recommendations from qualified medical personnel;  
(4) Periodically review and reappraise medical staff privileges using peer review data;  
(5) Periodically review and amend the scope of procedures performed in the ambulatory surgical facility;  
(6) If the ambulatory surgical facility 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; and  
(7) Report practitioners for discipline of unprofessional conduct according to RCW 70.230.120. |
| **Nursing Services** | **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. | **WAC § 246-330-120**  
The ambulatory surgical facility leaders must:  
(1) Identify patient care responsibilities for all nursing personnel;  
(2) Assure nursing services are provided in accordance with state nurse licensing law and recognized standards of practice;  
(3) Assure a registered nurse is available for emergency treatment at all times a patient is present in the facility; … .  
**WAC § 246-330-205**  
An ambulatory surgical facility must:  
(2) Have a registered nurse available for consultation in the ambulatory surgical facility at all times patients are present; … .  
**WAC § 246-330-210**  
An ambulatory surgical facility must:  
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<tr>
<th>Medical Records</th>
<th>42 C.F.R. § 416.47</th>
<th>WAC § 246-330-150</th>
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| These provisions set forth requirements related to the form and content of medical records as well as their collection, storage and use. | 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. | An ambulatory surgical facility must:  
(1) Provide medical staff, employees and other authorized persons with access to patient information systems, resources, and services;  
(2) Maintain confidentiality, security, and integrity of information;  
(3) Initiate and maintain a medical record for every patient assessed or treated including a process to review records for completeness, accuracy, and timeliness;  
(4) Create medical records that:  
(a) Identify the patient;  
(b) Have clinical data to support the diagnosis, course and results of treatment for the patient; |
Ambulatory Surgical Center Medicare Conditions for Coverage

- (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.

Ambulatory Surgical Facility Licensure Requirements

- (c) Have signed consent documents;
- (d) Promote continuity of care;
- (e) Have accurately written, signed, dated, and timed entries;
- (f) Indicates authentication after the record is transcribed;
- (g) Are promptly filed, accessible, and retained according to facility policy; and
- (h) Include verbal orders that are accepted and transcribed by qualified personnel.

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.

### WAC § 246-330-200

An ambulatory surgical facility must:

- (1) Only administer, dispense or deliver legend drugs and controlled substances to patients receiving care in the facility;
- (2) Assure drugs dispensed to patients are dispensed and labeled consistent with the requirements of RCW 18.64.246, and chapters 69.41 and 69.50 RCW;
- (3) Establish a process for selecting medications based on evaluating their relative therapeutic merits, safety, and cost; and
- (4) Designate a pharmacist consultant who is licensed in Washington state. The pharmacist consultant can be either employed or contracted by the facility. The pharmacist consultant is responsible for:
  - (a) Establishing policy and procedures related to:
    - (i) Purchasing, ordering, storing, compounding, delivering, dispensing and administering of controlled substances or legend drugs;
    - (ii) Assuring drugs are stored, compounded, delivered or dispensed according to all applicable state and federal rules and regulations;
    - (iii) Maintaining accurate inventory records and patient medical records related to the administration of controlled substances and legend drugs;
    - (iv) Maintaining any other records required by state and federal regulations;
| Laboratory and 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. |
| Patient Rights | **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, regulations:  
(v) Security of legend drugs and controlled substances; and  
(vi) Controlling access to controlled substances and legend drugs.  
(b) Establishing a process for completing all forms for the purchase and order of legend drugs and controlled substances; and  
(c) Establishing a method for verifying receipt of all legend drugs and controlled substances purchased and ordered by the ambulatory surgical facility. |
| Ambulatory Surgical Center  
Medicare Conditions for Coverage | **Ambulatory Surgical Facility Licensure Requirements**  
Ambulatory surgical facilities must:  
(1) Adopt and implement policies and procedures that define each patient’s right to:  
(a) Be treated and cared for with dignity and respect;  
(b) Confidentiality, privacy, security, complaint resolution, spiritual care, and communication. If communication restrictions are necessary for patient care and safety, the facility must document and explain the restrictions to the patient and family;  
(c) Be protected from abuse and neglect;  
(d) Access protective services;  
(e) Complain about their care and treatment without fear of |
specific requirements related to advance directives.

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<td>(2) Standard: Advance directives. The ASC must comply with the following requirements:</td>
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<td>(i) Provide the patient or, as appropriate, the patient’s representative in 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.</td>
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<td>(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.</td>
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<td>(iii) Document in a prominent part of the patient’s current medical record, whether or not the individual has executed an advance directive.</td>
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<td>(f) Timely complaint resolution;</td>
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<td>(g) Be involved in all aspects of their care including:</td>
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<td>(i) Refusing care and treatment; and</td>
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<td>(ii) Resolving problems with care decisions.</td>
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<td>(h) Be informed of unanticipated outcomes according to RCW 70.230.150;</td>
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<td>(i) Be informed and agree to their care; and</td>
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<td>(j) Family input in care decisions, in compliance with existing legal directives of the patient or existing court-issued legal orders.</td>
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(2) Provide each patient a written statement of patient rights from subsection (1) of this section.

(3) Adopt and implement policies and procedures to address research, investigation, and clinical trials including:

(a) How to authorize research;

(b) Require staff to follow informed consent laws; and

(c) Not hindering a patient’s access to care if a patient refuses to participate.
| **Ambulatory Surgical Center**  
| Medicare Conditions for Coverage | **Ambulatory Surgical Facility**  
| Licensure Requirements | 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.
(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*  
| **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

| **WAC§ 246-330-176**  
| An ambulatory surgical facility must:
   (1) Develop, implement and maintain a written infection control and surveillance program;
(2) Designate staff to:
   (a) Manage the activities of the infection control program;
   (b) Assure the infection control program conforms with patient care and safety policies and procedures; and
   (c) Provide consultation on the infection control program, policies
**Ambulatory Surgical Center**  
**Medicare Conditions for Coverage**

| designation of infection control personnel. | 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. |
|---|---|
| Ambulatory Surgical Facility Licensure Requirements | and procedures throughout the entire facility.  
(3) Ensure staff managing the infection control program have:  
(a) A minimum of two years experience in a health related field; and  
(b) Training in the principles and practices of infection control;  
(4) Develop and implement infection control policies and procedures consistent with the guidelines of the centers for disease control and prevention (CDC);  
(5) Assure the infection control policies and procedures address, but are not limited to the following:  
(a) Routine surveillance, outbreak investigations and interventions including pathogen distributions and antimicrobial susceptibility profiles consistent with the 2006 CDC healthcare infection control practices advisory committee guideline, Management of Multidrug-Resistant Organisms in Healthcare Settings;  
(b) Patient care practices in all clinical care areas;  
(c) Receipt, use, disposal, sterilizing, processing, or reuse of equipment to prevent disease transmission;  
(d) Preventing cross contamination of soiled and clean items during sorting, processing, transporting, and storage;  
(e) Environmental management and housekeeping functions;  
(f) Approving and properly using disinfectants, equipment, and sanitation procedures;  
(g) Cleaning areas used for surgical procedures before, between, and after use;  
(h) Facility-wide daily and periodic cleaning;  
(i) Occupational health consistent with current practice;  
(j) Clothing;  
(k) Traffic patterns;  
(l) Antisepsis;  
(m) Handwashing;  
(n) Scrub technique and surgical preparation;  
(o) Biohazardous waste management according to applicable federal, state, and local regulations;  
(p) Barrier, transmission and isolation precautions; and  
(q) Pharmacy and therapeutics.  
(6) Establish and implement a plan for:  
(a) Reporting communicable diseases including cluster or outbreaks of postoperative infections according to chapter 246-100 WAC; and  
(b) Surveying and investigating communicable disease occurrences in the ambulatory surgical facility consistent with chapter 246-100 |
Patient Admission, Assessment and Discharge

These provisions set forth requirements for patient admission, pre-surgical assessment, post-surgical assessment and discharge.

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<td><strong>WAC</strong> xi and (c) Collecting, measuring and assessing data on infection rates, pathogen distributions and antimicrobial susceptibility profiles.**</td>
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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 the discharge notes.

(c) **Standard: Discharge.** The ASC must—
(1) Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a followup 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

WAC § 246-330-205

An ambulatory surgical facility must:
(1) Provide personnel, space, equipment, reference materials, training, and supplies for the appropriate care and treatment of patients;
(2) Have a registered nurse available for consultation in the ambulatory surgical facility at all times patients are present;
(3) Adopt, implement, review and revise patient care policies and procedures designed to guide staff that address:
(a) Criteria for patient admission;
(b) Reliable method for personal identification of each patient;
(c) Conditions that require patient transfer to outside facilities;
(d) Patient safety measures;
(e) Staff access to patient care areas;
(f) Use of physical and chemical restraints or seclusion consistent with CFR 42.482;
(g) Use of preestablished patient care guidelines or protocols;
(When used, these must be documented in the medical record and be preapproved or authenticated by an authorized practitioner or advanced registered nurse practitioner;
(h) Care and handling of patients whose condition require special medical consideration;
(i) Preparation and administration of blood and blood products; and
(j) Discharge planning.
(4) Have a system to plan and document care in an interdisciplinary manner, including:
(a) Development of an individualized patient plan of care, based on an initial assessment;
(b) Assessment for risk of falls, skin condition, pressure ulcers, pain, medication use, therapeutic effects and side or adverse effects.
(5) Complete and document an initial assessment of each patient’s physical condition, emotional, and social needs in the medical record. Initial assessment includes:
(a) Dependent upon the procedure and the risk of harm or injury, a patient history and physical assessment including but not limited to falls, mental status and skin condition;
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<td>their prescriptions, post-operative instructions and physician contact information for followup 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.</td>
<td>(b) Current needs; (c) Need for discharge planning; (d) When treating pediatric patients, the immunization status; (e) Physical examination, if within thirty days prior to admission, and updated as needed if patient status has changed; and (f) Discharge plans when appropriate, coordinated with: (i) Patient, family or caregiver; and (ii) Receiving agency, when necessary.</td>
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**WAC § 246-330-220**

An ambulatory surgical facility must:

(1) Adopt and implement policies and procedures that define the qualifications and oversight of staff delivering recovery services;

(2) Assure a physician or advanced registered nurse practitioner capable of managing complications and providing cardiopulmonary resuscitation is immediately available for patients recovering from anesthesia; and

(3) Assure a registered nurse trained and current in advanced cardiac life support measures is immediately available for patients recovering from anesthesia.

*Ms. Studebaker is Of Counsel with Garvey Schubert Barer, P.S. and serves as General Counsel to the Washington Ambulatory Surgery Center Association. She can be contacted at estudebaker@gsblaw.com or (206) 816-1417.*
Section 1832(a)(2)(F)(i).

“General anesthesia” is defined as “a state of unconsciousness intentionally produced by anesthetic agents, with absence of pain sensation over the entire body, in which the patient is without protective reflexes and is unable to maintain an airway. Lower levels of sedation that unintentionally progress to the point at which the patient is without protective reflexes and is unable to maintain an airway is not considered general anesthesia.” WAC § 246-330-001(17).

“Surgical services” is defined as “invasive medical procedures that: (a) [u]tilize a knife, laser, cautery, cytogenics, or chemicals; and (b) [r]emove, correct, or facilitate the diagnosis or cure of disease, process or injury through that branch of medicine that treats diseases, injuries and deformities by manual or operative methods by a practitioner.” WAC § 246-330-001(48).

RCW 70.230.120 requires an ASF to report unprofessional conduct under certain circumstances pursuant to the Uniform Disciplinary Act.

RCW 70.230.150 requires an ASF to have in place policies to assure that, when appropriate, information about unanticipated outcomes is provided to patients or their families or surrogate decision makers.

RCW 70.230.080 requires an ASF to maintain a coordinated quality improvement program for the improvement of the quality of health care services rendered to patients and the identification and prevention of medical malpractice and sets forth specific requirements for that program.

RCW 70.230.060 requires an ASF to have a facility safety and emergency training program, which includes 1) on-site equipment, medication, and trained personnel to facilitate handling of services sought or provided and to facilitate the management of any medical emergency that may arise in connection with services sought or provided, 2) written transfer agreements with local hospitals licensed under chapter 70.41 RCW, approved by the ambulatory surgical facility’s medical staff, and 3) a procedural plan for handling medical emergencies that shall be available for review during surveys and inspections.

RCW 70.56.020 establishes an adverse health events and incident notification and reporting system, which sets forth specific requirements for notification and reporting of adverse events.

RCW 70.230.080(1)(d) requires an ASF’s coordinated quality improvement program to include a procedure for the prompt resolution of grievances by patients or their representatives related to accidents, injuries, treatment, and other events that may result in claims of medical malpractice.

Chapter 70.230 RCW set forth specific requirement related to access to and release of confidential medical records.

RCW 18.64.246, chapters 69.41 and 69.50 RCW set forth requirements for prescription drug labels.

Chapter 246-100 WAC sets forth specific requirements related to controlling communicable and certain other diseases.

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