



# PROPOSED RULE MAKING

## CR-102 (June 2004)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

**Agency:** Department of Health

- Preproposal Statement of Inquiry was filed as WSR 08-10-090 ; or
- Expedited Rule Making--Proposed notice was filed as WSR \_ ; or
- Proposal is exempt under RCW 34.05.310(4).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

**Title of rule and other identifying information:** (Describe Subject)

Chapter 246-330 WAC Ambulatory Surgical Facilities  
Establishing a new chapter in WAC for licensing requirements, operational standards and a fee schedule for ambulatory surgical facilities.

**Hearing location(s):** Department of Health  
Point Plaza East  
310 Israel Rd SE  
Tumwater, Washington 98501  
Rooms 152 & 153

Date: 03/10/2009 Time: 9:30am

**Submit written comments to:**

Name: John Hilger  
Address: Department of Health  
PO Box 47852  
Olympia, Washington 98504-7852  
Website: <http://www3.doh.wa.gov/policyreview/>  
fax (360) 236-2901 by (date) 03/10/2009

**Assistance for persons with disabilities:** Contact

John Hilger by 03/09/2009

TTY (800) 833-6388 or () 711

**Date of intended adoption:** 04/07/2009

(Note: This is NOT the effective date)

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:**

The purpose of the proposal is to establish a new chapter in WAC to promote safe and adequate care of individuals in ambulatory surgical facilities. The proposal is in response to legislation passed in 2007 (ESHB 1414) which added a new chapter to Title 70 RCW and directed the department to license ambulatory surgical facilities by July 1, 2009. Ambulatory surgical facilities are defined as entities that provide specialty or multi-specialty outpatient surgical services in which patients are admitted to and discharged by the facility within 24 hours and do not require inpatient hospitalization. The anticipated effects of licensing these facilities will be overall quality improvement of patient services, increased patient safety and positive health outcomes.

**Reasons supporting proposal:**

Reasons supporting the proposal are: (1) Rules will ensure that ambulatory surgical facilities are licensed by July 1, 2009 as mandated by ESHB 1414; (2) Rules will promote safe and adequate care of individuals in ambulatory surgical facilities through the development, establishment and enforcement of minimum standards for maintenance and operation; (3) Rules will promote positive health outcomes for patients.

**Statutory authority for adoption:**

Chapter 70.230 RCW

**Statute being implemented:**

Chapter 70.230 RCW

**Is rule necessary because of a:**

- Federal Law?  Yes  No
  - Federal Court Decision?  Yes  No
  - State Court Decision?  Yes  No
- If yes, CITATION:

**DATE** 02/04/09

**NAME** (type or print)  
Mary C. Selecky

**SIGNATURE**

**TITLE**  
Secretary of Health

**CODE REVISER USE ONLY**

OFFICE OF THE CODE REVISER  
STATE OF WASHINGTON  
FILED

**DATE:** February 04, 2009

**TIME:** 10:19 AM

**WSR 09-04-095**

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:**

None

**Name of proponent:** (person or organization) Department of Health

- Private
- Public
- Governmental

**Name of agency personnel responsible for:**

Name	Office Location	Phone
Drafting..... Byron Plan	310 Israel Rd SE, Tumwater, WA	(360) 236-2916
Implementation....Linda Foss	310 Israel Rd SE, Tumwater, WA	(360) 236-2920
Enforcement.....Steve Saxe	310 Israel Rd SE, Tumwater, WA	(360) 236-2902

**Has a small business economic impact statement been prepared under chapter 19.85 RCW?**

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name: John Hilger

Address: PO Box 47852  
Olympia, WA 98504-7852

phone (360) 236-2929

fax (360) 236-2901

e-mail [john.hilger@doh.wa.gov](mailto:john.hilger@doh.wa.gov)

No. Explain why no statement was prepared.

**Is a cost-benefit analysis required under RCW 34.05.328?**

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name: John Hilger

Address: PO Box 47852  
Olympia, WA 98504-7852

phone (360) 236-2929

fax (360) 236-2901

e-mail [john.hilger@doh.wa.gov](mailto:john.hilger@doh.wa.gov)

No: Please explain:

## Chapter 246-330 WAC

### AMBULATORY SURGICAL FACILITIES

#### NEW SECTION

**WAC 246-330-001 Purpose and applicability of chapter.** The Washington state department of health adopts this chapter to implement chapter 70.230 RCW and establish minimum health and safety requirements for the licensing, inspection, operation, maintenance, and construction of ambulatory surgical facilities.

(1) Compliance with the regulations in this chapter does not constitute release from the requirements of applicable federal, state and local codes and ordinances. Where regulations in this chapter exceed other codes and ordinances, the regulations in this chapter will apply.

(2) The department will update or adopt references to codes and regulations in this chapter as necessary.

#### NEW SECTION

**WAC 246-330-010 Definitions.** For the purposes of this chapter, the following words and phrases will have the following meanings unless the context clearly indicates otherwise:

(1) "Abuse" means injury or sexual abuse of a patient indicating the health, welfare, and safety of the patient is harmed:

(a) "Physical abuse" means acts or incidents which may result in bodily injury or death.

(b) "Emotional abuse" means to impose willful or reckless mental or emotional anguish by threat, verbal behavior, harassment, or other verbal or nonverbal actions which may result in emotional or behavioral stress or injury.

(2) "Advanced registered nurse practitioner" means an individual licensed under chapter 18.79 RCW.

(3) "Adverse health event" or "adverse event" means the list of serious reportable events adopted by the national quality forum in 2002 (and as updated), in its consensus report on serious reportable events in health care.

(4) "Agent," when referring to a medical order or procedure, means any power, principle, or substance, whether physical, chemical, or biological, capable of producing an effect upon the human body.

(5) "Alteration" means any change, addition, functional change, or modification to an existing ambulatory surgical facility or a portion of an existing ambulatory surgical facility.

"Minor alteration" means renovation that does not require an increase in capacity to structural, mechanical or electrical systems, does not affect fire and life safety, and does not add facilities in addition to that for which the ambulatory surgical facility is currently licensed. Minor alterations do not require prior review and approval by the department.

(6) "Ambulatory surgical facility" 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.

(7) "Assessment" means the:

- (a) Systematic collection and review of patient-specific data;
- (b) A process for obtaining appropriate and necessary information about individuals seeking entry into the ambulatory surgical facility or service; and
- (c) Information used to match an individual with an appropriate setting or intervention. The assessment is based on the patient's diagnosis, care setting, desire for care, response to any previous treatment, consent to treatment, and education needs.

(8) "Authentication" means the process used to verify an entry is complete, accurate, and final.

(9) "Change of ownership" means:

(a) A sole proprietor who transfers all or part of the ambulatory surgical facility's ownership to another person or persons;

(b) The addition, removal, or substitution of a person as a general, managing, or controlling partner in an ambulatory surgical facility owned by a partnership where the tax identification number of that ownership changes; or

(c) A corporation that transfers all or part of the corporate stock which represents the ambulatory surgical facility's ownership to another person where the tax identification number of that ownership changes.

(10) "Clinical evidence" means the same as original clinical evidence used in diagnosing a patient's condition or assessing a clinical course and includes, but is not limited to:

- (a) X-ray films;
- (b) Digital records;
- (c) Laboratory slides;

(d) Tissue specimens; or

(e) Medical photographs.

(11) "Department" means the Washington state department of health.

(12) "Double-checking" means verifying patient identity, agent to be administered, route, quantity, rate, time, and interval of administration by two persons.

(13) "Drugs" as defined in RCW 18.64.011(3) means:

(a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(c) Substances (other than food) intended to affect the structure or any function of the body of man or other animals; or

(d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection but not including devices or component parts or accessories.

(14) "Emergency medical condition" means a condition manifesting itself by acute symptoms of severity (including severe pain, symptoms of mental disorder, or symptoms of substance abuse) that absent of immediate medical attention could result in:

(a) Placing the health of an individual in serious jeopardy;

(b) Serious impairment to bodily functions;

(c) Serious dysfunction of a bodily organ or part; or

(d) With respect to a pregnant woman who is having contractions:

(i) That there is inadequate time to provide a safe transfer to a hospital before delivery; or

(ii) That the transfer may pose a threat to the health or safety of the woman or the unborn child.

(15) "Emergency services" means health care services medically necessary to evaluate and treat a medical condition that manifests itself by the acute onset of a symptom or symptoms, including severe pain, that would lead a prudent layperson acting reasonably to believe that a health condition exists that requires immediate medical attention, and that the absence of immediate medical attention could reasonably be expected to result in serious impairment to bodily functions or serious dysfunction of an organ or part of the body, or would place the person's health, or in the case of a pregnant woman, the health of the woman or her unborn child, in serious jeopardy.

(16) "Family" means individuals designated by a patient who need not be relatives.

(17) "General anesthesia" means 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.

(18) "Governing authority/body" means the person or persons responsible for establishing the purposes and policies of the ambulatory surgical facility.

(19) "Hospital" means any institution, place, building, or agency providing accommodations, facilities, and services as defined in chapter 70.41 RCW.

(20) "Individualized treatment plan" means a written and/or electronically recorded statement of care planned for a patient based upon assessment of the patient's developmental, biological, psychological, and social strengths and problems, and including:

(a) Treatment goals, with stipulated time frames;

(b) Specific services to be utilized;

(c) Designation of individuals responsible for specific service to be provided;

(d) Discharge criteria with estimated time frames; and

(e) Participation of the patient and the patient's designee as appropriate.

(21) "Invasive medical procedure" means a procedure involving puncture or incision of the skin or insertion of an instrument or foreign material into the body including, but not limited to, percutaneous aspirations, biopsies, cardiac and vascular catheterizations, endoscopies, angioplasties, and implantations. Excluded are venipuncture and intravenous therapy.

(22) "Maintenance" means the work of keeping something in safe, workable or suitable condition.

(23) "Medical equipment" means equipment used in a patient care environment to support patient treatment and diagnosis.

(24) "Medical staff" means practitioners and advanced registered nurse practitioners appointed by the governing authority.

(25) "Medication" means any substance, other than food or devices, intended for use in diagnosing, curing, mitigating, treating, or preventing disease.

(26) "Near miss" means an event which had the potential to cause serious injury, death, or harm but did not happen due to chance, corrective action or timely intervention.

(27) "Neglect" means mistreatment or maltreatment; a disregard of consequences or magnitude constituting a clear and present danger to an individual patient's health, welfare, and safety.

(a) "Physical neglect" means physical or material deprivation, such as lack of medical care, lack of supervision, inadequate food, clothing, or cleanliness.

(b) "Emotional neglect" means acts such as rejection, lack of stimulation, or other acts that may result in emotional or behavioral problems, physical manifestations, and disorders.

(28) "New construction" means any renovation, alteration or new facility to be licensed as an ambulatory surgical facility.

(29) "Nonambulatory" means an individual physically or mentally unable to walk or traverse a normal path to safety without the physical assistance of another.

(30) "Operating room" means a room intended for invasive and noninvasive procedures.

(31) "Patient" means an individual receiving (or having received) preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative health services.

(32) "Patient care areas" means all areas of the ambulatory surgical facility where direct patient care is delivered and where patient diagnostic or treatment procedures are performed.

(33) "Person" means any individual, firm, partnership, corporation, company, association, joint stock association, and the legal successor thereof.

(34) "Pharmacist" means an individual licensed by the state board of pharmacy under chapter 18.64 RCW.

(35) "Pharmacy" means every place properly licensed by the board of pharmacy where the practice of pharmacy is conducted.

(36) "Physician" means an individual licensed under chapter 18.71 RCW, Physicians, chapter 18.22 RCW, Podiatric medicine and surgery, or chapter 18.57 RCW, Osteopathy--Osteopathic medicine and surgery.

(37) "Practitioner" means any physician or surgeon licensed under chapter 18.71 RCW, an osteopathic physician or surgeon licensed under chapter 18.57 RCW, or a podiatric physician or surgeon licensed under chapter 18.22 RCW.

(38) "Prescription" means an order for drugs or devices issued by a practitioner authorized by law or rule in the state of Washington for a legitimate medical purpose.

(39) "Procedure" means a particular course of action to relieve pain, diagnose, cure, improve, or treat a patient's condition or that directs care for a patient.

(40) "Protocols" and "standing order" mean written or electronically recorded descriptions of actions and interventions for implementation by designated ambulatory surgical facility staff under defined circumstances recorded in policy and procedure.

(41) "Recovery unit" means a physical area for the segregation, concentration, and close or continuous nursing observation of patients for less than twenty-four hours immediately following anesthesia, surgery, or other diagnostic or treatment procedures.

(42) "Registered nurse" means an individual licensed under chapter 18.79 RCW.

(43) "Restraint" means any method used to prevent or limit free body movement including, but not limited to, involuntary confinement, a physical or mechanical device, or a drug given not required to treat a patient's symptoms.

(44) "Room" means a space set apart by floor-to-ceiling partitions on all sides with proper access to a corridor and with all openings provided with doors or windows.

(45) "Sedation" means the administration of drugs to obtund, dull, reduce the intensity of pain or awareness, allay patient anxiety and control pain during a diagnostic or therapeutic procedure where the administration of those drugs by any route carries the risk of loss of protective reflexes to include any of the following:

(a) "Minimal sedation or anxiolysis" is a state during which

patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected;

(b) "Moderate or conscious sedation" is a depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained; and

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

(46) "Sexual assault" means one or more of the following:

(a) Rape or rape of a child;

(b) Assault with intent to commit rape or rape of a child;

(c) Incest or indecent liberties;

(d) Child molestation;

(e) Sexual misconduct with a minor;

(f) Custodial sexual misconduct;

(g) Crimes with a sexual motivation; or

(h) An attempt to commit any of the offenses in (a) through (h) of this subsection.

(47) "Severe pain" means a level of pain reported by a patient of 8 or higher based on a 10-point scale with 1 being the least and 10 being the most pain.

(48) "Staff" means paid employees, leased or contracted persons, students, and volunteers.

(49) "Surgical services" means invasive medical procedures that:

(a) Utilize a knife, laser, cautery, cytogenics, or chemicals; and

(b) Remove, 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.

(50) "Surrogate decision-maker" means an individual appointed to act on behalf of another when an individual is without capacity or has given permission.

(51) "Transfer agreement" means a written agreement providing an effective process for the transfer of a patient requiring emergency services to a hospital providing emergency services and for continuity of care for that patient.

(52) "Treatment" means the care and management of a patient to combat, improve, or prevent a disease, disorder, or injury, and may be:

(a) Pharmacologic, surgical, or supportive;

(b) Specific for a disorder; or

(c) Symptomatic to relieve symptoms without effecting a cure.

(53) "Vulnerable adult" means:

(a) As defined in chapter 74.34 RCW, a person sixty years of age or older who lacks the functional, physical, or mental ability to care for him or herself;

(b) An adult with a developmental disability per RCW 71A.10.020;

(c) An adult with a legal guardian per chapter 11.88 RCW;

(d) An adult living in a long-term care facility (an adult family home, boarding home or nursing home);

(e) An adult living in their own or a family's home receiving services from an agency or contracted individual provider; or

(f) An adult self-directing their care per RCW 74.39.050;

(g) For the purposes of requesting background checks pursuant to RCW 43.43.832, it shall also include adults of any age who lack the functional, mental, or physical ability to care for themselves.

(54) "Well-being" means free from actual or potential harm, abuse, neglect, unintended injury, death, serious disability or illness.

## PART I OPERATIONAL RULES

### NEW SECTION

**WAC 246-330-020 Department responsibilities--Licensing, change of ownership--Adjudicative proceeding.** This section outlines the actions and roles of the department for licensing an ambulatory surgical facility.

(1) Before issuing an initial license to facilities that exist prior to July 1, 2009, the department will verify compliance with chapter 70.230 RCW and this chapter by:

(a) Receipt and approval of the initial license application;

(b) Receipt of the correct licensing fee;

(c) Receipt of a completed and accepted inspection conducted by:

(i) The Centers for Medicare and Medicaid Services;

(ii) The Joint Commission;

(iii) The Accreditation Association for Ambulatory Health Care;

(iv) The American Association for Accreditation of Ambulatory Surgery Facilities; or

(d) For facilities that have not been inspected by medicare or one of the accrediting organizations listed in (c) of this subsection, the following:

(i) Receipt of a certificate of need, when needed, as provided in chapter 70.38 RCW;

(ii) Receipt of a certificate of occupancy by the local jurisdiction;

(iii) Receipt of the ambulatory surgical facility's safety and emergency training program; and

(iv) Successfully completing an on-site licensing inspection conducted by the department.

(2) Before issuing an initial license after July 1, 2009, the department will verify compliance with chapter 70.230 RCW and this chapter including, but not limited to:

(a) Approval of construction documents in accordance with this chapter;

(b) Receipt of a certificate of need, when needed, as provided in chapter 70.38 RCW;

(c) Receipt and approval of the initial license application;

(d) Receipt of the correct license fee;

(e) Receipt of the ambulatory surgical facility's safety and emergency training program; and

(f) Receipt of a completed and accepted inspection conducted by:

(i) The Centers for Medicare and Medicaid Services;

(ii) The Joint Commission;

(iii) The Accreditation Association for Ambulatory Health Care;

(iv) The American Association for Accreditation of Ambulatory Surgery Facilities; or

(g) Successfully completing an on-site licensing inspection conducted by the department.

(3) Before reissuing a renewal license, the department will:

(a) Approve the amended ambulatory surgical facility application form; and

(b) Confirm receipt of the correct fee.

(4) Before issuing a change of ownership license, the department will:

(a) Approve the change of ownership application;

(b) Confirm receipt of the change of ownership fee; and

(c) Confirm the change of ownership will not alter the certificate of need status or require a certificate of need review.

**Note:** A change of ownership application does not require a construction review or on-site inspection. A change of ownership may or may not require a certificate of need review and approval per chapter 70.38 RCW.

(5) The department may issue a provisional license to allow the operation of an ambulatory surgical facility, if the department determines that the applicant or licensed ambulatory surgical facility failed to comply with chapter 70.230 RCW or this chapter.

(6) The department may deny, suspend, modify, or revoke a license when it finds an applicant or ambulatory surgical facility has failed or refused to comply with chapter 70.230 RCW or this chapter. The department's notice of a license denial, suspension, modification, or revocation will be consistent with RCW 43.70.115. The proceeding is governed by the Administrative Procedure Act chapter 34.05 RCW, this chapter, and chapter 246-10 WAC. An

applicant or license holder has the right to an adjudicative proceeding to contest the decision as described in WAC 246-330-100 (4)(c) of this chapter.

NEW SECTION

**WAC 246-330-025 Department responsibility--On-site survey and complaint investigation.** This section outlines the department's on-site survey and complaint investigation activities and roles.

(1) Surveys. The department will:

(a) Conduct on-site surveys of each ambulatory surgical facility every eighteen months or more often using the health and safety standards in this chapter and chapter 70.230 RCW;

(b) Accept, in accordance with RCW 70.230.100(2), as a substitute for the department's eighteen months on-site survey, on-site surveys conducted by the Joint Commission, Accreditation Association for Ambulatory Health Care, American Association for Accreditation of Ambulatory Surgery Facilities or the Centers for Medicare and Medicaid Services as substituting for the eighteen month state survey requirement once every three years;

(c) Notify the ambulatory surgical facility in writing the survey findings following each on-site survey;

(d) Require each ambulatory surgical facility to submit a corrective action plan addressing each deficient practice identified in the survey findings; and

(e) Notify the ambulatory surgical facility when their submitted plan of correction adequately addresses the survey findings.

(2) Complaint investigations. The department will:

(a) Conduct an investigation of every complaint against an ambulatory surgical facility that concerns patient well-being;

(b) Notify the ambulatory surgical facility in writing of complaint investigation findings following each complaint investigation;

(c) Require each ambulatory surgical facility to submit a corrective action plan addressing each deficient practice identified in the complaint investigation findings; and

(d) Notify the ambulatory surgical facility when the facility submitted plan of correction adequately addresses the complaint investigation findings.

(3) The department may:

(a) For the purpose of meeting the every eighteen month survey requirement in RCW 70.230.100(2), allow an ambulatory surgical facility to conduct a self-survey once every three years if the previous three department inspections did not reveal any significant deficient practice;

(b) Direct an ambulatory surgical facility on how to implement a corrective action plan based on the findings from an on-site

survey or complaint investigation; or

(c) Contact an ambulatory surgical facility to discuss the findings of the Joint Commission, Accreditation Association for Ambulatory Health Care or American Association for Accreditation of Ambulatory Surgery Facilities on-site accreditation survey.

#### NEW SECTION

**WAC 246-330-030 Operating without a license--Adjudicative proceeding.** This section outlines the department's responsibility and authority over ambulatory surgical facilities that operate after July 1, 2009, without a department issued license.

(1) The department will investigate complaints of an ambulatory surgical facility operating without a license.

(2) Upon confirming that an ambulatory surgical facility is operating without a license, the secretary of the department may:

(a) Issue a notice of intention to issue a cease and desist order; or

(b) Issue a temporary cease and desist order after making a written finding of fact that the public interest will be irreparably harmed by delay in issuing the order. The temporary cease and desist order will remain in effect until further order by the secretary of the department.

(3) The person receiving a temporary cease and desist order is entitled to a prompt hearing. Actions taken under this section are governed by the Administrative Procedure Act chapter 34.05 RCW, this chapter, and chapter 246-10 WAC.

#### NEW SECTION

**WAC 246-330-035 Exemptions, interpretations, alternative methods.** (1) The department may exempt an ambulatory surgical facility from complying with portions of this chapter when:

(a) The exemption will not change the purpose and intent of chapter 70.230 RCW or this chapter;

(b) Patient safety, health or well-being is not threatened;

(c) Fire and life safety regulations, infection control standards or other codes or regulations would not be reduced; and

(d) Structural integrity of the building is not compromised.

(2) The department will send a written interpretation of a rule within thirty calendar days after the department has received complete information relevant to the request for interpretation.

(3) The department may approve an ambulatory surgical facility to use alternative materials, designs, and methods if the

documentation and supporting information:

- (a) Meets the intent and purpose of these rules; and
- (b) Is equivalent to the methods prescribed in this chapter.
- (4) The department will keep copies of each exemption, alternative, or interpretation issued.

NEW SECTION

**WAC 246-330-100 Application for license--Annual update of ambulatory surgical facilities information--License renewal--Right to contest a license decision.** This section identifies the actions and responsibilities of an applicant or ambulatory surgical facility for a license.

(1) Initial license. An applicant must submit an application packet and fee to the department at least sixty days before the intended opening date of the new ambulatory surgical facility.

(2) Annual update. Before December 31st of each calendar year, a licensed ambulatory surgical facility must submit to the department an annual update documentation form.

(3) License renewal. No later than thirty days before the license expiration date, a licensed ambulatory surgical facility must submit to the department a renewal application form and fee.

(4) An applicant or ambulatory surgical facility has the right to contest a department decision to deny, modify, suspend or revoke a license by:

(a) Sending a written request for an adjudicative proceeding within twenty-eight days of receipt of the department's licensing decision showing proof of receipt with the office of the Adjudicative Service Unit, Department of Health, P.O. Box 47879, Olympia, WA 98504-7879; and

(b) Include as part of the written request:

(i) A specific statement of the issues and law involved;

(ii) The grounds for contesting the department decision; and

(iii) A copy of the contested department decision.

(c) The adjudicative proceeding is governed by the Administrative Procedure Act chapter 34.05 RCW, this chapter, and chapter 246-10 WAC.

NEW SECTION

**WAC 246-330-105 Ambulatory surgical facility responsibilities.** This section identifies the actions and responsibilities of a licensed ambulatory surgical facility.

(1) An ambulatory surgical facility must comply with chapter

70.230 RCW and this chapter;

(2) An ambulatory surgical facility certified by the Centers for Medicare and Medicaid Services or accredited by the Joint Commission, Accreditation Association for Ambulatory Health Care or American Association for Accreditation of Ambulatory Surgery Facilities must:

(a) Notify the department of a certification or an accreditation survey within two business days following completion of the survey; and

(b) Notify the department in writing of the accreditation decision and any changes in accreditation status within thirty calendar days of receiving the accreditation report.

#### NEW SECTION

**WAC 246-330-110 Requests for exemptions, interpretations, alternative methods.** This section outlines a process to request an exemption, interpretation, or approval to use an alternative method and the department's response. This section is not intended to prevent use of systems, materials, alternate design, or methods of construction as alternatives to those prescribed by this chapter.

(1) A licensed ambulatory surgical facility requesting exemption from this chapter must:

(a) Send a written request to the department;

(b) Include in the request:

(i) The specific section of this chapter to be exempted;

(ii) Explain the reasons for requesting the exemption;

(iii) How the exemption will not change the purpose and intent of chapter 70.230 RCW or this chapter;

(iv) Why the exemption does not threaten patient safety or health;

(v) How the exemption will not reduce or alter fire and life safety or infection control requirements; and

(vi) Why the exemption does not compromise structural integrity of the building.

(2) A licensed ambulatory surgical facility or person requesting an interpretation of a rule in this chapter must:

(a) Send a written request to the department;

(b) Include in the request:

(i) The specific section of this chapter to be interpreted;

(ii) Explain the reason or circumstances for requesting the interpretation; and

(iii) Where or how the rule is being applied.

(c) Provide additional information when required by the department.

(3) A licensed ambulatory surgical facility requesting use of alternative materials, design, and methods must:

(a) Send a written request to the department; and

(b) Explain and support with technical documentation the reasons the department should consider the request.

(4) The licensed ambulatory surgical facility must keep and make available copies of each exemption, alternative, or interpretation received from the department.

(5) The department will, in response to a written request for an exemption or approval to use alternative materials, designs, and methods, send a written determination within thirty days after the department has received complete information relevant to the request.

#### NEW SECTION

**WAC 246-330-115 Governance.** This section outlines the organizational guidance and oversight responsibilities of ambulatory surgical facility resources and staff to support safe patient care.

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:

(1) Selecting and periodically evaluating a chief executive officer or administrator;

(2) Appointing and periodically reviewing a medical staff;

(3) Approving the medical staff bylaws;

(4) Reporting practitioners according to RCW 70.230.120;

(5) Informing patients of any unanticipated outcomes according to RCW 70.230.150;

(6) Establishing and approving a coordinated quality performance improvement plan according to RCW 70.230.080;

(7) Establishing and approving a facility safety and emergency training program according to RCW 70.230.060;

(8) Reporting adverse events and conducting root cause analyses according to RCW 70.56.020;

(9) Providing a patient and family grievance process including a time frame for resolving each grievance according to RCW 70.230.080 (1)(d);

(10) Defining who can give and receive patient care orders that are consistent with professional licensing laws; and

(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.

NEW SECTION

**WAC 246-330-120 Leadership.** This section describes leaderships' role in assuring care is provided consistently throughout the facility according to patient needs.

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;
- (4) Establish and implement a facility-wide procedure for double-checking certain drugs, biologicals, and agents;
- (5) Ensure immediate staff access to and appropriate dosages for emergency drugs;
- (6) Require individuals conducting business in the ambulatory surgical facility comply with facility policies and procedures;
- (7) Post the complaint hotline notice according to RCW 70.230.160; and
- (8) Adopt and implement policies and procedures to report suspected abuse within forty-eight hours to local police or appropriate law enforcement agency according to RCW 26.44.030.

NEW SECTION

**WAC 246-330-125 Patient rights and organizational ethics.** The purpose of this section is to improve patient care and outcomes by respecting every patient and maintaining ethical relationships with the public.

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 retribution or denial of care;
  - (f) Timely complaint resolution;
  - (g) Be involved in all aspects of their care including:
    - (i) Refusing care and treatment; and
    - (ii) Resolving problems with care decisions.
  - (h) Be informed of unanticipated outcomes according to RCW 70.230.150;

- (i) Be informed and agree to their care; and
- (j) Family input in care decisions.
- (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.

NEW SECTION

**WAC 246-330-130 Adverse events.** (1)(a) For the purpose of this section, "serious disability" means a physical or mental impairment that substantially limits the major life activities of a patient.

(b) Ambulatory surgical facilities must:

(i) Notify the department according to RCW 70.56.020 whenever an adverse event is confirmed in the facility; and

(ii) Send the department a report regarding the event according to RCW 70.56.020.

(2) The department will assure all notifications and reports submitted to the department are maintained confidentially according to RCW 70.56.050.

NEW SECTION

**WAC 246-330-140 Management of human resources.** This section ensures that ambulatory surgical facilities provide competent staff consistent with scope of services.

Ambulatory surgical facilities must:

(1) Create and periodically review job descriptions for all staff;

(2) Supervise staff performance to assure competency;

(3) Verify and document licensure, certification, or registration of staff;

(4) Complete tuberculosis screening for new and current employees consistent with the *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Healthcare Facilities*, 2005. *Morbidity Mortality Weekly Report (MMWR) Volume 54*, December 30, 2005;

(5) Provide infection control information to staff upon hire and annually which includes:

(a) Education on general infection control according to chapter 296-823 WAC blood borne pathogens exposure control; and

(b) General and specific infection control measures related to patient care.

(6) Establish and implement an education plan that verifies staff training on prevention, transmission, and treatment of human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) consistent with RCW 70.24.310.

#### NEW SECTION

**WAC 246-330-145 Medical staff.** This section requires development of a medical staff structure, consistent with clinical competence, to ensure a safe patient care environment.

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.

#### NEW SECTION

**WAC 246-330-150 Management of information.** The purpose of this section is to improve patient outcomes and ambulatory surgical facility performance through obtaining, managing, and use of information.

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;

(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 chapter 5.46 RCW; and

(h) Include verbal orders that are accepted and transcribed by qualified personnel.

(5) Establish a systematic method for identifying each medical record, identification of service area, filing, and retrieval of all patient's records; and

(6) Adopt and implement policies and procedures that address:

(a) Who has access to and release of confidential medical records according to chapter 70.02 RCW;

(b) Retention and preservation of medical records;

(c) Transmittal of medical data to ensure continuity of care;

and

(d) Exclusion of clinical evidence from the medical record.

#### NEW SECTION

**WAC 246-330-155 Coordinated quality improvement program.** The purpose of this section is to ensure the establishment and on-going maintenance of a coordinated quality improvement program. The intent is to improve the quality of health care services provided to patients and to identify and prevent medical malpractice.

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 events according to chapter 70.56 RCW;

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

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

(i) Confirmed transfusion reactions;

(j) Patient grievances, needs, expectations, and satisfaction;  
and

(k) Quality control and risk management activities.

#### NEW SECTION

**WAC 246-330-176 Infection control program.** The purpose of this section is to identify and reduce the risk of acquiring and transmitting infections and communicable diseases between patients, staff, medical staff, and visitors.

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 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 WAC; and

(c) Collecting, measuring and assessing data on infection rates, pathogen distributions and antimicrobial susceptibility profiles.

NEW SECTION

**WAC 246-330-199 Fees--License, survey, change of ownership, refund process.** This section establishes the license, survey, and change of ownership fees, a late penalty fee and request for refund of an initial fee. The license and survey fee are good for the entire three-year license period. The change of ownership fee is good for that transaction and does not change the original license ending date.

(1) Initial license. Applicants for an initial license must send the department:

(a) An initial license fee of two hundred dollars; and

(b) An initial survey fee based on the number of known or expected annual visits as follows:

(i) One thousand two hundred dollars for under one thousand annual patient visits;

(ii) One thousand six hundred dollars for one thousand one to five thousand annual patient visits; or

(iii) Two thousand two hundred dollars for more than five thousand annual patient visits.

(2) Renewal license. Licensees must send the department a license renewal and survey fee at least thirty days before the license expiration date as follows:

(a) One thousand three hundred dollars for under one thousand annual patient visits;

(b) One thousand seven hundred dollars for one thousand one to five thousand annual patient visits; or

(c) Two thousand three hundred dollars for more than five thousand annual patient visits.

(3) Late fee. A licensee must send the department a late fee in the amount of twenty-five dollars per day, not to exceed five hundred dollars, whenever the renewal fee is not paid by thirty days before the license expiration (date as indicated by the postmark).

(4) Change of ownership. The person purchasing or taking over ownership of a licensed ambulatory surgical facility must:

(a) Send the department a change of ownership fee in the amount of two hundred fifty dollars. The fee is paid thirty days before the change of ownership becomes final; and

(b) Receive from the department a new license valid for the remainder of the current license period.

(5) An applicant may request a refund for initial licensure as follows:

(a) Two-thirds of the initial fee paid after the department has received an application and not conducted an on-site survey or provided technical assistance; or

(b) One-third of the initial fee paid after the department has received an application and conducted either an on-site survey or provided technical assistance but not issued a license.

NEW SECTION

**WAC 246-330-200 Pharmaceutical services.** This section assures patient pharmaceutical needs are met in a planned and organized manner. This section is consistent with the requirements for a health care entity license under RCW 18.64.450 and chapter 246-904 WAC.

An ambulatory surgical facility must:

(1) Designate a pharmacist in charge who is licensed in Washington state. The pharmacist in charge can be either employed by the facility or be a pharmacy consultant. The pharmacist in charge is responsible for:

(a) Assure drugs are stored, compounded, delivered or dispensed according to all applicable state and federal rules and regulations;

(b) Creating and implementing policy and procedures related to:

(i) Purchasing, ordering, storing, compounding, delivering, dispensing and administering of controlled substances or legend drugs;

(ii) Maintaining accurate inventory records and patient medical records related to the administration of controlled substances and legend drugs;

(iii) Maintaining any other records required by state and federal regulations;

(iv) Security of legend drugs and controlled substances; and

(v) Controlling access to controlled substances and legend drugs.

(c) Completing all forms for the purchase and order of legend drugs and controlled substances; and

(d) Verifying receipt of all legend drugs and controlled substances purchased and ordered by the ambulatory surgical facility.

(2) Only administer, dispense or deliver legend drugs and controlled substances to patients receiving care in the facility;

(3) 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; and

(4) Establish and use a process for selecting medications based on evaluating their relative therapeutic merits, safety, and cost.

NEW SECTION

**WAC 246-330-205 Patient care services.** This section guides the development of a plan for patient care. The ambulatory surgical facility accomplishes this by supervising staff, establishing, monitoring, and enforcing policies and procedures

that define and outline the use of materials, resources, and promote the delivery of care.

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 or medical-legal 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;

(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.

NEW SECTION

**WAC 246-330-210 Surgical services.** The purpose of this section is to guide the development and management of surgical services.

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.

NEW SECTION

**WAC 246-330-215 Anesthesia services.** The purpose of this section is to guide the management and care of patients receiving anesthesia and sedation.

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.

NEW SECTION

**WAC 246-330-220 Recovery care.** The purpose of this section is to guide the management of patients recovering from anesthesia and sedation.

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.

NEW SECTION

**WAC 246-330-225 Emergency services.** The purpose of this section is to guide the management and care of patients receiving emergency services.

An ambulatory surgical facility must:

(1) Develop, implement and maintain a facility safety and emergency training program that includes:

(a) On-site equipment, medication and trained personnel to manage any medical emergency that may arise from the services provided or sought;

(b) A written and signed transfer agreement with one or more local hospitals that has been approved by the ambulatory surgical facility's medical staff;

(c) Policies and a procedural plan for handling medical emergencies; and

(d) Define the qualifications and oversight of staff delivering emergency care services.

(2) Assure at least one registered nurse skilled and trained in emergency care services on duty and in the ambulatory surgical facility at all times a patient is present, who is:

(a) Immediately available to provide care; and

(b) Trained and current in advanced cardiac life support.

(3) Assure communication with agencies and health care providers as indicated by patient condition; and

(4) Assure emergency equipment, supplies and services necessary to meet the needs of patients are immediately available.

**PART II**  
**ENVIRONMENT OF CARE**

NEW SECTION

**WAC 246-330-230 Management of environment for care.** The purpose of this section is to manage environmental hazards and risks, prevent accidents and injuries, and maintain safe conditions for patients, visitors, and staff.

(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 procedures with staff; and

(iii) When the facility has security staff, train the security staff to a level of skill and competency for their assigned responsibility.

(c) Hazardous materials and waste:

(i) Establish and implement a program to safely control hazardous materials and waste according to federal, state, and local regulations;

(ii) Provide space and equipment for safe handling and storage of hazardous materials and waste;

(iii) Process to investigate all hazardous material or waste spills, exposures, and other incidents, and report as required to appropriate authority; and

(iv) Method to educate staff on hazardous materials and waste policies and procedures.

(d) Emergency preparedness:

(i) Establish, implement and periodically review a disaster plan for internal and external disasters that is specific to the facility and community;

(ii) Process to educate and train staff on the disaster plan;

- (iii) Process to periodically conduct drills to test the plan.
- (e) Fire safety:
  - (i) Policies and procedures on fire prevention and emergencies including an evacuation plan; and
  - (ii) Process to orient, educate, and conduct drills with staff fire prevention, emergency and evacuation policies and procedures.
- (f) Medical equipment:
  - (i) Method to operate and maintain medical equipment properly, safely and according to manufacturer's recommendations;
  - (ii) Perform and document preventive maintenance; and
  - (iii) Process to investigate, report, and evaluate procedures in response to equipment failures.
- (g) Utility systems:
  - (i) Policies and procedures to operate and maintain a safe and comfortable environment; and
  - (ii) Process to investigate and evaluate utility systems problems, failures, or user errors and report incidents.
- (h) Physical environment:
  - (i) Process to keep the physical environment clean including cleaning the operating room between surgical procedures;
  - (ii) Operate and maintain a water supply providing hot and cold water under pressure which conforms to chapter 246-290 WAC, (department of health, division of drinking water);
  - (iii) Assure hot water for handwashing does not exceed 120°F;
  - (iv) Assure cross connection controls meet the requirements of the state plumbing code; and
  - (v) Operate and maintain ventilation to prevent objectionable odors and excessive condensation.

### **PART III NEW CONSTRUCTION**

Note: The new construction regulations apply only to facilities submitted to the construction review program after July 1, 2009. Facilities participating in the medicare/medicaid program prior to July 1, 2009, must be able to show compliance with the federal requirements for existing facilities. Facilities participating in medicare/medicaid submitted after July 1, 2009, must comply with the federal requirements for new facilities.

#### NEW SECTION

**WAC 246-330-500 Applicability of WAC 246-330-500 through 246-330-510.** The purpose of the new construction regulations is to provide minimum standards for the construction, maintenance and operation of ambulatory surgical facilities and the establishment of a safe and adequate care and treatment environment. These rules

are consistent with other accrediting organizations and federal agency rules and regulations without redundancy and contradictory requirements. Compliance with these new construction regulations does not relieve an ambulatory surgical facility of the need to comply with applicable state and local building and zoning codes.

(1) These regulations apply to ambulatory surgical facilities as defined in RCW 70.230.010:

(a) New buildings to be licensed as an ambulatory surgical facility;

(b) Conversion of an existing building or portion thereof for use as an ambulatory surgical facility;

(c) Additions to an existing ambulatory surgical facility;

(d) Alterations to an existing ambulatory surgical facility.

(2) This requirement does not apply to:

(a) Any ambulatory surgical facility existing and operating prior to July 1, 2009, that is certified by the Centers for Medicare and Medicaid Services or accredited by the Joint Commission, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities that is not doing any of the things described in subsection (1)(b) through (d) of this section after July 1, 2009;

(b) Any minor alteration to an ambulatory surgical facility;  
or

(c) Any area of an ambulatory surgical facility unaffected by an alteration of that ambulatory surgical facility.

(3) The requirements of this chapter in effect at the time the application, fee, and construction documents are submitted to the department for review will apply for the duration of the construction project.

#### NEW SECTION

**WAC 246-330-505 Department responsibilities--Construction review, approval of plans.** (1) This section identifies the actions and responsibilities of the department for reviewing and approving new construction of ambulatory surgical facilities.

(2) Before issuing an approval of plans, the department will verify compliance with chapter 70.230 RCW and this chapter which includes, but is not limited to:

(a) Review of all construction documents for compliance with these standards and other applicable federal and state regulations;

(b) Assure the issuance of a certificate of need, when needed, as provided in chapter 70.38 RCW;

(c) Receipt of the application for construction review services and a full plan review fee based on chapter 246-314 WAC;

(d) Approval by the local jurisdiction has been obtained;

(e) Approval of the initial license application;

(f) Verify compliance with the applicable chapters of the 2006

*Guidelines for the Design and Construction of Healthcare Facilities.*

NEW SECTION

**WAC 246-330-510 Design, construction review, and approval of plans.** (1) Drawings and specifications for new construction, must be prepared by, or under the direction of, an architect registered under chapter 18.08 RCW. The services of a consulting engineer registered under chapter 18.43 RCW must be used for the various branches of the work where appropriate. The services of a registered professional engineer may be used in lieu of the services of an architect if work involves engineering only.

(2) An ambulatory surgical facility must submit construction documents for proposed new construction to the department for review and approval prior to new construction as required in RCW 70.230.050 (1)(b).

(3) The facility must submit:

(a) A written functional program containing, at a minimum:

(i) Information concerning surgical services to be provided and operational methods to be used; and

(ii) Description of work, patient, soiled waste and clean processing flows.

(b) Two sets of construction drawings and specifications to include coordinated civil, architectural, structural, mechanical, fire sprinkler, fire alarm and electrical work. Each room, area, and item of fixed equipment and major movable equipment must be identified on all drawings to demonstrate that the required facilities for each function are provided.

(c) Floor plan of the building showing the alterations and additions including location of any service or support areas.

(d) For additions and/or alterations:

(i) A plan to show how the ambulatory surgical facility will ensure the health and safety of occupants during construction and installation of finishes. This includes taking appropriate infection control measures, keeping the surrounding area free of dust and fumes, and assuring rooms or areas are well-ventilated, unoccupied, and unavailable for use until free of volatile fumes and odors.

(ii) A plan to show how the ambulatory surgical facility will provide safety during construction consistent with the fire code showing required paths of egress, exit discharge and interim life safety measures serving the alterations or additions.

(4) An ambulatory surgical facility must:

(a) Respond to requests for additional or corrected documents;

(b) Submit to the department for review and approval any addenda or modifications to the original department approved construction documents;

(c) Assure construction is completed in compliance with the final "department approved" documents; and

(d) Notify the department when construction is completed and provide a copy of the local jurisdiction's approval for occupancy if requested by the department.

(5) An ambulatory surgical facility will not use any new construction, alterations or additions until:

(a) The construction documents are approved by the department;  
and

(b) The local jurisdictions have issued an approval to occupy;  
and

(c) Notification to the department that the construction has been completed, the proposed occupancy date, final declared construction cost and that any additional fees have been paid.

Small Business Economic Impact Statement  
For the  
Ambulatory Surgical Facility Rule  
Chapter 246-330 WAC  
February 2009

**Describe scope of proposed rule package**

The 2007 legislature passed ESHB 1414, which required the Secretary of Health to create a license and survey program for ambulatory surgical facilities in Washington State. Ambulatory surgical facilities are defined as entities that provide specialty or multispecialty outpatient surgical services in which patients are admitted to and discharged by the facility within 24 hours and do not require inpatient hospitalization. These facilities must be licensed starting July 1, 2009. The Secretary of Health is authorized to adopt rules that are intended to establish minimum health and safety standards to protect the health and welfare of patients.

Of the 220 Washington State Medicare certified ambulatory surgery centers, the department estimates that 100 of these centers will also be required to obtain a license as an ASF. ASFs that are currently Medicare certified or accredited will need to submit an application and fee but will not be required to complete an on-site survey prior to receiving an initial license. Medicare certified and accredited ASFs will have at least one on-site survey by the department in order to receive a renewal license. It is anticipated that the number of ASFs that are neither certified or accredited, and thus required to submit an initial application along with completing an on-site survey, is a very low number.

ASFs provide a range of surgical services, typically in the following areas: Ear, Nose and Throat (ENT), Gastroenterology, Gynecology, Orthopedics, Ophthalmology, Pain Management, Plastic Surgery, Podiatry and Urology.

These rules place additional requirements beyond those for Medicare certification. Examples of these differences include requiring ASFs to review and revise policies to help direct the activities of their staff, potentially hire new staff to function as circulating nurses in operating rooms and to report adverse events. Some ASFs may need to purchase additional emergency equipment to assure that equipment is available as required.

A license is not required for an ambulatory surgical facility that is maintained and operated by a hospital or a dental office, or for outpatient surgical services that do not require general anesthesia and are routinely and customarily performed in the office of a practitioner in an individual or group practice.

**Minor cost threshold determination summary**

The department calculated the minor cost thresholds for businesses using both methods prescribed in RCW. The values are shown in the table below.

Freestanding Ambulatory Surgical and Emergency Center  
NAICS Code (621493)

Data year	Minor Cost Threshold Type	Minor Cost Threshold Dollar Amount
2002	.3% of Average Receipts	\$6,976
2006	1% of Average Payroll	\$9,489

**\*Taken from Information from North American Industry Classification System (NAICS)- U.S. Census Bureau. For more information, see Appendix A & B**

**Cost estimate of the proposed rule on impacted businesses**

***Total Rule Costs:***

The rules are designed to protect and improve the health and safety of people who receive care at ambulatory surgical facilities. This analysis shows ASFs could incur \$9,200 to \$20,700 for initial one time costs. It also shows ASFs incur ongoing annual costs from \$58,117 to \$99,919. These costs include record keeping, reporting, professional services (consultants), equipment, and administration. The department believes that although there are significant costs for ASFs to comply with the requirements in this rule, the overall benefit of providing safe facilities, reducing patient health complications, reducing disability that could potentially save a person’s life outweighs the total probable costs.

**Total Probable Cost of Rule**

WAC Section	Initial Low	Costs High	Annual Low	Cost High	Notes
246-330-115 Governance	\$4,000	\$8,000	\$0	\$0	No additional state requirements, existing cost of being certified or accredited
246-330-120 Leadership			\$250	\$750	Annual review of specific state requirements
246-330-125 Patient Rights & Org. Ethics			\$500	\$1,500	State requires responding to unanticipated outcomes.
246-330-140 Management of Human Resources			\$100	\$200	State requires annually providing infection control information and training to staff
246-330-145 Medical Staff			\$100	\$200	State requires reporting practitioners
246-330-150 Management of Information			\$200	\$750	Reviewing state imposed system requirements and revising policies as needed
246-330-176 Infection Control			\$10,000	\$20,000	State requirements more specific, probably requiring a dedicated person part time
246-330-205 Patient Care Services			\$250	\$500	Annual review and possible revision of policies and procedures
246-330-210 Surgical Services			\$250	\$500	Annual review and possible revision of policies and procedures
246-330-215 Anesthesia Services			\$250	\$500	Annual review and possible revision of policies and procedures
246-330-220 Recovery Care			\$40,000	\$60,000	Immediate availability of a RN or physician, RN current in advanced cardiac life support
246-330-100 Application	\$50	\$50	\$50	\$50	Complete and submit application.
246-330-105 ASF Responsibilities	\$50	\$50	\$50	\$50	Notify DOH of accreditation status. Costs incurred by less than 20% of ASFs.
246-330-110 Exemptions	\$0	\$0	\$0	\$0	The costs of seeking exemptions are a benefit not a mandated cost.
246-330-130 Adverse Events	\$0	\$0	\$1,000	\$4,000	Assumes one adverse event per year.
246-330-155 CQIP	\$2,000	\$6,000	\$1,000	\$3,000	Costs due to specific State requirements.
246-330-199 Fees	\$600	\$600	\$567	\$567	Annualized 3 year license cost for a medium sized ASF.
246-330-200 Pharmaceuticals	\$1,000	\$2,000	\$3,000	\$6,000	Assumes a contract Pharmacist in charge
246-330-225 Emergency Srvs	\$500	\$1,000	\$300	\$600	Assumes no emergency equipment costs.
246-330-230 Environment Management	\$1,000	\$3,000	\$250	\$750	Develop, review and update facility plan, policy and procedures.
246-330-500 Construction	\$0	\$0	\$0	\$0	Only applies for ASFs planning new construction. No annual cost est.
<b>Total:</b>	<b>\$9,200</b>	<b>\$20,700</b>	<b>\$58,117</b>	<b>\$99,917</b>	

**Determination if the proposed rule imposes more than minor costs on the average business.**

Estimated initial one-time costs	
Low:	\$9,200
High:	\$20,700
Estimated on-going annual costs	
Low:	\$58,117
High:	\$99,917
Minor cost threshold- 1% payroll	\$ 9,489 (82 businesses- 2006)
Minor cost threshold- .3% Receipts	\$ 6,976 (63 businesses- 2002)

Does the average cost per business exceed the minor cost threshold? (Yes)

**Disproportionate cost analysis (comparing costs for compliance for small versus large businesses)**

**Disproportionate Analysis Findings**

#	Cost Basis Per Employee	Largest 10% of Large Businesses	Small Businesses
1	# of employees per business	175	13
2	Initial one time cost of rule per business		
	Low	\$53	\$708
	High	\$118	\$1,592
3	Ongoing annual cost of rule per business		
	Low	\$332	\$4,471
	High	\$571	\$7,686

The table above shows that the probable costs of this rule will cost more per employee for small businesses, as compared to the cost per employee for the largest 10% of large businesses. Therefore, this rule will have a disproportionate impact on small businesses.

The following shows how the department attempted to mitigate this disparity.

- 1) The department worked to reduce, modify, or eliminate substantive regulatory requirements

The department worked closely with constituents and the public to minimize the burden of this rule. The department held numerous meeting beginning in 2007 to establish a reasonable fee schedule. During 2008 the department provided the community four separate review and comment periods. The department accomplished this by providing draft rule documents electronically and getting comments and suggested changes back

electronically. The department compiled the comments, responded to each one and made suggested changes. Since the rules are not intended to impose an unreasonable burden upon an applicant or licensee, reduced or eliminated language. The following example demonstrates the efforts to reduce the impact on the regulated facilities.

**Example #1:** Circulating Nurse. The department drafted rules requiring a nurse circulator. Many attempts were made to modify the type of staff who could qualify to be a nurse circulator to provide flexibility to ASFs. This approach ended up not being acceptable under professional licensing requirements. The department ended up looking at where a circulating nurse was needed and concluded that, this oversight was related to the type of anesthesia or level of sedation. As a result the department proposed requiring a nurse circulator only when using general anesthesia and deep sedation.

**Example #2:** Adverse Events. Originally the department proposed to list all of the reportable adverse events in rule. The proposed rules were later altered to exclude certain events that would likely not occur in an ASF. It was determined that the least burdensome and costly approach would be to require what is identified in the law by simply referencing the RCW in the proposed rule.

**Example # 3:** Medical staff. The department originally proposed rule language that closely mirrored the hospital rules. Based on stakeholder input it was determined that this was too burdensome. The proposed rules reflect stakeholder input and are less burdensome

**Example # 4:** Pharmacy section. Originally the rules were proposed requiring similar standards to the hospital pharmacy rule. Stakeholders felt this was overly burdensome. The department revised the section to be less burdensome and more consistent with the requirements that ASFs already follow under Medicare.

2) The department worked to simplify, reduce, or eliminate record keeping and reporting requirements. The department made every effort to require only record keeping related to patient care, health and safety. The department created a simple application process, allow phone, electronic mail or fax communication for reporting an adverse event, and allow facilities to develop their own policies and procedures specific to their care delivery model and business plan.

3) The department is proposing issuing a time limited provisional license. The department would issue this type of license to allow a facility that needs time to correct a violation or complete the July 1, 2009 application without having to close their business.

### **Small businesses involvement and input in rule development.**

A large majority of the impacted businesses are small businesses. The department of Health conducted several work group meetings before starting the draft rule writing process as mandated in the law. The department's efforts began in September 2007 by

openly inviting all interested parties to meet with us to establish a reasonable fee schedule and what types of requirements should be included in the rule.

Out of the first meeting, the department established seven working groups that reviewed and made recommendations on the following: fees, construction, facility management and staffing, survey process, facility safety, coordinated quality improvement plan, and definitions. Members of the workgroups represented all sizes of ambulatory surgical facilities (small, medium, large) and types (Ear, Nose and Throat (ENT), Gastroenterology, Gynecology, Orthopedics, Ophthalmology, Pain Management, Plastic Surgery, Podiatry and Urology). These workgroups spent three months developing recommendations that they provided to the department in a December 2007 report. Those recommendations became the basis for the rules.

Once the department created a draft document, members of these work groups and other interested parties provided the department comments during four stakeholder review periods. Participants in the stakeholder review process were encouraged to comment and make suggested changes, deletions or additions to the rule document. The department reviewed, responded to and compiled the comments in a report after each stakeholder review period. The department incorporated several proposed changes into the next stakeholder rule review document that addressed concerns expressed by these small business representatives. The department followed these steps throughout the stakeholder comment period.

**Estimate of the number of jobs that will be created or lost as a result of compliance with the proposed rule.**

Information from the North American Industry Classification System (NAICS) estimates that on average, Freestanding Ambulatory Surgical and Emergency Centers generate \$2,325,492. Given the economic impact on these firms, the department's analysis concludes that there will not be any jobs created or lost as a result of the proposed rule. The department assumes that any additional costs incurred by individual ambulatory surgical facilities from these rules will be incorporated as a cost of business and passed on to patients receiving care.

Appendix A.

**Minor Cost Threshold (Payroll) For Freestanding Ambulatory Surgical and Emergency Centers (#621493)**

Ambulatory Surgery Facility Rule Chapter 246-330 WAC			
29-Jan-09			
SBEIS Disproportionate Analysis Template	# in NAICS	Average Employee Assumption	Employee Per Firm Size Estimate
Total number of establishment in Washington	82 <sup>1</sup>		
Total Employees	1267		
Average Employees per business	15		
Total Annual Payroll	\$ 77,807,000		
Average Payroll per Business	\$ 948,866		
Minor Cost Threshold-1% of Payroll	\$ 9,489		
Number of firms with 1-4	30	2.5	75
Number of firms with 5-9	11	7	77
Number of firms with 10-19	21	15	315
Number of firms with 20-49	17	35	595
Number of firms with 50-99	2	75	150
Number of firms with 100-249	1	175	175
Number of firms with 250-499	0	375	0
Number of firms with 500-999	0	750	0
Number of firms with 1000 or more	0	1000	0
Summed Employees Estimate for Industry			1387
Average Employees per Small Business			13
Average Employees per Large Business			108.3333
Average Employees per Largest 10% of Large Business			175
Information Taken from NAICS Website			
Data Year	2006		

**Information from North American Industry Classification System (NAICS)- U.S. Census Bureau.**

<sup>1</sup> Department of Health Staff estimates that there are approximately 100 ASF that have to comply with this rule. The 82 business figure was taken from the NAICS for the year 2006.

Appendix B.

**Minor Cost Threshold (Gross Receipts) For Freestanding Ambulatory Surgical and Emergency Centers (#621493)**

Establishments	Receipts (1000)	Employees
63	146,506	890
Receipts	146,506,000	
Receipts per business	2,325,492	
3/10% of receipts per business	\$ 6,976.48	

**Information from North American Industry Classification System (NAICS)- U.S. Census Bureau.**

**2002 data for 63 firms (the department assumes that current gross receipts in the calendar year 2009 would be substantially greater than the figures for 2002. In addition to an increase in the number of ASFs, there has been a subsequent growth in surgical procedures performed in ASFs)**