

PRELIMINARY DRAFT
Ambulatory Surgical Facility Rules

WAC 246-XXX-001 Purpose and applicability of chapter.

This chapter is adopted by the Washington state department of health 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.

WAC 246-XXX-010 Definitions.

For the purposes of this chapter and chapter 70.230 RCW, 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 verbal behavior, harassment, or other actions which may result in emotional or behavioral stress or injury.

(2) "Adverse health event" or "adverse event" means the list serious reportable events adopted by the national quality forum in 2002 (and updates in 2006), in its consensus report on serious reportable events in health care.

(3) "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.

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

(a) "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.

(5) "Ambulatory surgical facility" means any distinct entity that operates for the primary purpose of providing specialty or multi-specialty 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.

(6) "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.

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

(8) "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; and

(e) Medical photographs.

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

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

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

(a) Articles recognized in the official U.S. 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.

(12) "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 effect 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.

(13) "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.

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

(15) "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.

(16) "Governing authority/body" means the person or persons responsible for establishing the purposes and

policies of the ambulatory surgical facility.

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

(18) "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.

(19) "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.

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

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

(23) "Medical staff" means physicians and other practitioners appointed by the governing authority.

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

(25) "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

(26) "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 which may result in

emotional or behavioral problems, physical manifestations, and disorders.

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

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

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

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

(31) "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.

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

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

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

(35) "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.

(36) "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.

(37) "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.

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

(39) "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.

(40) "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.

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

(42) "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.

(43) "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.

(44) "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 aforementioned offenses.

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

(47) "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.

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

(49) "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.

(50) "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.

(51) "Vulnerable adult" means, as defined in chapter 74.34 RCW, a person 60 years of age or older who lacks the functional, physical, or mental ability to care for him or herself; an adult with a developmental disability per RCW 71A.10.020; an adult with a legal guardian per chapter 11.88 RCW; an adult living in a long-term care facility (an adult family home, boarding home or nursing home); an adult living in their own or a family's home receiving services from an agency or contracted individual provider; or an adult self-directing their care per 74.39.050 RCW. For the purposes of requesting background checks pursuant to 43.43.832 RCW, it shall also include adults of any age who lack the functional, mental, or physical ability to care for themselves.

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

WAC 246-XXX-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) Approval of the initial license application;
- (b) Receipt of the correct licensing fee; and either
- (c) Accepting proof of certification or accreditation in good standing from:
 - (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
- (d) Approval of construction documents in accordance with this Chapter. ; and
 - (i) Receipt of a certificate of need, when needed, as provided in chapter 70.38 RCW;
 - (ii) Approval by the local jurisdiction of all local codes and ordinances;
 - (iii) Approval of the initial license application;

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

(vi) Conducting an on-site licensing survey in accordance with WAC 246-XXX-025.

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

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

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

(c) Approval by the local jurisdiction of all local codes and ordinances;

(d) Approval of the initial license application;

(e) Receipt of the correct license fee;

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

(g) Conducting an on-site licensing survey in accordance with WAC 246-XXX-025.

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

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

(b) Assure receipt of the correct fee.

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

(a) Approve the change of ownership application, and

(b) Assure receipt of the change of ownership fee.

(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 chapters 246-08 and 246-10 WAC. If this chapter conflicts with chapter 246-08 or 246-10 WAC, this chapter governs.

WAC 246-XXX-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 on average at least every 18 months or more often using the health and safety standards in this chapter and chapter 70.230 RCW:

(b) Notify the ambulatory surgical facility at least four weeks prior to the scheduled date of the on-site survey;

(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.

(f) Accept 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 meeting the 18 month survey requirement in accordance with RCW 70.320.100(2).

(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) 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

(b) 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.

**WAC 246-XXX-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 chapters 246-08
and 246-10 WAC. If this chapter conflicts with chapter
246-08 or 246-10 WAC, this chapter governs

**WAC 246-XXX-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
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.

Move to proposed section 199

WAC 246-XXX-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 31 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 license decision 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, PO 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 chapters 246-08 and 246-10 WAC. If this chapter conflicts with chapter 246-08 or 246-10 WAC, this chapter governs.

WAC 246-XXX-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 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 an accreditation survey within 2 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.

WAC 246-XXX-110 Requests for Exemptions, Interpretations, Alternative Methods. This section outlines a process to request an exemption, interpretation, or approval to use an alternative method. 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; and

(iii) When appropriate, provide documentation to support the request.

(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.

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

The governing authority must:

(1) Establish and review governing authority policies including requirements for:

(a) Reporting practitioners according to RCW 70.230.120;

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

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

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

(e) Providing organizational management and planning;

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

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

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

(h) Providing communication and conflict resolution between the medical staff and the governing authority;

(2) Establish a process for selecting and periodically evaluating a chief executive officer or administrator.

(3) Appoint and approve a medical staff.

(4) Require written or electronic orders, authenticated by a legally authorized practitioner, for all drugs, intravenous solutions, blood, and medical treatments.

(5) Approve and periodically review bylaws, rules, and regulations adopted by the medical staff before they become effective.

WAC 246-XXX-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) Appoint or assign a nurse:
 - (a) direct the nursing services; and
 - (b) approve patient care policies, nursing practices and procedures.
- (2) Establish facility-wide patient care services appropriate for the patients served and available resources that includes:
 - (a) Approving specific scope of services;
 - (b) Integrating and coordinating patient care services;
 - (c) Standardizing the uniform performance of patient care processes;
 - (d) Establishing a facility-approved procedure for double checking certain drugs, biologicals, and agents by appropriately licensed personnel;
 - (e) Ensuring immediate access and appropriate dosages for emergency drugs.
- (3) Adopt and implement policies and procedures which define standards of care for each specialty service.
- (4) Provide all patients access to safe and appropriate care.
- (5) Adopt and implement policies and procedures addressing patient care and nursing practices.
- (6) Require individuals conducting business in the ambulatory surgical facility comply with facility policies and procedures.
- (7) Establish and implement processes for:
 - (a) Gathering, assessing and acting on information regarding patient and family satisfaction with the services provided; and
 - (b) Posting the complaint hotline notice according to RCW 70.230.160.
- (8) Plan, promote, and conduct organization-wide performance-improvement activities according to section 246-XXX-155 WAC.
- (10) Adopt and implement policies and procedures to require suspected abuse is reported within 48 hours to local police or appropriate law enforcement agency according to RCW 26.44.030.

WAC 246-XXX-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 section (1).

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

(i) how to authorize research;
(ii) require staff to follow informed consent laws;

and

(iii) Not hindering a patient's access to care if a patient refuses to participate.

WAC 246-XXX-130 Adverse Events. For the purpose of this sub-section, "serious disability" means a physical or mental impairment that substantially limits the major life activities of a patient. Ambulatory surgical facilities must:

(1) Notify the department whenever any of the following adverse events have occurred:

- (a) Surgery performed on the wrong body part;
- (b) Surgery performed on the wrong patient;
- (c) Wrong surgical procedure performed on a patient;

- (d) Unintended retention of a foreign object in a patient after surgery or other procedure;
- (e) Intraoperative or immediately post-operative death in an ASA Class 1 patient;
- (f) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility;
- (g) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended;
- (h) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility;
- (i) Infant discharged to wrong person;
- (j) Patient death or serious disability associated with patient elopement (disappearance);
- (k) Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility;
- (l) Patient death or serious disability associated with a medication error (e.g. errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration);
- (m) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products;
- (n) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the healthcare facility;
- (o) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility;
- (p) Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia neonates;
- (q) Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility;
- (r) Patient death or serious disability associated with electric shock or elective cardioversion while being cared for in a healthcare facility;
- (s) Any incident in which a line designed for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;
- (t) Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility;

(u) Patient death associated with a fall while being cared for in a healthcare facility;

(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility;

(w) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider;

(x) Abduction of a patient of any age;

(y) Sexual assault on a patient within or on the grounds of a healthcare facility;

(z) Death or significant injury of a patient or staff member resulting from a physical assault (i.e. battery) that occurs within or on the grounds of a healthcare facility;

(aa) Artificial insemination with the wrong donor sperm or egg.

(2) Notify the department using the internet reporting system within forty-eight hours of confirmation by the ambulatory surgical facility when any adverse event has occurred. The notice must include:

(a) The ambulatory surgical facility's name;

(b) The type of event identified from the list above;

and

(c) The date the event occurred.

(3) Conduct a root cause analysis of each adverse event following the procedures and methods of:

(a) The joint commission;

(b) The department of veterans affairs national center for patient safety; or

(c) Another nationally recognized root cause analysis methodology found acceptable by the department.

(4) Create and implement a corrective action plan for each adverse event consistent with the findings of the root cause analysis. Each corrective action plan must include:

(a) How each finding will be addressed and corrected;

(b) When each correction will be completed;

(c) Who is responsible to make the corrections;

(d) What action will be taken to prevent each finding from reoccurring; and

(e) A monitoring schedule for assessing the effectiveness of the corrective action plan including who is responsible for the monitoring schedule.

(5) If an ambulatory surgical facility determines there is no need to create a corrective action plan for a particular adverse event, provide a written explanation of the reasons for not creating a corrective action plan.

(6) Complete and submit a report using the internet-based adverse events and incident reporting system within forty-five days after confirming an adverse event has occurred.

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

Ambulatory surgical facilities must:

- (1) Establish, review, and update written job descriptions for each job classification;
- (2) Conduct periodic staff performance reviews;
- (3) Assure qualified staff available including a process for competency, skill assessment and development;
- (4) Assure supervision of staff;
- (5) Document verification of staff licensure, certification, or registration;
- (6) 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;
- (7) Orient staff to their assigned work environment;
- (8) Give infection control information to staff upon hire and annually which includes:
 - (a) Education on general infection control according to WAC 296-823 blood borne pathogens exposure control; and
 - (b) General and specific infection control measures related to patient care.
- (9) Establish and implement an education plan that verifies or arranges for the training of staff on prevention, transmission, and treatment of human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) consistent with RCW 70.24.310.

WAC 246-XXX-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) Adopt bylaws, rules, regulations, and organizational structure that address:
 - (a) Qualifications for membership;
 - (b) Verification of application data;

- (c) Appointment and reappointment process;
- (d) Length of appointment and reappointment;
- (e) Granting of delineated clinical privileges;
- (f) Provision for continuous patient care;
- (g) Assessment of credentialed practitioner's performance;
- (h) Due process; and
- (i) Reporting practitioners according to RCW 70.230.120;
- (j) Provide for medical staff communication and conflict resolution with the governing authority;
- (2) Forward medical staff recommendations for membership and clinical privileges to the governing authority for action.

WAC 246-XXX-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.

WAC 246-XXX-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 which 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 use;
 - (e) Medication management or administration related to

wrong medication, wrong dose, wrong time, near misses and any other medication errors and incidents;

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

(g) Adverse events listed in WAC 246-XXX-130;

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

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

(j) Confirmed transfusion reactions;

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

(l) Quality control and risk management activities.

WAC 246-320-176 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, employees, medical staff, volunteers, 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) and other nationally recognized professional bodies or organizations.

(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, 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) Attire;

(k) Traffic patterns;

(l) Antisepsis;

(m) Hand washing;

(n) Scrub technique and surgical preparation;

(o) Biohazardous waste management according to applicable federal, state, and local regulations;

(p) Barrier and transmission precautions; and

(q) Pharmacy and therapeutics;

(6) Establish and implement a plan for:

(a) Reporting communicable diseases according to chapter 246-100 WAC; and

(b) Surveying and investigating communicable disease occurrences in the ambulatory surgical facility consistent with WAC 246-XXX-XXX.

WAC 246-XXX-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.

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

(a) An initial license fee of XXX dollars; and

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

(i) XXX dollars for under 1000 annual patient visits;

(ii) XXX dollars for 1001 to 5000 annual patient visits; or

(iii) XXX dollars for more than 5000 annual patient visits.

(2) Renewal License. Licensees must send the department a license renewal and survey fee at least 30 days before the license expiration date as follows:

(a) XXX dollars for under 1000 annual patient visits;

(b) XXX dollars for 1001 to 5000 annual patient visits; or

(c) XXX dollars for more than 5000 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 30 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.

WAC 246-XXX-200 Pharmaceutical Services. This section assures patient pharmaceutical needs are met in a planned and organized manner.

An ambulatory surgical facility must

(1) Meet the requirements in chapter 246-873 WAC, and

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

WAC 246-XXX-205 Patient Care Services. This section guides the development of a plan for patient care. This is accomplished 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 pre established patient care guidelines or protocols. When used, these must be documented in the medical record and be pre approved or authenticated by an authorized 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) 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) Immunization status for pediatric patients;
- (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.

WAC 246-XXX-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'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) Timely 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 that a registered nurse qualified by training and experience functions as the circulating nurse in every operating room during surgical procedures.

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

An ambulatory surgical facility must:

- (1) Adopt and implement policies and procedures that:
 - (a) Identify the types of anesthesia that may be used;
 - (b) Identify areas where each type of anesthesia may

be used; and

(c) Define the staff qualifications and oversight for administering each type of anesthesia used in the facility;

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

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

WAC 246-XXX-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 licensed independent 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.

WAC 246-XXX-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; and

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

(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.

WAC 246-XXX-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) Ambulatory surgical facilities must have 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) The ambulatory surgical facility must designate a person responsible to develop, implement, monitor, and follow-up on all aspects of the management plan.
- (3) Safety. The ambulatory surgical facility must establish and implement a plan to:
 - (a) Maintain a physical environment free of hazards;
 - (b) Reduce the risk of injury to patients, staff, and visitors;
 - (c) Investigate and report safety related incidents;
 - (d) Correct or take steps to avoid reoccurrence of the incidents in the future;
 - (e) Develop and implement policies and procedures on safety related issues such as but not limited to physical hazards and injury prevention; and
 - (f) Educate and periodically review with staff, policies and procedures relating to safety and job-related hazards.
- (4) Security. The ambulatory surgical facility must:
 - (a) Establish and implement a plan to maintain a secure environment for patients, visitors, and staff, to include preventing abduction of patients;
 - (b) Educate staff on security procedures; and
 - (c) Train security staff to a level of skill and competency for their assigned responsibility.
- (5) Hazardous materials and waste. The ambulatory surgical facility must:
 - (a) Establish and implement a program to safely control hazardous materials and waste according to federal, state, and local regulations;

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

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

(d) Educate staff on policies and procedures relating to safe handling and control of hazardous materials and waste.

(6) Emergency preparedness. The ambulatory surgical facility must:

(a) Establish and implement a disaster plan designed to address both internal and external disasters. The plan is:

- (i) Specific to the facility;
- (ii) Relevant to the geographic area;
- (iii) Readily put into action; and
- (iv) Reviewed and revised periodically;

(b) Ensure the disaster plan identifies:

- (i) Who is responsible for each aspect of the plan;

and

(ii) Essential and key personnel responding to a disaster;

(c) Include in the plan:

- (i) A staff education and training component;
- (ii) A process for testing each aspect of the plan;

and

(iii) A component for debriefing and evaluation after each disaster, incident or drill.

(7) Fire Safety. The ambulatory surgical facility must:

(a) Establish and implement a plan to maintain a fire-safe environment;

(b) Investigate fire protection deficiencies, failures, and user errors; and

(c) Orient, educate, and conduct drills with staff on policies and procedures relating to fire prevention and emergencies.

(8) Medical Equipment. The ambulatory surgical facility must establish and implement a plan to:

(a) Complete a technical and engineering review to verify medical equipment will function safely within building support systems;

(b) Inventory all patient equipment and related technologies that require preventive maintenance;

(c) Perform and document preventive maintenance;

(d) Develop and implement a quality control program;

(e) Assure consistent service of equipment,

independent of service vendors or methodology;

(f) Investigate, report, and evaluate procedures in response to equipment failures; and

(g) Educate staff on the proper and safe use of medical equipment.

(9) Utility systems. The ambulatory surgical facility must establish and implement policies, procedures and a plan to:

(a) Maintain a safe and comfortable environment;

(b) Assess and minimize risks of utility system failures;

(c) Ensure operational reliability of utility systems;

(d) Investigate and evaluate utility systems problems, failures, or user errors and report incidents and corrective actions;

(e) Perform and document preventive maintenance; and

(f) Educate staff on utility management policies and procedures.

(10) Physical Environment. The ambulatory surgical facility must provide:

(b) Plumbing with:

(i) A water supply providing hot and cold water under pressure which conforms to WAC 246-290, (Department of Health, division of drinking water);

(ii) Hot water supplied for hand washing not exceeding 120°F;

(iii) Cross connection controls meeting requirements of the state plumbing code;

(c) Ventilation to prevent objectionable odors and/or excessive condensation; and

(d) Clean interior surfaces and finishes.

WAC 246-320-500 Applicability of WAC 246-XXX-500 through 246-XXX-XXX. 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 an ambulatory surgical facility as defined in RCW 70.230-010:

(a) Including:

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

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

(iii) Additions to an existing ambulatory surgical facility;

(iv) Alterations to an existing ambulatory surgical facility; and

(2) The requirements of chapter 246-XXX WAC 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.

WAC 246-XXX-505 Department Responsibilities - Construction Review, Approval of Plans. This section identifies the actions and responsibilities of the department for reviewing and approving new construction of ambulatory surgical facilities.

(1) Before issuing an approval, 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 appropriate construction review fee;

(d) Approval by the local jurisdiction has been obtained

(e) Approval of the initial license application;

(f) Receipt of the ambulatory surgical facility's functional program.

(g) Verify compliance with the applicable chapters of the 2006 Guidelines for the Design and Construction of Healthcare Facilities

(i) Receipt of full plan review fee based on Chapter 246-314 WAC.

WAC 246-320-510 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(b).

(3) The construction documents must include:

(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.

(iii) For Additions and/or Alterations, 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;

(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; and

(c) Floor plan of the building showing the alterations and additions including:

(i) Location of any service or support areas; and

(ii) 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 construction documents;

(c) Submit to the department for review and approval

any addenda or modifications to the original department approved construction documents;

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

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

(4) 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 construction cost declared and that any additional fees have been paid.