



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 ; 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)

WAC 246-330-010 License, survey, change of ownership, refund process and WAC 246-330-199 Fees, amending rules to update the definition of ambulatory surgical facilities and increase fees.

Hearing location(s): Department of Health
310 Israel Road - Point Plaza East Room 152/153
Tumwater, Washington 98501

Date: 03/27/12

Time: 2:30 p.m.

Submit written comments to:

Name: Debra Fisher
Address: PO Box 47852
Olympia, WA 98504-7852
Website: <http://www3.doh.wa.gov/policyreview/>
fax 360-236-2901 by (date) 03/27/2012

Assistance for persons with disabilities: Contact

Debra Fisher by 03/20/2012

TTY (800) 833-6388 or () 711

Date of intended adoption: 04/06/2012

(Note: This is NOT the effective date)

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

The proposed rule increases licensing fees for Ambulatory Surgical Facilities (ASF) to more adequately fund the operation of the ASF Program. The rule changes the existing fee structure to a new nine-tier structure with fees ranging from \$3,630 to \$10,068. The rule also updates the ASF definition in WAC 246-330-010 to reflect the ASF definition in RCW 70.230.010.

Reasons supporting proposal:

In 2007, ASF was established as a new licensing category (effective 2009) to protect the public's health by ensuring a safe environment for ASF patients. RCW 43.70.250 requires the cost of each licensing program be fully borne by the licensees. Since 2009, costs to operate the ASF program have far exceeded revenue. In 2011, the department was given the authority in the operating budget (E2SHB1087) to increase fees to fund the costs of the program. In addition, HB1575 (2011) was passed redefining ASFs that fall under the licensing requirement. The proposed rule also reflects that change.

Statutory authority for adoption:

Chapter 43.70 RCW and 2ESHB1087 (2011)

Statute being implemented:

Chapter 43.70 RCW and 2ESHB1087 (2011)

Is rule necessary because of a:

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

DATE 02/22/12

NAME (type or print)

Mary C. Selecky

SIGNATURE

TITLE

Secretary

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: February 22, 2012

TIME: 10:05 AM

WSR 12-05-116

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

None

Name of proponent: (person or organization) Washington State Department of Health

- Private
 Public
 Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Debra Fisher	310 Israel Rd, Tumwater, WA 98501	360-236-2942
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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:

Address:

phone

fax

e-mail

No. Explain why no statement was prepared.

A small business economic impact statement (SBEIS) was not prepared. Under RCW 19.85.025 and 34.05.310(4)(f), a SBEIS is not required for proposed rules that set or adjust fees or rates pursuant to legislative standards.

Is a cost-benefit analysis required under RCW 34.05.328?

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

Name:

Address:

phone

fax

e-mail

No: Please explain: The agency did not complete a cost benefit analysis under RCW 34.05.328. RCW 34.05.328(5)(b)(vi) exempts rules that set or adjust fees or rates pursuant to legislative standards.

AMENDATORY SECTION (Amending WSR 09-09-032, filed 4/7/09, effective 5/8/09)

WAC 246-330-199 Fees--License, (~~survey,~~) change of ownership, refund process. This section establishes the initial and renewal license fees, (~~survey, and~~) change of ownership fee(~~s~~), (~~a~~) late (~~penalty~~) fee, and request for refund of an initial license fee for an ambulatory surgical facility (ASF). (~~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 and renewal license fees. An initial license or a renewal license and fee are valid for three years. An applicant(~~s~~) for an initial or renewal license must (~~send~~) submit one of the following fees to the department:

Ambulatory Surgical Facility Initial and Renewal Fees

<u>Fee Type</u>	<u>Fees</u>		
<u>Initial and Renewal License</u>	<u>Performs 1,000 or Fewer Surgical Procedures on an Annual Basis</u>	<u>Performs 1,001 - 5,000 Surgical Procedures on an Annual Basis</u>	<u>Performs More than 5,000 Surgical Procedures on an Annual Basis</u>
<u>Accredited</u>	<u>\$3,630</u>	<u>\$4,447</u>	<u>\$5,410</u>
<u>Medicare Certified</u>	<u>\$4,781</u>	<u>\$5,925</u>	<u>\$7,273</u>
<u>State Licensed Only</u>	<u>\$6,507</u>	<u>\$8,142</u>	<u>\$10,068</u>

~~(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)) Accredited, for purposes of the initial and renewal fee, means an ASF is accredited by one of the organizations identified~~

in WAC 246-330-025 (1)(b) at the level that meets medicare's conditions of coverage.

(b) Medicare certified means an ASF is certified by the Centers for Medicare and Medicaid Services (CMS).

(c) State licensed only means an ASF that is not accredited at the level that meets medicare's conditions of coverage and is not medicare certified.

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

~~((+4))~~ (3) Change of ownership. The change of ownership fee is good for that transaction and does not change the original license ending date. The person purchasing or taking over ownership of a licensed ~~((ambulatory surgical facility))~~ ASF must:

(a) Send the department a change of ownership fee in the amount of ~~((two))~~ five 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))~~ (4) 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.

AMENDATORY SECTION (Amending WSR 09-09-032, filed 4/7/09, effective 5/8/09)

WAC 246-330-010 Definitions. (~~For the purposes of this chapter, the following words and phrases will have the following meanings~~) The definitions in this section apply throughout this chapter unless the context clearly ((indicates)) requires 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 as referenced in chapter 70.56 RCW.

(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.~~) An ambulatory surgical facility includes one or more surgical suites

that are adjacent to and within the same building as, but not in, the office of a practitioner in an individual or group practice, if the primary purpose of the one or more surgical suites is to provide specialty or multispecialty outpatient surgical services, irrespective of the type of anesthesia administered in the one or more surgical suites. An ambulatory surgical facility that is adjacent to and within the same building as the office of a practitioner in an individual or group practice may include a surgical suite that shares a reception area, restroom, waiting room, or wall with the office of the practitioner in an individual or group practice.

(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 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 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 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) "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) "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.

(45) "Sexual assault" means, according to RCW 70.125.030, 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.

(46) "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.

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

(48) "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.

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

(50) "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.

(51) "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.

(52) "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.

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