



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)

Title 246 WAC. Adding a new chapter to consolidate four separate adverse health event reporting rules into one section and amending existing rules to reference the new chapter 246-302 WAC. See the CR-102 Attachment.

Hearing location(s): Washington State Department of Health
111 Israel Rd., SE, (Town Center 2) Room 158
Tumwater, WA 98501

Date: 6/27/12 Time: 1:30 p.m.

Submit written comments to:

Name: Dianna Staley
Address: PO Box 47860
Olympia, WA 98504-7860
Website: <http://www3.doh.wa.gov/policyreview/>
fax 360-236-4626 by (date) 06/27/2012

Assistance for persons with disabilities: Contact

Dianna Staley by 06/20/2012

TTY (800) 833-6388 or () 711

Date of intended adoption: 06/28/2012

(Note: This is NOT the effective date)

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

The proposed rules update the National Quality Forum 2011 listing of serious reportable events (adverse health events) that medical facilities must report and clarify definitions. The proposed rules consolidate existing reporting requirements for hospitals, psychiatric hospitals, childbirth centers, and ambulatory surgical facilities from four chapters into one new chapter. The proposed rules also amend existing rules to reference the new chapter 246-302 WAC.

Reasons supporting proposal:

The National Quality Forum adopted an updated list of serious reportable events (adverse health events) in December 2011. Chapter 70.56 RCW requires the department to amend agency rules when the list is changed. To ensure consistency, the proposed adverse event reporting rules create a new chapter in Title 246 WAC to consolidate the various existing rules from four chapters and to also amend the other existing rules to reference the new chapter.

Statutory authority for adoption:

Chapter 70.56 RCW

Statute being implemented:

Chapter 70.56 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 05/17/12

NAME (type or print)

Mary C. Selecky

SIGNATURE

TITLE

Secretary

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: **May 17, 2012**

TIME: **11:35 AM**

WSR **12-11-079**

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..... Dianna Staley	111 Israel Rd., SE, Tumwater, WA 98507	360-236-4997
Implementation....Kathy Schmitt	111 Israel Rd., SE, Tumwater, WA 98507	360-236-2869
Enforcement.....Kathy Schmitt	111 Israel Rd., SE, Tumwater, WA 98507	360-236-2869

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)(c), a SBEIS is not required for proposed rules that adopt or incorporate by reference - without material change - federal statutes or regulations, Washington state law, the rules of other Washington state agencies, or national consensus codes that generally establish industry 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)(iii) exempts rules that adopt or incorporate by reference without material change federal statutes or regulations, Washington state law, the rules of other Washington state agencies, or national consensus codes that generally establish industry standards.

CR-102 Attachment
 Title 246 WAC.
 Adding a new section to consolidate existing reporting requirements
 Amending existing rules

WAC	Title – Effect of Proposed Rules	Facility
Chapter 246-302 WAC	Adverse Health Events	New consolidated chapter
246-320-010	Definitions - delete definition no longer needed	Hospitals
246-320-131	Governance – reference new chapter	Hospitals
246-320-146	Adverse health events – clarify requirement, reference new chapter	Hospitals
246-320-151	Reportable events – reference new chapter	Hospitals
246-320-171	Improving organizational performance – reference new chapter	Hospitals
246-322-260	Adverse health events – clarify requirement, reference new chapter	Private psychiatric hospitals
246-329-045	Applicant or licensee rights and responsibilities – reference new chapter	Childbirth centers
246-330-010	Definitions – delete definition no longer needed	Ambulatory surgical facilities
246-330-115	Governance – reference new chapter	Ambulatory surgical facilities
246-330-130	Adverse health events – clarify requirement, reference new chapter	Ambulatory surgical facilities
246-330-155	Coordinated quality improvement program – reference new chapter	Ambulatory surgical facilities

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 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 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))~~ (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.

"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))~~ (5) "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))~~ (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.

~~((+8+))~~ (7) "Authentication" means the process used to verify an entry is complete, accurate, and final.

~~((+9+))~~ (8) "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+))~~ (9) "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+))~~ (10) "Department" means the Washington state department of health.

~~((+12+))~~ (11) "Double-checking" means verifying patient identity, agent to be administered, route, quantity, rate, time, and interval of administration by two persons.

~~((+13+))~~ (12) "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+))~~ (13) "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))~~ (14) "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))~~ (15) "Family" means individuals designated by a patient who need not be relatives.

~~((17))~~ (16) "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))~~ (17) "Governing authority/body" means the person or persons responsible for establishing the purposes and policies of the ambulatory surgical facility.

~~((19))~~ (18) "Hospital" means any institution, place, building, or agency providing accommodations, facilities, and services as defined in chapter 70.41 RCW.

~~((20))~~ (19) "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))~~ (20) "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))~~ (21) "Maintenance" means the work of keeping something in safe, workable or suitable condition.

~~((23))~~ (22) "Medical equipment" means equipment used in a patient care environment to support patient treatment and diagnosis.

~~((24))~~ (23) "Medical staff" means practitioners and advanced registered nurse practitioners appointed by the governing authority.

~~((25))~~ (24) "Medication" means any substance, other than food or devices, intended for use in diagnosing, curing, mitigating, treating, or preventing disease.

~~((26))~~ (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.

~~((27))~~ (26) "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))~~ (27) "New construction" means any renovation, alteration or new facility to be licensed as an ambulatory surgical facility.

~~((29))~~ (28) "Nonambulatory" means an individual physically or mentally unable to walk or traverse a normal path to safety without the physical assistance of another.

~~((30))~~ (29) "Operating room" means a room intended for invasive procedures.

~~((31))~~ (30) "Patient" means an individual receiving (or having received) preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative health services.

~~((32))~~ (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.

~~((33))~~ (32) "Person" means any individual, firm, partnership, corporation, company, association, joint stock association, and the legal successor thereof.

~~((34))~~ (33) "Pharmacist" means an individual licensed by the state board of pharmacy under chapter 18.64 RCW.

~~((35))~~ (34) "Pharmacy" means every place properly licensed by the board of pharmacy where the practice of pharmacy is conducted.

~~((36))~~ (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.

~~((37))~~ (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.

~~((38))~~ (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.

~~((+39+))~~ (38) "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+))~~ (39) "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+))~~ (40) "Registered nurse" means an individual licensed under chapter 18.79 RCW.

~~((+42+))~~ (41) "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+))~~ (42) "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+))~~ (43) "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+))~~ (44) "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))~~ (45) "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))~~ (46) "Staff" means paid employees, leased or contracted persons, students, and volunteers.

~~((48))~~ (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.

~~((49))~~ (48) "Surrogate decision-maker" means an individual appointed to act on behalf of another when an individual is without capacity or has given permission.

~~((50))~~ (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.

~~((51))~~ (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.

~~((52))~~ (51) "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))~~ (52) "Well-being" means free from actual or potential harm, abuse, neglect, unintended injury, death, serious disability or illness.

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

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~~)) chapter 246-302 WAC;
- (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.

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

WAC 246-330-130 Adverse health events reporting requirements.

~~((1) As found in 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, "serious disability" means a physical or mental impairment that substantially limits the major life activities of a patient.~~

~~(2) Ambulatory surgical facilities must:~~

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

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

~~(3) The department will assure all notifications and reports~~

~~submitted to the department are maintained confidentially according to RCW 70.56.050.)~~ The National Quality Forum identifies and defines twenty-nine serious reportable events (adverse health events) as updated and adopted in 2011.

(1) An ambulatory surgical facility must report adverse health events to the department.

(2) An ambulatory surgical facility must comply with the reporting requirements under chapter 246-302 WAC.

(3) Adverse health events are listed in chapter 246-302 WAC.

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

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)~~) 246-302 WAC;

(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.

AMENDATORY SECTION (Amending WSR 07-07-075, filed 3/16/07, effective 4/16/07)

WAC 246-329-045 Applicant or licensee rights and responsibilities. This section describes the applicant or licensee's responsibilities in the fulfillment of the requirements of this chapter.

- (1) An applicant or licensee must:
 - (a) Comply with chapter 18.46 RCW and this chapter;
 - (b) Establish, implement and periodically review all policies and procedures which address the contents of this chapter;
 - (c) Display the license issued by the department in an area accessible to the public;
 - (d) Notify the department in writing:
 - (i) Within thirty days of changes of an administrator, owner or the director of clinical services;
 - (ii) Thirty or more days before ceasing operations;
 - (e) Cooperate with the department during surveys which may include reviewing licensee and client records and conducting client interviews with client consent;
 - (f) Respond to a statement of deficiencies by submitting to the department:
 - (i) A written plan of correction, within ten working days of receipt. The applicant or licensee must complete all corrections within sixty days after the survey exit date, unless otherwise specified by the department; and
 - (ii) A progress report describing corrections made and ongoing monitoring actions, within ninety days after the survey exit date, unless the department specifies another date.
- (2) An applicant or licensee may:
 - (a) Discuss findings observed during a survey with the surveyor; and
 - (b) Discuss the statement of deficiencies with the department's manager.
- (3) ~~((As required by chapter 70.56 RCW, the licensed childbirth center shall notify the department if any of the following events have been confirmed to have occurred in the birth center:~~
 - ~~(a) An infant abduction or discharge to the wrong family;~~
 - ~~(b) Sexual assault or rape of a patient or staff member while in the birth center;~~
 - ~~(c) Maternal death or serious disability with labor or delivery in a low-risk pregnancy while being cared for in a health care facility;~~
 - ~~(d) Patient death or serious disability associated with:~~
 - ~~(i) The use of contaminated drugs, devices, or biologics provided by the health care facility;~~

~~(ii) The use or function of a device in which the device is used or functions other than as intended;~~

~~(iii) Intravascular air embolism that occurs while being cared for in a health care facility;~~

~~(iv) A medication error (errors involving wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration);~~

~~(v) Hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility;~~

~~(vi) Failure to identify and treat hyperbilirubinemia in neonates;~~

~~(vii) An electric shock while being cared for in a health care facility; or~~

~~(viii) A burn incurred from any source while being cared for in a health care facility.~~

~~(e) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;~~

~~(f) Patient suicide, or attempted suicide resulting in serious disability, that occurs while the patient is receiving care in a health care facility;~~

~~(g) Death or significant injury of a patient or staff member resulting from physical assault that occurs within or on the grounds of a health care facility;~~

~~(h) Any instance of care ordered by someone impersonating a physician, nurse, pharmacist or other licensed health care provider;~~

~~(i) Patient death associated with a fall while being cared for in a health care facility;~~

~~(j) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility; and~~

~~(k) Sexual assault on a patient within or on the grounds of a health care facility.~~

~~(4) The licensed childbirth center must also notify the department if either of the following events have been confirmed to have occurred in the birth center:~~

~~(a) An unanticipated death, stillbirth or major loss of function; or~~

~~(b) Any catastrophic incident, such as fire or flood, or any incident which may cause interruption or cessation of the delivery of services, or another interruption of services which would affect the health and safety of the client.~~

~~(5) The report required in subsection (3) and (4) of this section must be submitted in writing to the department as required by chapter 70.56 RCW. The birth center is encouraged to confirm these events through a review or assessment by the birth center's quality improvement or risk management process. Each notice to the department must include:~~

~~(a) The licensee's name;~~

~~(b) The name of the affected client, if applicable;~~

~~(c) The date the event occurred;~~

~~(d) A description of the event and a clinical summary if the~~

~~event is client-related;~~

~~(e) Root cause analysis and corrective action plans as required by chapter 70.56 RCW.~~

~~(6) The report note in subsection (3) of this section:~~

~~(a) Will allow the department to be informed of events which in the interest of the public will be reviewed and reported as required by chapter 70.56 RCW;~~

~~(b) Will be confidentially maintained by the department in accordance with the protections of the Public Disclosure Act, chapter 42.17 RCW, and other applicable laws and reporting requirements; and~~

~~(c) Does not relieve a birth center from complying with other applicable reporting or notification requirements of this chapter or those requirements relating to law enforcement or professional regulatory agencies.~~

(7)) (a) A childbirth center must report adverse health events to the department. The National Quality Forum identifies and defines twenty-nine serious reportable events (adverse health events) as updated and adopted in 2011.

(b) A childbirth center must comply with the reporting requirements under chapter 246-302 WAC. Reporting requirements under chapter 246-302 WAC do not relieve a birth center from complying with other applicable reporting or notification requirements of this chapter or those requirements relating to law enforcement or professional regulatory agencies.

(c) Adverse health events are listed in chapter 246-302 WAC.

(4) An applicant or licensee has the right to respond to and contest a statement of charges according to the following provisions:

(a) RCW 43.70.115, department of health authority for license approval, denial, restriction, conditioning, modification, suspension and revocation;

(b) Chapter 34.05 RCW, the Administrative Procedure Act; and

(c) Chapter 246-10 WAC, Adjudicative proceedings.

AMENDATORY SECTION (Amending WSR 09-07-051, filed 3/11/09, effective 4/11/09)

WAC 246-322-260 Adverse health events ((and incident)) reporting ((system)) requirements. ((The purpose of this section is to outline each psychiatric hospital's responsibilities for reporting and addressing adverse events. In this section, "serious disability" means a physical or mental impairment that substantially limits the major life activities of a patient.

Psychiatric hospitals must:

(1) Notify the department whenever any of the following adverse events as defined by the National Quality Forum, *Serious Reportable Events in Health Care* occur:

1. Surgery performed on the wrong body part.
2. Surgery performed on the wrong patient.
3. Wrong surgical procedure performed on a patient.
4. Unintended retention of a foreign object in a patient after surgery or other procedure.
5. Intraoperative or immediately postoperative death in an ASA Class 1 patient.
6. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility.
7. 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.
8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility.
9. Infant discharged to wrong person.
10. Patient death or serious disability associated with patient elopement (disappearance).
11. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a health care facility.
12. 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).
13. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products.
14. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the health care facility.

- ~~15. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility.~~
- ~~16. Patient death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia neonates.~~
- ~~17. Stage 3 or 4 pressure ulcers acquired after admission to a health care facility.~~
- ~~18. Patient death or serious disability due to spinal manipulative therapy.~~
- ~~19. Patient death or serious disability associated with electric shock or electric cardioversion while being cared for in a health care facility.~~
- ~~20. 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.~~
- ~~21. Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility.~~
- ~~22. Patient death or serious disability associated with a fall while being cared for in a health care facility.~~
- ~~23. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility.~~
- ~~24. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.~~
- ~~25. Abduction of a patient of any age.~~
- ~~26. Sexual assault on a patient within or on the grounds of a health care facility.~~
- ~~27. 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 health care facility.~~
- ~~28. Artificial insemination with the wrong donor sperm or egg.~~

~~(2) Notify the department within forty-eight hours of confirmation by the psychiatric hospital when any adverse event has occurred using established procedures. The notice must include:~~

- ~~(a) The psychiatric hospital's name;~~
- ~~(b) The type of event identified in subsection (1) of this section;~~
- ~~(c) The date the event was confirmed; and~~
- ~~(d) Any additional contextual information the hospital chooses to provide.~~

~~(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) As part of the root cause analysis, include the following information:~~

~~(a) The number of patients, registered nurses, licensed practical nurses, and unlicensed assistive personnel present in the relevant patient care unit at the time the reported adverse event occurred;~~

~~(b) The number of nursing personnel present at the time of the adverse event who have been supplied by temporary staffing agencies including traveling nurses; and~~

~~(c) The number of nursing personnel, if any, on the patient care unit working beyond their regularly scheduled number of hours or shifts at the time of the event and the number of consecutive hours worked by each such nursing personnel at the time of the adverse event.~~

~~(5) 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;~~

~~(6) If a psychiatric hospital 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;~~

~~(7) Complete and submit a root cause analysis report, within forty-five days after confirming an adverse health event has occurred, to the department.)~~ The National Quality Forum identifies and defines twenty-nine serious reportable events (adverse health events) as updated and adopted in 2011.

(1) Psychiatric hospitals must report adverse health events to the department.

(2) Psychiatric hospitals must comply with the reporting requirements under chapter 246-302 WAC.

(3) Adverse health events are listed in chapter 246-02 WAC.

AMENDATORY SECTION (Amending WSR 09-07-050, filed 3/11/09, effective 4/11/09)

WAC 246-320-010 Definitions. For the purposes of this chapter and chapter 70.41 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 of *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))~~ (3) "Alcoholism" means a disease, characterized by a dependency on alcoholic beverages, loss of control over the amount and circumstances of use, symptoms of tolerance, physiological or psychological withdrawal, or both, if use is reduced or discontinued, and impairment of health or disruption of social or economic functioning.

~~((5))~~ (4) "Alteration" means any change, addition, or modification to an existing hospital or a portion of an existing hospital.

"Minor alteration" means renovation that does not require an increase in capacity to structural, mechanical or electrical systems, which does not affect fire and life safety, and which does not add beds or facilities in addition to that for which the hospital is currently licensed.

~~((6))~~ (5) "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 a health care setting 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))~~ (6) "Authentication" means the process used to verify

an entry is complete, accurate, and final.

~~((+8+))~~ (7) "Bed, bed space or bassinet" means the physical environment and equipment (both movable and stationary) designed and used for twenty-four hour or more care of a patient including level 2 and 3 bassinets. This does not include stretchers, exam tables, operating tables, well baby bassinets, labor bed, and labor-delivery-recovery beds.

~~((+9+))~~ (8) "Child" means an individual under the age of eighteen years.

~~((+10+))~~ (9) "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.

~~((+11+))~~ (10) "Critical care unit or service" means the specialized medical and nursing care provided to patients facing an immediate life-threatening illness or injury. Care is provided by multidisciplinary teams of highly skilled physicians, nurses, pharmacists or other health professionals who interpret complex therapeutic and diagnostic information and have access to sophisticated equipment.

~~((+12+))~~ (11) "Department" means the Washington state department of health.

~~((+13+))~~ (12) "Dietitian" means an individual meeting the eligibility requirements for active membership in the American Dietetic Association described in *Directory of Dietetic Programs Accredited and Approved, American Dietetic Association*, edition 100, 1980.

~~((+14+))~~ (13) "Double-checking" means verifying patient identity, agent to be administered, route, quantity, rate, time, and interval of administration by two persons.

~~((+15+))~~ (14) "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.

~~((+16+))~~ (15) "Electrical receptacle outlet" means an outlet where one or more electrical receptacles are installed.

~~((+17+))~~ (16) "Emergency care to victims of sexual assault" means medical examinations, procedures, and services provided by a hospital emergency room to a victim of sexual assault following an alleged sexual assault.

~~((+18+))~~ (17) "Emergency contraception" means any health care

treatment approved by the Food and Drug Administration that prevents pregnancy, including, but not limited to, administering two increased doses of certain oral contraceptive pills within seventy-two hours of sexual contact.

~~((19))~~ (18) "Emergency department" means the area of a hospital where unscheduled medical or surgical care is provided to patients who need care.

~~((20))~~ (19) "Emergency room" means a space where emergency services are delivered and set apart by floor-to-ceiling partitions on all sides with proper access to an exit access and with all openings provided with doors or windows.

~~((21))~~ (20) "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 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 another hospital before delivery; or

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

~~((22))~~ (21) "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.

~~((23))~~ (22) "Emergency triage" means the immediate patient assessment by a registered nurse, physician, or physician assistant to determine the nature and urgency of the person's medical need for treatment.

~~((24))~~ (23) "Family" means individuals designated by a patient who need not be relatives.

~~((25))~~ (24) "General hospital" means a hospital that provides general acute care services, including emergency services.

~~((26))~~ (25) "Governing authority/body" means the person or persons responsible for establishing the purposes and policies of the hospital.

~~((27))~~ (26) "High-risk infant" means an infant, regardless of age, whose existence is compromised, prenatal, natal, or postnatal factors needing special medical or nursing care.

~~((28))~~ (27) "Hospital" means any institution, place, building, or agency providing accommodations, facilities, and services over a continuous period of twenty-four hours or more, for observation, diagnosis, or care of two or more individuals not

related to the operator who are suffering from illness, injury, deformity, or abnormality, or from any other condition for which obstetrical, medical, or surgical services would be appropriate for care or diagnosis. "Hospital" as used in this chapter does not include:

(a) Hospice care centers which come within the scope of chapter 70.127 RCW;

(b) Hotels, or similar places, furnishing only food and lodging, or simply domiciliary care;

(c) Clinics or physicians' offices, where patients are not regularly kept as bed patients for twenty-four hours or more;

(d) Nursing homes, as defined in and which come within the scope of chapter 18.51 RCW;

(e) Birthing centers, which come within the scope of chapter 18.46 RCW;

(f) Psychiatric or alcoholism hospitals, which come within the scope of chapter 71.12 RCW; nor

(g) Any other hospital or institution specifically intended for use in the diagnosis and care of those suffering from mental illness, mental retardation, convulsive disorders, or other abnormal mental conditions;

(h) Furthermore, nothing in this chapter will be construed as authorizing the supervision, regulation, or control of the remedial care or treatment of residents or patients in any hospital conducted for those who rely primarily upon treatment by prayer or spiritual means in accordance with the creed or tenets of any well-recognized church or religious denominations.

~~((29))~~ (28) "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.

~~((30))~~ (29) "Infant" means an individual not more than twelve months old.

~~((31))~~ (30) "Invasive 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.

~~((32))~~ (31) "Licensed practical nurse" means an individual licensed under provisions of chapter 18.79 RCW.

~~((33))~~ (32) "Maintenance" means the work of keeping something in safe, workable or suitable condition.

~~((34))~~ (33) "Medical equipment" means equipment used in a patient care environment to support patient treatment and

diagnosis.

~~((35))~~ (34) "Medical staff" means physicians and other practitioners appointed by the governing authority.

~~((36))~~ (35) "Medication" means any substance, other than food or devices, intended for use in diagnosing, curing, mitigating, treating, or preventing disease.

~~((37))~~ (36) "Multidisciplinary treatment team" means a group of individuals from various disciplines and clinical services who assess, plan, implement, and evaluate treatment for patients.

~~((38))~~ (37) "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.

~~((39))~~ (38) "Neonate" means a newly born infant under twenty-eight days of age.

~~((40))~~ (39) "Neonatologist" means a pediatrician who is board certified in neonatal-perinatal medicine or board eligible in neonatal-perinatal medicine, provided the period of eligibility does not exceed three years, as defined and described in *Directory of Residency Training Programs* by the Accreditation Council for Graduate Medical Education, American Medical Association, 1998 or the *American Osteopathic Association Yearbook and Directory*, 1998.

~~((41))~~ (40) "New construction" means any of the following:

(a) New facilities to be licensed as a hospital;

(b) Renovation; or

(c) Alteration.

~~((42))~~ (41) "Nonambulatory" means an individual physically or mentally unable to walk or traverse a normal path to safety without the physical assistance of another.

~~((43))~~ (42) "Nursing personnel" means registered nurses, licensed practical nurses, and unlicensed assistive nursing personnel providing direct patient care.

~~((44))~~ (43) "Operating room (OR)" means a room intended for invasive and noninvasive surgical procedures.

~~((45))~~ (44) "Patient" means an individual receiving (or having received) preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative health services.

(a) "Inpatient" means services that require admission to a hospital for twenty-four hours or more.

(b) "Outpatient" means services that do not require admission to a hospital for twenty-four hours or more.

~~((46))~~ (45) "Patient care areas" means all areas of the hospital where direct patient care is delivered and where patient diagnostic or treatment procedures are performed.

~~((47))~~ (46) "Patient care unit or area" means a physical space of the hospital including rooms or areas containing beds or

bed spaces, with available support ancillary, administrative, and services for patient.

~~((48))~~ (47) "Person" means any individual, firm, partnership, corporation, company, association, or joint stock association, and the legal successor thereof.

~~((49))~~ (48) "Pharmacist" means an individual licensed by the state board of pharmacy chapter 18.64 RCW.

~~((50))~~ (49) "Pharmacy" means every place properly licensed by the board of pharmacy where the practice of pharmacy is conducted.

~~((51))~~ (50) "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.

~~((52))~~ (51) "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.

~~((53))~~ (52) "Procedure" means a particular course of action to relieve pain, diagnose, cure, improve, or treat a patient's condition.

~~((54))~~ (53) "Protocols" and "standing order" mean written or electronically recorded descriptions of actions and interventions for implementation by designated hospital staff under defined circumstances under hospital policy and procedure.

~~((55))~~ (54) "Psychiatric service" means the treatment of patients pertinent to a psychiatric diagnosis.

~~((56))~~ (55) "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, obstetrical delivery, surgery, or other diagnostic or treatment procedures.

~~((57))~~ (56) "Registered nurse" means an individual licensed under chapter 18.79 RCW.

~~((58))~~ (57) "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.

~~((59))~~ (58) "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.

~~((60))~~ (59) "Seclusion" means the involuntary confinement of a patient in a room or area where the patient is physically prevented from leaving.

~~((61))~~ (60) "Seclusion room" means a secure room designed and organized for temporary placement, care, and observation of one patient with minimal sensory stimuli, maximum security and protection, and visual and auditory observation by authorized personnel and staff. Doors of seclusion rooms have staff-controlled locks.

~~((62))~~ (61) "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 items in (a) through (g) of this subsection.

~~((63))~~ (62) "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.

~~((64))~~ (63) "Specialty hospital" means a subclass of hospital that is primarily or exclusively engaged in the care and treatment of one of the following categories:

(a) Patients with a cardiac condition;
(b) Patients with an orthopedic condition;
(c) Patients receiving a surgical procedure; and
(d) Any other specialized category of services that the secretary of health and human services designates as a specialty hospital.

~~((65))~~ (64) "Staff" means paid employees, leased or contracted persons, students, and volunteers.

~~((66))~~ (65) "Surgical procedure" means any manual or operative procedure performed upon the body of a living human being for the purpose of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defect, prolonging life or relieving suffering, and involving any of the following:

(a) Incision, excision, or curettage of tissue;
(b) Suture or repair of tissue including a closed as well as an open reduction of a fracture;
(c) Extraction of tissue including the premature extraction of the products of conception from the uterus; or
(d) An endoscopic examination.

~~((67))~~ (66) "Surrogate decision-maker" means an individual appointed to act on behalf of another when an individual is without capacity as defined in RCW 7.70.065 or has given permission.

~~((68))~~ (67) "Transfer agreement" means a written agreement providing an effective process for the transfer of a patient requiring emergency services to a general hospital providing emergency services and for continuity of care for that patient.

~~((69))~~ (68) "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.

~~((70))~~ (69) "Unlicensed assistive personnel (UAP)" means individuals trained to function in an assistive role to nurses in the provision of patient care, as delegated by and under the supervision of the registered nurse. Typical activities performed by unlicensed assistive personnel include, but are not limited to: Taking vital signs; bathing, feeding, or dressing patients; assisting patient with transfer, ambulation, or toileting. Definition includes: Nursing assistants; orderlies; patient care

technicians/assistants; and graduate nurses (not yet licensed) who have completed unit orientation. Definition excludes: Unit secretaries or clerks; monitor technicians; therapy assistants; student nurses fulfilling educational requirements; and sitters who are not providing typical UAP activities.

~~((71))~~ (70) "Victim of sexual assault" means a person is alleged to have been sexually assaulted and who presents as a patient.

~~((72))~~ (71) "Vulnerable adult" means, 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; an adult with a developmental disability under RCW 71A.10.020; an adult with a legal guardian under 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 under RCW 74.39.050. 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. For the purposes of this chapter, it shall also include hospitalized adults.

~~((73))~~ (72) "Well-being" means free from actual or potential harm, abuse, neglect, unintended injury, death, serious disability or illness.

AMENDATORY SECTION (Amending WSR 09-07-050, filed 3/11/09, effective 4/11/09)

WAC 246-320-131 Governance. This section provides organizational guidance and oversight responsibilities of hospital resources and staff to support safe patient care.

For the purposes of this section "practitioner" means pharmacists as defined in chapter 18.64 RCW; advanced registered nurse practitioners as defined in chapter 18.79 RCW; dentists as defined in chapter 18.32 RCW; naturopaths as defined in chapter 18.36A RCW; optometrists as defined in chapter 18.53 RCW; osteopathic physicians and surgeons as defined in chapter 18.57 RCW; osteopathic physicians' assistants as defined in chapter 18.57A RCW; physicians as defined in chapter 18.71 RCW; physician assistants as defined in chapter 18.71A RCW; podiatric physicians and surgeons as defined in chapter 18.22 RCW; and psychologists as defined in chapter 18.83 RCW.

The governing authority must:

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

(a) Reporting practitioners according to RCW 70.41.210;

(b) Informing patients of any unanticipated outcomes according to RCW 70.41.380;

- (c) Establishing and approving a performance improvement plan;
 - (d) Providing organizational management and planning;
 - (e) Reporting adverse events and conducting root cause analyses according to ((RCW 70.56.020)) chapter 246-302 WAC;
 - (f) Providing a patient and family grievance process including a time frame for resolving each grievance;
 - (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, medical treatments, and nutrition; and
 - (5) Approve and periodically review bylaws, rules, and regulations adopted by the medical staff before they become effective.

AMENDATORY SECTION (Amending WSR 09-07-050, filed 3/11/09, effective 4/11/09)

WAC 246-320-146 Adverse health events ((and incident)) reporting ((system)) requirements. ((The purpose of this section is to outline each hospital's responsibilities for reporting and addressing adverse events. In this section, "serious disability" means a physical or mental impairment that substantially limits the major life activities of a patient.

~~Hospitals must:~~

~~(1) Notify the department whenever any of the following adverse events as defined by the National Quality Forum, Serious Reportable Events in Health Care occur:~~

- ~~1. Surgery performed on the wrong body part;~~
- ~~2. Surgery performed on the wrong patient;~~
- ~~3. Wrong surgical procedure performed on a patient;~~
- ~~4. Unintended retention of a foreign object in a patient after surgery or other procedure;~~
- ~~5. Intraoperative or immediately postoperative death in an ASA Class I patient;~~
- ~~6. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility;~~
- ~~7. 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;~~

- ~~8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility;~~
- ~~9. Infant discharged to wrong person;~~
- ~~10. Patient death or serious disability associated with patient elopement (disappearance);~~
- ~~11. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a health care facility;~~
- ~~12. 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);~~
- ~~13. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products;~~
- ~~14. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the health care facility;~~
- ~~15. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility;~~
- ~~16. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia neonates;~~
- ~~17. Stage 3 or 4 pressure ulcers acquired after admission to a health care facility;~~
- ~~18. Patient death or serious disability due to spinal manipulative therapy;~~
- ~~19. Patient death or serious disability associated with electric shock or electric cardioversion while being cared for in a health care facility;~~
- ~~20. 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;~~
- ~~21. Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility;~~
- ~~22. Patient death or serious disability associated with a fall while being cared for in a health care facility;~~
- ~~23. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility;~~
- ~~24. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider;~~
- ~~25. Abduction of a patient of any age;~~
- ~~26. Sexual assault on a patient within or on the grounds of a health care facility;~~

~~27. 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 health care facility; and~~

~~28. Artificial insemination with the wrong donor sperm or egg;~~

~~(2) Notify the department within forty-eight hours of confirmation by the hospital when any adverse event has occurred using established procedures. The notice must include:~~

~~(a) The hospital's name;~~

~~(b) The type of event identified in subsection (1) of this section;~~

~~(c) The date the event was confirmed; and~~

~~(d) Any additional contextual information the hospital chooses to provide;~~

~~(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) As part of the root cause analysis, include the following information:~~

~~(a) The number of patients, registered nurses, licensed practical nurses, and unlicensed assistive personnel present in the relevant patient care unit at the time the reported adverse event occurred;~~

~~(b) The number of nursing personnel present at the time of the adverse event who have been supplied by temporary staffing agencies, including traveling nurses; and~~

~~(c) The number of nursing personnel, if any, on the patient care unit working beyond their regularly scheduled number of hours or shifts at the time of the event and the number of consecutive hours worked by each such nursing personnel at the time of the adverse event;~~

~~(5) 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;~~

~~(6) If a hospital 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;~~

~~(7) Complete and submit a root cause analysis within forty-~~

~~five days, after confirming an adverse health event has occurred, to the department.)~~ The National Quality Forum identifies and defines twenty-nine serious reportable events (adverse health events) as updated and adopted in 2011.

(1) Hospitals must report adverse health events to the department.

(2) Hospitals must comply with the reporting requirements under chapter 246-302 WAC.

(3) Adverse health events are listed in chapter 246-302 WAC.

AMENDATORY SECTION (Amending WSR 09-07-050, filed 3/11/09, effective 4/11/09)

WAC 246-320-151 Reportable operational or maintenance events.

The purpose of this section is to outline each hospital's responsibility for reporting serious events that affect the operation and maintenance of the facility.

(1) Hospitals must notify the department within forty-eight hours whenever any of the following events have occurred:

(a) A failure or facility system malfunction such as the heating, ventilation, fire alarm, fire sprinkler, electrical, electronic information management, or water supply affecting patient diagnosis, treatment, or care within the facility; or

(b) A fire affecting patient diagnosis, treatment, or care within the facility.

(2) Each notice to the department must include:

(a) The hospital's name;

(b) The event type from subsection (1) of this section; and

(c) The date the event occurred.

AMENDATORY SECTION (Amending WSR 09-07-050, filed 3/11/09, effective 4/11/09)

WAC 246-320-171 Improving organizational performance. The purpose of this section is to ensure that performance improvement activities of staff, medical staff, and outside contractors result in continuous improvement of patient health outcomes. In this section "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.

Hospitals must:

(1) Have a hospital-wide approach to process design and performance measurement, assessment, and improving patient care services according to RCW 70.41.200 and include, but not be 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 hospital;

(g) Adverse events listed in chapter 246-302 WAC (~~(246-320-146)~~);

(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 hospital);

(j) Confirmed transfusion reactions;

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

and

(l) Quality control and risk management activities.

Chapter 246-302 WAC

ADVERSE HEALTH EVENTS

ADVERSE HEALTH EVENTS REPORTING

NEW SECTION

WAC 246-302-010 Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise. Definitions for other terms in this section are described in the National Quality Forum list of serious reportable events.

(1) "Adverse health event" or "adverse event" means the list of twenty-nine serious reportable events updated and adopted by the National Quality Forum in 2011, in its consensus report on serious reportable events in health care. Adverse health events are listed in WAC 246-302-030.

(2) "Ambulatory surgical facility" means a facility licensed under chapter 70.230 RCW.

(3) "Childbirth center" means a facility licensed under chapter 18.46 RCW.

(4) "Department" means the department of health.

(5) "Hospital" means a facility licensed under chapter 70.41 RCW.

(6) "Medical facility" means a licensed ambulatory surgical facility, childbirth center, hospital, or psychiatric hospital.

(7) "Psychiatric hospital" means a hospital facility licensed as a psychiatric hospital under chapter 71.12 RCW.

NEW SECTION

WAC 246-302-020 How and when to report. Medical facilities must report confirmed adverse health events to the department. A medical facility must:

(1) Notify the department that an adverse health event has occurred within forty-eight hours of confirmation of the adverse health event. The notification must include:

- (a) The name of the medical facility;
- (b) The date the adverse event was confirmed;
- (c) The type of adverse health event; and
- (d) Any additional contextual information the medical facility chooses to provide.

(2) Submit a report to the department within forty-five days of the confirmation of the adverse health event. The report must include a root cause analysis and corrective action plan. The root cause analysis must:

- (a) Follow the procedures and methods of:
 - (i) The joint commission;
 - (ii) The department of veterans affairs national center for patient safety; or
 - (iii) Another nationally recognized root cause analysis methodology the department has found acceptable.
- (b) Include the following information:
 - (i) The findings regarding the root cause of the adverse health event;
 - (ii) The number of patients, registered nurses, licensed practical nurses, and unlicensed assistive personnel present in the relevant patient care unit at the time the reported adverse health event occurred;
 - (iii) The number of nursing personnel present at the time of the adverse health event who have been supplied by temporary staffing agencies, including traveling nurses; and
 - (iv) The number of nursing personnel, if any, on the patient care unit working beyond their regularly scheduled number of consecutive hours worked by each such nursing personnel at the time of the adverse health event.

The corrective action plan must be consistent with the findings of the root cause analysis and 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 the adverse health event from reoccurring; and
- (E) A monitoring schedule to assess the effectiveness of the corrective action plan, including who is responsible for the monitoring schedule.

(3) If a medical facility determines there is no need to create a corrective action plan for a particular adverse health event, the medical facility must provide to the department a written explanation of the reasons for not creating a corrective action plan.

(4) The medical facility may amend the notification or report within sixty days of the submission.

(5) The report shall not include any identifying information for any health care professional, facility employee, or patient involved.

(6) Notification and reporting under this rule does not remove

a medical facility's responsibility to report a licensed practitioner's unprofessional conduct to the department, as defined under RCW 18.130.180.

NEW SECTION

WAC 246-302-030 Adverse health events. The National Quality Forum identifies and defines twenty-nine serious reportable events. The twenty-nine adverse health events described in the National Quality Forum 2011 update are listed in WAC 246-302-030.

(1) Surgical or invasive procedure events:

(a) Surgery or other invasive procedure performed on the wrong site.

(b) Surgery or other invasive procedure performed on the wrong patient.

(c) Wrong surgical or other invasive procedure performed on a patient.

(d) Unintended retention of a foreign object in a patient after surgery or other invasive procedure.

(e) Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient.

(2) Product or device events:

(a) Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the health care setting.

(b) Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended.

(c) Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a health care setting.

(3) Patient protection events:

(a) Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person.

(b) Patient death or serious injury associated with patient elopement (disappearance).

(c) Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a health care setting.

(4) Care management events:

(a) Patient death or serious injury 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).

(b) Patient death or serious injury associated with unsafe administration of blood products.

(c) Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a health care setting.

(d) Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy.

(e) Patient death or serious injury associated with a fall while being cared for in a health care setting.

(f) Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a health care setting.

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

(h) Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen.

(i) Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results.

(5) Environmental events:

(a) Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a health care setting.

(b) Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances.

(c) Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a health care setting.

(d) Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a health care setting.

(6) Radiologic events: The death or serious injury of a patient or staff associated with the introduction of a metallic object into the magnetic resonance imaging (MRI) area.

(7) Potential criminal events:

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

(b) Abduction of a patient/resident of any age.

(c) Sexual abuse/assault on a patient or staff member within or on the grounds of a health care setting.

(d) Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a health care setting.