

**Chapter 246-302 WAC
ADVERSE HEALTH EVENTS**

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WAC

ADVERSE HEALTH EVENTS REPORTING

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ADVERSE HEALTH EVENTS REPORTING

WAC 246-302-010 Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(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 including all appendices. 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.

[Statutory Authority: Chapter 70.56 RCW. WSR 12-16-057, § 246-302-010, filed 7/30/12, effective 10/1/12.]

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 for the type of facility reporting an adverse health event.

(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.

[Statutory Authority: Chapter 70.56 RCW. WSR 12-16-057, § 246-302-020, filed 7/30/12, effective 10/1/12.]

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.

[Statutory Authority: Chapter 70.56 RCW. WSR 12-16-057, § 246-302-030, filed 7/30/12, effective 10/1/12.]