

OREGON PATIENT SAFETY COMMISSION

ADMINISTRATIVE RULES

CHAPTER 325

DIVISION 10

Oregon Patient Safety Reporting Program for Hospitals

325-010-0001

Definitions

As used in OAR 325-010-0001 to 325-010-0060:

- (1) **“Commission”** means the Oregon Patient Safety Commission.
- (2) **“Event Report”** means the form designated by the Commission to be used by Hospital Participants for the reporting of Reportable Hospital Serious Adverse Events.
- (3) **“Hospital Participant”** means a hospital that has volunteered to participate in the Oregon Patient Safety Reporting Program. A hospital pharmacy is considered to be part of the hospital.
- (4) **“Oregon Patient Safety Reporting Program”** means the Patient Safety Reporting Program, as defined in Oregon Laws 2003, Chapter 686, Section 4, and operated by the Commission.
- (5) **“Participant”** means an entity that reports Patient Safety Data to a Patient Safety Reporting Program, and any agent, employee, consultant, representative, volunteer or medical staff member of the entity.
- (6) **“Patient Safety Activities”** include but are not limited to:
 - (a) The collection and analysis of Patient Safety Data by a Participant;
 - (b) The collection and analysis of Patient Safety Data by the Oregon Patient Safety Commission established in Oregon Laws 2003, Chapter 686 and ORS 442.820;
 - (c) The utilization of Patient Safety Data by Participants;
 - (d) The utilization of Patient Safety Data by the Oregon Patient Safety Commission to improve the quality of care with respect to patient safety and to provide assistance to health care providers to minimize patient risk; and
 - (e) Oral and written communication regarding Patient Safety Data among two or more Participants with the intent of making a disclosure to or preparing a report to be submitted to a Patient Safety Reporting Program.
- (7) **“Patient Safety Data”** means oral communication or written reports, data, records, memoranda, analyses, deliberative work, statements, root cause analyses or action plans that are collected or developed to improve patient safety or health care quality that:
 - (a) Are prepared by a Participant for the purpose of reporting Patient Safety Data voluntarily to a Patient Safety Reporting Program, or that are communicated among two or more Participants with the intent of making a disclosure to or preparing a report to be submitted to a Patient Safety Reporting Program; or

(b) Are created by or at the direction of the Patient Safety Reporting Program, including communication, reports, notes or records created in the course of an investigation undertaken at the direction of the Oregon Patient Safety Commission.

(8) “Reportable Serious Adverse Event” for the purposes of OAR 325-010-0001 to 325-010-0060 means any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury, including the events described in Appendix A. Appendix A is incorporated by reference.

325-010-0005

Enrollment in the Oregon Patient Safety Reporting Program

- (1) Participation in the Oregon Patient Safety Reporting Program is voluntary. Hospital Participants are entitled to the benefits and subject to the obligations set forth in these administrative rules.
- (2) Interested hospitals may apply for participation in the Oregon Patient Safety Reporting Program by completing the Commission’s registration form and submitting the applicable annual fee. The registration form must include the name of a designated contact person.
- (3) In agreeing to participate a hospital must affirm that it is willing to fully share requested Patient Safety Data with the Commission. This statement must be co-signed by the hospital’s Chief Executive Officer, Chairperson of the Board of Directors, and the Director of Quality Management, or their equivalents.
- (4) Upon enrolling in the Oregon Patient Safety Reporting Program, a Hospital Participant must have adopted policies and procedures describing patient safety activities, including how it triages adverse events; how it investigates adverse events, including root cause analysis protocols; and how it provides notice of adverse events to a patient and/or patient’s personal representative. The Hospital Participant must provide copies to the Commission upon request.
- (5) Within 30 calendar days of receipt and acceptance of the registration form and fee the Commission will issue a certificate establishing a Hospital Participant’s enrollment in the Oregon Patient Safety Reporting Program. The Hospital Participant should conspicuously post the certificate in an area where patients are admitted.
- (6) The Commission will issue a press release on a regular basis which will provide a list of Hospital Participants to the public.

325-010-0010

Annual Hospital Participant Fee

- (1) A Hospital Participant must pay an annual fee, as follows:
 - a. \$1,000 for a hospital with 3,000 or fewer patient discharges per year.
 - b. \$3,500 for a hospital with 3,001 to 10,000 patient discharges per year.
 - c. \$8,500 for a hospital with more than 10,000 patient discharges per year.

- (2) Initial fees will be assessed at the time of enrollment in the Oregon Patient Safety Reporting Program and will expire on December 31 following the date of issue. Annual Hospital Participant fees will be due by December 31 for the next year's enrollment. A delinquent renewal fee of up to 25% of the renewal fee may be assessed against a Hospital Participant submitting fees postmarked after December 31st.
- (3) No participation fees will be refunded due to withdrawal or termination from the Oregon Patient Safety Reporting Program.

325-010-0015

Termination of Participation

- (1) The Commission's reporting program relies on voluntary reporting. However, the Commission is responsible for ensuring that those who choose to participate also comply with the standards established by the Commission.
- (2) Participation requirements include the reporting of all Reportable Serious Adverse Events; fully completing Event Reports; creating and implementing acceptable action plans; and providing written disclosure to patients or their personal representatives following a Reportable Serious Adverse Event.
- (3) If the Commission believes a Hospital Participant is not meeting its participation requirements, the Commission must provide the Hospital Participant with a written notice explaining why. The Hospital Participant will have 30 calendar days to respond and come into compliance.
- (4) The Commission may deny, suspend or revoke a Hospital Participant's status when the Commission finds that there has been a substantial failure to comply with the provisions of participation.

Upon written notification by the Commission of revocation, suspension, or denial of a Hospital Participant enrollment in the Oregon Patient Safety Reporting Program, a Hospital Participant may request a hearing. Hearings will be held in accordance with ORS 183.310 to 183.470.

325-010-0020

Re-Issue of Suspended or Revoked Participation Certificate

The Commission may re-issue a participation certificate that has been suspended or revoked if the Commission determines that the Hospital applying for re-enrollment meets the provisions of participation.

325-010-0025

Reporting Serious Adverse Events

- (1) The Commission will provide an Event Report form to be used by Hospital Participants for reporting Reportable Serious Adverse Events. The Event Report will include: a summary description of the event; an overview of the Hospital Participant's complete, thorough and credible root cause analysis for that event; information about plans to implement

improvements to reduce risk. The meaning of terms “complete,” “thorough,” and “credible” are explained in OAR 325-010-0035.

- (2) Hospital Participants must use the Event Report form when reporting Serious Adverse Events to the Commission.
- (3) Hospital Participants must submit a completed Event Report to the Commission within 45 calendar days of discovery of a Reportable Serious Adverse Event.
- (4) If a Hospital Participant believes the Commission should immediately issue an alert to all Oregon hospitals based on a specific Reportable Serious Adverse Event, the Hospital Participant should provide an initial report to the Commission within 3 business days of discovery of the event, or sooner. The Hospital Participant and Commission will work together to identify information to include in the alert.

325-010-0030

Hospital Reporting of Less Serious Adverse Events or Close Calls

- (1) In addition to Reportable Serious Adverse Events, Participating Hospitals are also encouraged to report less serious adverse events or close calls. Participating Hospitals should do so when they believe other organizations will benefit from the information.
- (2) To report such events, Hospital Participants should use the appropriate sections of the Event Report form. Hospital Participants will not be required to complete detailed root cause analysis for these less serious events or close calls.
- (3) Hospital Participants are not required by the Commission to provide written disclosure of less serious adverse events or close calls to patients or their personal representatives.

325-010-0035

Commission Review of Reports

- (1) When the Commission receives an Event Report from a Hospital Participant, the Commission will determine whether that Event Report is complete, thorough, credible and acceptable. The definitions for the terms *thorough*, *credible* and *acceptable* can be found in the Joint Commission on Accreditation of Health Care Organization’s Sentinel Event Policy and Procedures, June 2005, and are adopted by reference. In general:
 - a. A report is *complete* if it contains all the information requested in the Event Report, or explains, to the Commission’s satisfaction, why that information is not available or not necessary to provide;
 - b. A report is *thorough* if the root cause analysis includes an analysis of all relevant systems issues and shows evidence of an inquiry into all appropriate areas;
 - c. A report is *credible* if it shows evidence that the investigation of the Reportable Hospital Serious Adverse Event included participation by leadership within the organization and was internally consistent; and

- d. A report is *acceptable* if all the above standards are met and the action plans clearly describe meaningful improvement strategies designed to minimize risk.
- (2) If the Commission believes that an Event Report received from a Hospital Participant is incomplete or unacceptable in some manner, it will inform the Hospital Participant's contact person within 10 business days of receipt of the Event Report.
- (3) On an annual basis, the Commission will query Hospital Participants regarding the status of action plans identified in their Event Reports.

325-010-0040

Public Health Officer Certification

- (1) At least annually, the Commission will request that the Public Health Officer certify the completeness, credibility, and thoroughness of each Hospital Participant's reporting during the applicable period.
- (2) The Commission will request that the Public Health Officer develop independent and objective standards to evaluate the overall integrity of the Patient Safety Reporting Program. On an annual basis the Commission will request that the Public Health Officer use those standards to certify the Oregon Patient Safety Reporting Program.
- (3) The Commission will provide information to the Public Health Officer to assist the Public Health Officer in completing the certification processes listed in (1) and (2) of this rule, consistent with OAR 325-010-0055.

325-010-0045

Patient Notification Of Reportable Serious Adverse Events

- (1) After a Reportable Serious Adverse Event occurs, a Hospital Participant must provide written notification to each affected patient, or, if necessary, to the patient's personal representative. Notification must be timely and should be consistent with the Hospital Participant's internal communication and disclosure policies.
- (2) As provided in Oregon Laws 2003, Chapter 686, Section 4(4), notice provided under this subsection may not be construed as an admission of liability in a civil action.

325-010-0050

Extensions And Waivers

- (1) The Commission may grant an extension of any time requirement stipulated in these rules if the Hospital Participant provides justification that the delay is due to factors beyond its control or that the delay will not adversely affect the purposes of the Commission. A Hospital Participant requesting a waiver must submit a written request to the Commission prior to the deadline for the required action. Facsimile requests are acceptable.
- (2) The Commission may grant a waiver of any other provision of these rules if the Hospital Participant provides justification that granting the waiver will not adversely affect the purposes of the Commission.

325-010-0055**Protection Of Patient Safety Data**

- (1) The Commission is subject to all the confidentiality provisions set forth in Oregon Laws 2003, Chapter 686, Sections 1, 4 to 6, 8 to 10, 12, and in ORS 442.820 to 442.835.
- (2) The Commission will maintain the confidentiality of all Patient Safety Data that identifies or could be reasonably used to identify a Hospital Participant or an individual who is receiving or has received health care from the Hospital Participant.
- (3) Before it takes receipt of any confidential Patient Safety Data, the Commission will have in place appropriate safeguards and security measures to ensure the technical integrity and physical safety of such data.
- (4) Pursuant to ORS 442.820(4), meetings or portions of meetings where the Oregon Patient Safety Commission Board of Directors, or subcommittees or advisory committees consider information that identifies a participant or patient are not subject to the Oregon Public Meetings Law, ORS 192.610 to 192.690.

325-010-0060**Commission's Use Of Patient Safety Data**

- (1) The Commission will create a standing committee on best practices in patient safety. This committee will advise the Commission on effective methods for making use of and sharing information gathered from the Commission's review of Event Reports.
- (2) At least quarterly, the Commission will provide Hospital Participants with patient safety quality improvement information derived from Patient Safety Data.
- (3) During the second quarter of each year, the Commission will publish a report to the public summarizing Patient Safety Data for the preceding calendar year. This report will use aggregate, de-identified data from the program and will describe statewide adverse event patterns and best practices to avoid the occurrence or minimize the effects of adverse events.
- (4) The Commission will maintain an easily accessible and well-publicized website to share patient safety information directly with consumers.
- (5) The Commission, within its resource limitations, will provide technical assistance to Hospital Participants, including but not limited to recommendations and advice regarding methodology, communication, dissemination of information, data collection, security and confidentiality.
- (6) The Commission will work with representatives of organizations participating in the Oregon Patient Safety Reporting Program and with other interested parties to develop recommendations for continued improvements in the collection and utilization of Patient Safety Data.

Appendix A
Reportable Hospital Serious Adverse Events

Type of Events	Additional Specifications
1. GENERAL CATEGORY	
Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury.	Category includes: <ul style="list-style-type: none"> • Any unanticipated, usually preventable event that results in serious physical injury, even if the harm is temporary. • Only events that are not related to the natural course of the patient’s illness or underlying condition. • Healthcare acquired infections that result in patient death or serious physical injury.
2. SURGICAL EVENTS	
A. Surgery performed on the wrong body part.	Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.
B. Surgery performed on the wrong patient.	Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures.
C. Wrong surgical procedure performed on a patient.	Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.
D. Retention of a foreign object in a patient after surgery or other procedure.	Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
E. Intraoperative or immediately post-operative death in an ASA Class I patient. (ASA is the American Society of Anesthesiologists. Class I means a healthy patient, no medical problems.)	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.

Type of Events	Additional Specifications
3. PRODUCT OR DEVICE EVENTS	
A. Patient death or serious physical injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility.	Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.
B. Patient death or serious physical 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 or is difficult to use as intended.	Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.
C. Patient death or serious physical injury associated with intravascular air embolism that occurs while being cared for in a healthcare facility.	Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
4. PATIENT PROTECTION EVENTS	
A. Infant discharged to the wrong person	
B. Patient death or serious physical injury associated with patient elopement (disappearance) for more than four hours.	Excludes events involving competent adults.
C. Patient suicide, or attempted suicide resulting in serious physical injury, while being cared for in a healthcare facility.	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.
5. CARE MANAGEMENT EVENTS	
A. Patient death or serious physical 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).	Excludes reasonable differences in clinical judgment on drug selection and dose.
B. Patient death or serious physical injury associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.	
C. Maternal death or serious physical injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility.	Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.
D. Patient death or serious physical injury associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.	
E. Death or serious physical injury (kernicterus) associated with failure to	Hyperbilirubinemia is defined as bilirubin levels >30 mg/dl.

Type of Events	Additional Specifications
identify and treat hyperbilirubinemia in neonates	Neonates refers to the first 28 days of life.
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.	Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
G. Patient death or serious physical injury due to spinal manipulative therapy.	
H. Any perinatal death or serious physical injury unrelated to a congenital condition in an infant having a birth weight greater than 2500 grams.	
6. ENVIRONMENTAL EVENTS	
A. Patient death or serious physical injury associated with an electric shock while being cared for in a healthcare facility.	Excludes events involving planned treatments such as electric countershock.
B. 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.	
C. Patient death or serious physical injury associated with a burn incurred from any source while being cared for in a healthcare facility.	
D. Patient death or serious physical injury associated with a fall while being cared for in a healthcare facility.	
E. Patient death or serious physical injury associated with the use of restraints or bedrails while being cared for in a healthcare facility.	