

OREGON PATIENT SAFETY COMMISSION
ADMINISTRATIVE RULES
CHAPTER 325
DIVISION 25

Oregon Patient Safety Reporting Program for Ambulatory Surgery Centers

325-025-0001

Definitions

As used in OAR 325-025-0001 to 325-025-0060:

- (1) **“Commission”** means the Oregon Patient Safety Commission.
- (2) **“Event Report”** means the form designated by the Commission to be used by Ambulatory Surgery Center Participants for the reporting of Reportable Ambulatory Surgery Center Adverse Events.
- (3) **“Ambulatory Surgery Center Participant”** means an ambulatory surgery center as defined in ORS 442.015, that has volunteered to participate in the Oregon Patient Safety Reporting Program.
- (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) “Serious Adverse Event” for the purposes of OAR 325-025-0001 to 325-025-0060 means any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury, either temporary or permanent.

(9) “Reportable Adverse Event” for the purposes of OAR 325-025-0001 to 325-025-0060 means any unanticipated, usually preventable consequence of patient care that results in patient harm, including the events described in Appendix A and any Serious Adverse Events. Appendix A is incorporated by reference.

325-025-0005

Enrollment in the Oregon Patient Safety Reporting Program

- (1) Participation in the Oregon Patient Safety Reporting Program is voluntary. Ambulatory Surgery Center Participants are entitled to the benefits and subject to the obligations set forth in these administrative rules.
- (2) Interested ambulatory surgery centers 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 an ambulatory surgery center must affirm that it is willing to fully share requested Patient Safety Data with the Commission. This statement must be co-signed by the ambulatory surgery center’s Chief Executive Officer, Chairperson of the Governing Body, and the Director of Quality Management, or their equivalents.
- (4) Upon enrolling in the Oregon Patient Safety Reporting Program, an Ambulatory Surgery Center Participant must have adopted policies and procedures describing patient safety activities, including how it triages adverse events; how it investigates adverse events; and how it provides notice of adverse events to a patient and/or patient’s personal representative. The Ambulatory Surgery Center 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 an Ambulatory surgery center Participant’s enrollment in the Oregon Patient Safety Reporting Program. The Ambulatory surgery center 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 Ambulatory surgery center Participants to the public.

325-025-0010

Annual Ambulatory surgery center Participant Fee

- (1) An Ambulatory Surgery Center participant must pay an annual fee of \$850 for each facility licensed under ORS 441.015.

- (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 Ambulatory Surgery Center 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 Ambulatory Surgery Center 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.

325-025-0015

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 Adverse Events; fully completing Event Reports; creating and implementing acceptable action plans; and providing written disclosure to patients or their personal representatives following a Serious Adverse Event.
- (3) If the Commission believes an Ambulatory Surgery Center Participant is not meeting its participation requirements, the Commission must provide the Ambulatory Surgery Center Participant with a written notice explaining why. The Ambulatory Surgery Center Participant will have 30 calendar days to respond and come into compliance.
- (4) The Commission may deny, suspend or revoke a Ambulatory Surgery Center 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 an Ambulatory Surgery Center Participant enrollment in the Oregon Patient Safety Reporting Program, an Ambulatory Surgery Center Participant may request a hearing. Hearings will be held in accordance with ORS 183.310 to 183.470.

325-025-0020

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 ambulatory surgery center applying for re-enrollment meets the provisions of participation.

325-025-0025

Reporting Adverse Events

- (1) The Commission will provide an Event Report form to be used by Ambulatory Surgery Center Participants for reporting Reportable Adverse Events. The Event Report will include: a summary description of the event; an overview of the Ambulatory Surgery Center Participant's complete, thorough and credible investigation for that event; information about plans to implement improvements to reduce risk. The meaning of terms "complete," "thorough," and "credible" are explained in OAR 325-025-0035.

- (2) Ambulatory Surgery Center Participants must use the Event Report form when reporting Reportable Adverse Events to the Commission.
- (3) Ambulatory Surgery Center Participants must submit a completed Event Report to the Commission within 45 calendar days of discovery of a Reportable Adverse Event.
- (4) Ambulatory Surgery Center Participants must make a good faith effort to report events that occur or are discovered following discharge from the ambulatory surgery center.
- (5) If an Ambulatory Surgery Center Participant believes the Commission should immediately issue an alert to all Oregon ambulatory surgery centers based on a specific Reportable Adverse Event, the Ambulatory Surgery Center Participant should provide an initial report to the Commission within three business days of discovery of the event, or sooner. The Ambulatory Surgery Center Participant and Commission will work together to identify information to include in the alert.

325-025-0030

Ambulatory Surgery Center Reporting of Less Serious Adverse Events and Close Calls

- (1) In addition to the list of Reportable Adverse Events, Participating Ambulatory Surgery Centers are also strongly encouraged to report less serious adverse events and close calls. Participating Ambulatory Surgery Centers should do so when they believe other organizations will benefit from the information.
- (2) To report such events, Ambulatory Surgery Center Participants should use the appropriate sections of the Event Report form. Ambulatory Surgery Center Participants will not be required to complete detailed investigation for these less serious events or close calls, but may do so when they believe other organizations will benefit from the information.
- (3) Ambulatory Surgery Center 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.

325-025-0035

Commission Review of Reports

- (1) When the Commission receives an Event Report from an Ambulatory Surgery Center 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's Sentinel Event Policy, October 2006, 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 investigation 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 Ambulatory Surgery Center 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 Ambulatory Surgery Center Participant is incomplete or unacceptable in some manner, it will inform the Ambulatory Surgery Center Participant's contact person within 10 business days of receipt of the Event Report.
- (3) On an annual basis, the Commission will query Ambulatory Surgery Center Participants regarding the status of action plans identified in their Event Reports.

325-025-0040

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 Ambulatory Surgery Center 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 325-025-0055.

325-025-0045

Patient Notification Of Serious Adverse Events

- (1) After a Serious Adverse Event occurs, an Ambulatory Surgery Center 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 Ambulatory Surgery Center 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.

325-025-0050

Extensions And Waivers

- (1) The Commission may grant an extension of any time requirement stipulated in these rules if the Ambulatory Surgery Center 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. An Ambulatory Surgery Center 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 Ambulatory Surgery Center Participant provides justification that granting the waiver will not adversely affect the purposes of the Commission.

325-025-0055**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 an Ambulatory Surgery Center Participant or an individual who is receiving or has received health care from the Ambulatory Surgery Center 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.

325-025-0060**Commission's Use Of Patient Safety Data**

- (1) The Commission will create a advisory group 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 Ambulatory Surgery Center 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 Ambulatory Surgery Center 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. The Commission will revise its reporting form as necessary based on feedback from Participants.
- (7) The Commission may initiate other projects using patient safety data when consistent with its mission and in accordance with existing confidentiality protections.

Appendix A –
Reportable Ambulatory Surgery Center Serious Adverse Events

Type of Events	Additional Specifications
1. SURGICAL EVENTS	
A. Unplanned admission to the hospital within 48 hours of discharge from an ambulatory surgery center	This includes any admission to the hospital or emergency department for symptoms related to the recent ASC procedure
B. Postoperative nausea that requires hospital admission	This includes both immediate post-operative and post-discharge hospital admission for symptoms of nausea within 24 hours
C. Any blood products transfusion	Defined as the use of any blood products for a patient during stay at ASC
D. Immediate postoperative bleeding that requires surgical treatment in the operating room (before discharge)	Includes all postoperative bleeding following the procedure and/or anesthesia that requires surgical treatment prior to discharge
E. Deep vein thrombosis with or without pulmonary embolism	Includes deep vein thrombosis or pulmonary embolism within 30 days of surgery
F. Unplanned 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.
G. Death postoperatively directly attributable to surgical procedure	
H. Intraoperative or immediately postoperative death	Includes all ASA Class I-IV 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
I. 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.
J. 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.
K. 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, anesthesia and other invasive procedures.
2. HEALTHCARE-ASSOCIATED INFECTIONS	
A. Surgical site infection up to 30 days postoperatively	Surgical site infections directly attributable to care provided in ASC
3. EQUIPMENT/PRODUCT/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.

Type of Events	Additional Specifications
4. 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. 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.	
5. 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 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.	
6. OTHER CATEGORY	
A. Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury.	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.