

**OREGON PATIENT SAFETY COMMISSION**

**ADMINISTRATIVE RULES**

**CHAPTER 325**

**DIVISION 20**

**Oregon Patient Safety Reporting Program for Long Term Care Facilities**

**325-020-0001**

**Definitions**

As used in OAR 325-020-0001 to 325-020-0055:

- (1) **“Commission”** means the Oregon Patient Safety Commission.
- (2) **“Event Report”** means the form designated by the Commission to be used by Long Term Care Facility Participants for the reporting of Reportable Long Term Care Facility Serious Adverse Events.
- (3) **“Long Term Care Facility Participant”** means a long term care facility as defined in ORS 442.015 and licensed under OAR 411, Division 085, 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) “Reportable Serious Adverse Event”** for the purposes of OAR 325-020-0001 to 325-020-0055 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.

### **325-020-0005**

#### **Enrollment in the Oregon Patient Safety Reporting Program**

- (1) Participation in the Oregon Patient Safety Reporting Program is voluntary. Long Term Care Facility Participants are entitled to the benefits and subject to the obligations set forth in these administrative rules.
- (2) Interested long term care facilities 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 long term care facility must affirm that it is willing to fully share requested Patient Safety Data with the Commission. This statement must be co-signed by the nursing home administrator, Director of Nursing Services, and the principal owner or Chairperson of the Board of Directors, or their equivalents.
- (4) Upon enrolling in the Oregon Patient Safety Reporting Program, a Long Term Care Facility 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 family member. The Long Term Care Facility 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 Long Term Care Facility Participant’s enrollment in the Oregon Patient Safety Reporting Program. The Long Term Care Facility Participant should post the certificate in public view.
- (6) The Commission will issue a press release on a regular basis which will provide a list of Long Term Care Facility Participants to the public.

### **325-020-0010**

#### **Annual Long Term Care Facility Participant Fee**

- (1) A long term care facility must pay an annual fee of \$700 for each long term care facility licensed under OAR 411, Division 085.
- (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. At the discretion of the

Commission, initial fees may be prorated. Annual Long Term Care Facility 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 Long Term Care Facility 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.
- (4) The Commission may, at its discretion, reduce fees based upon development of an incentive program for participation. However, such an incentive program must be broad-based and uniform in its application.

### **325-020-0015**

#### **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 families following a Reportable Serious Adverse Event.
- (3) If the Commission believes a Long Term Care Facility Participant is not meeting its participation requirements, the Commission must provide the Long Term Care Facility Participant with a written notice explaining why. The Long Term Care Facility Participant will have 30 calendar days to respond and come into compliance.
- (4) The Commission may deny, suspend or revoke a Long Term Care Facility 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 Long Term Care Facility Participant enrollment in the Oregon Patient Safety Reporting Program, a Long Term Care Facility Participant may request a hearing. Hearings will be held in accordance with ORS 183.310 to 183.470.

### **325-020-0020**

#### **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 long term care facility applying for re-enrollment meets the provisions of participation.

### **325-020-0025**

#### **Reporting Serious Adverse Events**

- (1) The Commission will provide an Event Report form to be used by Long Term Care Facility Participants for reporting Reportable Serious Adverse Events. The Event Report will include: a

summary description of the event; an overview of the Long Term Care Facility Participant's complete, thorough and credible investigation of that event; and information about improvement strategies designed to minimize risk of future events. The meaning of terms "complete," "thorough," and "credible" are explained in OAR 325-020-0030.

- (2) Long Term Care Facility Participants must use the Event Report form when reporting Serious Adverse Events to the Commission.
- (3) Long Term Care Facility Participants must submit a completed Event Report to the Commission within 30 calendar days of discovery of a Reportable Serious Adverse Event.
- (4) Subject to a separate written agreement between the Commission and Long Term Care Facility Participant, Participant will share additional resident assessment data with the Commission, to the extent permitted by state and federal law.
- (5) If a Long Term Care Facility Participant believes the Commission should immediately issue an alert to all Oregon Long Term Care Facilities or other types of Participants based on a specific Reportable Serious Adverse Event, the Long Term Care Facility Participant should provide an initial report to the Commission within 3 business days of discovery of the event, or sooner. The Long Term Care Facility Participant and Commission will work together to identify information to include in the alert.

### **325-020-0030**

#### **Commission Review of Reports**

- (1) When the Commission receives an Event Report from a Long Term Care Facility Participant, the Commission will determine whether that Event Report is complete, thorough, credible and acceptable. The definitions for the terms *thorough*, *credible* and *acceptable* are described 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 Long Term Care Facility 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 Long Term Care Facility Participant is incomplete or unacceptable in some manner, it will inform the Long Term Care Facility Participant's contact person within 10 business days of receipt of the Event Report.
- (3) On an annual basis, the Commission will query Long Term Care Facility Participants to better understand what lessons have been learned from the action plans identified in their Event Reports.

**325-020-0035****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 Long Term Care Facility Participant's reporting to the Commission 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 325-010-0050.

**325-020-0040****Patient Notification Of Reportable Serious Adverse Events**

- (1) After a Reportable Serious Adverse Event occurs, a Long Term Care Facility 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 Long Term Care Facility 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.

**325-020-0045****Extensions And Waivers**

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

**325-020-0050****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 Long Term Care Facility Participant or an individual who is receiving or has received health care from the Long Term Care Facility 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.

### **325-020-0055**

#### **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 Long Term Care Facility Participants with aggregate 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 Long Term Care Facility 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 Long Term Care Facility Serious Adverse Events

An unanticipated, usually preventable\*...

1. Elopement – that results in death, serious physical injury\*\*, or requires notification of an outside party;
2. Medication related event that leads to death or serious physical injury;
3. Device or equipment-related event that leads to death or serious physical injury;
4. Aspiration or choking that leads to death or serious physical injury;
5. Allergy that leads to death or serious physical injury (food allergy and medication allergy in separate subcategories);
6. Burn – second or third degree that leads to death or serious physical injury;
7. Suicide or attempted suicide, excluding suicide ideation.
8. Strangulation that results in death or serious physical injury (Events related to restraint devices would be reportable in a separate category);
9. Poisoning that leads to death or serious physical injury;
10. Treatment related event that leads to death or serious physical injury (includes omission and incorrect treatment). Includes intravascular embolisms related to IV therapy, fecal impaction, dehydration, pressure ulcers, diabetic coma, contractures;
11. Event related to use of restraints that lead to death or serious physical injury;
12. Fall that results in death or serious physical injury.
13. Facility acquired infection that results in death or serious physical injury.
14. Other serious adverse event that results in death or serious physical injury.

\* “Unanticipated, usually preventable” refers to adverse events that are caused, at root, by an issue of medical or patient management, rather than the underlying disease.

\*\* Serious physical injury includes, but is not limited to injuries that require a patient to be transferred to a higher level of care.