

OREGON PATIENT SAFETY COMMISSION

ADMINISTRATIVE RULES

CHAPTER 325

DIVISION 15

Oregon Patient Safety Reporting Program for Pharmacies

325-015-0001

Definitions

As used in OAR 325-015-0001 to 325-015-0060:

- (1) **“Commission”** means the Oregon Patient Safety Commission.
- (2) **“Event Report”** means the form designated by the Commission to be used by Pharmacy Participants for the reporting of Reportable Pharmacy Adverse Events.
- (3) **“Pharmacy Participant”** means a pharmacy licensed under ORS chapter 689 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 Adverse Event” for the purposes of OAR 325-015-0001 to 325-015-0060 means any unanticipated, usually preventable consequences of patient care that result in patient harm or the risk of harm. This includes events that:

- (a) Are not related to the natural course of the patient’s illness or underlying condition, and
- (b) Resulted in temporary and/or permanent physical harm, or
- (c) Posed a risk for temporary or permanent physical harm.

"Reportable Adverse Event" includes only those events where a patient receives or has control of the medication.

(9) “Serious Adverse Event” for the purposes of OAR 325-015-0001 to 325-015-0060 means any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury, either temporary or permanent.

325-015-0005

Enrollment in the Oregon Patient Safety Reporting Program

- (1) Participation in the Oregon Patient Safety Reporting Program is voluntary. Pharmacy Participants are entitled to the benefits and subject to the obligations set forth in these administrative rules.
- (2) Interested pharmacies 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 the Pharmacist-in-Charge and a designated contact person. Changes to any information on the registration form must be reported to the Commission with 30 days of the effective change.
- (3) In agreeing to participate, a pharmacy must affirm that it is willing to share fully all requested Patient Safety Data with the Commission. This statement must be signed by the pharmacy’s Owner, responsible executive, and Quality manager, or their equivalents.
- (4) Upon enrolling in the Oregon Patient Safety Reporting Program, a Pharmacy 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 serious adverse events to a patient and/or family member. The Pharmacy 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 Pharmacy Participant’s enrollment in the Oregon Patient Safety Reporting Program. The Pharmacy Participant should conspicuously post the certificate in public view.
- (6) The Commission will issue a press release on a regular basis, which will provide a list of Pharmacy Participants to the public.

325-015-0010

Annual Pharmacy Participant Fee

- (1) A Pharmacy Participant must pay an annual fee of \$150.00 per pharmacy licensed under ORS chapter 689.
- (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.

- (3) Annual Pharmacy 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 Pharmacy Participant submitting fees postmarked after December 31st.
- (4) No participation fees will be refunded due to withdrawal or termination from the Oregon Patient Safety Reporting Program.
- (5) The Commission may, in its discretion, reduce fees based upon development of an incentive program for participation

325-015-0015

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

325-015-0020

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 Pharmacy applying for re-enrollment meets the provisions of participation.

325-015-0025

Reporting Adverse Events

- (1) The Commission will provide an Event Report form to be used by Pharmacy Participants for reporting Adverse Events. The Event Report will include a summary description of the event; a description of the Pharmacy Participant's complete, thorough, and credible 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 325-015-0035.
- (2) Pharmacy Participants must use the Event Report form when reporting Adverse Events to the Commission.

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

325-015-0030

Pharmacy Reporting of Close Calls

- (1) In addition to Reportable Adverse Events, Participating Pharmacies are also encouraged to report close calls. Participating Pharmacies should do so when they believe such events present the potential for significant harm.
- (2) To report such events, Pharmacy Participants should use the appropriate sections of the Event Report form. Pharmacy Participants will not be required to complete detailed root cause analysis for these close calls.

325-015-0035

Commission Review of Reports

- (1) When the Commission receives an Event Report from a Pharmacy Participant, the Commission will determine whether that Event Report is complete, thorough, credible, and acceptable. As used by the Commission:
 - 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 (root cause analysis) of the event 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 Pharmacy Adverse Event included participation by leadership within the organization and was logically consistent; and
 - d. A report is *acceptable* if all the above standards are met and the action plans clearly describe meaningful system-level improvement strategies designed to minimize risk, or indicate why only individual improvement strategies are appropriate for the reported event.
- (2) If the Commission believes that an Event Report received from a Pharmacy Participant is incomplete or unacceptable in some manner, it will inform the Pharmacy Participant's contact person within 10 business days of receipt of the Event Report.
- (3) On an annual basis, the Commission will query Pharmacy Participants regarding the status of action plans identified in their Event Reports.

325-015-0040**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 Pharmacy 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 325-015-0055.

325-015-0045**Patient Notification of "Serious Adverse Events"**

- (1) After a Serious Adverse Event occurs, a Pharmacy 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 Pharmacy 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.

325-015-0050**Extensions and Waivers**

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

325-015-0055**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 Pharmacy Participant or an individual who is receiving or has received health care from the Pharmacy 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.

325-015-0060

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 Pharmacy 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 Pharmacy 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.