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LAVONNE GRIFFIN-VALADE
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CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 325
OREGON PATIENT SAFETY COMMISSION

FILED
12/06/2023 9:30 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Consolidation of five rule divisions into one, and other updates, following statute changes.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 01/22/2024 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Sydney Edlund
503-928-6158
info@oregonpatientsafety.org

PO Box 285
Portland,OR 97207

Filed By:
Sydney Edlund
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 01/17/2024
TIME: 1:00 PM - 1:30 PM
OFFICER: Sydney Edlund

REMOTE MEETING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 1-503-446-4951
CONFERENCE ID: 112428983
SPECIAL INSTRUCTIONS:
Meeting ID: 278 463 917 904
Passcode: qocADM

Or call in (audio only)
+1 503-446-4951, 112428983# United States, Portland
Phone Conference ID: 112 428 983#

NEED FOR THE RULE(S)

The Oregon Patient Safety Commission's statute (ORS 442.819-442.851) was modified by SB 229 in 2023. Revisions are needed to keep the rules consistent with the statute.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

SB229: https://olis.oregonlegislature.gov/liz/2023R1/Measures/Overview/SB229

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The mission of OPSC is to improve the safety of Oregon's healthcare system for every Oregonian, making equity integral to everything we do. Therefore, we are committed to developing rules that foster diversity, equity, and inclusion.

Evaluating who proposed administrative rules will impact, and how the rules may impact some groups of people differently than others, is essential to providing equitable service.

WHAT PERSONS AND GROUPS ARE SUBJECT TO THE RULES?
Oregon hospitals, ambulatory surgery centers, nursing facilities, pharmacies, outpatient renal dialysis centers, birthing centers, extended stay centers, and independent professional healthcare societies or associations

WHAT ISSUES ARE THE RULES SEEKING TO ADDRESS? WHICH RACIAL GROUPS ARE LIKELY TO BE AFFECTED BY THOSE ISSUES?
Revisions are needed to keep OPSC's administrative rules consistent with OPSC's statute following changes made by SB229 in 2023. The rules pertain to OPSC's voluntary Patient Safety Reporting Program (PSRP). Participants submit patient safety data to PSRP so that OPSC can broadly share what they've learned from patient harm events to make healthcare safer in Oregon. All Oregon hospitals, ambulatory surgery centers, nursing facilities, pharmacies, outpatient renal dialysis centers, birthing centers, and extended stay centers are eligible to participate in PSRP. These healthcare facilities treat Oregonians from all racial groups.

ULTIMATELY, WHAT IMPACTS DO THESE RULES HAVE ON RACIAL EQUITY?
OPSC's mission, as defined in statute, is "to improve patient safety by reducing the risk of serious adverse events occurring in Oregon's healthcare system and by encouraging a culture of patient safety in Oregon" (ORS 442.820). When an organization's culture of safety (an organization's shared perceptions, beliefs, values, and attitudes that combine to create a commitment to safety and an effort to minimize harm) does not address health equity head on, it can deepen the systemic biases and injustices that are already present. The proposed rules direct participants to share their policies and procedures describing patient safety activities with OPSC, including how the participant incorporates health equity into its patient safety activities (proposed OAR 325-011-0045(4)(a)). Therefore, these rules could have a positive impact on health equity in Oregon by codifying it as a critical patient safety component.

FISCAL AND ECONOMIC IMPACT:

The proposed revisions to OAR 325-001-0000 to 325-030-0060 will have no fiscal impact and would maintain the current funding model for the program included in the statutes—the Patient Safety Reporting Program (PSRP).

COST OF COMPLIANCE:
(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

PSRP is funded through annual fees assessed on eligible licensed Oregon healthcare facilities (ORS 442.850). Annual fees are set in administrative rule (current: OAR 325-010-0001 to 325-030-0060; proposed: 325-011-055) and support operating costs for the program. The Oregon Patient Safety Commission Board of Directors annually adjusts fees at a rate equal to the annual average Consumer Price Index (CPI) for All Urban Consumers.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

We held a RAC that included representatives for Ambulatory Surgery Centers, Community Pharmacies, Hospitals,

Nursing Facilities, physicians and nurses.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:
325-001-0000, 325-001-0001, 325-010-0000, 325-010-0001, 325-010-0005, 325-010-0010, 325-010-0015, 325-010-0020, 325-010-0025, 325-010-0030, 325-010-0035, 325-010-0040, 325-010-0045, 325-010-0050, 325-010-0055, 325-010-0060, 325-011-0001, 325-011-0002, 325-011-0005, 325-011-0010, 325-011-0015, 325-011-0020, 325-011-0025, 325-011-0030, 325-011-0035, 325-011-0040, 325-011-0045, 325-011-0050, 325-011-0055, 325-015-0001, 325-015-0005, 325-015-0010, 325-015-0015, 325-015-0020, 325-015-0025, 325-015-0030, 325-015-0035, 325-015-0040, 325-015-0045, 325-015-0050, 325-015-0055, 325-015-0060, 325-020-0001, 325-020-0005, 325-020-0010, 325-020-0015, 325-020-0020, 325-020-0025, 325-020-0026, 325-020-0030, 325-020-0035, 325-020-0040, 325-020-0045, 325-020-0050, 325-020-0055, 325-025-0001, 325-025-0005, 325-025-0010, 325-025-0015, 325-025-0020, 325-025-0025, 325-025-0030, 325-025-0035, 325-025-0040, 325-025-0045, 325-025-0050, 325-025-0055, 325-025-0060, 325-030-0001, 325-030-0005, 325-030-0010, 325-030-0015, 325-030-0020, 325-030-0025, 325-030-0030, 325-030-0035, 325-030-0040, 325-030-0045, 325-030-0050, 325-030-0055, 325-030-0060

REPEAL: 325-001-0000

RULE SUMMARY: This rule is being repealed because it is no longer necessary.

CHANGES TO RULE:

~~325-001-0000~~
~~Notice of Rule~~
~~OAR 325-001-0001 is made retroactive to September 26, 2005.~~
~~Statutory/Other Authority: ORS 442.820, Sec. 9 Ch. 686 OL 2003~~
~~Statutes/Other Implemented: ORS 183.341(4)~~

AMEND: 325-001-0001

RULE SUMMARY: Updates list of interested parties.

CHANGES TO RULE:

325-001-0001
Notice To Interested Persons ¶

Before adopting, amending, or repealing any permanent rule, the Patient Safety Commission will give notice of its intended action:¶
(1) In the Secretary of State's Bulletin referred to in ORS 183.360 at least 21 days before the effective date of the rule;¶
(2) By providing a copy of the notice to persons on the Patient Safety Commission's distribution list established pursuant to ORS 183.335(8) at least 28 days before the effective date of the rule;¶
(3) By providing a copy of the notice to legislators specified in ORS 183.335(15) at least 49 days before the effective date of the rule; and¶
(4) By providing a copy of the notice to:¶
(a) The ~~Oregon~~Hospital Association of ~~Hospitals and Health Systems~~Oregon;¶
(b) The Oregon Health Care Association;¶
(c) Oregon State Pharmacy Association;¶
(d) Oregon Medical Association;¶
(e) The Oregon Board of Pharmacy;¶
(f) Oregon Nurses Association;¶
(g) The Oregon Ambulatory Surgery Center Association; ¶
(h) Affected health care facilities and pharmacies;¶
~~(h) Capitol Press Room;~~ and¶
(5) By putting a copy of proposed rules on the Commission website.
Statutory/Other Authority: ORS 442.820, 442.831
Statutes/Other Implemented: ORS 183.341(4)

REPEAL: 325-010-0000

RULE SUMMARY: This rule is repealed because it's no longer necessary.

CHANGES TO RULE:

~~325-010-0000~~
~~Applicability of Rules~~
~~OAR 325-010-0001 to 0060 are made retroactive to February 2, 2006.~~
~~Statutory/Other Authority: ORS 686, 182.456 - 182.472, OL 2003 Sec. 4, 6, 9~~
~~Statutes/Other Implemented: ORS 442.820 - 442.835~~

REPEAL: 325-010-0001

RULE SUMMARY: This rule is repealed and replaced by OAR 325-011-0001.

CHANGES TO RULE:

~~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, as defined in ORS 442.015(15) 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 ORS 442.837, 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 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 incorporated by reference.¶~~
~~[ED. NOTE: Appendices referenced are available from the agency.]~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819 - 442.851~~

REPEAL: 325-010-0005

RULE SUMMARY: This rule is repealed and replaced by 325-011-0045.

CHANGES TO RULE:

~~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 participation agreement. The participation agreement 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 family member. The Hospital Participant must provide copies to the Commission upon request.¶~~
~~(5) Within 30 calendar days of receipt and acceptance of the participation agreement 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 maintain and update a website that lists all Hospital Participants.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-010-0010

RULE SUMMARY: This rule is repealed and replaced by 325-011-0055.

CHANGES TO RULE:

~~325-010-0010~~
~~Annual Hospital Participant Fee~~
~~(1) All hospitals licensed under ORS 441.015 must pay an annual fee. Per ORS 442.850 these fees will be assessed independent of participation status in the Oregon Patient Safety Reporting Program. Fees for hospitals are as follows:¶~~
~~(a) $1,150 for a hospital with 3,000 or fewer patient discharges per year.¶~~
~~(b) $4,000 for a hospital with 3,001 to 10,000 patient discharges per year.¶~~
~~(c) $9,750 for a hospital with more than 10,000 patient discharges per year.¶~~
~~(2) Initial fees will be due by December 31 of the year a hospital becomes licensed by the state of Oregon. Annual fees will be due by December 31 each year. Any uncollected fees are turned over to the Department of Revenue for collection on or after April 1 following the date of invoice.¶~~
~~(3) No participation fees will be refunded due to withdrawal or termination from the Oregon Patient Safety Reporting Program.¶~~
~~(4) Fees shall be annually adjusted by the Commission Board, at a rate equal to the annual average Consumer Price Index for All Urban Consumers of the Portland, Oregon, Metropolitan Statistical Area, as compiled by the United States Department of Labor, Bureau of Labor Statistics, for every fiscal year beginning on or after July 1, 2008.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.850, 442.851.~~

REPEAL: 325-010-0015

RULE SUMMARY: This rule is repealed and replaced by 325-011-0050.

CHANGES TO RULE:

~~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 families 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.¶~~
~~(5) 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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442. 819- 442.851~~

REPEAL: 325-010-0020

RULE SUMMARY: This rule is repealed and replaced by 325-011-0045.

CHANGES TO RULE:

~~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.~~
~~Statutory/Other Authority: ORS 441.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-010-0025

RULE SUMMARY: This rule is repealed and replaced by 325-011-0005.

CHANGES TO RULE:

~~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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-010-0030

RULE SUMMARY: This rule is repealed and replaced by 325-011-0010.

CHANGES TO RULE:

~~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. (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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-010-0035

RULE SUMMARY: This rule is repealed following changes to the OPSC statute made by SB229 in 2023.

CHANGES TO RULE:

~~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 complete, thorough, credible and acceptable are:¶~~
~~(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.~~
~~Statutory/Other Authority: ORS 686, 182.456 - 182.472, OL 2003 Sec. 4, 6, 9~~
~~Statutes/Other Implemented: ORS 442.820 - 442.835~~

REPEAL: 325-010-0040

RULE SUMMARY: This rule is repealed and replaced by 325-011-0020.

CHANGES TO RULE:

~~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.~~
~~Statutory/Other Authority: ORS: 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-010-0045

RULE SUMMARY: This rule is repealed and replaced by 325-011-0025.

CHANGES TO RULE:

~~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 ORS 442.837(4), notice provided under this subsection may not be construed as an admission of liability in a civil action.~~
~~Statutory/Other Authority: ORS442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-010-0050

RULE SUMMARY: This rule is repealed and replaced by 325-011-0030.

CHANGES TO RULE:

~~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.¶~~
~~(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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-010-0055

RULE SUMMARY: This rule is repealed and replaced by 325-011-0035.

CHANGES TO RULE:

~~325-010-0055~~
~~Protection Of Patient Safety Data~~
~~(1) The Commission is subject to all the confidentiality provisions set forth in ORS 442.820, 442.831, 442.837, and 442.846.¶~~
~~(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, 192.610 to 192.690.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-010-0060

RULE SUMMARY: This rule is repealed and replaced by 325-011-0040.

CHANGES TO RULE:

~~325-010-0060~~
~~Commissions Use Of Patient Safety Data~~
~~(1) The Commission will create an ad hoc 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.~~
~~Statutory/Other Authority: ORS 686, 182.456 - 182.472, OL 2003 Sec. 4, 6, 9~~
~~Statutes/Other Implemented: ORS 442.820 - 442.835~~

ADOPT: 325-011-0001

RULE SUMMARY: This rule defines terms for Chapter 325, Division 11 and replaces repealed rules 325-010-0001, 325-015-0001, 325-020-0001, 325-025-0001, and 325-030-0001.

CHANGES TO RULE:

325-011-0001
Definitions
As used in OAR 325-011-0001 to 325-011-0055:¶
(1) "Adverse event" means an objective and definable negative consequence of patient care, or the risk of an objective and definable negative consequence of patient care, that: ¶
(a) Is unanticipated and usually preventable; and¶
(b) Results in or presents a risk of resulting in physical injury to the patient.¶
(2) "Health care facility" as defined in ORS 442.015 means a hospital, a long term care facility, an ambulatory surgical center, a freestanding birthing center, an outpatient renal dialysis facility, or an extended stay center.¶
(3) "Oregon Patient Safety Reporting Program" means the Patient Safety Reporting Program, as defined in ORS 442.837, and operated by OPSC.¶
(4) "Participant" means an entity that reports Patient Safety Data to the Oregon Patient Safety Reporting Program, and any agent, employee, consultant, representative, volunteer or medical staff member of the entity. ¶
(5) "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 (OPSC) established in ORS 442.820;¶
(c) The utilization of Patient Safety Data by Participants;¶
(d) The utilization of Patient Safety Data by OPSC to improve the quality of care with respect to patient safety and to provide assistance to health care providers to minimize patient risk; ¶
(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; and¶
(f) Collaboration between OPSC and participants on patient safety initiatives.¶
(6) "Patient Safety Data" means oral communication or written reports, data, records, memoranda, analyses, deliberative work, statements, event investigations and 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 or otherwise working with the 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 the Patient Safety Reporting Program; ¶
(b) Are collected or prepared by a patient safety organization certified by the United States Department of Health and Human Services under 42 U.S.C. 299b-24; or¶
(c) Are created by or at the direction of the Patient Safety Reporting Program, including communication, reports, notes or records created in the course of a patient safety initiative undertaken at the direction of or in collaboration with OPSC.¶
(7) "Patient Safety Report" means a form designated by the Oregon Patient Safety Commission (OPSC) to be used for the reporting of Patient Safety Data.¶
(8) "Serious adverse event" for the purposes of OAR 325-011-0001 to 325-011-0055 means an objective and definable negative consequence of patient care, or the risk of an objective and definable negative consequence of patient care, that:¶
(a) Is unanticipated and usually preventable; and ¶
(b) Results in, or presents a significant risk of, the patient's death or serious physical injury.¶
(9) "These rules" means OAR 325-011-0001 to 325-011-0055.
Statutory/Other Authority: ORS 442.820, 442.831
Statutes/Other Implemented: ORS 442.819-442.851

ADOPT: 325-011-0002

RULE SUMMARY: This rule defines participation in the Oregon Patient Safety Reporting Program.

CHANGES TO RULE:

325-011-0002
Participation in the Oregon Patient Safety Reporting Program
(1) Participation in the Oregon Patient Safety Reporting Program is voluntary. ¶
(2) The following entities are eligible to participate:¶
(a) Hospitals as defined in ORS 442.015;¶
(b) Long term care facilities as defined in ORS 442.015;¶
(c) Pharmacies licensed under ORS chapter 689;¶
(d) Ambulatory surgical centers as defined in ORS 442.015;¶
(e) Outpatient renal dialysis facilities as defined in ORS 442.015;¶
(f) Freestanding birthing centers as defined in ORS 442.015;¶
(g) Independent professional health care societies or associations; and¶
(h) Extended stay centers licensed under ORS 441.026.
Statutory/Other Authority: ORS 442.820, 442.831
Statutes/Other Implemented: ORS 442.819-442.851

ADOPT: 325-011-0005

RULE SUMMARY: This rule describes reporting to the Oregon Patient Safety Reporting Program and replaces repealed rules 325-010-0025, 325-015-0025, 325-020-0025, 325-025-0025, and 325-030-0025.

CHANGES TO RULE:

325-011-0005
Reporting Patient Safety Data
(1) The Oregon Patient Safety Commission (OPSC) will provide Participants with the means to submit Patient Safety Reports. ¶
(2) Participants must use the format specified by OPSC when reporting Patient Safety Data. ¶
(3) If a Participant submits Patient Safety Data that does not meet established reporting requirements, OPSC may request additional information or choose not to accept submission. ¶
(4) If a Participant believes OPSC should immediately issue an alert based on a specific Adverse Event, the Participant should provide an initial report to the Commission. The Participant and Commission will work together to identify information to include in the alert.
Statutory/Other Authority: ORS 442.820, 442.831
Statutes/Other Implemented: ORS 442.819-442.851

ADOPT: 325-011-0010

RULE SUMMARY: This rule describes reporting less serious adverse events or close calls and replaces repealed rules 325-010-0030, 325-015-0030, 325-020-0026, 325-025-0030, and 325-030-0030.

CHANGES TO RULE:

325-011-0010
Reporting of Less Serious Adverse Events or Close Calls
In addition to Serious Adverse Events, Participants are also encouraged to report less serious adverse events and close calls. Participants should do so when they believe other organizations will benefit from the information or when they believe such events present the potential for significant harm.
Statutory/Other Authority: ORS 442.820, 442.831
Statutes/Other Implemented: ORS 442.819-442.851

ADOPT: 325-011-0015

RULE SUMMARY: This rule describes Board of Directors auditing and oversight of the Oregon Patient Safety Reporting Program.

CHANGES TO RULE:

325-011-0015
Auditing and oversight of the Oregon Patient Safety Reporting Program
The Oregon Patient Safety Commission (OPSC) Board of Directors will establish auditing and oversight procedures for the Oregon Patient Safety Reporting Program, including a process to: ¶
(1) Evaluate the effectiveness of the Oregon Patient Safety Reporting Program in advancing the mission of OPSC described in ORS 442.820 (2), including:¶
(a) Operating the Oregon Patient Safety Reporting Program; ¶
(b) Sharing system-level improvement techniques to reduce systems' errors; and¶
(c) Sharing evidence-based prevention practices to improve patient safety;¶
(2) Review the list of objective and definable adverse events and OPSC's definition of active participation, including:¶
(a) Determining a regular cadence at which the OPSC Board of Directors will do this review; and¶
(b) Defining criteria to evaluate if changes are needed; and¶
(3) Obtain certification by the Public Health Officer that OPSC is administering the Oregon Patient Safety Reporting Program consistent with the mission described in ORS 442.820 (2) and the requirements of 442.831 (1).
Statutory/Other Authority: ORS 442.820, 442.831
Statutes/Other Implemented: ORS 442.819-442.851

ADOPT: 325-011-0020

RULE SUMMARY: This rule describes public health officer certification and replaces repealed rules 325-010-0040, 325-015-0040, 325-020-0035, 325-025-0040, and 325-030-0040.

CHANGES TO RULE:

325-011-0020
Public Health Officer Certification
(1) At least annually, the Oregon Patient Safety Commission (OPSC) will request that the Public Health Officer certify that OPSC is administering the patient safety reporting program consistent with the mission described in ORS 442.820 (2) and the requirements of ORS 442.831 (1). OPSC will request that the Public Health Officer:¶
(a) Develop independent and objective standards for their evaluation; and¶
(b) Use those standards to certify the Oregon Patient Safety Reporting Program.¶
(2) OPSC will provide information to the Public Health Officer to assist the Public Health Officer in completing the certification processes listed in (1) of this rule, consistent with OAR 325-011-0035.
Statutory/Other Authority: ORS 442.820, 442.831
Statutes/Other Implemented: ORS 442.819-442.851

ADOPT: 325-011-0025

RULE SUMMARY: This rule describes patient notification of serious adverse events and replaces repealed rules 325-010-0045, 325-015-0045, 325-020-0040, 325-025-0045, and 325-030-0045.

CHANGES TO RULE:

325-011-0025
Patient Notification of Serious Adverse Events
(1) After a Serious Adverse Event occurs, a Participant must notify each affected patient or the patient's personal representative. Notification must be timely and should be consistent with the Participant's internal communication and disclosure policies.¶
(2) The Oregon Patient Safety Commission (OPSC) encourages Participants to notify each affected patient or the patient's personal representative of less serious adverse events.¶
(3) As provided in ORS 442.837(4), notification provided under this subsection may not be construed as an admission of liability in a civil action.
Statutory/Other Authority: ORS 442.820, 442.831
Statutes/Other Implemented: ORS 442.819-442.851

ADOPT: 325-011-0030

RULE SUMMARY: This rule describes extensions and waivers and replaces repealed rules 325-010-0050, 325-015-0050, 325-020-0045, 325-025-0050, and 325-030-0050.

CHANGES TO RULE:

325-011-0030
Extensions and Waivers
(1) The Oregon Patient Safety Commission (OPSC) may grant an extension of any time requirement associated with reporting Patient Safety Data if the Participant provides justification that the extension will not adversely affect OPSC's purposes. ¶
(2) OPSC may waive any other provision of these rules if the Participant provides justification that the waiver will not adversely affect OPSC's purposes.
Statutory/Other Authority: ORS 442.820, 442.831
Statutes/Other Implemented: ORS 442.819-442.851

ADOPT: 325-011-0035

RULE SUMMARY: This rule describes protection of patient safety data and replaces repealed rules 325-010-0055, 325-015-0055, 325-020-0050, 325-025-0055, and 325-030-0055.

CHANGES TO RULE:

325-011-0035
Protection of Patient Safety Data
(1) The Oregon Patient Safety Commission (OPSC) is subject to all the confidentiality provisions set forth in ORS 442.820, 442.831, 442.837, and 442.846. ¶
(2) OPSC will maintain the confidentiality of all Patient Safety Data that identifies or could be reasonably used to identify a Participant or an individual who is receiving or has received health care from the Participant. ¶
(3) Before it takes receipt of any confidential Patient Safety Data, OPSC 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, 192.610 to 192.690.
Statutory/Other Authority: ORS 442.820, 442.831
Statutes/Other Implemented: ORS 442.819-442.851

ADOPT: 325-011-0040

RULE SUMMARY: This rule describes the Commissions use of patient safety data and replaces repealed rules 325-010-0060, 325-015-0060, 325-020-0055, 325-025-0060, and 325-030-0060.

CHANGES TO RULE:

325-011-0040
Commissions Use of Patient Safety Data
(1) The Oregon Patient Safety Commission (OPSC) may create ad hoc committees to advise OPSC on best practices in patient safety, including but not limited to learning from and sharing Patient Safety Data. ¶
(2) At least quarterly, OPSC will provide Participants with patient safety information derived from Patient Safety Data. ¶
(3) At least annually, OPSC will publish a report to the public summarizing Patient Safety Data for the preceding calendar year. ¶
(4) OPSC 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 use of Patient Safety Data. ¶
(5) OPSC, within its resource limitations, will provide technical assistance to Participants, including but not limited to recommendations or advice regarding patient safety systems and practices, and use of the Oregon Patient Safety Reporting Program. ¶
(6) OPSC may initiate other projects using patient safety data when consistent with its mission and in accordance with existing confidentiality protections.
Statutory/Other Authority: ORS 442.820, 442.831
Statutes/Other Implemented: ORS 442.819-442.851

ADOPT: 325-011-0045

RULE SUMMARY: This rule describes enrollment in the Oregon Patient Safety Reporting Program and replaces repealed rules 325-010-0005, 325-010-0020, 325-015-0005, 325-015-0020, 325-020-0005, 325-020-0020, 325-025-0005, 325-025-0020, 325-030-0005, and 325-030-0020.

CHANGES TO RULE:

325-011-0045
Enrollment in the Oregon Patient Safety Reporting Program
(1) Participants in the Oregon Patient Safety Reporting Program are entitled to the benefits and subject to the obligations set forth in these rules.¶
(2) Eligible entities may apply for participation in the Oregon Patient Safety Reporting Program by completing Oregon Patient Safety Commission (OPSC)'s participation agreement. The participation agreement must include the name of a designated contact person. Participants are responsible for informing OPSC of any changes to information on the participation agreement.¶
(3) In agreeing to participate an eligible entity must affirm that it is willing to fully share requested Patient Safety Data with OPSC. This statement must be signed by a facility executive who is authorized to sign.¶
(4) Upon enrolling in the Oregon Patient Safety Reporting Program, the Participant must provide copies to OPSC upon request of its policies and procedures describing patient safety activities, including, how it: ¶
(a) Incorporates health equity into its patient safety activities;¶
(b) Monitors the effectiveness of patient safety or quality improvement efforts over time; ¶
(c) Triages adverse events; ¶
(d) Investigates adverse events; and¶
(e) Notifies affected patients or their personal representatives of a serious adverse event.¶
(5) OPSC will make an enrollment determination and notify the applicant of that decision within 30 calendar days of receipt of the participation agreement.¶
(6) A participant that withdraws from the Oregon Patient Safety Program may re-apply for enrollment under section (2) of this rule.
Statutory/Other Authority: ORS 442.820, 442.831
Statutes/Other Implemented: ORS 442.819-442.851

ADOPT: 325-011-0050

RULE SUMMARY: This rule describes withdrawal from the Oregon Patient Safety Reporting Program and replaces repealed rules 325-010-0015, 325-015-0015, 325-020-0015, 325-025-0015, and 325-030-0015.

CHANGES TO RULE:

325-011-0050
Withdrawal from the Oregon Patient Safety Reporting Program
If a Participant chooses to withdraw from the Oregon Patient Safety Reporting Program, it must submit its withdrawal request in writing to the Oregon Patient Safety Commission (OPSC). The request must include its reason for withdrawing from the program. OPSC will process the request and remove the facility from the list of participants within 30 days.
Statutory/Other Authority: ORS 442.820, 442.831
Statutes/Other Implemented: ORS 442.819-442.851

ADOPT: 325-011-0055

RULE SUMMARY: This rule defines annual participant fees for the Oregon Patient Safety Reporting Program and replaces repealed rules 325-010-0010, 325-015-0010, 325-020-0010, 325-025-0010, and 325-030-0010.

CHANGES TO RULE:

325-011-0055
Annual Participant Fee
(1) All hospitals, ambulatory surgery centers, and renal dialysis facilities licensed under ORS 441.015, all community retail pharmacies licensed under ORS 689, and all long term care facilities licensed under OAR 411, division 085 must pay an annual fee. Per ORS 442.850 these fees will be assessed independent of participation status in the Oregon Patient Safety Reporting Program. Health care facilities must pay according to the following table for the 2024 calendar year: [See attached table.]¶
(2) Initial fees will be due by December 31 of the year a health care facility becomes licensed by the state of Oregon. Annual fees for a calendar year will be due by December 31 of the prior calendar year. Any uncollected fees are turned over to the Department of Revenue for collection on or after April 1 following the date of invoice. ¶
(3) Participation fees will not be refunded due to participant withdrawal from the Oregon Patient Safety Reporting Program.¶
(4) Fees shall be annually adjusted by the Oregon Patient Safety Commission (OPSC) Board of Directors, at a rate equal to the annual average Consumer Price Index for All Urban Consumers, West Region (All Items), as published by the United States Department of Labor, Bureau of Labor Statistics for every fiscal year.
Statutory/Other Authority: ORS 442.820, 442.831
Statutes/Other Implemented: ORS 442.850-442.851

RULE ATTACHMENTS DO NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

Oregon Patient Safety Reporting Program Annual Participant Fee Table

Health Care Facility Type	Size	2024 Fee Per Facility
Ambulatory surgery centers licensed under ORS 441.015		$1,272
Hospitals licensed under ORS 441.015	Hospital with 3,000 or fewer patient discharges per year	$1,499
	Hospital with 3,001 to 10,000 patient discharges per year	$5,213
	Hospital with more than 10,000 patient discharges per year	$12,708
Community retail pharmacies licensed under ORS Chapter 689	Pharmacies with less than 20 locations	$260
	Pharmacies with 20 locations or more	$619
Long term care facilities licensed under OAR 411, division 085	Long term care facilities with six beds or less	$195
	Long term care facilities with greater than six beds	$1,043
Renal dialysis facilities as defined in ORS 442.015		$750

REPEAL: 325-015-0001

RULE SUMMARY: This rule is repealed and replaced by OAR 325-011-0001.

CHANGES TO RULE:

~~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 ORS 442.837, 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 ORS 442.820, 442.837;¶~~
~~(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.~~
~~Statutory/Other Authority: ORS ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-015-0005

RULE SUMMARY: This rule is repealed and replaced by 325-011-0045.

CHANGES TO RULE:

~~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 participation agreement. The participation agreement must include the name of the Pharmacist-in-Charge and a designated contact person. Changes to any information on the participation agreement 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 participation agreement 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 maintain and update a website that lists all Pharmacy Participants.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-015-0010

RULE SUMMARY: This rule is repealed and replaced by 325-011-0055.

CHANGES TO RULE:

~~325-015-0010~~
~~Annual Pharmacy Participant Fee~~
~~(1) All community retail pharmacies licensed under ORS Chapter 689 must pay an annual fee. Per ORS 442.850 these fees will be assessed independent of participation status in the Oregon Patient Safety Reporting Program. Pharmacies with less than 20 locations will pay an annual fee of $200 per pharmacy. Pharmacies with 20 locations or more will pay an annual fee of $475 per pharmacy.¶~~
~~(2) Initial fees will be due by December 31 of the year a pharmacy becomes licensed by the state of Oregon. Annual fees will be due by December 31 each year. Any uncollected fees are turned over to the Department of Revenue for collection on or after April 1 following the date of invoice.¶~~
~~(3) No participation fees will be refunded due to withdrawal or termination from the Oregon Patient Safety Reporting Program.¶~~
~~(4) Fees shall be annually adjusted by the Commission Board, at a rate equal to the annual average Consumer Price Index for All Urban Consumers of the Portland, Oregon, Metropolitan Statistical Area, as compiled by the United States Department of Labor, Bureau of Labor Statistics, for every fiscal year beginning on or after July 1, 2008.~~
~~Statutory/Other Authority: ORS 442.820.~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-015-0015

RULE SUMMARY: This rule is repealed and replaced by 325-011-0050.

CHANGES TO RULE:

~~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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-015-0020

RULE SUMMARY: This rule is repealed and replaced by 325-011-0045.

CHANGES TO RULE:

~~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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-015-0025

RULE SUMMARY: This rule is repealed and replaced by 325-011-0005.

CHANGES TO RULE:

~~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.~~
~~Statutory/Other Authority: ORS442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-015-0030

RULE SUMMARY: This rule is repealed and replaced by 325-011-0010.

CHANGES TO RULE:

~~325-015-0030~~
~~Pharmacy Reporting of Less Serious Adverse Events or Close Calls~~
~~(1) In addition to Reportable Adverse Events, Participating Pharmacies are also encouraged to report less serious events or 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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-015-0035

RULE SUMMARY: This rule is repealed following changes to the OPSC statute made by SB229 in 2023.

CHANGES TO RULE:

~~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. The definitions for the terms complete, thorough, credible and acceptable are:¶~~
~~(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 (e.g., 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 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 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.~~
~~Statutory/Other Authority: ORS 442.820.~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-015-0040

RULE SUMMARY: This rule is repealed and replaced by 325-011-0020.

CHANGES TO RULE:

~~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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-015-0045

RULE SUMMARY: This rule is repealed and replaced by 325-011-0025.

CHANGES TO RULE:

~~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 ORS 442.837(4), notice provided under this subsection may not be construed as an admission of liability in a civil action.~~
~~Statutory/Other Authority: ORS 442.820.~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-015-0050

RULE SUMMARY: This rule is repealed and replaced by 325-011-0030.

CHANGES TO RULE:

~~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.¶~~
~~(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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-015-0055

RULE SUMMARY: This rule is repealed and replaced by 325-011-0035.

CHANGES TO RULE:

~~325-015-0055~~
~~Protection of Patient Safety Data~~
~~(1) The Commission is subject to all the confidentiality provisions set forth in ORS 442.820, 442.831, 442.837, and 442.846.¶~~
~~(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, 192.610 to 192.690~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-015-0060

RULE SUMMARY: This rule is repealed and replaced by 325-011-0040.

CHANGES TO RULE:

~~325-015-0060~~
~~Commissions Use of Patient Safety Data~~
~~(1) The Commission will create an ad hoc 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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-020-0001

RULE SUMMARY: This rule is repealed and replaced by OAR 325-011-0001.

CHANGES TO RULE:

~~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(18) 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 ORS 442.837, 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 ORS 442.837 and 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, incorporated by reference.¶~~
~~[ED. NOTE: Appendices referenced are available from the agency.]~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-020-0005

RULE SUMMARY: This rule is repealed and replaced by 325-011-0045.

CHANGES TO RULE:

~~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 participation agreement. The participation agreement 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 participation agreement 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 maintain and update a website that lists all Long Term Care Facility Participants.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-020-0010

RULE SUMMARY: This rule is repealed and replaced by 325-011-0055.

CHANGES TO RULE:

~~325-020-0010~~
~~Annual Long Term Care Facility Participant Fee~~
~~(1) All long term care facilities licensed under OAR 411, division 085 must pay an annual fee. Per ORS 442.850 these fees will be assessed independent of participation status in the Oregon Patient Safety Reporting Program. Long term care facilities with six beds or less will pay an annual fee of $150 per long term care facility. Long term care facilities with greater than six beds will pay an annual fee of $800 per long term care facility.¶~~
~~(2) Initial fees will be due by December 31 of the year a long term care facility becomes licensed by the state of Oregon. Annual fees will be due by December 31 each year. Any uncollected fees are turned over to the Department of Revenue for collection on or after April 1 following the date of invoice.¶~~
~~(3) No participation fees will be refunded due to withdrawal or termination from the Oregon Patient Safety Reporting Program.¶~~
~~(4) Fees shall be annually adjusted by the Commission Board, at a rate equal to the annual average Consumer Price Index for All Urban Consumers of the Portland, Oregon, Metropolitan Statistical Area, as compiled by the United States Department of Labor, Bureau of Labor Statistics, for every fiscal year beginning on or after July 1, 2008.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-020-0015

RULE SUMMARY: This rule is repealed and replaced by 325-011-0050.

CHANGES TO RULE:

~~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.¶~~
~~(5) 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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: 442.819-442.851~~

REPEAL: 325-020-0020

RULE SUMMARY: This rule is repealed and replaced by 325-011-0045.

CHANGES TO RULE:

~~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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-020-0025

RULE SUMMARY: This rule is repealed and replaced by 325-011-0005.

CHANGES TO RULE:

~~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 45 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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-020-0026

RULE SUMMARY: This rule is repealed and replaced by 325-011-0010.

CHANGES TO RULE:

~~325-020-0026~~
~~Long Term Care Reporting of Less Serious Adverse Events or Close Calls~~
~~(1) In addition to Reportable Serious Adverse Events, Long Term Care Facility Participants are also encouraged to report less serious adverse events or close calls. Long Term Care Facility Participants should do so when they believe other organizations will benefit from the information.¶~~
~~(2) To report such events, Long Term Care Facility Participants should use the appropriate sections of the Event Report form.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-020-0030

RULE SUMMARY: This rule is repealed following changes to the OPSC statute made by SB229 in 2023.

CHANGES TO RULE:

~~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 complete, thorough, credible and acceptable are:¶~~
~~(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 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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-020-0035

RULE SUMMARY: This rule is repealed and replaced by 325-011-0020.

CHANGES TO RULE:

~~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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-020-0040

RULE SUMMARY: This rule is repealed and replaced by 325-011-0025.

CHANGES TO RULE:

~~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 ORS 837(4), notice provided under this subsection may not be construed as an admission of liability in a civil action.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-020-0045

RULE SUMMARY: This rule is repealed and replaced by 325-011-0030.

CHANGES TO RULE:

~~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.¶~~
~~(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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-020-0050

RULE SUMMARY: This rule is repealed and replaced by 325-011-0035.

CHANGES TO RULE:

~~325-020-0050~~
~~Protection Of Patient Safety Data~~
~~(1) The Commission is subject to all the confidentiality provisions set forth in ORS 442.820, 442.831, 442.837, and 442.846.¶~~
~~(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, 192.610 to 192.690.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-020-0055

RULE SUMMARY: This rule is repealed and replaced by 325-011-0040.

CHANGES TO RULE:

~~325-020-0055~~
~~Commissions Use Of Patient Safety Data~~
~~(1) The Commission will create an ad hoc 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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-025-0001

RULE SUMMARY: This rule is repealed and replaced by OAR 325-011-0001.

CHANGES TO RULE:

~~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 ORS 442.837, 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 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.¶~~
~~[ED. NOTE: Appendices referenced are available from the agency.]~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-025-0005

RULE SUMMARY: This rule is repealed and replaced by 325-011-0045.

CHANGES TO RULE:

~~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 participation agreement. The participation agreement 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 participation agreement 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 maintain and update a website that lists all Ambulatory Surgery Center Participants.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-025-0010

RULE SUMMARY: This rule is repealed and replaced by 325-011-0055.

CHANGES TO RULE:

~~325-025-0010~~
~~Annual Ambulatory surgery center Participant Fee~~
~~(1) All ambulatory surgery centers licensed under ORS 441.015 must pay an annual fee of $975 for each facility. Per ORS 442.850 these fees will be assessed independent of participation status in the Oregon Patient Safety Reporting Program.¶~~
~~(2) Initial fees will be due by December 31 of the year an ambulatory surgery center becomes licensed by the state of Oregon. Annual fees will be due by December 31 each year. Any uncollected fees are turned over to the Department of Revenue for collection on or after April 1 following the date of invoice.¶~~
~~(3) No participation fees will be refunded due to withdrawal or termination from the Oregon Patient Safety Reporting Program.¶~~
~~(4) Fees shall be annually adjusted by the Commission Board, at a rate equal to the annual average Consumer Price Index for All Urban Consumers of the Portland, Oregon, Metropolitan Statistical Area, as compiled by the United States Department of Labor, Bureau of Labor Statistics, for every fiscal year beginning on or after July 1, 2008.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-025-0015

RULE SUMMARY: This rule is repealed and replaced by 325-011-0050.

CHANGES TO RULE:

~~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 an 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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-025-0020

RULE SUMMARY: This rule is repealed and replaced by 325-011-0045.

CHANGES TO RULE:

~~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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-025-0025

RULE SUMMARY: This rule is repealed and replaced by 325-011-0005.

CHANGES TO RULE:

~~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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-025-0030

RULE SUMMARY: This rule is repealed and replaced by 325-011-0010.

CHANGES TO RULE:

~~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 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.¶~~
~~(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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-025-0035

RULE SUMMARY: This rule is repealed following changes to the OPSC statute made by SB229 in 2023.

CHANGES TO RULE:

~~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 complete, thorough, credible and acceptable are:¶~~
~~(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 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 an 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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-025-0040

RULE SUMMARY: This rule is repealed and replaced by 325-011-0020.

CHANGES TO RULE:

~~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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-025-0045

RULE SUMMARY: This rule is repealed and replaced by 325-011-0025.

CHANGES TO RULE:

~~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 ORS 442.837(4), notice provided under this subsection may not be construed as an admission of liability in a civil action.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-025-0050

RULE SUMMARY: This rule is repealed and replaced by 325-011-0030.

CHANGES TO RULE:

~~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.¶~~
~~(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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-025-0055

RULE SUMMARY: This rule is repealed and replaced by 325-011-0035.

CHANGES TO RULE:

~~325-025-0055~~
~~Protection Of Patient Safety Data~~
~~(1) The Commission is subject to all the confidentiality provisions set forth in ORS 442.820, 442.831, 442.837, and 442.846.¶~~
~~(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, 192.610 to 192.690.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-025-0060

RULE SUMMARY: This rule is repealed and replaced by 325-011-0040.

CHANGES TO RULE:

~~325-025-0060~~
~~Commissions Use Of Patient Safety Data~~
~~(1) The Commission will create an ad hoc 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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819-442.851~~

REPEAL: 325-030-0001

RULE SUMMARY: This rule is repealed and replaced by OAR 325-011-0001.

CHANGES TO RULE:

~~325-030-0001~~
~~Definitions~~
~~As used in OAR 325-030-0001 to 325-030-0060:¶~~
~~(1) "Commission" means the Oregon Patient Safety Commission.¶~~
~~(2) "Event Report" means the form designated by the Commission to be used by Renal Dialysis Participants for the reporting of Reportable Renal Dialysis Adverse Events.¶~~
~~(3) "Renal Dialysis Participant" means an outpatient renal dialysis facility 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 ORS 442.837, and operated by the Commission.¶~~
~~(5) "Participant" means an entity that reports Patient Safety Data to the Oregon 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 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 the Oregon 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 the Oregon 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 the Oregon 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 325-030-0001 to 325-030-0060 means any unanticipated, usually preventable consequences of patient care that result in patient death or serious physical injury. 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.¶~~
~~NOTE: In addition, Reportable Adverse Events include those described in Appendix A. Appendix A is incorporated by reference.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819 - 442.851, 442.837(2)(e)~~

REPEAL: 325-030-0005

RULE SUMMARY: This rule is repealed and replaced by 325-011-0045.

CHANGES TO RULE:

~~325-030-0005~~
~~Enrollment in the Oregon Patient Safety Reporting Program~~
~~(1) Participation in the Oregon Patient Safety Reporting Program is voluntary. Renal Dialysis Participants are entitled to the benefits and subject to the obligations set forth in these administrative rules.¶~~
~~(2) Interested Renal Dialysis Facilities may apply for participation in the Oregon Patient Safety Reporting Program by completing the Commission's participation agreement. The participation agreement must include the name of a designated contact person. Changes to any information on the participation agreement must be reported to the Commission with 30 days of the effective change.¶~~
~~(3) In agreeing to participate, a Renal Dialysis Facility must affirm that it is willing to share fully all requested Patient Safety Data with the Commission. This statement must be signed by the Renal Dialysis Facility's regional chief executive and Quality Director, or their equivalents.¶~~
~~(4) Upon enrolling in the Oregon Patient Safety Reporting Program, a Renal Dialysis 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 Renal Dialysis Participant must provide copies to the Commission upon request.¶~~
~~(5) Within 30 calendar days of receipt and acceptance of the participation agreement the Commission will issue a certificate establishing a Renal Dialysis Participant's enrollment in the Oregon Patient Safety Reporting Program. The Renal Dialysis Participant should conspicuously post the certificate in public view.¶~~
~~(6) The Commission will maintain and update a website that lists all Renal Dialysis Participants.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819 - 442.851, 442.837(2)(e)~~

REPEAL: 325-030-0010

RULE SUMMARY: This rule is repealed and replaced by 325-011-0055.

CHANGES TO RULE:

~~325-030-0010~~
~~Annual Renal Dialysis Fee~~
~~(1) All renal dialysis facilities, as defined in ORS 442.015, must pay an annual fee of $750. Per ORS 442.850 these fees will be assessed independent of participation status in the Oregon Patient Safety Reporting Program.¶~~
~~(2) Initial fees will be due by December 31 of the year a renal dialysis facility becomes licensed by the state of Oregon. Annual fees will be due by December 31 each year. Any uncollected fees are turned over to the Department of Revenue for collection on or after April 1 following the date of invoice.¶~~
~~(3) Fees shall be annually adjusted by the Commission Board, at a rate equal to the annual average Consumer Price Index for All Urban Consumers of the Portland, Oregon, Metropolitan Statistical Area, as compiled by the United States Department of Labor, Bureau of Labor Statistics, for every fiscal year beginning on or after July 1, 2008.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819 - 442.851, 442.837(2)(c)~~

REPEAL: 325-030-0015

RULE SUMMARY: This rule is repealed and replaced by 325-011-0050.

CHANGES TO RULE:

~~325-030-0015~~
~~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 Adverse Event.¶~~
~~(3) If the Commission believes a Renal Dialysis Participant is not meeting its participation requirements, the Commission must provide the Renal Dialysis Participant with a written notice explaining why. The Renal Dialysis Participant will have 30 calendar days to respond and come into compliance.¶~~
~~(4) The Commission may deny, suspend, or revoke a Renal Dialysis 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 Renal Dialysis Participant enrollment in the Oregon Patient Safety Reporting Program, a Renal Dialysis Participant may request a hearing. Hearings will be held in accordance with ORS 183.310 to 183.470.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819 - 442.851, 442.837(2)(e)~~

REPEAL: 325-030-0020

RULE SUMMARY: This rule is repealed and replaced by 325-011-0045.

CHANGES TO RULE:

~~325-030-0020~~
~~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 Renal Dialysis applying for re-enrollment meets the provisions of participation.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819 - 442.851, 442.837(2)(c)~~

REPEAL: 325-030-0025

RULE SUMMARY: This rule is repealed and replaced by 325-011-0005.

CHANGES TO RULE:

~~325-030-0025~~
~~Reporting Adverse Events~~
~~(1) The Commission will provide an Event Report form to be used by Renal Dialysis Participants for reporting Reportable Adverse Events. The Event Report will include a summary description of the event; a description of the Renal Dialysis 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 325-030-0035.¶~~
~~(2) Renal Dialysis Participants must use the Event Report form when reporting Adverse Events to the Commission.¶~~
~~(3) Renal Dialysis Participants must submit a completed Event Report to the Commission within 45 calendar days of discovery of a Reportable Adverse Event.¶~~
~~(4) If a Renal Dialysis Participant believes the Commission should immediately issue an alert to all Oregon Renal Dialysis Facilities based on a specific Reportable Adverse Event, the Renal Dialysis Participant should provide an initial report to the Commission within 3 business days of discovery of the event, or sooner. The Renal Dialysis Participant and Commission will work together to identify information to include in the alert.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819 - 442.851, 442.837(2)(e)~~

REPEAL: 325-030-0030

RULE SUMMARY: This rule is repealed and replaced by 325-011-0010.

CHANGES TO RULE:

~~325-030-0030~~
~~Renal Dialysis Reporting of Close Calls and Less Serious Events~~
~~(1) In addition to Reportable Adverse Events, Participating Renal Dialysis Facilities are also encouraged to report less serious events and close calls/near misses. Participating Renal Dialysis Facilities should do so when they believe such events present the potential for significant harm.¶~~
~~(2) To report such events, Renal Dialysis Participants should use the appropriate sections of the Event Report form.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819 - 442.851, 442.837(2)(e)~~

REPEAL: 325-030-0035

RULE SUMMARY: This rule is repealed following changes to the OPSC statute made by SB229 in 2023.

CHANGES TO RULE:

~~325-030-0035~~
~~Commission Review of Reports~~
~~(1) When the Commission receives an Event Report from a Renal Dialysis Participant, the Commission will determine whether that Event Report is complete, thorough, credible, and acceptable. The definitions for the terms complete, thorough, credible and acceptable are:¶~~
~~(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 Renal Dialysis 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 Renal Dialysis Participant is incomplete or unacceptable in some manner, it will inform the Renal Dialysis Participant's contact person within 10 business days of receipt of the Event Report.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819 - 442.851, 442.837(2)(e)~~

REPEAL: 325-030-0040

RULE SUMMARY: This rule is repealed and replaced by 325-011-0020.

CHANGES TO RULE:

~~325-030-0040~~
~~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 Renal Dialysis 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 325-030-0055.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819 - 442.851, 442.837(2)(e)~~

REPEAL: 325-030-0045

RULE SUMMARY: This rule is repealed and replaced by 325-011-0025.

CHANGES TO RULE:

~~325-030-0045~~
~~Patient Notification~~
~~(1) After a Reportable Adverse Event that results in death or serious physical injury, a Renal Dialysis 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 Renal Dialysis Participant's internal communication and disclosure policies.¶~~
~~(2) As provided in ORS 442.837(4), notice provided under this subsection may not be construed as an admission of liability in a civil action.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819 - 442.851, 442.837(2)(e)~~

REPEAL: 325-030-0050

RULE SUMMARY: This rule is repealed and replaced by 325-011-0030.

CHANGES TO RULE:

~~325-030-0050~~
~~Extensions and Waivers~~
~~(1) The Commission may grant an extension of any time requirement stipulated in these rules if the Renal Dialysis 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 Renal Dialysis Participant requesting a waiver must submit a written request to the Commission prior to the deadline for the required action.¶~~
~~(2) The Commission may grant a waiver of any other provision of these rules if the Renal Dialysis Participant provides justification that granting the waiver will not adversely affect the purposes of the Commission.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819 - 442.851, 442.837(2)(e)~~

REPEAL: 325-030-0055

RULE SUMMARY: This rule is repealed and replaced by 325-011-0035.

CHANGES TO RULE:

~~325-030-0055~~
~~Protection of Patient Safety Data~~
~~(1) The Commission is subject to all the confidentiality provisions set forth in ORS 442.820, 442.831, 442.837, and 442.846.¶~~
~~(2) The Commission will maintain the confidentiality of all Patient Safety Data that identifies or could be reasonably used to identify a Renal Dialysis Participant or an individual who is receiving or has received health care from the Renal Dialysis 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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819 - 442.851, 442.837(2)(e)~~

REPEAL: 325-030-0060

RULE SUMMARY: This rule is repealed and replaced by 325-011-0040.

CHANGES TO RULE:

~~325-030-0060~~
~~Commissions Use of Patient Safety Data~~
~~(1) The Commission will create an ad hoc 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 Renal Dialysis 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 Renal Dialysis 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.~~
~~Statutory/Other Authority: ORS 442.820~~
~~Statutes/Other Implemented: ORS 442.819 - 442.851, 442.837(2)(e)~~