## **Oregon Patient Safety Commission**

## Chapter 325

The goal of the proposed rules is to consolidate what are currently five separate divisions with minor differences into a single division.

Current OAR Chapter 325 Divisions can be found on the Secretary of State website:

- OAR Chapter 325, Division 10 Oregon Patient Safety Reporting Program for Hospitals
- OAR Chapter 325, Division 15 Oregon Patient Safety Reporting Program for Pharmacies
- OAR Chapter 325, <u>Division 20</u> Oregon Patient Safety Reporting Program for Long Term Care
   Facilities
- OAR Chapter 325, <u>Division 25</u> Oregon Patient Safety Reporting Program for Ambulatory Surgery Centers
- OAR Chapter 325, <u>Division 30</u> Oregon Patient Safety Reporting Program for Outpatient Renal Dialysis Facilities

#### Division 1 PROCEDURAL RULES

#### <del>325 001 0000</del>

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) History: PSC 1 2008. f. & cert. ef. 4 14 08

#### 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 Association of Hospitals and Health Systems Hospital Association of Oregon; (b) The Oregon Health Care Association; Commented [ES\*O1]: Repeal 325-001-0000

(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;

(g h) Affected health care facilities and pharmacies; and

(h) Capitol Press Room; and

(5) By putting a copy of proposed rules on the Commission website

 Statutory/Other Authority: ORS 442.820, ORS 442.831

 Statutes/Other Implemented: ORS 183.341(4)

 History:

 PSC 2-2015, f. & cert. ef. 7-10-15

 PSC 1-2008, f. & cert. ef. 4-14-08

 Reverted to PSC 3-2005, f. & cert. ef. 9-26-05

 PSC 5-2007 (Temp), f. & cert. ef. 10-19-07 thru 4-11-08

 PSC 3-2005, f. & cert. ef. 9-26-05

#### 325-001-0005

#### **Model Rules of Procedure**

The Oregon Patient Safety Commission adopts, in their entirety, the current Attorney General's Uniform and Model Rules of Procedure under the Administrative Procedures Act.

Statutory/Other Authority: ORS 442.820 & 442.831 Statutes/Other Implemented: ORS 183.341 History: PSC 2-2015, f. & cert. ef. 7-10-15 PSC 1-2005, f. & cert. ef. 6-8-05

## Division 5 BOARD-COMMISSION ADMINISTRATION

## 325-005-0015

#### **Biennial Budget**

The Oregon Patient Safety Commission (OPSC) hereby establishes the OPSC 2023-2025 biennial budget of \$4,021,452 covering the period July 1, 2023, through June 30, 2025. The OPSC Executive Director will amend budgeted accounts as necessary, within the approved budget of \$4,021,452 for the effective operation of the agency. OPSC will not exceed the approved 2023-2025 biennium budget without amending this rule, notifying interested parties, and holding a public hearing as required by ORS Chapter 182.462. Copies of the budget are available from the OPSC office and are posted on the OPSC website.

[ED. NOTE: To view attachments referenced in rule text, click here to view rule.]

Statutory/Other Authority: ORS 442.820-442.835, ORS 442.831

Statutes/Other Implemented: ORS 182.462 History:

PSC 1-2023, amend filed 05/17/2023, effective 07/01/2023 PSC 1-2022, amend filed 12/16/2022, effective 12/19/2022 PSC 1-2021, amend filed 06/03/2021, effective 07/01/2021 PSC 1-2019, amend filed 05/21/2019, effective 06/30/2019 PSC 3-2017, f. & cert. ef. 8-1-17 PSC 2-2017, f. 5-19-17, cert. ef. 6-30-17 PSC 1-2017, f. 2-28-17, cert. ef. 3-1-17 PSC 1-2016, f. & cert. ef. 1-29-16 PSC 2-2015, f. & cert. ef. 7-10-15 PSC 1-2015. f. & cert. ef. 3-17-15 PSC 1-2014, f. 3-18-14, cert. ef. 3-21-14 PSC 2-2013, f. & cert. ef. 7-3-13 PSC 1-2013, f. & cert. ef. 4-25-13 PSC 1-2012, f. 3-27-12, cert. ef. 4-1-12 PSC 1-2011, f. & cert. ef. 7-1-11 PSC 1-2009, f. & cert. ef. 6-26-09 PSC 4-2007. f. & cert. ef. 7-2-07 PSC 1-2006, f. & cert. ef. 2-6-06

#### Division 10

Oregon Patient Safety Reporting Program for Hospitals

#### **Division 11**

## OREGON PATIENT SAFETY REPORTING PROGRAM

#### 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;

Commented [ES\*O2]: Repeal entire division

Commented [ES\*O3]: New Division

**Commented [SE4]:** For comparison to current rules, see:

- •325-010-0001
- •325-015-0001
- •325-020-0001
- •325-025-0001 •325-030-0001

(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, ORS 442.831 Statutes/Other Implemented: ORS 442.819 - 442.851 History:

#### 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.

- **Commented [SE5]:** For comparison to current rules, see:
  - •325-010-0001 (3) "Hospital participant"
  - •325-015-0001 (3) "Pharmacy participant"
  - •325-020-0001 (3) "Long Term Care Facility Participant" •325-025-0001 (3) "Ambulatory Surgery Center
- •325-025-0001 (3) /
- •325-030-0001 (3) "Renal Dialysis Participant"

Statutory/Other Authority: ORS 442.820, ORS 442.831 Statutes/Other Implemented: ORS 442.819 - 442.851 History:

#### 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, ORS 442.831 Statutes/Other Implemented: ORS 442.819-442.851 History:

#### 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, ORS 442.831 Statutes/Other Implemented: ORS 442.819-442.851 History:

#### 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

Commented [SE6]: For comparison to current rules, see:

- •325-010-0025
- •325-015-0025
- •325-020-0025
- •325-025-0025 •325-030-0025

Commented [SE7]: For comparison to current rules, see:

- •325-010-0030
- •325-015-0030
- •325-020-0026 •325-025-0030
- 325-025-0030
  325-030-0030

**Commented [SE8]:** New section that is not found in OPSC's existing administrative rules.

(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, ORS 442.831 Statutes/Other Implemented: ORS 442.819-442.851 History:

#### 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, ORS 442.831 Statutes/Other Implemented: ORS 442.819-442.851 History:

#### 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, ORS 442.831 Statutes/Other Implemented: ORS 442.819-442.851 History:

#### 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.

#### Commented [SE9]: For comparison to current rules, see:

- •325-010-0040 •325-015-0040
- •325-015-0040
- •325-020-0035 •325-025-0040
- •325-030-0040

Commented [SE10]: For comparison to current rules, see: •325-010-0045

- •325-010-0
  - •325-015-0045
- •325-020-0040
- •325-025-0045 •325-030-0045

Commented [SE11]: For comparison to current rules, see:

- •325-010-0050
- •325-015-0050
- •325-020-0045 •325-025-0050
- •325-030-0050

(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, ORS 442.831 Statutes/Other Implemented: ORS 442.819-442.851 History:

#### 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, ORS 442.831 Statutes/Other Implemented: ORS 442.819-442.851 History:

#### 325-011-0040

#### **Commission's Use of Patient Safety Data**

 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.
 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, ORS 442.831 Statutes/Other Implemented: ORS 442.819-442.851 History:

#### Commented [SE12]: For comparison to current rules, see: •325-010-0055

- •325-010-0055 •325-015-0055
- •325-020-0050
- •325-025-0055
- •325-030-0055

Commented [SE13]: For comparison to current rules, see:

- •325-010-0060
- •325-015-0060
- •325-020-0055
- •325-025-0060
- •325-030-0060

#### 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, ORS 442.831 Statutes/Other Implemented: ORS 442.819-442.851 History:

#### 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, ORS 442.831 Statutes/Other Implemented: ORS 442.819-442.851 History:

#### 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

#### Commented [SE14]: For comparison to current rules, see:

- •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 & 325-030-0020

Commented [SE15]: For comparison to current rules, see: •325-010-0015

- •325-010-0015 •325-015-0015
- •325-020-0015
- •325-025-0015
- •325-030-0015

Commented [SE16]: For comparison to current rules, see:

- •325-010-0010
- •325-015-0010 •325-020-0010
- •325-025-0010
- •325-030-0010

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.

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
<b>Community retail pharmacies</b> 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

Statutory/Other Authority: ORS 442.820, ORS 442.831 Statutes/Other Implemented: ORS 442.850-442.851 History:

#### Division 15

**Oregon Patient Safety Reporting Program for Pharmacies** 

#### Division 20

Oregon Patient Safety Reporting Program for Long Term Care Facilities

#### Division 25

Oregon Patient Safety Reporting Program for Ambulatory Surgery Centers

## Division 30

Oregon Patient Safety Reporting Program for Outpatient Renal Dialysis Facilities

Commented [ES\*O17]: Repeal

# Summary of Recommendations from the Rules Advisory Committee (RAC)

## Rules Advisory Committee (RAC) Description

RAC Date: 11/20/2023

#### **RAC Members**

- Bob Dannenhoffer (OPSC Board, Physician Seat)
- Therese Hooft (Oregon Nurses Association)
- Dan Kennedy (Oregon State Pharmacy Association)
- Shanie Mason (Oregon Medical Association)
- Jessica Morris (OPSC Board, Consumer Seat)
- Nicolette Reilly (Oregon Health Care Association)
- Dana Selover (OPSC Board, Public Health Seat)
- Chris Skagen (Oregon Ambulatory Surgery Center Association)
- Meghan Slotemaker (Hospital Association of Oregon)
- Erin Sprando (OPSC Board, Nursing Facility Seat)

The goal of the proposed rules is to consolidate what is currently five separate divisions with minor differences into a single division.

## Recommendations

## 325-001-0001 Notice to Interested Persons

RAC Member	Recommendation	Agency Response
Meghan Slotemaker (HAO)	Update (4) (a) to use the current name for the Hospital Association of Oregon	Accept recommendation
Chris Skagan (OASCA)	Add OASCA to the list of interested persons	Accept recommendation
Meghan Slotemaker (HAO)	Related to (4) (g) "Affected health care facilities and	No change needed
	pharmacies"	OPSC receives quarterly lists of eligible facilities from licensing
	Question: how does OPSC accomplish this?	agencies and works to keep our mailing list up to date.

## 325-011-0001 Definitions

RAC Member	Recommendation	Agency Response
Nicolette Reilly (OHCA)	Part of definition 6 ("Patient	Accept recommendation
	Safety Data") does not match	
	the definition in statute. It	

RAC Member	Recommendation	Agency Response
	should say "of a patient safety	
	initiative" instead of "of an	
	investigation."	
	6(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 an investigation undertaken	
	at the direction of or in	
	collaboration with OPSC.	

## 325-011-0015 Auditing and oversight of the Oregon Patient Safety Reporting Program

RAC Member	Recommendation	Agency Response
Bob Dannenhoffer (OPSC Board,	Oversight is misspelled.	Accept recommendation
Physician Seat)		
	"The Oregon Patient Safety	
	Commission (OPSC) Board of	
	Directors will establish auditing	
	and <mark>oversite</mark> procedures for the	
	Oregon Patient Safety Reporting	
	Program, including a process	
	to:"	

## 325-011-0020 Public Health Officer Certification

RAC Member	Recommendation	Agency Response
Nicolette Reilly	Oregon is misspelled. (1) (b) Use those standards to certify the <mark>Orgon</mark> Patient Safety	Accept recommendation
	Reporting Program	

## 325-011-0045 Enrollment in the Oregon Patient Safety Reporting Program

RAC Member	Recommendation	Agency Response
Meghan Slotemaker (HAO)	Related to (4) (a) "Incorporates health equity into its patient	No change needed
	safety activities"	Patient safety activities are broader than just adverse
	Question: Will facilities know what OPSC is looking for here?	events. OPSC has heard from facilities that their patient safety
	Should this be tied to adverse	work includes prevention efforts before an adverse event occurs,

RAC Member	Recommendation	Agency Response
	events rather than patient	and health equity should be
	safety activities?	included in those policies and
		procedures as well.

## 325-011-0050 Withdrawal from the Oregon Patient Safety Reporting Program

RAC Member	Recommendation	Agency Response
Nicolette Reilly	Final sentence also appears in 325-011-0055 (2). It does not need to appear in both places and could be deleted in 325- 011-0050.	Accept recommendation
	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. Participation fees will not be refunded due to participant withdrawal from the Oregon Patient Safety Reporting Program.	

## 325-011-0055 Annual Participant Fee

RAC Member	Recommendation	Agency Response
Meghan Slotemaker (HAO)	Review language in 325-011-055	Accept recommendation
	(1): "Initial fees will be due by	
	December 31 of the year a	Proposed clarification: "Initial
	health care facility becomes	fees will be due by December
	licensed by the state of Oregon.	31 of the year a health care
	Annual fees will be due by	facility becomes licensed by the
	December 31 each year."	state of Oregon. Annual fees <mark>for</mark>
		<mark>a calendar year</mark> will be due by
	It's not clear if the rules mean	December 31 <mark>of the prior</mark>
	by December 31 of the current	<mark>calendar year</mark> ."
	year or the following year. The	
	wording in the proposed rule	
	could use clarification.	

RAC Member	Recommendation	Agency Response
Meghan Slotemaker (HAO)	Review language in 325-011-055	Accept recommendation
	(5): "Eligible entities must pay	
	according to the following	Proposed clarification: Re-
	table:"	ordering the paragraphs in this
		section and moving the text
	It's not clear if the fee table is	from (5) into the new paragraph
	the starting point for fee	(1), with a little clarifying
	calculations or the current fees	language. Additionally,
	facilities must pay.	removing the final clause of
	lacinties must pay.	paragraph (3), which would
		become paragraph (4).
		(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 OR
		442.850 these fees will be
		assessed independent of
		participation status in the
		Oregon Patient Safety Reporting
		Program. <mark>Health care facilities</mark>
		must pay according to the
		following table for the 2024
		<mark>calendar year: [See attached</mark>
		table.]
		(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 beginning
		<del>on or after July 1, 2008</del> .

# Rules Revision Fiscal Impact and Equity Statements

## **Equity Statement**

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 Impact Statement**

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).

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 OPSC Board of Directors annually adjusts fees at a rate equal to the annual average Consumer Price Index (CPI) for All Urban Consumers.