

# Oregon Patient Safety Commission

## Chapter 325

### Division 1

### PROCEDURAL RULES

~~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)~~

#### **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;

(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) 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

1 Reverted to PSC 3-2005, f. & cert. ef. 9-26-05  
2 PSC 5-2007 (Temp), f. & cert. ef. 10-19-07 thru 4-11-08  
3 PSC 3-2005, f. & cert. ef. 9-26-05  
4

5 325-001-0005

6 **Model Rules of Procedure**

7 The Patient Safety Commission adopts, in their entirety, the current Attorney General's Uniform and  
8 Model Rules of Procedure under the Administrative Procedures Act.  
9

10 **Statutory/Other Authority:** ORS 442.820 & 442.831

11 **Statutes/Other Implemented:** ORS 183.341

12 **History:**

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

14 PSC 1-2005, f. & cert. ef. 6-8-05  
15

16 **Division 5**

17 ~~BOARD~~ COMMISSION ADMINISTRATION

18 325-005-0015

19 **Biennial Budget**

20 The Oregon Patient Safety Commission (OPSC) hereby establishes the OPSC 2023-2025 biennial budget  
21 of \$4,021,452 covering the period July 1, 2023, through June 30, 2025. The OPSC Executive Director will  
22 amend budgeted accounts as necessary, within the approved budget of \$4,021,452 for the effective  
23 operation of the agency. OPSC will not exceed the approved 2023-2025 biennium budget without  
24 amending this rule, notifying interested parties, and holding a public hearing as required by ORS Chapter  
25 182.462. Copies of the budget are available from the OPSC office and are posted on the OPSC website.  
26

27 [ED. NOTE: To view attachments referenced in rule text, click here to view rule.]  
28

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

30 **Statutes/Other Implemented:** ORS 182.462

31 **History:**

32 PSC 1-2023, amend filed 05/17/2023, effective 07/01/2023

33 PSC 1-2022, amend filed 12/16/2022, effective 12/19/2022

34 PSC 1-2021, amend filed 06/03/2021, effective 07/01/2021

35 PSC 1-2019, amend filed 05/21/2019, effective 06/30/2019

36 PSC 3-2017, f. & cert. ef. 8-1-17

37 PSC 2-2017, f. 5-19-17, cert. ef. 6-30-17

38 PSC 1-2017, f. 2-28-17, cert. ef. 3-1-17

39 PSC 1-2016, f. & cert. ef. 1-29-16

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

41 PSC 1-2015, f. & cert. ef. 3-17-15

42 PSC 1-2014, f. 3-18-14, cert. ef. 3-21-14

43 PSC 2-2013, f. & cert. ef. 7-3-13

- 1 PSC 1-2013, f. & cert. ef. 4-25-13
- 2 PSC 1-2012, f. 3-27-12, cert. ef. 4-1-12
- 3 PSC 1-2011, f. & cert. ef. 7-1-11
- 4 PSC 1-2009, f. & cert. ef. 6-26-09
- 5 PSC 4-2007, f. & cert. ef. 7-2-07
- 6 PSC 1-2006, f. & cert. ef. 2-6-06

7

8 ~~Division 10~~

9 ~~Oregon Patient Safety Reporting Program for Hospitals~~

10 ~~Division 11~~

11 OREGON PATIENT SAFETY REPORTING PROGRAM

12 325-011-0001

13 **Definitions**

14 As used in OAR 325-011-0001 to 325-011-0055:

15 (1) "Adverse event" means an objective and definable negative consequence of patient care, or the risk  
16 of an objective and definable negative consequence of patient care, that:

17 (a) Is unanticipated and usually preventable; and

18 (b) Results in or presents a risk of resulting in physical injury to the patient.

19 (2) "Health care facility" as defined in ORS 442.015 means a hospital, a long term care facility, an  
20 ambulatory surgical center, a freestanding birthing center, an outpatient renal dialysis facility, or an  
21 extended stay center.

22 (3) "Oregon Patient Safety Reporting Program" means the Patient Safety Reporting Program, as defined  
23 in ORS 442.837, and operated by OPSC.

24 (4) "Participant" means an entity that reports Patient Safety Data to the Oregon Patient Safety Reporting  
25 Program, and any agent, employee, consultant, representative, volunteer or medical staff member of the  
26 entity.

27 (5) "Patient Safety Activities" include but are not limited to:

28 (a) The collection and analysis of Patient Safety Data by a Participant;

29 (b) The collection and analysis of Patient Safety Data by the Oregon Patient Safety Commission  
30 (OPSC) established in ORS 442.820;

31 (c) The utilization of Patient Safety Data by Participants;

32 (d) The utilization of Patient Safety Data by OPSC to improve the quality of care with respect to  
33 patient safety and to provide assistance to health care providers to minimize patient risk;

34 (e) Oral and written communication regarding Patient Safety Data among two or more

35 Participants with the intent of making a disclosure to or preparing a report to be submitted to a  
36 Patient Safety Reporting Program; and

37 (f) Collaboration between OPSC and participants on patient safety initiatives.

38 (6) "Patient Safety Data" means oral communication or written reports, data, records, memoranda,  
39 analyses, deliberative work, statements, event investigations and analyses or action plans that are  
40 collected or developed to improve patient safety or health care quality that:

41 (a) Are prepared by a Participant for the purpose of reporting Patient Safety Data voluntarily to  
42 or otherwise working with the Patient Safety Reporting Program, or that are communicated

1 among two or more Participants with the intent of making a disclosure to or preparing a report  
2 to be submitted to the Patient Safety Reporting Program;

3 (b) Are collected or prepared by a patient safety organization certified by the United States  
4 Department of Health and Human Services under 42 U.S.C. 299b-24; or

5 (c) Are created by or at the direction of the Patient Safety Reporting Program, including  
6 communication, reports, notes or records created in the course of an investigation undertaken at  
7 the direction of or in collaboration with OPSC.

8 (7) "Patient Safety Report" means a form designated by the Oregon Patient Safety Commission (OPSC) to  
9 be used for the reporting of Patient Safety Data.

10 (8) "Serious adverse event" for the purposes of OAR 325-011-0001 to 325-011-0055 means an objective  
11 and definable negative consequence of patient care, or the risk of an objective and definable negative  
12 consequence of patient care, that:

13 (a) Is unanticipated and usually preventable; and

14 (b) Results in, or presents a significant risk of, the patient's death or serious physical injury.

15 (9) "These rules" means OAR 325-011-0001 to 325-011-0055.

16  
17 **Statutory/Other Authority:** ORS 442.820, ORS 442.831

18 **Statutes/Other Implemented:** ORS 442.819 - 442.851

19 **History:**

20  
21 [325-011-0002](#)

## 22 **Participation in the Oregon Patient Safety Reporting Program**

23 (1) Participation in the Oregon Patient Safety Reporting Program is voluntary.

24 (2) The following entities are eligible to participate:

25 (a) Hospitals as defined in ORS 442.015;

26 (b) Long term care facilities as defined in ORS 442.015;

27 (c) Pharmacies licensed under ORS chapter 689;

28 (d) Ambulatory surgical centers as defined in ORS 442.015;

29 (e) Outpatient renal dialysis facilities as defined in ORS 442.015;

30 (f) Freestanding birthing centers as defined in ORS 442.015;

31 (g) Independent professional health care societies or associations; and

32 (h) Extended stay centers licensed under ORS 441.026.

33 **Statutory/Other Authority:** ORS 442.820, ORS 442.831

34 **Statutes/Other Implemented:** ORS 442.819 - 442.851

35 **History:**

36  
37 [325-011-0005](#)

## 38 **Reporting Patient Safety Data**

39 (1) The Oregon Patient Safety Commission (OPSC) will provide Participants with the means to submit  
40 Patient Safety Reports.

41 (2) Participants must use the format specified by OPSC when reporting Patient Safety Data.

42 (3) If a Participant submits Patient Safety Data that does not meet established reporting requirements,  
43 OPSC may request additional information or choose not to accept submission.

1 (4) If a Participant believes OPSC should immediately issue an alert based on a specific Adverse Event,  
2 the Participant should provide an initial report to the Commission. The Participant and Commission will  
3 work together to identify information to include in the alert.

4  
5 **Statutory/Other Authority:** ORS 442.820, ORS 442.831

6 **Statutes/Other Implemented:** ORS 442.819-442.851

7 **History:**

8  
9 325-011-0010

#### 10 **Reporting of Less Serious Adverse Events or Close Calls**

11 In addition to Serious Adverse Events, Participants are also encouraged to report less serious adverse  
12 events and close calls. Participants should do so when they believe other organizations will benefit from  
13 the information or when they believe such events present the potential for significant harm.

14  
15 **Statutory/Other Authority:** ORS 442.820, ORS 442.831

16 **Statutes/Other Implemented:** ORS 442.819-442.851

17 **History:**

18  
19 325-011-0015

#### 20 **Auditing and oversight of the Oregon Patient Safety Reporting Program**

21 The Oregon Patient Safety Commission (OPSC) Board of Directors will establish auditing and oversight  
22 procedures for the Oregon Patient Safety Reporting Program, including a process to:

23 (1) Evaluate the effectiveness of the Oregon Patient Safety Reporting Program in advancing the mission  
24 of OPSC described in ORS 442.820 (2), including:

25 (a) Operating the Oregon Patient Safety Reporting Program;

26 (b) Sharing system-level improvement techniques to reduce systems' errors; and

27 (c) Sharing evidence-based prevention practices to improve patient safety;

28 (2) Review the list of objective and definable adverse events and OPSC's definition of active participation,  
29 including:

30 (a) Determining a regular cadence at which the OPSC Board of Directors will do this review; and

31 (b) Defining criteria to evaluate if changes are needed; and

32 (3) Obtain certification by the Public Health Officer that OPSC is administering the Oregon Patient Safety  
33 Reporting Program consistent with the mission described in ORS 442.820 (2) and the requirements of  
34 442.831 (1).

35  
36 **Statutory/Other Authority:** ORS 442.820, ORS 442.831

37 **Statutes/Other Implemented:** ORS 442.819-442.851

38 **History:**

39  
40 325-011-0020

#### 41 **Public Health Officer Certification**

42 (1) At least annually, the Oregon Patient Safety Commission (OPSC) will request that the Public Health  
43 Officer certify that OPSC is administering the patient safety reporting program consistent with the

1 mission described in ORS 442.820 (2) and the requirements of ORS 442.831 (1). OPSC will request that  
2 the Public Health Officer:

3 (a) Develop independent and objective standards for their evaluation; and

4 (b) Use those standards to certify the Oregon Patient Safety Reporting Program.

5 (2) OPSC will provide information to the Public Health Officer to assist the Public Health Officer in  
6 completing the certification processes listed in (1) of this rule, consistent with OAR 325-011-0035.

7  
8 **Statutory/Other Authority:** ORS 442.820, ORS 442.831

9 **Statutes/Other Implemented:** ORS 442.819-442.851

10 **History:**

11  
12 [325-011-0025](#)

### 13 **Patient Notification of Serious Adverse Events**

14 (1) After a Serious Adverse Event occurs, a Participant must notify each affected patient or the patient's  
15 personal representative. Notification must be timely and should be consistent with the Participant's  
16 internal communication and disclosure policies.

17 (2) The Oregon Patient Safety Commission (OPSC) encourages Participants to notify each affected patient  
18 or the patient's personal representative of less serious adverse events.

19 (3) As provided in ORS 442.837(4), notification provided under this subsection may not be construed as  
20 an admission of liability in a civil action.

21  
22 **Statutory/Other Authority:** ORS 442.820, ORS 442.831

23 **Statutes/Other Implemented:** ORS 442.819-442.851

24 **History:**

25  
26 [325-011-0030](#)

### 27 **Extensions and Waivers**

28 (1) The Oregon Patient Safety Commission (OPSC) may grant an extension of any time requirement  
29 associated with reporting Patient Safety Data if the Participant provides justification that the extension  
30 will not adversely affect OPSC's purposes.

31 (2) OPSC may waive of any other provision of these rules if the Participant provides justification that the  
32 waiver will not adversely affect OPSC's purposes.

33  
34 **Statutory/Other Authority:** ORS 442.820, ORS 442.831

35 **Statutes/Other Implemented:** ORS 442.819-442.851

36 **History:**

37  
38 [325-011-0035](#)

### 39 **Protection of Patient Safety Data**

40 (1) The Oregon Patient Safety Commission (OPSC) is subject to all the confidentiality provisions set forth  
41 in ORS 442.820, 442.831, 442.837, and 442.846.

1 (2) OPSC will maintain the confidentiality of all Patient Safety Data that identifies or could be reasonably  
2 used to identify a Participant or an individual who is receiving or has received health care from the  
3 Participant.

4 (3) Before it takes receipt of any confidential Patient Safety Data, OPSC will have in place appropriate  
5 safeguards and security measures to ensure the technical integrity and physical safety of such data.

6 (4) Pursuant to ORS 442.820(4), meetings or portions of meetings where the Oregon Patient Safety  
7 Commission Board of Directors, or subcommittees or advisory committees consider information that  
8 identifies a Participant or patient are not subject to the Oregon Public Meetings Law, 192.610 to  
9 192.690.

10

11 **Statutory/Other Authority:** ORS 442.820, ORS 442.831

12 **Statutes/Other Implemented:** ORS 442.819-442.851

13 **History:**

14

15 [325-011-0040](#)

16 **Commission’s Use of Patient Safety Data**

17 (1) The Oregon Patient Safety Commission (OPSC) may create ad hoc committees to advise OPSC on best  
18 practices in patient safety, including but not limited to learning from and sharing Patient Safety Data.

19 (2) At least quarterly, OPSC will provide Participants with patient safety information derived from Patient  
20 Safety Data.

21 (3) At least annually, OPSC will publish a report to the public summarizing Patient Safety Data for the  
22 preceding calendar year.

23 (4) OPSC will work with representatives of organizations participating in the Oregon Patient Safety  
24 Reporting Program and with other interested parties to develop recommendations for continued  
25 improvements in the collection and use of Patient Safety Data.

26 (5) OPSC, within its resource limitations, will provide technical assistance to Participants, including but  
27 not limited to recommendations or advice regarding patient safety systems and practices, and use of the  
28 Oregon Patient Safety Reporting Program.

29 (6) OPSC may initiate other projects using patient safety data when consistent with its mission and in  
30 accordance with existing confidentiality protections.

31

32 **Statutory/Other Authority:** ORS 442.820, ORS 442.831

33 **Statutes/Other Implemented:** ORS 442.819-442.851

34 **History:**

35

36 [325-011-0045](#)

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

38 (1) Participants in the Oregon Patient Safety Reporting Program are entitled to the benefits and subject  
39 to the obligations set forth in these rules.

40 (2) Eligible entities may apply for participation in the Oregon Patient Safety Reporting Program by  
41 completing Oregon Patient Safety Commission (OPSC)’s participation agreement. The participation  
42 agreement must include the name of a designated contact person. Participants are responsible for  
43 informing OPSC of any changes to information on the participation agreement.

1 (3) In agreeing to participate an eligible entity must affirm that it is willing to fully share requested  
2 Patient Safety Data with OPSC. This statement must be signed by a facility executive who is authorized to  
3 sign.

4 (4) Upon enrolling in the Oregon Patient Safety Reporting Program, the Participant must provide copies  
5 to OPSC upon request of its policies and procedures describing patient safety activities, including, how it:

6 (a) Incorporates health equity into its patient safety activities;

7 (b) Monitors the effectiveness of patient safety or quality improvement efforts over time;

8 (c) Triage adverse events;

9 (d) Investigates adverse events; and

10 (e) Notifies affected patients or their personal representatives of a serious adverse event.

11 (5) OPSC will make an enrollment determination and notify the applicant of that decision within 30  
12 calendar days of receipt of the participation agreement.

13 (6) A participant that withdraws from the Oregon Patient Safety Program may re-apply for enrollment  
14 under section (2) of this rule.

15  
16 **Statutory/Other Authority:** ORS 442.820, ORS 442.831

17 **Statutes/Other Implemented:** ORS 442.819-442.851

18 **History:**

19  
20 [325-011-0050](#)

### 21 **Withdrawal from the Oregon Patient Safety Reporting Program**

22 If a Participant chooses to withdraw from the Oregon Patient Safety Reporting Program, it must submit  
23 its withdrawal request in writing to the Oregon Patient Safety Commission (OPSC). The request must  
24 include its reason for withdrawing from the program. OPSC will process the request and remove the  
25 facility from the list of participants within 30 days. Participation fees will not be refunded due to  
26 participant withdrawal from the Oregon Patient Safety Reporting Program.

27  
28 **Statutory/Other Authority:** ORS 442.820, ORS 442.831

29 **Statutes/Other Implemented:** ORS 442.819-442.851

30 **History:**

31  
32 [325-011-0055](#)

### 33 **Annual Participant Fee**

34 (1) Initial fees will be due by December 31 of the year a health care facility becomes licensed by the state  
35 of Oregon. Annual fees will be due by December 31 each year. Any uncollected fees are turned over to  
36 the Department of Revenue for collection on or after April 1 following the date of invoice.

37 (2) Participation fees will not be refunded due to participant withdrawal from the Oregon Patient Safety  
38 Reporting Program.

39 (3) Fees shall be annually adjusted by the Oregon Patient Safety Commission (OPSC) Board of Directors,  
40 at a rate equal to the annual average Consumer Price Index for All Urban Consumers, West Region (All  
41 Items), as published by the United States Department of Labor, Bureau of Labor Statistics, for every fiscal  
42 year beginning on or after July 1, 2008.

43 (4) All hospitals, ambulatory surgery centers, and renal dialysis facilities licensed under ORS 441.015, all  
44 community retail pharmacies licensed under ORS 689, and all long term care facilities licensed under



1 OAR 411, division 085 must pay an annual fee. Per ORS 442.850 these fees will be assessed independent  
 2 of participation status in the Oregon Patient Safety Reporting Program.  
 3 (5) Eligible entities must pay according to the following table: [See attached table.]  
 4

Health Care Facility Type	Size	2023 Fee Per Facility
<b>Ambulatory surgery centers</b> licensed under ORS 441.015		\$1,178
<b>Hospitals</b> licensed under ORS 441.015	Hospital with 3,000 or fewer patient discharges per year	\$1,388
	Hospital with 3,001 to 10,000 patient discharges per year	\$4,827
	Hospital with more than 10,000 patient discharges per year	\$11,767
<b>Community retail pharmacies</b> licensed under ORS Chapter 689	Pharmacies with less than 20 locations	\$241
	Pharmacies with 20 locations or more	\$573
<b>Long term care facilities</b> licensed under OAR 411, division 085	Long term care facilities with six beds or less	\$181
	Long term care facilities with greater than six beds	\$966
<b>Renal dialysis facilities</b> as defined in ORS 442.015		\$750

5  
 6 **Statutory/Other Authority:** ORS 442.820, ORS 442.831  
 7 **Statutes/Other Implemented:** ORS 442.850-442.851  
 8 **History:**  
 9

- 10 ~~Division 15~~
- 11 ~~Oregon Patient Safety Reporting Program for Pharmacies~~
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- 13 ~~Division 20~~
- 14 ~~Oregon Patient Safety Reporting Program for Long Term Care Facilities~~
- 15
- 16 ~~Division 25~~
- 17 ~~Oregon Patient Safety Reporting Program for Ambulatory Surgery~~
- 18 ~~Centers~~
- 19
- 20 ~~Division 30~~
- 21 ~~Oregon Patient Safety Reporting Program for Outpatient Renal Dialysis~~
- 22 ~~Facilities~~