

Guide to Adverse Event Reporting for Oregon Nursing Homes



*North Star Goal:
Oregon will have the safest health care system in the
country by 2010*

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The Purpose of Reporting

“A system is a network of interdependent components that work together to try to accomplish the aim of the system. A system must have an aim. Without an aim, there is no system.”

W. Edwards Deming, 1900-1993

The mission of the Oregon Patient Safety Commission is to reduce the risk of adverse events occurring in Oregon’s health care system and to encourage a culture of patient/resident safety. One way the Commission fulfills this mission is through its confidential adverse event reporting program. As nursing homes report serious adverse events, the Commission will aggregate and share the de-identified data with participants. Data will include the types of events, harm levels, contributing factors that led to the events, and action plans to prevent recurrence.

This reporting program relies on your active participation. Together, the Commission and nursing homes are creating a joint learning tool. When nursing homes confidentially share insights about adverse events, the Commission can bundle that information in ways that allow everyone to provide safer, higher quality care to residents. Your active participation is encouraged and appreciated.

What to Report and When to Report

“What we need to do is learn to work in the system, by which I mean that everybody, every team, every platform, every division, every component is there not for individual competitive profit or recognition, but for contribution to the system as a whole on a win-win basis.”

W. Edwards Deming

What

A reportable event for Oregon nursing homes is any listed adverse event that results in serious physical injury or death (see page 5 for listing).

The Commission uses a scale of 1-9 to describe levels of harm. Nursing homes only report harm scores of 7 (serious temporary harm), 8 (permanent harm) or 9 (death). The scale accounts for both the degree (serious, moderate, minimal, and no detectable) and the duration (permanent or temporary) of harm. Serious harm severely impacts a resident’s status or functional ability. Permanent harm is present at discharge and the resolution is uncertain. For a more complete description of harm levels, please refer to page 6 (NCC MERP, National Coordinating Council for Medication Error Reporting and Prevention).

Serious adverse events are:

- Unanticipated
- Usually preventable
- Result in serious physical injury or death

“Unanticipated and usually preventable” events are caused, at root, by an issue of medical or resident management. These events do not arise from the natural course of the resident’s illness or condition.

“Serious physical injury” results in transferring a resident to a higher level of care.

For a complete list of reportable events, please refer to page 5.

When

Nursing home participants must report events within 30 days of discovery. If the nursing home is not able to complete the investigation within the 30-day timeframe, the facility may request an extension.

If the nursing home believes that an adverse event points to an immediate hazard to other nursing homes (often these are equipment defects or medication problems), the Commission requests an initial notice within three business days. The Commission, in partnership with the reporting nursing home would then consider issuing an Alert to the entire healthcare community.

The Commission’s reporting program is built on quality improvement and sharing lessons learned to prevent future adverse events. Therefore, the Commission encourages reporting of all adverse events regardless of harm level. Nursing homes may use the same form to report less serious events and near misses. To make reporting easier, the list of data requirements for these types of events is shorter.

Reportable Long Term Care Facility Serious Adverse Events

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

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

Comparison of Oregon Patient Safety Commission Harm Levels with NCC MERP Harm Categories

NCC MERP Category	Definition	Commission Level	Definition
A	Circumstances or events that have the capacity to cause error	—	—
B	An error occurred but the error did not reach the patient	1	Did not reach the patient
C	An error occurred that reached the patient, but did not cause patient harm	2	No detectable harm
D	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm	2	No detectable harm
		3	Minimal Temporary Harm
E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention	5	Moderate Temporary Harm
		7	Serious Temporary Harm
F	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	7	Serious Temporary Harm
G	An error occurred that may have contributed to or resulted in permanent patient harm	4	Minimal Permanent Harm
		6	Moderate Permanent Harm
		8	Serious Permanent Harm
H	An error occurred that required intervention necessary to sustain life	7	Serious Temporary Harm
		8	Serious Permanent Harm
I	An error occurred that may have contributed to or resulted in the patient's death.	9	Death

Serious Harm (harm level 7 or greater) is that which severely impacts a resident's status or functional ability. It may be life threatening, increase length of stay, contribute to transfer to a higher level of care, or involve significant intervention in terms of testing or treatment.

Review of Submitted Reports (OAR 325-020-0030)

The Commission's reporting program represents a shared learning tool. To function as intended, this quality improvement effort requires that participants submit useful reports. As such, the Commission has established reporting guidelines.

Oregon Administrative Rule (OAR) 325-020-0030 states that submitted reports must be complete, thorough, credible and acceptable (please see the Joint Commission's Sentinel Event Policy, October 2006, for a complete description of these concepts).

The Commission's Nursing Home Field Coordinator will provide feedback to participants as reports are submitted. The intent is to help participants better understand how to submit acceptable reports and improve subsequent ones. Such feedback will not be punitive or regulatory.

Commission Review of Reports (OAR 325-020-0030)

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.

How to submit a complete report (all three must be present to meet review requirement):

- The event description narrative fully explains the event.
- The event description narrative includes the sequence of actions leading up to the event.
- The event description narrative includes relevant environmental conditions (ex: noise, lighting, census, etc.).

A report is thorough if the investigation includes an analysis of all relevant systems issues and shows evidence of an inquiry into all appropriate areas.

How to submit a thorough report (the first two items below must be present to meet review requirement):

- Identify at least one system-level contributing factor most primarily associated with the event (choose from Contributing Factors list on report form).
- Identify at least one root cause in the findings section on the report form.
- Identify additional root causes, if present.
- Identify proximate causes, if present.
 - Proximate causes are the more obvious or apparent reasons/causes that precede an adverse event. For example, administering the wrong medication that has an adverse outcome is a proximate cause. The root cause, however, might be inadequate checks and balances in the Pharmacy system, staffing that led to an overworked, fatigued nurse,

multiple distractions during the med pass, etc. Root causes represent the system-level reasons the adverse event occurred.

Tips to submit a thorough report

Use the Nursing Home Event Investigation Guide to drive your investigation.



Demonstrate a deep level of inquiry in your investigation (ex: use Five-Whys to determine root cause, include multi-disciplinary representation in the event investigation and review, etc.).

A report is *credible* if it shows evidence that the investigation included participation by leadership within the organization and was internally consistent

How to submit a credible report (all three must be present to meet review requirement):

- Demonstrate one of the following:
 - Notify senior management of the event. Senior management is identified as a representative of a corporate organization, management company, ownership or board of directors who works outside of the nursing home on a day-to-day basis.
 - Include senior management in the event analysis. Senior management is defined above.
- Internal consistency: the event description, contributing factors and findings correspond with one another. The analysis does not contradict itself, include inconsistencies or leave obvious questions unanswered.
- Fewer than three inconsistencies or contradictions exist between the event description, contributing factors and findings.

A report is *acceptable* if all the above standards are met and the action plans clearly describe meaningful improvement strategies designed to minimize risk.



Public Health Officer's Certification

In addition to OAR 325-020-0030, the legislation that created the Patient Safety Commission (Oregon Laws 2003 c. 686) includes a distinctive public accountability feature, the Public Health Officer's (PHO) Certification. This independent program audit assesses the quantity and quality of the submitted reports, in addition to the overall integrity of the reporting programs (nursing homes, hospitals, ambulatory surgery centers). The PHO uses the same criteria (complete, thorough, credible and acceptable) that the Field Coordinator uses to review submitted reports.

The PHO Certification is completed annually and shared with the public. Its purpose is to provide independent feedback to the public about the integrity of the Commission's reporting program. No nursing home will be individually identified, and all information will be released in the aggregate only. The certification process has no regulatory status, and is not punitive in nature.

Working With the Reporting Form

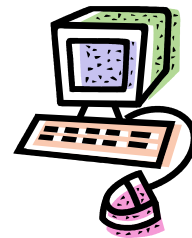
Participants report serious adverse events to the Commission through a web-based reporting form. The form is a pdf file.

Participants will need *Adobe Reader 8.0* or higher to open and complete the form; earlier versions of Adobe Reader will not work. If you do not have version 8.0 or higher, you may download it from <http://www.adobe.com/products/acrobat/readstep2.html>, or contact your IT staff regarding installation. Participants may obtain a reporting form from the Commission website (www.oregon.gov/OPSC) or contact the Commission for a copy.

This pdf is a “smart” form. Therefore, the required fields for completion will appear depending on the type of reporting organization and the harm level of the event. The form uses drop down and pop-up menus. The form also allows cut and paste from Word documents into the text fields. Note that the character limits include spacing and punctuation.

The Basics:

- ◆ Save the form to your computer as a “master”; name the file so it fits with your current naming conventions. This form may be re-used for subsequent reports
- ◆ Enter the required information. You may save the incomplete report on your hard drive and return to it later, if needed.
- ◆ To save the form, go to the top of the document and click <Save>. Give the form a different name than the blank or master form saved earlier.
- ◆ After saving the completed report to your hard drive, return to the top of the form and click <Submit to Patient Safety>. If any required information is missing, you will be requested to check the form and fill in any highlighted boxes. The highlighting will remain after you fill in the fields, but you will be able to submit the document.



Completing the Form (for serious adverse events, harm level 7 and above)

Reporting organization –

- ♦ **Complete this box first.** “Nursing Home” should show as the reporting organization. If not, choose “Nursing Home” from the drop-down choices. If there is any doubt about which reporting organization to choose, please contact the Commission.

Level of patient harm –

- ♦ **Complete this box second.** Use drop-down menu.
- ♦ Indicate eventual harm (the final outcome to the resident as a result of the adverse event).
- ♦ See page 6 for comparison of Commission harm levels 1-9 with NCC MERP harm categories A-I.

Date of event –

- ♦ Use date that the event occurred, not the date of the outcome, if different. For example, use date of fall, not date of transfer to higher level of care, if different.
- ♦ Enter the date formatted as MM-DD-YYYY or select from drop-down calendar.

Time of event –

- ♦ Use a 24 hour clock (military time).
- ♦ Indicate ‘Unknown’ if you have been unable to determine a time (for example, the time of an infection).

Date discovered –

- ♦ Use the date that an Incident Report was initiated.

Facility code –

- ♦ Enter the number assigned to your building. If you are unclear about what code to use, please contact the Commission.

Resident Information

Sex –

- ♦ Use drop-down menu.
- ♦ For transgender individual, use sex as noted on medical record (face sheet).

Age –

- ♦ Enter number.
- ♦ If not years, select alternative (months, days, etc.) from drop-down menu.

Race/ethnicity –

- ♦ Check all that apply
- ♦ Check 'Other' if resident's race/ethnicity does not appear in the form listing. Enter race/ethnicity in text box.
- ♦ Check 'Unknown' if there is no indication of race/ethnicity in medical record/face sheet.

Type of adverse event –

- ♦ Select all that apply; for example, a medication error that contributed to a resident's fall would be coded both as medication error (including specific type of error) and fall.
- ♦ Medication errors include contrast, other diagnostic medium, local, and topical agents, regional or general anesthetic, etc. in addition to what is commonly considered a medication.
- ♦ Check equipment/device only if the equipment is used or functions other than as intended or is difficult to use as intended. If the wrong equipment was used, check 'Other' and describe briefly.

Nursing Home Event Overview

Date admitted –

- ♦ Enter the date formatted as MM-DD-YYYY or select from drop-down calendar.
- ♦ Use the admission date in which the event occurred.

Date DNS notified –

- ♦ Enter the date formatted as MM-DD-YYYY or select from drop-down calendar.

Date Administrator notified –

- ♦ Enter the date formatted as MM-DD-YYYY or select from drop-down calendar.

Where the event occurred –

- ♦ Select all that apply
- ♦ Use 'Other' if location does not appear in the form listing. Enter location in text box.
- ♦ Use this text box to provide necessary detail regarding the location if necessary.

Payor Source –

- ♦ Select all that apply
- ♦ Use 'Other' if payor source does not appear in the form listing. Enter payor source in text box.

Level of care -

- ♦ Select all that apply

- ◆ Use 'Other' if level of care does not appear in the form listing. Enter level of care in the text box.

Resident's discharge status –

- ◆ Select all that apply
- ◆ Select 'Home or previous residence' if the resident is returning to the same level of care as when at baseline. For example, choose assisted living for a resident admitted from assisted living, hospitalized for hip fracture, admitted to SNF and returning to assisted living.
- ◆ Use 'Other' if the discharge status does not appear in the form listing. Enter discharge status in the text box.

Who was interviewed during the investigation –

- ◆ Select all that apply
- ◆ Use 'Other' if an interviewed department does not appear in the form listing. Enter department in text box.

Admitting diagnosis –

- ◆ Use ICD-9-CM code for admitting diagnosis and describe. For example, 17.1, Stroke (cerebrovascular).

Co-morbidities –

- ◆ List only co-morbidities that directly relate to the event or current health status.

Procedures –

- ◆ List only procedures related to the event or the resident's current health status.

Nursing Home Event Description and Analysis

Complete account of this event –

- ◆ Fully explain the event including the sequence of actions and relevant environmental conditions (e.g., noise, lighting, distractions).
- ◆ Only include information on clinical progress of the resident to describe the event and clarify activities/circumstances surrounding the event.
- ◆ The event description should be specific enough that someone unfamiliar with the event would have a clear understanding of how the event happened, the sequence of actions and surrounding circumstances.
- ◆ It is helpful to begin with a summary sentence that captures the main features.

Contributing factors –

- ◆ Select all that apply, specifically those that are primarily associated with the event; choose at least one.
- ◆ Use 'Other' if contributing factor does not appear in the form listing. Enter contributing factor and/or additional detail in the text box.
- ◆ If selecting 'non-compliance with policy' use 'Other' to give reasons for the noncompliance, including organizational or system influences.

Factors that helped reduce the seriousness or consequences of this event –

- ♦ Describe factors, including any actions by staff that decreased harm or prompted rapid intervention (for example: good communication, rapid response to event, etc.)

Additional factors that played a role in this event –

- ♦ If you choose 'yes' a text box will appear.
- ♦ Use to describe anything else about the event.

Event Notification and Review

Date review and analysis completed –

- ♦ Enter the date formatted as MM-DD-YYYY or select from drop-down calendar.

Person hours spent on review –

- ♦ Calculate based on the number of hours spent by each person involved in investigating/reviewing the event. For example, two people working 30 minutes each would be one person hour; two people working two hours each would be four person hours.

Event Notification and Review –

- ♦ Select all that apply.
- ♦ Senior management is identified as a representative of a corporate organization, management company, ownership or board of directors who works outside of the nursing home on a day-to-day basis.
- ♦ The Board is considered notified if they receive a summary report, including harm level.
- ♦ If you choose 'None of these were notified,' enter the reason / alternative notification in text box.

Written notification –

- ♦ Select all that apply.
- ♦ If you choose, 'None has been given' enter the reason / alternative notification in the text box.

System Level Action Plans

- ♦ For each finding (root cause), use a row to describe the action plan and timeline for completion.
- ♦ To add rows, click the box to the left of the row twice.
- ♦ The form allows five rows.
- ♦ If you have more than five findings (root causes) and action plans, you may include more than one finding and action plan per row.

Findings (root causes) –

- ♦ List the identified findings (root causes) for which you have developed action plans; choose at least one.
- ♦ Correlate findings (root causes) to the event description and contributing factors (fewer than three inconsistencies or contradictions).
- ♦ List your findings (root causes) as cause-effect statements. For example, “Multiple admissions without additional Nursing staff led to an untimely skin assessment that resulted in the care plan not including skin care directives and the resident developing a pressure ulcer” instead of “Nurse did not complete assessment and resident developed pressure ulcer.”
- ♦ As a rule, ‘non-compliance with policy’ is not considered a root cause but may be included as a proximate cause or contributing factor (use Five-Whys to determine why the policy was not followed).
- ♦ List proximate causes for which you have developed action plans.

Action Plans –

- ♦ For each identified finding (root cause), describe the actions taken and include a timeline for completion.
- ♦ It is possible for one finding (root cause) to require more than one action plan. It is possible to have one action plan address more than one finding (root cause).
- ♦ Identify strong system-level solutions that would decrease the likelihood of such events in the future.

Recommended Hierarchy of Actions*

Stronger actions

Architectural/physical plant changes
New device with usability testing before purchasing
Engineering control or interlock (forcing functions)
Simplify the process and remove unnecessary steps
Standardize on equipment or process or caremaps
Tangible involvement and action by leadership in support of patient safety

Intermediate Actions

Increase in staffing/decrease in workload
Software enhancements/modifications
Eliminate/reduce distractions (sterile medical environment)
Checklist/cognitive aid
Eliminate look and sound alike
Read back
Enhanced documentation/communication
Redundancy

Weaker Actions

Double checks
Warnings and labels
New procedure / memorandum / policy
Training
Additional study/analysis

*from the VA National Center for Patient Safety available at <http://www.patientsafety.gov/CogAids/RCA/index.html>

Do the Findings (root causes) and Action Plans Meet the Common Sense Test?

(Don't forget to use the Event Investigation Guide)

- ◆ Have you described the cause using specific and objective words? Avoid negative and vague words (e.g.: poorly, inadequately, improperly, carelessness, etc.)
- ◆ If you are tempted to cite 'human error' as the cause of the problem ('she made a mistake'), can you find a reason for that mistake?
- ◆ If a procedure was violated, can you find a reason? (distractions, workarounds or shortcuts, knowledge of procedure, etc)?



- ◆ If you eliminate this cause/contributing factor, will the problem really go away?
- ◆ Will your action plans prevent the next person from the same/similar error?

Contact information –

- ◆ The contact person is the one most familiar with the reported event. This may not be the person completing the form.
- ◆ Type in the phone number without spaces, or dots; either 5035554321 or 503-555-4321.

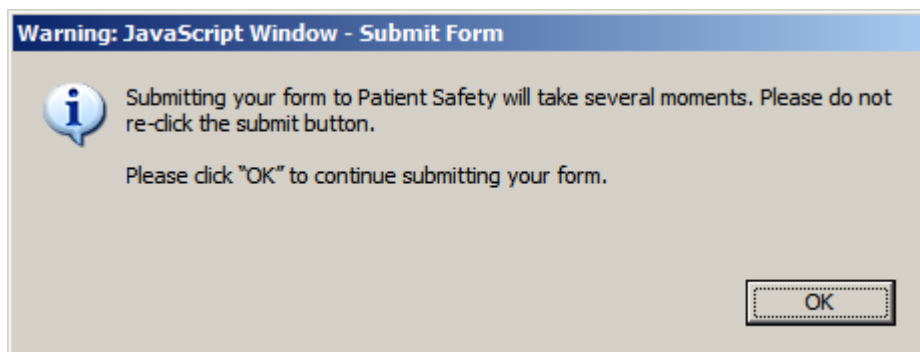
Submitting the Report

Follow these steps to submit the completed report form:

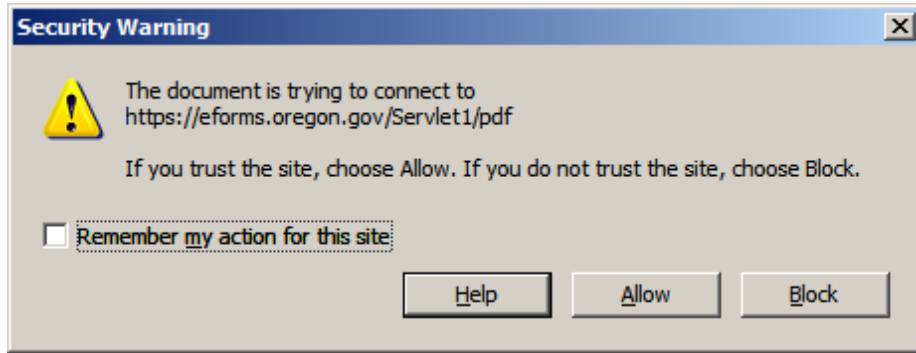
- ◆ Save the form to your computer as a “master”; name the file so it fits with your current naming conventions. This form may be re-used for subsequent reports
- ◆ Enter the required information. You may save the incomplete report on your hard drive and return to it later, if needed.
- ◆ To save the form, go to the top of the document and click <Save>. Give the form a different name than the blank or master form saved earlier.
- ◆ When the report is complete and you are ready to submit, be sure to save the completed report to your hard drive.
- ◆ After saving the completed report to your hard drive, return to the top of the form and click <Submit to Patient Safety> If any required information is missing, you will be requested to check the form and fill in any highlighted boxes. The highlighting will remain after you fill in the fields, but you will be able to submit the document.



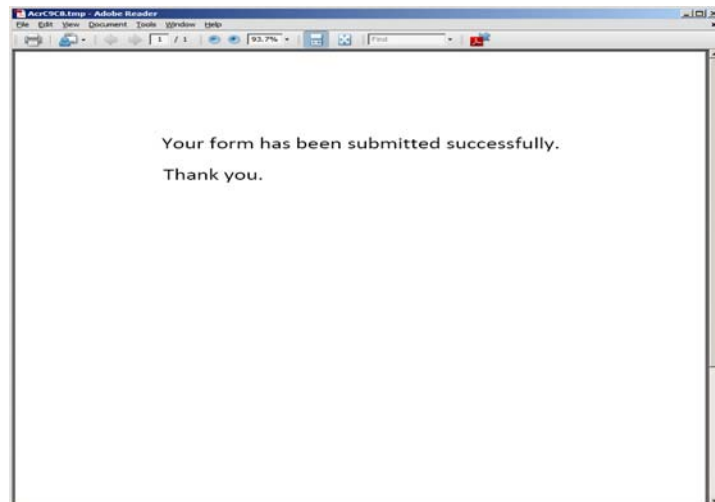
- ◆ If you have trouble submitting a report that involves a medication error, check to be sure you have completed the type of medication error (this field will not highlight if left blank).
- ◆ When you click <Submit to Patient Safety> a box will appear; follow the instructions by clicking on <OK>.



- ◆ After clicking OK, another box will appear, asking if you wish to allow connection to the secure website. Click <Allow>. You may bypass this window in the future by clicking “Remember my action for this site”.



- ◆ When the document finishes uploading onto the server, a window pops up notifying you that your form has been submitted successfully.



A Final Note
about Adverse Event Reporting for Oregon Nursing Homes

“It is not necessary to change. Survival is not mandatory.”

W. Edwards Deming

Adverse event reporting in Oregon supports the larger goal of decreasing risks to residents from preventable errors and missteps. To meet that goal, it is essential for nursing homes to share the learnings from analyses of adverse events. The most useful reports include information that can assist other nursing homes in identifying issues and solutions to the same or similar events.

The Commission appreciates your active participation. Thank you for your commitment to improving quality and safety in Oregon’s nursing homes.

Questions? Contact

Amy Gryziec, Nursing Home Field Coordinator

503.227.2632

amy.gryziec@oregonpatientsafety.org