



**Public Health Officer
Certification Report 2008**

**Oregon Patient Safety Commission
Adverse Event Reporting Programs**

**Oregon Department of Human Services
Public Health Division**

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Executive Summary

The annual Public Health Officer Certification is a distinctive public accountability feature of a statewide voluntary patient safety reporting system. No other state has anything like it. It assesses the overall integrity of the reporting program as well as the completeness, thoroughness, credibility and acceptability of all adverse event reports. The certification is an independent review and is intended to improve the reporting programs.

This is a report of the Public Health Officer Certification for the Oregon Patient Safety Commission's reporting programs for hospitals, nursing homes, ambulatory surgery centers and retail pharmacies. The certification uses independently developed criteria to assess the quantity and quality of the reports submitted by facilities in 2008 as well as the overall integrity of the reporting programs (Table 1 and Appendix A). Although the criteria are very similar for the different programs, the assessment and recommendations of the Public Health Officer will consider the developmental stage of each program and reporting participants. This report is not a detailed analysis of the reported adverse events and implications for improving patient safety in Oregon healthcare facilities. The Patient Safety Commission provides analysis and information about facility reports received (<http://www.oregon.gov/OPSC>).

The Oregon Patient Safety Commission was created in July 2003 by the Legislature to improve patient safety by reducing the risk of serious adverse events and by encouraging a culture of patient safety in Oregon (Oregon Laws 2003 c.686). It was directed to establish a confidential, voluntary serious adverse event reporting system for six types of health care facilities: hospitals, retail pharmacies, nursing homes, ambulatory surgery centers (ASCs), outpatient renal dialysis facilities and freestanding birthing centers. Each program has different reportable adverse events (Appendix B).

As of December 2008, all reporting programs combined had 279 voluntary participants. Hospitals began reporting in May 2006, while nursing homes and ASCs started reporting in September 2007. The retail pharmacy reporting program has been delayed until enrollment of a minimum number of participants. The program of renal dialysis facilities is in progress and should be collecting reports in late 2009 or early 2010. Birthing center reporting has been postponed until 2010 or later due to resource limitations at the Commission.

The patient safety reporting programs made good progress but also faced obstacles during 2008. Reporting programs are finding increased acceptance as participants become more familiar with purpose and benefits of the programs. Steady support from partners such as the Oregon Association of Hospitals and Health Systems, the Oregon Health Care Association, the Oregon Alliance for Senior and Health Services, the Oregon ASC Association and others plays an important role in the program strength. Some accomplishments of the past year include: comprehensive reporting program guides for hospitals, nursing homes and ASCs, strong *Learning Network* activities, which are partner projects for patient safety improvement (e.g. Joint Pressure Ulcer project, root cause analysis training, and more), implementation of electronic reporting system in December 2008, regular newsletters to all facility types (program updates, literature scan, examples of best practices, and other relevant items) and quality improvement tips and tools for the retail pharmacy program participants.

The Oregon Patient Safety Commission is a small organization with limited resources and a large mission that goes beyond the scope of the reporting programs. Like all such organizations, they must work hard to meet competing demands. The supporting activities that accompany the reporting programs such as frequent communication with participants about when and how to submit reports, discussing how to improve the event investigations and strategies to prevent similar events in the future, are time and labor intensive. This is particularly true for facilities just getting started with new patient safety programs. Some examples of challenges in 2008 include: developing the remaining

reporting programs for retail pharmacies, renal dialysis facilities and birthing centers, implementing the ASC and nursing home programs while waiting for the final electronic reporting option and following up with hospitals about preventive action plans to find out which solutions worked and which did not.

There are opportunities for future improvement of all programs: Integrate the *Learning Network* activities more with the reporting programs, use the reporting program data for analysis and development of best practices and work with the leadership of participating facilities to promote the reporting program benefits and improve the quality and quantity of reports. Additional recommendations for specific facility types are offered in the following summary sections.

Certification summary by facility type:

Hospitals:

The hospital reporting program made progress in most areas and yet, there are still elements that need improvement. The program passed the preliminary PHO certification for 2008. It is a pilot year because the new certification standards (Table 4) were finalized in 4th Quarter 2008, which was too late for the reporting program to make changes*. The program for hospitals passed four of seven required standards: program enrollment, adverse event report review, feedback to all facilities and written notification. Two standards were nearly met: report quantity and total report quality; and one standard, action plan follow-up, has not yet been addressed by the Commission.

- Enrollment in the hospital adverse event reporting program has been excellent from the beginning and has remained so in 2008, 56 of 58 hospitals in Oregon. The enrollment met the minimum standard of hospitals covering $\geq 90\%$ statewide annual discharges. This level of participation is an indicator of continuing hospital commitment to support the program.
- Report Quantity: After three years of reporting (2006-08), there were still 27% of all hospitals that have not submitted any adverse event reports (by hospital size: all large hospitals have submitted at least on event, while 25% of medium and 38% of small hospitals have not reported any events in past three years) . This is just slightly missed the standard of no more than 20% non-reporting hospitals in the previous three cumulative years. This is an important marker of quantity and level of participation, which generally improves as a reporting program matures. Comparing the non-reporting rate for 2008 only (44%), Oregon is better than three comparator states of similar age and structure and not as good as four other comparator states with older, more established programs.

The reporting program collected 108 adverse event reports from hospitals in 2008, an increase from the 94 reports in 2007. The increased reporting is an encouraging sign of improved ability and willingness of hospitals to identify, investigate and report these events. The adverse event rates are within the range of those found in other comparable statewide programs. This is a notable achievement for the only voluntary adverse event reporting system in the nation. All others have some mandatory component. However, estimates from the general patient safety literature suggest many more adverse events in Oregon and across the country. Although Oregon hospitals join the program on a voluntary basis, each facility signs an agreement to report all serious adverse events. Robust reporting is a critical element of any patient safety program.

* The first official PHO Certification will be released in 2010 using the reports from 2009.

- **Report Quality:** The total hospital report quality continued to be very good in 2008 although still slightly below the minimum standard of 90% or more in the “high quality” category. The proportion of “high quality” adverse event reports was 67.3% in 2006, 89.4% in 2007 and 80% in 2008. The decrease may be partially attributed to minor changes in quality requirements for the 2008 reports. The certification criteria will remain the same for the coming years making it easier to track improvement over time.
- **Overall Program Integrity:** The Public Health Officer finds that the overall program integrity for hospitals is good in 2008. The Commission successfully completed review of all submitted reports, gave feedback to all hospitals and increased the proportion of written notification to patients and families for serious adverse events as required by certification standards. The action plan follow-up for serious adverse events is a critical element of patient safety improvement. This criterion still needs to be implemented for the reporting program.

The Commission may consider the following recommendations to improve the hospital reporting program:

- Set clearer expectations for hospital participants about certification criteria
- Monitor whether the obligations in the original participation agreements have been met and develop a shared accountability model
- Provide regular detailed feedback to hospitals about their individual report quantity and quality as well as comparisons to similar-sized hospitals
- Implement action plan follow-up and share aggregate results with all hospitals
- Improve strategies for increasing written notification

The Public Health Officer challenges hospital participants to share responsibility for building a strong program by considering the following recommendations:

- Review the *Guide to Adverse Event Reporting for Oregon Hospitals* from the Commission. It includes what to report, tips for submitting a good report, using the electronic reporting system and more
- Review patient safety systems for identifying reportable adverse events and look for opportunities to improve
- Engage hospital leadership in actively promoting the purpose and outcomes of the reporting program
- Promote diffusion of the reporting program to the frontline providers

Nursing homes

The nursing home reporting program had very good enrollment levels and promising report quality, while the quantity of reports could be higher. The program was still in the early development phase in 2008. This year is the first of two assessments before the official certification standards are finalized in 2010. The resident safety and quality improvement approach in nursing homes is very different from hospitals and the results were interpreted with these differences in mind.

- Enrollment in the nursing home adverse event reporting program was very good in 2008, 108 of 141 eligible facilities in Oregon. There was an initial willingness to pursue a new proactive systems-based approach rather than primarily responding to rules requirements as a means of improving resident safety.

- **Report Quantity:** In 2008, nine of 141 (8%) of enrolled nursing homes submitted at least one report. The reporting program collected 17 adverse event reports from nursing homes in 2008, an increase from the one report submitted in 2007. The increase in reporting is moving in the right direction, but there is much to do to improve active participation of nursing homes in 2009. Strong reporting is crucial for a successful program. The slow pace may be due in part to delays in Commission program implementation. Deferred rollout of the electronic reporting resulted in the shift of the program orientation until 1st Quarter 2009. Most statewide reporting programs with similar reportable events do not include nursing homes or other long-term care and if they do, the data are not readily available. Two data sources offer some broad measure for expectations of reporting quantity in Oregon: The Tennessee program and the National Nursing Home Survey. Together, they suggest that there are more reportable events in Oregon's nursing homes than currently being collected. More events reported Commission staff means more patient safety information to analyze and share with others, which is a major goal of the reporting program. The Commission should make a strong effort to increase the proportion of nursing homes that submit reports and the number of reports.
- **Report Quality:** The total nursing home report quality was promising in 2008 considering the stage of the program implementation and the challenges previously mentioned. The proportion of high, medium and low quality adverse event reports was 18%, 35% and 47% respectively in 2008.
- **Overall Program Integrity:** The Public Health Officer finds that the overall reporting program integrity for nursing homes is good as illustrated by the growing enrollment levels, review of all submitted reports, and individual feedback to nursing homes for about a third of reports. The elements that need improvement are the regular feedback summaries to nursing homes, the proportion of written notification to residents and families and action plan follow-up for serious adverse events.

The Commission may consider the following recommendations to improve the nursing home reporting program:

- Set clearer expectations for nursing homes about certification criteria
- Review the program participation agreements with all nursing homes to determine if the obligations are being met
- Provide regular detailed feedback to nursing homes about their individual report quantity and quality as well as comparisons to aggregate of all nursing home participants
- Provide frequent and constructive feedback about quality of reports and make quality improvement tools and resources available.
- Design specific recommendations for written notification in nursing homes

Reducing unanticipated harm to residents will depend on joint responsibility of nursing homes and the Commission. Oregon nursing home participants can actively contribute with the following:

- Review the *Guide to Adverse Event Reporting for Oregon Nursing Homes* from the Commission. It includes what to report, tips for submitting a good report, using the electronic reporting system and more.
- Review resident safety systems for identifying reportable adverse events and look for opportunities to improve identification
- Engage nursing home leadership in actively promoting the purpose and outcomes of the reporting program

- Design adapted processes for root cause analysis and action plan development to expedite completion of Commission report form

Ambulatory Surgery Centers:

The PHO Certification found some encouraging signs and also opportunities for improvement in the reporting program for ASCs in 2008. Like the nursing home program there were implementation delays due to problems with the electronic reporting system. The ASC care environment often views patient safety from a clinical and individual provider perspective as opposed to a proactive systems-based approach. In addition, the availability of quality improvement tools for identification and investigation of adverse events is often limited. The assessment of the ASC reporting program takes the differences into account.

- In 2008 the enrollment in the ASC adverse event reporting program was moderate, 41 of 82 (50%) eligible facilities in Oregon. This is about the same as 2007 (39 of 78) and less than anticipated. It is important to note that there is great variation in the amount and complexity of surgeries and procedures being performed in Oregon ASCs. The program is designed to offer useful information for all types of ASCs. Nonetheless, a strong program requires a commitment from a broad base of ASCs. The Commission should make a new effort to improve the enrollment in the ASC program.
- Report quantity: The most remarkable accomplishment of this program was the quantity of reports submitted and the number of facilities submitting. In 2008, 18 of 41 (44%) of enrolled ASCs submitted at least one report. There were 86 adverse event reports in all and 80 were less serious with 6 serious adverse events. This is an increase from 21 reports in the partial reporting year of 2007. There are a few other states that include ASCs in their statewide reporting programs. Minnesota, Connecticut and Indiana all use the somewhat similar NQF definitions while Tennessee and Pennsylvania have broader descriptions of what is reportable. Because the Oregon program was designed to include more common adverse events, it is somewhere in the middle. Overall, considering the limitations of comparing different programs, Oregon's ASC report quantity is strong.
- Report Quality: In 2008 the total ASC report quality was low. The proportion of high, medium and low quality adverse event reports was 7%, 5% and 88% respectively. Separating by report section, the quality of the adverse event description was 51% low, 47% medium and 2% high, the analysis quality was 87% low, 2% medium and 10% high and the action plan quality was 88% low, 8% medium and 4% high. The program implementation delays most likely had some effect on ASC report quality. Many ASCs are taking their first steps at identifying how outside factors like communication and teamwork can influence patient safety improvement. In spite of the mitigating circumstances, it is apparent that ASCs need more training in systems-based investigation of adverse events.
- Overall Program Integrity: The Public Health Officer finds that the overall reporting program integrity for ASCs is mixed. Achievements include the report quantity, proportion of reporting ASCs, and review of all submitted reports. The Commission needs to strengthen the aggregate and individual feedback to ASCs about the program, and the proportion of written notification to patients and families and the action plan follow-up for serious adverse events.

The Commission may consider the following recommendations to improve the ASC reporting program:

- Set clearer expectations for ASCs about certification criteria
- Review the program participation agreements with all ASCs to determine if the obligations are being met
- Provide regular detailed feedback to ASCs about their individual report quantity and quality as well as comparisons to aggregate of all ASC participants
- Provide frequent and constructive feedback about quality of reports and make quality improvement tools and resources available
- Design specific recommendations for written notification in ASCs

The improvement of patient safety requires active ASC engagement. Oregon ASC participants can help build an effective reporting program:

- Review the *Guide to Adverse Event Reporting for Oregon ASCs* from the Commission. It includes what to report, tips for submitting a good report, using the electronic reporting system and more.
- Design adapted processes for root cause analysis and action plan development to expedite completion of Commission report form.
- Review patient safety systems for identifying reportable adverse events and look for opportunities to improve identification.
- Engage ASC leadership in actively promoting the purpose and outcomes of the reporting program

Retail Pharmacies:

The reporting program for retail pharmacies has been delayed by lack of a critical mass of chain and independent pharmacies to ensure confidentiality of the program. There were 74 of about 700 eligible pharmacies that agreed to participate in the Commission's reporting program by the end of 2008. Of these, 50 (81%) were large chain drug stores and 24 (19%) were independent retail pharmacies and small chains (<10 stores). In 2008, the participating pharmacies received complimentary access to the Institute of Safe Medication Practices Newsletter as an interim step. As an additional recruiting effort, the Commission has submitted a grant proposal to the Agency for Healthcare Research & Quality to sponsor a "Quality Summit" for retail pharmacies in Oregon.

Progress has been much slower than with the other programs. This raises concern about being able to certify the program in a reasonable timeframe. Although some retail pharmacies are to be commended for willingness to engage in statewide patient safety improvement, most national chains and many independents have shown continued resistance to participation in the program. The Commission made numerous efforts to recruit retail pharmacy participants and build the program. As one of only two retail pharmacy patient safety reporting programs in the nation, Oregon has an exceptional opportunity to pursue statewide patient safety in this care setting. The PHO Certification will waive the report quality and quantity and reporting program integrity assessment for 2008.

The Commission may consider the following recommendations to improve the retail pharmacy reporting program:

- The Commission is required to provide regular updates to the Legislature, which includes recommendations about changes to the program and possible implementation of mandatory reporting systems. If no improvement is seen by the end of 2010 it may be necessary to consider a switch to mandatory reporting for retail pharmacies.

Renal Dialysis Facilities:

The Commission formed an expert advisory group to design the specific patient safety program with integrated reporting program and draft administrative rules.

Birthing Centers:

Due to resource limitations at the Commission the development of this program and administrative rules has been deferred until 2010 or later.

Introduction

This is a report of the Public Health Officer (PHO) Certification for the Oregon Patient Safety Commission's Reporting Program for hospitals freestanding ambulatory surgery centers, nursing homes, retail pharmacies, freestanding birthing centers and outpatient renal dialysis centers. The PHO Certification is an assessment of the *quantity and quality* of the reports submitted by hospitals, ambulatory surgery centers and nursing homes in 2008 and the *overall integrity* of the reporting programs. It is not a detailed analysis of the reported adverse events and implications for improving patient safety in Oregon health care facilities.

The Patient Safety Commission provides analysis and information about facility reports received (<http://www.oregon.gov/OPSC>).

The Oregon Patient Safety Commission: Adverse Event Reporting Programs – Update 2008

The mission of the Oregon Patient Safety Commission is to improve patient safety by reducing the risk of serious adverse events and by encouraging a culture of patient safety in Oregon. The statute directs the Commission to do three things to accomplish their mission: 1) establish a confidential, voluntary serious adverse event reporting system to identify adverse events, 2) establish quality improvement techniques to reduce systems' errors contributing to serious adverse events and 3) disseminate evidence-based prevention practices to improve patient outcomes (Oregon Laws 2003, c. 686).

In 2008, the Commission faced some specific challenges in administering their reporting programs. Some technical issues in the development of the electronic reporting system led to delays in formal program orientation for ASCs and nursing homes. The Commission wanted to avoid the confusion of training participants on two different reporting systems. The decision was made to defer thorough training until availability of the final electronic reporting. This may have influenced the quantity and quality of reports from ASCs and nursing homes. In spite of renewed and repeated efforts, the retail pharmacy program does not have a critical mass of participants to collect reports. Further, there were limited resources that delayed the implementation of the remaining reporting programs (renal dialysis facilities and birthing centers) until 2009.

Reporting Program Progress in 2008:

- Hospitals submitted the second full year of reporting in 2008
- Nursing home and freestanding ambulatory surgery center programs collected their first full year of reports
- Comprehensive reporting guides now available for all three active reporting programs
- Electronic reporting system implemented in December 2008
- Webinar training for nursing homes and ASCs provided in 1st Quarter 2009
- Nursing Home Expert Panel established
- Retail pharmacy program participants gained access to quality improvement information in the Institute for Safe Medication Practices (ISMP) Newsletters
- Renal dialysis centers advisory group formed to develop program and administrative rules

Public Health Officer Certification Process – Update 2008

The annual Public Health Officer Certification is a distinctive public accountability feature of Oregon's voluntary patient safety reporting system. It is an independent assessment of the reporting programs (OAR 325, Division 10, 15, 20 and 25). No other state has anything like it. It certifies the overall integrity of the reporting programs as well as the completeness, thoroughness, credibility and acceptability of all adverse event reports.

The Public Health Officer designed the annual certification process in 2006 guided by the statute (Oregon Laws 2003, c. 686) and the administrative rules (OAR 325, Division 10, 15, 20 and 25). The certification requirements were developed over time as each of the reporting programs was implemented. The requirements include criteria, which are general categories and minimum standards, which are specific quantitative minimums for each of the criteria.

In 2008, the Public Health Officer finalized general criteria for all existing programs (see Table 1 and Appendix A).

Table 1: PHO Certification Criteria Overview

PHO Certification – General Criteria for all facility types
Program Enrollment – percent of eligible facilities that have signed participation agreements for reporting program and proportion of total patient volume in facility type
Report quantity: proportion of cumulatively non-reporting facilities after 3 full years of report submissions
Total report quality: percent in the high quality category
Percent of facilities that have a representative sample of submitted reports reviewed by Commission
Percent of participating facilities that received feedback about reporting at least once per year
Action Plan follow-up: percent of serious adverse events that received Commission follow-up with participants
Written Notification: percent completed for serious adverse events
Survey Participant satisfaction (planned for 2010)

In addition, the minimum standards for the hospital program were finalized during 2008. **The minimum standards for hospitals will initially be applied on a trial basis since they were completed in 4th Quarter 2008, too late for the Commission to make improvements for the 2008 hospital reports.** The Public Health Officer also aligned the assessment of report quality with the report review done by the Commission. Program participants now have clear unified expectations regarding submitted reports.

Although the criteria are very similar for the different programs, the assessment and recommendations of the Public Health Officer will consider the developmental stage of each program and reporting participants, (Table 2).

Table 2: Public Health Officer Certification – proposed timetable*

	Reports submitted in 2006	Reports submitted in 2007	Reports submitted in 2008	Reports submitted in 2009	Reports submitted in 2010
Hospitals	Assessment	Setting standards	Preliminary Certification [†]	Certification	Certification
ASCs	Progress development	Progress development	Assessment	Setting standards	Pilot Certification
Nursing homes	Progress development	Progress development	Assessment	Setting standards	Pilot Certification
Retail pharmacies	Progress development	Progress development	Program development	Program development	Assessment
Birthing Centers	Program deferment	Program deferment	Program deferment	Program deferment	Program development
Renal dialysis centers	Program deferment	Program deferment	Program deferment	Program development	Assessment

Certification

Criteria and Standards

The revised certification criteria for assessing the reporting programs for hospitals, nursing homes and ambulatory surgery centers are included in Appendix A. The assessment is tailored to the developmental stages of each program. Each facility type is certified in the categories described in Table 1.

At this stage, there are minimum standards for the hospital reporting program, since they are in the third year of reporting (Table 4). **The minimum standards will initially be applied on a trial basis since they were completed in 4th Quarter 2008, too late for the Commission to make improvements for the 2008 hospital reports.** Other programs are assessed using the general criteria in Table 1. The results are reported in sections for the individual facility types: hospitals, nursing homes, ambulatory surgery centers, retail pharmacies, birthing centers and outpatient renal dialysis centers.

Methods

Data –

The Public Health Officer collects data from Commission and from submitted reports to perform the certification. Specifically, the report quality, quantity and written notification elements come directly from the reports. The remaining data is submitted to Public Health by the reporting program field coordinators.

* Note that the actual review and assessment occurs in the year following report submission (i.e. the reports submitted in 2008 will be certified in 2009).

[†] Pilot Certification only for 2008 reports because the finalization occurred in 4th Quarter 2008 and there no time for the Patient Safety Commission to make improvements to meet standards.

Adverse Event Reports –

All participants report adverse events using an electronic reporting form for each facility type provided by the [Commission](#). In 2008, there were still some hand-written reports faxed to the Commission. The lists of required reportable events (Appendix B) were adapted from definitions created by the Joint Commission and the National Quality Forum (NQF)[1]. Reportable events for hospitals and nursing homes are mostly those that result in death or serious physical injury. The reportable events for freestanding ambulatory surgery centers and retail pharmacies were adapted to better reflect their clinical realities. As a result they include some specific types of low harm adverse events.

The form collects information about general demographics, adverse event description, investigation of contributing factors and causes (also root cause analysis) and action plans to prevent similar adverse events in the future.

Certification Elements –

Program enrollment: It is calculated by dividing the number of facilities that have signed a letter of agreement to participate by total facilities eligible (determined by licensure in various categories). Strong participation in a voluntary reporting program is an important ingredient in a robust program.

Quantity: The certification of participant reporting includes all reports submitted for calendar year 2008. The *report quantity* criterion is the percent of non-reporting facilities (no reports submitted) over three cumulative previous years. It is a good general metric of participation and robustness of the program across all participants. This indicator was selected because there is no accepted minimum number of reports or minimum annual increase. The certification still comments generally on the absolute number of reports.

Quality: The *report quality* is determined by the completeness, thoroughness and credibility of the individual reports. These overarching criteria are specified in the statute and rules (Oregon Laws 2003 c.686 §9 and OAR 325, Division 10, 15, 20, and 25) and originate from similar review guidelines of Sentinel Event Reports submitted to the Joint Commission [2].

Overview of *report quality* assessment:

1. Reports submitted by participants (differentiated by harm-level)
2. Each report is reviewed by the Commission staff (clarifications and changes as necessary)
3. Reports are finalized and saved to secure data base
4. PHO reviews each report using quality criteria in Table 3
5. Total quality score determined
6. Quality category assigned (high/medium/low)

The quality areas are evaluated using a scoring system that matches the report review done by the Commission (Table 3). For comparison purposes it is important to note the changes from previous quality assessments: minor wording changes in some measures and two dropped questions (completeness of form filled out and involvement of closely involved personnel in investigation). There are three main areas of quality that mirror elements in the report form: event description, event analysis and action plan development. The areas are combined to assess ***total report quality***.

Table 3: Report Quality Scoring

Patient Safety Commission Criteria (points possible)	Definition Oregon Administrative Rules 325-010-0035 (1)a-d	Location in Adverse Event Report	Common Quality Requirement descriptions	PHO Certification – Quality areas (quality points possible)
COMPLETE (2)	Contains all information requested in the Event report, or explains to the Commission's satisfaction why that information is not available or not necessary to provide	Event Description	Narrative explains the event by including the sequence of actions and relevant environmental conditions in the description	Event description (0/1/2)
THOROUGH (3)	Includes analysis of all relevant systems issues and shows evidence of an inquiry into all appropriate areas	Contributing Factors Section	Primarily identify system-level contributing factors most directly associated with the event	Analysis (0/1)
		Findings	At least one relevant root cause identified; presence of additional root or proximal causes	Analysis (0/1/2)
CREDIBLE (2)	Shows evidence that the investigation of the event included participation by leadership within the organization and was internally consistent	Notification (for serious events only)	At least one of the following: administrator notification, senior management notification, leader on review team, or post-review briefing	Analysis (0/1)
		Event Description, CF, Findings	# of inconsistencies and/or contradictions among the sections: more than three inconsistencies = 0 points	Analysis (0/1)
ACCEPTABLE ACTION PLANS (3)	Action plans clearly describe meaningful improvement strategies designed to minimize risk	Action Plans Findings	Emphasize strong and system-level solutions that would decrease the likelihood of such events in the future Action plans address the identified causes	Action Plans (0/1/2) (0/1)

The total quality score for serious and less serious is different because of the total possible points. Less serious events do not ask the question about notification and have only 9 total points compared to 10 possible for serious adverse events. They are then grouped into quality categories:

Quality category	Serious event – points range	Less-serious event – points range	Percent of total points possible
High	7-10	7-9	68-100%
Medium	4-6	4-6	34-67%
Low	0-3	0-3	0-33%

Report review: The *report review* criterion is general and measures the Commission effort to ensure that the submitted reports are acceptable. The certification element for the review process asks about use of systematic and consistent review tools and review of a representative sample of submitted hospital reports. It is assessed as met or not met.

Feedback to participants: This criterion is also relatively open ended and measures the level of response to facilities about their reporting quality and quantity. Participants should know how they fared according to expectations and how they compared with submissions with other similar facilities. The certification element asks about feedback to each hospital participant about report quantity and quality at least once yearly. It does not specify the exact content of the feedback communication.

Action plan follow-up: This criterion for serious adverse events is based on a statutory requirement to oversee action plans to assess whether participants are taking sufficient steps to prevent occurrence of serious adverse events (Oregon Laws 2003 c.686 §4). It is an additional public accountability aspect of the voluntary program. Revisiting the effectiveness of preventive action plans also strengthens the concept of sharing what works and what doesn't with other facilities.

Written Notification: The notification of patients and families following a serious adverse event is also specifically in the statute and is self-reported in the form submitted to the Commission.

Hospitals – Results and Discussion

The revised certification criteria (Appendix A) and the minimum standards (Table 4) for certification were applied to the hospital reports from 2008. Because the standards were developed in the last quarter of 2008, this year's **certification is a pilot year**. In 2010*, after three full years of reporting (2007-2009), the hospital program will receive the first official Public Health Officer Certification.

Table 4: Hospital Results

Certification Criteria and Standards	Results 2007	Results 2008	Certified 2008 (preliminary)
Program Enrollment: maintain participants that represent $\geq 90\%$ of statewide annual discharges	99.3%	99.5%	Yes
Report quantity: Reduce the proportion of cumulatively non-reporting hospitals to $\leq 20\%$ after 3 full years of report submissions (2007-2009)	Non-reporting hospitals as of 12-31-2007: 33% Total reports: 94	Non-reporting hospitals as of 12-31-2008: 27% Total reports: 108	No
Total report quality: $\geq 90\%$ in the high quality category	89% high, 10% medium, 1% low quality	80% high, 12% medium, 8% low quality [†]	No
Report review: 100% hospitals have a representative sample of submitted reports reviewed by Commission	100% reviewed	100% reviewed	Yes
Feedback: 100% of participating hospitals received feedback about reporting at least once per year	n/a	All received aggregate feedback Individual report feedback: about 30 reports	Yes
Action Plan follow-up: Commission completed follow-up for $\geq 90\%$ of serious adverse events	Completed for 6 (11%) hospitals	Not completed	No
Written Notification: 100% for all serious adverse events by 2012 (interim goals: at least 10% increase each year compared to previous year)	2006: 67% 2007: 44%	62% (40 of 65 reports)	Yes

The overall certification is a composite of total standards with three possible levels:

- Pass with no reservations – 6-7 standards achieved
- Pass with reservations – 4-5 standards achieved

* The PHO Certification for reports submitted in 2009 will occur in 2010

[†] Report quality assessment changed in 2008 and not directly comparable to previous years

- No pass – 3 or less standards achieved

The hospital reporting program met four of the seven certification standards and is preliminarily certified with reservations for the 2008 reporting year.

Program Enrollment

Hospitals have shown a strong commitment to the Oregon Patient Safety Reporting Program with excellent levels of voluntary enrollment. Fifty six of Oregon's 58 acute care hospitals participated in the program in 2008, representing 99.5% of total annual discharges. The distribution of participation by hospital size is 100%, 100%, and 94% for large, medium and small facilities respectively, Table 5.

Table 5: Voluntary Hospital Enrollment

Size	Hospitals in Oregon	Percent of Total Statewide Discharges	Participation Agreement	Percent of Total Statewide Discharges Participating
Small 0-3000 Discharges	31	11%	29 (94%)	11%
Medium 3001-10,000 Discharges	16	32%	16 (100%)	32%
Large over 10,000 Discharges	11	57%	11 (100%)	57%
Totals	58	100%	56 (97%)	99.5%

- Assessment: excellent hospital enrollment rates.
- Recommendations: Maintain high enrollment in the future.

Hospital Report Quantity

After careful consideration, the Public Health Officer finalized the certification standard for *report quantity*: proportion of non-reporting hospitals* over previous cumulative three years at 20% or less. The longer time period is important since many of Oregon's hospitals are very small and may not have a serious event to report every year. When hospitals submit reports with results of their investigations and possible solutions for prevention, the Commission can analyze the material and share with other hospitals. This is an important goal of the adverse event reporting program. The PHO Certification also evaluates the overall number of reports submitted to provide a better understanding of how the Oregon program compares with others.

The official certification will occur after three full years of reporting in 2010. To date, the certification looked at one partial year of data in 2006 and two full years, 2007-2008. The cumulative percentage of hospital non-reporting went from 33% in 2007 to 27% in 2008. The proportion of non-reporting hospitals (hospitals that have not submitted any adverse event reports to the program in 2008) in Oregon (44%)

* submitted no reports in a defined time period

is lower than three other states. All other comparator states have mandatory reporting systems. By hospital size all large hospitals and about three quarters of medium sized hospitals submitted at least one report in 2008, while 41% of the small hospitals submitted one report or more, Table 6.

During the calendar year 2008, the Patient Safety Commission received a total of 108 adverse event reports from 34 of 56 participating hospitals, Table 6. Of the 108 reports, 43 were less serious and 65 were serious adverse events. There were 55 total reports in 2006 (22 less serious and 33 serious) and 94 reports submitted in 2007 (34 less serious and 60 serious).

Table 6: Events Reported by Hospital Size, 2008

Hospital Size	Number of hospitals in program	Number and percentage of hospitals submitting at least one report in 2008	Number and percentage of hospitals submitting at least one report in cumulative past 3 years	Total reports submitted in 2008 (% of total)	Percentage of statewide discharges represented by reporting hospitals in 2008
Small (0-3000 Discharges)	29	12 (41%)	18 (62%)	14 (13%)	11%
Medium (3001-10,000 Discharges)	16	11 (73%)	12 (75%)	34 (31%)	32%
Large (Over 10,000 Discharges)	11	11 (100%)	11 (100%)	60 (56%)	57%
TOTAL	56	34 (66%)	41 (73%)	108 (100%)	100%

There is no well-established measure of serious adverse event rates. This leaves us with no benchmark of how many reports to expect. The rate of adverse events depends in part on the definition of what constitutes an adverse event and also on what is reportable and to which external organization. The rate also depends on the ability of systems to detect and identify preventable harm. The PHO certification attempts to put some context around the number of adverse event reports received by the Commission by considering some estimates from the literature and reporting volumes from similar state programs.

There are many estimates of harm to patients. We illustrate a few examples here. The most commonly cited number is 44,000 to 98,000 hospital deaths due to medical errors annually from the *To Err is Human* report [3]. This translates roughly to a range of 932 to 1837 potentially preventable deaths of Oregonians cared for in inpatient settings (using hospital discharge numbers from 2004 [365,031]). The studies that contributed to these approximations used retrospective medical record review in hospitals to make their estimates, which is not the common method that hospitals use to prospectively identify adverse events.

Other estimates of patient harm in the broadest sense come from the Institute for Healthcare Improvement's Global Trigger Tool [4]. This tool is designed to assess harm instead of trying to separate events that can be seen as errors. The definition of harm in the Global Trigger tool is: Adverse event is an injury or harm related to the delivery of care. The harm identified by the tool ranges from temporary harm to the patient and required intervention or initial or prolonged hospitalization, permanent patient harm to death. The tool also uses retrospective chart review in a hospital setting and reveals approximately 40-50 patient injuries per 100 hospital admissions.

The Pennsylvania Patient Safety Authority is one of the more established state-level reporting programs. The definition of reportable events differs substantially from those in the Oregon program. The reporting system collects two types of occurrences: incidents (events without harm to patients) and serious events (adverse events resulting in patient harm) [5]. They received reports of 8,645 serious events (and 211,229 incidents) from 525 hospitals, ambulatory surgery centers and birthing centers in 2008. Using this rate of 0.0046 events per hospital discharge, (2007 PA hospital discharge numbers*) Oregon would have close to 1600 serious events as defined in Pennsylvania. Although Pennsylvania has been recognized for its strong reporting levels, their rates may not necessarily be considered the universal benchmark.

For purposes of comparison, there is no other state or system with exactly the same list of reportable events and a confidential voluntary structure. However, it is important to understand the Oregon data in a broad context in order to see how Oregon's model measures up to other states. Oregon's list of reportable adverse events (Appendix B) for hospitals uses the National Quality Forum's *Never Events* as a starting point [1]. As previously mentioned, many other states use this list or a modified version to define what is reportable in their mandatory reporting programs. Specifically, Minnesota [6], Connecticut [7], New Jersey [8], Indiana [9], Massachusetts [10], Maryland [11] and Washington [12] have released annual reports describing their results (Table 7). Any the following program variations may function as incentives to provide more reports or disincentives against reporting.

Caveats in the cross state comparison:

- Maturity of adverse event reporting program
- Definition of reportable events
- Structure of program [i.e. mandatory, public reporting, electronic reporting, funding for communication and training, etc.]
- Support from stakeholder and regulatory organizations
- Legal risks, confidentiality of reports
- Statewide culture of patient safety

Like Oregon, Connecticut, and Maryland publicly report adverse events only in the aggregate for all hospitals, while Minnesota, Indiana, Massachusetts and Washington disclose events at the facility level in their annual reports. New Jersey made program changes this year and will partially disclose adverse events at the facility level. While Oregon, Washington and Indiana are newer to adverse event reporting, Minnesota, Connecticut, Massachusetts, Maryland and New Jersey are more mature programs. Connecticut, New Jersey and Maryland have a somewhat broader definition of the injury that could potentially lead to more reports. Minnesota added two new reportable events and saw their report numbers climb substantially in 2008. They estimate that without the definitional changes, they would have 141 events reported in the previous reporting period [6].

* Used admissions data from Kaiser Family Foundation www.StateHealthFacts.org to estimate event rates

Table 7: Selected Other States - Patient Safety Program results for from hospitals

State, Original Implementation Date	Number of Events, timeframe, year	Confidentiality	Definition of Reportable Events	Events/10,000 hospital admissions per year* (estimated)	Non-reporting hospitals
New Jersey, 2005	456/ 12 months, 2007	Public reporting at facility level and partly in aggregate [†]	NQF with additions and exclusions	4.2	6%
Connecticut, 2004	195/12 months, 2007	Public reporting in aggregate only	NQF with additions	4.7	6%
Massachusetts, 2000,	338/12 months, 2008	Public reporting at facility level	NQF definitions verbatim	4.0	17%
Maryland, 2004	182/12 months, 2008	Public reporting in aggregate only	NQF with additions	2.6	23%
Oregon, 2006	108/ 12 months, 2008	Public reporting in aggregate only	NQF with additions and exclusions	3.1	44%
Washington, 2006	210 / 12 months, 2008	Public reporting at facility level	NQF definitions verbatim	3.7	49%
Minnesota, 2003	312 / 12 months, 2007/2008	Public reporting at facility level	NQF with additions	5.8	56%
Indiana, 2006	101/12 months, 2007	Public reporting at facility level	NQF definitions verbatim	1.5	61%

The estimated rate of reported adverse events in Oregon is well within the range of what is being seen in other similar state reporting programs. In spite of the many minor differences, Table 7 does provide us with broad comparisons.

Although reporting levels in Oregon are within the range of that seen in similar state programs, this should not be regarded as the standard. Realizing that there is currently no clear expected rate of serious adverse events as defined in Oregon, we do find estimated ranges from the literature [3-5] to consider. The Public Health Officer Certification finds that the total number of submitted reports from all hospitals combined is lower and the proportion of non-reporting hospitals is higher than the literature would suggest. The broad analysis of other estimates leads us to believe that there are more reportable serious adverse events to be identified and reported by Oregon hospitals.

* Used admissions data from Kaiser Family Foundation www.StateHealthFacts.org to estimate event rates.

[†] New Jersey recently designated a portion of the adverse events to be publicly disclosed by facility.

- *Assessment: The proportion of non-reporting hospitals is still too high. Total number of submitted reports from all hospitals combined is increasing as expected, but still lower than literature estimates.*
- *Recommendations: Set clearer expectations for hospitals about certification criteria. Monitor whether the obligations in the original participation agreements have been met and develop a shared accountability model. Continue to identify and work to help hospitals reduce barriers to reporting, keep the administrative burden as low as possible without compromising the data needed for effective quality-improvement, support more diffusion to the frontline providers and continue to gain the support of executive and clinical leadership in hospitals.*

Report Quality

The submitted reports for 2008 were similar* in total quality (80% high, 12% medium and 8% low) (Fig. 1) compared with 2007 (89% high, 10% medium and 1% low) and 2006 (67% high, 22% medium and 11% low). By harm level, there are more high quality reports in serious compared with the less serious category, 91% vs. 63%. This is a switch from 2007 results when the less serious event reports showed higher total quality compared with serious events.

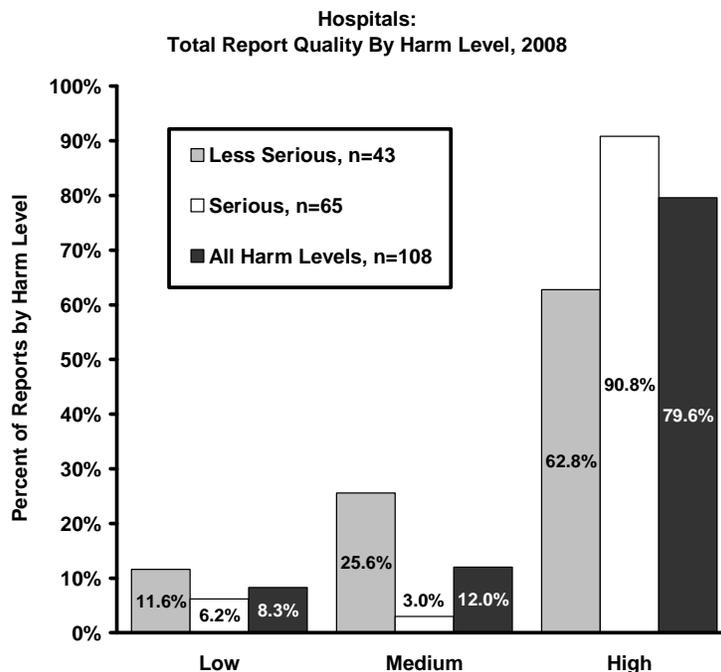


Figure 1 Total Quality for Adverse Event Reports.

As previously noted there were a few changes in report quality assessment for 2008. The report completeness no longer includes points for filling out the whole report since the electronic reporting will not allow submission of incomplete reports. Other changes were minor language updates and alignment with Commission.

Although there are minor changes in report quality assessment since 2006, there has been progress in the individual report quality elements, Fig. 2. The quality of the *event description* component improved

* Report quality assessment changed in 2008 and not directly comparable to previous years

in 2008 with 42% high quality and only 6% in the low category. The *analysis* component for 2008 is also better than the first year. There was a slight decrease in high quality *analysis* from 2007 to 2008, which is likely attributable to the change in assessment criteria. The quality of *action plans* assessment has changed the most of the three elements and may be the most affected by the 2008 revisions. However, even for this element the proportion of low quality has steadily decreased over time.

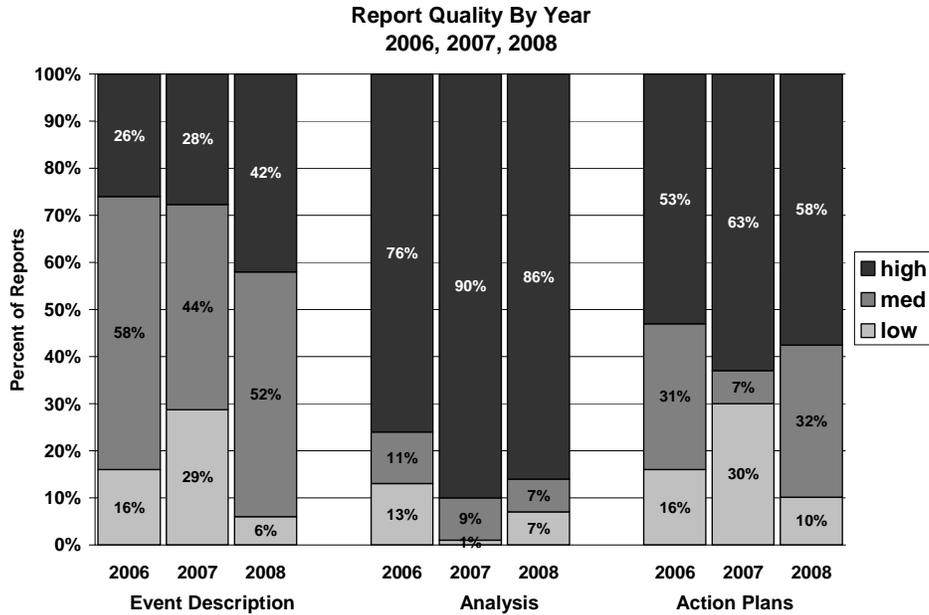


Figure 2 Report Quality by Element*.

- *Assessment: Very good total report quality –80% of the reports were found to be high quality, while 12% were in the medium quality category and 8% were determined to have a low total report quality.*
- *Recommendations: Set expectations for report quality from hospitals and provide feedback when a report does not meet the Commission standards.*

Adverse Event Report Review

In 2008 Commission staff reviewed 100% of submitted reports with an assessment tool to determine completeness, thoroughness, credibility and acceptability for each submitted report. This tool was aligned with the PHO certification report quality assessment in order to provide clearer expectations to hospital participants (Table 3).

- *Assessment: The report review standard was met in 2008. All 2008 reports were reviewed by Commission staff.*
- *Recommendations: Continue to review reports and communicate the results of report review to hospitals on a regular basis.*

Feedback to Hospitals

* Report quality assessment had minor changes each year and are only roughly comparable.

In August 2008, each participating hospital CEO received a letter from the Commission with a high level reporting summary including: total reports by year and hospital size, comparisons with hospitals of similar size, percent of completed written notification and senior leadership notification following serious adverse events.

Other feedback activity:

The field coordinator contacted about 30 individual hospitals with feedback about strengths of individual reports and opportunities for improvement.

In April 2008, the Commission began including monthly of hospital reports received and a brief description of event types in their newsletters for hospital participants.

- *Assessment: All hospital participants received feedback once in 2008.*
- *Recommendations: Consider including more detailed information about each hospital's report quality and quantity and suggestions for improvement where appropriate.*

Action Plan Follow-up

Action Plan Follow-up asks if the Commission completed follow-up with the hospital participants about the implementation and effectiveness of action plans for serious adverse events. Each serious event usually has two or more action plans. It is important to close the improvement loop and review which strategies worked for each serious adverse event. The minimum standard for certification is follow-up of action plans for 90% or more of serious events.

The annual Commission follow-up with hospitals regarding their proposed action plans for prevention of recurrence for serious adverse events from 2007 was due to occur in 2008. It was not completed in 2008.

- *Assessment: The serious adverse event action plan follow-up with hospitals was not completed in 2008*
- *Recommendations: Create and implement a strategy for the annual action plan follow-up that is simple for hospitals to complete and provides useful learning for other facilities. Offer support to hospitals on how to best track the success of action plans.*

Written Notification

The *written notification* requirement for serious adverse events was included in the statute as a way to demonstrate patient-centered care. It is an additional public accountability component of the voluntary reporting programs. The statutory expectation is that participating hospitals will provide written notification to all patients and families that have experienced a serious adverse event in a timely and consistent manner (Oregon Laws 2003 c.686 § 4). The minimum standard for certification in 2010 is a gradual increase of at least 10% each year with a goal of 100% for the 2012 reports.

The rate of written disclosure to patients and families who have experienced serious adverse events increased in 2008. In 40 (62%) of the cases hospitals sent letters to patients and family as part of the disclosure process, while 25 cases received no written disclosure. This certification element is self-reported in the adverse event report form. Many hospitals reported oral disclosure instead of written disclosure; however, this is not the standard being measured.

The concept of disclosure regarding adverse events in writing remains a relatively new and unfamiliar one for health care providers and patients alike. There is some concern from risk managers and medical malpractice insurers about the implications of such written communication. There is growing evidence showing that oral disclosure done well with executive level support has some positive effects [13-15]. National health care quality organizations such as the Joint Commission and the National Quality Forum are strongly supporting the improved communication with patients about medical errors and adverse events [16].

All hospital participants in Oregon have signed agreements to fulfill the *written notification* requirement even though it can be a complicated arrangement between physician, hospital and the various medical malpractice insurers. Many have successfully completed the process and are looking for ways to honor the concept of patient-centeredness. Others are not complying and it is important to understand where the challenges and barriers lie.

The PHO Certification expects continued progress toward 100% written notification for each serious adverse event, while accepting that there may be rare exceptions. We recommend that the Commission move forward to offer further assistance to hospitals to do this well for the benefit of the patients and families.

- *Assessment: The rate of completed written notification to the patients and families has increased from 44%% in 2007 to 62% in 2008. The minimum standard of 10% annual increase was met for 2008.*
- *Recommendations: Continue to help hospitals address the barriers and provide a clear vision of the patient-centered foundation of the written notification. Include rate of notification in the annual feedback to hospitals and set expectations for 2009.*

Nursing Homes – Results and Discussion

The certification for nursing homes mirrors that for hospitals with a few exceptions (see Appendix A). The nursing home list of reportable adverse events (see Appendix B) differs from the hospital list in order to account for the differences in practice scope and care setting. Nursing homes report events that result in death or serious physical injury. They are also encouraged to submit less serious events that may provide valuable learning for others.

Nursing homes have a different quality improvement infrastructure than hospitals and are in the early development stages using root cause analysis tools. Historically, certified nursing homes have focused on regulatory requirements. They report a wide range of incidents to the regulatory agency including medication management issues, resident protection and safe food storage and preparation. Nursing home surveys are done by regulatory agencies on average once annually and as necessary to respond to self reports and complaints.

In 2008 the program collected the first full year of reports, Table 8. Program activities in 2008 included formation of the Nursing Home Expert Panel, development of falls management toolkit, leading a transitional care collaborative to prevent pressure ulcers, and development of a reporting guide specifically for nursing homes. Due to delays in the electronic reporting system, the more comprehensive reporting program orientation was done in the first Quarter 2009. The Commission offered the official reporting guide, webinars and individual assistance.

Table 8: Nursing Home Results

Certification Criteria	Results 2007	Results 2008
Program Enrollment: percent of eligible facilities that have signed participation agreements for reporting program and proportion of total patient volume in facility type	61% enrolled (87/142 eligible)	77% (108/141 eligible)
	Not available	78% (9687/12423 licensed beds)
Report quantity: proportion of non-reporting facilities and total reports	Non-reporting NHs as of 12-31-2007: 99% Total reports: 1	Non-reporting NHs as of 12-31-2008: 92% Total reports: 17
Total report quality: percent in the each quality category	n/a	18% high, 35% medium, 47% low quality
Report review: Percent of facilities that have a representative sample of submitted reports reviewed by Commission	100% reviewed	100% reviewed
Feedback: percent of participating facilities that received feedback about reporting at least once per year	n/a	29% received individual feedback
Action Plan follow-up: percent of serious adverse events that received Commission follow-up with participants	n/a	n/a for 2008
Written Notification to patients/families: percent for all serious adverse events	n/a	28% (5 of 14) done (self report)

Program Enrollment

There are 141 eligible nursing homes in Oregon, many of which belong to multi-facility groups. As of December 31, 2008 there were 108 nursing home participants enrolled. This represents 77% (up from 60% in 2007) of all eligible nursing homes and 78% of total nursing facility beds in Oregon.

- *Assessment: Very good nursing home enrollment rate in 2008.*
- *Recommendations: Continue to recruit the remaining nursing homes by creating value in the program, e.g. patient safety program tools, evidence-based best practices.*

Report Quantity

The reporting program received 17 adverse event reports for the calendar year 2008 from eight nursing homes. Fourteen were serious adverse events and three were less serious. The rate of non-reporting nursing homes was 92% (8 of 108 enrolled nursing homes) in 2008.

Few other states collect this type of adverse event reporting from nursing homes. Nursing homes have historically focused on reporting incidents to regulatory agencies and are still adjusting to the systems-based patient safety reporting of the Commission. This shift represents a new way of thinking about systems of care and requires the development of a new monitoring and investigation infrastructure.

Tennessee posts their patient safety incidents semiannually in the Unusual Event Reports* for all facilities including licensed nursing homes. The definitions of reportable events are not based on the NQF list as in Oregon, but there is some overlap in a few categories that could offer context for the Oregon program. In 2008, 731 cases of falls with fractures, 24 cases of elopement and 3 cases of medication harm. About 301 (77%) of 392 eligible facilities reported at least one event. The program in Tennessee, although structured differently, may offer insight into types and frequency of preventable harm in the nursing home setting.

The National Nursing Home Survey also reports some details that provide context for expectations from nursing home reporting [17]. The survey is a snapshot from a representative sample of nursing homes. It reports about a third of nursing home resident had at least one fall in the previous 6 months, about 7% had at least one hospitalization in the previous 90 days and 8% had at least one visit to the emergency room. These events do not necessarily represent any preventable harm, but they may offer opportunities for system improvement.

There are several factors that may explain the high rate of non-reporting nursing homes and low report quantity: the challenges of shifting from a culture of safety through regulation to one of continuous quality improvement, initial unfamiliarity with what to report, delayed implementation of electronic reporting and reporting guidelines, potential confusion with regulatory reporting and the Commission, and limited infrastructure to view resident safety and event investigation from a systems-based approach.

- *Assessment: The number of submitted reports and proportion of facilities reporting improved in 2008 compared with 2007. This is still not a participation level that will allow meaningful analysis of the adverse events across the state and sharing of best prevention practice.*
- *Recommendations: Provide continued orientation and communication to nursing home participants about the patient safety reporting program. Set clearer expectations about reporting and differentiate from the regulatory incident reporting. Review the program participation agreements with all nursing homes to determine if the obligations are being met. Work on improving the culture of resident safety*

Report Quality

The total report quality for nursing home reports submitted in 2008 was 18% high, 35% medium and 47% low quality. Separating by report section, the quality of the adverse event description was 24% low and 77% medium, the analysis quality was 24% low, 59% medium and 18% high and the action plan quality was 65% low and 35% medium. The scoring for nursing home reports uses the same criteria as the hospital certification, Table 1. However, we need to view resident safety from the nursing home perspective to interpret the results.

Some possible explanations for the differences between nursing home baseline and current hospital submissions: Hospitals have been building capacity in quality improvement for over a decade in response to expectations from accreditation bodies, CMS and other industry pressures, delayed implementation of comprehensive orientation and electronic reporting, focus on regulatory reporting of incidents as noted above, and, limited infrastructure for systems approach to event investigation,. The quality of 2008 nursing home reports is a starting point. With more support and a strong vision for change, the Public Health Officer anticipates increased quality of reports for the coming year.

* received 2008 reports by request from Tennessee Department of Health, <http://health.state.tn.us/IPS/quarterly.htm>

- *Assessment: Moderate baseline level of report quality considering program orientation delays and early stages of quality improvement infrastructure in nursing homes.*
- *Recommendations: Provide frequent and constructive feedback to reporting nursing homes about quality of submissions. Make quality improvement tools and resources readily available to all nursing home participants. Work with professional organizations to provide root cause analysis training. Set expectations for report submissions. Dedicate additional time and resources to assisting nursing homes to make the transition to a culture of patient safety.*

Adverse Event Report Review

All submitted nursing home reports were reviewed for completeness, thoroughness, credibility and acceptability using the same internal criteria for hospital and ASC reports, Table 3.

- *Assessment: All submitted adverse event reports were reviewed by the Commission staff using standardized review criteria.*
- *Recommendations: Continue to review all reports and share the assessment and possible improvements with reporting participants.*

Feedback to Nursing Homes

The field coordinator for the nursing home program provided specific report feedback to nursing homes for five of the seventeen reports.

- *Assessment: Specific report feedback for 29% of the submitted reports. No aggregate feedback or quarterly reports to all participants.*
- *Recommendations: Provide all participants with summary of reporting received in 2009.*

Action Plan Follow-up

The action plan follow-up is waived until 2010.

Written Notification

Nursing home participants are also required to notify residents and their families in writing about reported serious adverse events in a timely and consistent manner. The statute leaves much flexibility about how this requirement may be satisfied. As some hospitals are still developing their policies, nursing homes also need to find the best way to meet this resident-centered accountability feature of the reporting program. It is common practice for nursing homes to make a note in the chart about an incident and have family confirm that they were notified with a signature. This may be a place to start with nursing home written notification.

Participants checked the written notification box on the report form in 28% of the reports. It is not clear if they fully understood the question since the implementation was delayed and there are no guidelines for nursing homes to approach written notification. The Commission may wish to contact facilities that report completed written notification and being the dialog about the best way to fulfill this important commitment to residents and their families.

The Commission is still developing recommendations for nursing homes. The PHO Certification will expect a steady increase in the short term and 100% written notification for each reported serious adverse event in the long term, while accepting that there may be rare exceptions.

- *Assessment: Almost one third (28%) of the adverse event reports from nursing homes reported completed written notification.*
- *Recommendations: Continue to support nursing homes with written notification and identify the best solution to fit their unique environment of care.*

Ambulatory Surgery Centers – Results and Discussion

The certification criteria for ASCs are also very similar to hospitals and nursing homes (see Appendix A). The quality improvement infrastructure in ASCs is still in the early stages and sometimes driven by accreditation organizations such as Joint Commission or Accreditation Association for Ambulatory Health Care. New requirements to Medicare coverage incorporate substantially more quality improvement and patient safety monitoring than previously. The new conditions combined with the ability of ASCs to keep patients for up to 24 hours may refocus ASCs toward more proactive patient safety activities. Until recently, the emphasis in patient safety improvement has often been on the clinical aspects of care as opposed to the systems approach.

The list of reportable adverse events for ASCs (see Appendix B) was specifically developed to match the care environment. Required reporting in ASCs includes events that may, but do not necessarily result in death or serious physical injury. The program was designed to collect the most useful patient safety information for ASCs instead of rare events that many other state reporting programs require [6, 7, 9].

A few reports were submitted in 4th Quarter 2007 but the first complete year of reports in 2008 represents a baseline for future comparison, Table 9. The Commission developed a reporting guide tailored to ASCs and worked with Oregon Ambulatory Surgery Center Association in regular meetings to improve the reporting program and patient safety in ASCs. Delays in the electronic reporting system moved the more comprehensive reporting program orientation to 1st Quarter 2009. The Commission offered the official reporting guide, webinars and individual assistance.

Table 9: Ambulatory Surgery Centers Results

Certification Criteria	Results 2007	Results 2008
Program Enrollment: percent of eligible facilities that have signed participation agreements for reporting program and proportion of total patient volume in facility type	50% enrolled (39/78 eligible)	50% enrolled (41/82 eligible)
Report quantity: proportion of non-reporting facilities and total reports	Non-reporting ASCs as of 12-31-2007: 87% Total reports: 12	Non-reporting ASCs as of 12-31-2008: 56% Total reports: 86
Total report quality: percent in the each quality category	n/a	7% high, 5% medium, 88% low quality
Report review: Percent of facilities that have a representative sample of submitted reports reviewed by Commission	100% reviewed	100% reviewed
Feedback: percent of participating facilities that received feedback about reporting at least once per year	n/a	22% received individual feedback
Action Plan follow-up: percent of serious adverse events that received Commission follow-up with participants	n/a	Not completed
Written Notification to patients/families: percent for all serious adverse events	n/a	0% (0 of 6 reports)

Program Enrollment

As of December 31, 2008 there were 41 ASC participants enrolled out of 82 eligible. This represents 50% of all licensed freestanding ASCs in Oregon.

- *Assessment: Less than anticipated progress in ASC program enrollment.*
- *Recommendations: Create and implement strategy to recruit more ASCs. Show the value of the program with tips and tools targeted to ASCs. Provide training in patient safety improvement to match the current QI activities. Dedicate additional time and resources to assisting ASCs.*

Report Quantity

The Patient Safety Commission received a total of 86 adverse event reports from 18 of 41 voluntary participating ASCs (56% non-reporting). There were 80 less serious adverse events and 6 serious events.

The level of reporting is impressive considering the limited orientation and delayed electronic reporting. Almost half of the enrolled facilities submitted at least one report. It is important to note that the reportable events (Appendix B) are adapted to the lower acuity of care in ASCs. They include events such as unplanned admission to the hospital within 24 hours of discharge and any surgical site infection directly attributable to care provided in ASCs within 30 days.

There are a few other states that collect adverse events from ASCs, but none with a similar list of reportable adverse events. As an overview of other state activities with all the comparative caveats, see Table 10.

Table 10: Selected Other States – Patient Safety Program results for ASCs

State, Original Implementation Date	Non-reporting ASCs	Number of Events, timeframe, year	Confidentiality	Definition of Reportable Events
Minnesota, 2003	(49/53 eligible) 92%	4 / 12 months, 2007/2008	Public reporting at facility level	NQF with additions
Tennessee, 2002	61% (100/163 eligible)	661/ 12 months, 2008	Public reporting in aggregate	Unusual events*
Indiana, 2006	98% (139/142 eligible)	4/12 months, 2007	Public reporting at facility level	NQF definitions verbatim
Connecticut, 2004	Not available	9/12 months, 2007	Public reporting in aggregate only	NQF with additions
Oregon, 2006	56% (23/41 participants)	86/ 12 months, 2008	Public reporting in aggregate only	NQF with additions of less serious events and exclusions

- *Assessment: Very good level of reporting from ASCs*
- *Recommendations: Summarize the reporting from 2008 into feedback communication for ASCs. Set expectations for reporting and demonstrate the benefits of reporting.*

Report Quality

The total report quality for ASC reports submitted in 2008 was 7% high, 5% medium and 88% low quality, Table 9. The scoring for ASC reports uses the same criteria as the hospital certification, Table 3. However, we interpret the results according to the development stage of the patient safety infrastructure in ASCs.

Many ASCs are taking their first steps in identifying how outside factors like communication and teamwork can influence patient safety improvement. Until recently, there has been more focus on clinical/patient factors and individual responsibility and performance. The low baseline report quality can also be explained by considering the following issues: Delayed implementation of comprehensive orientation and electronic reporting, few resources or infrastructure for systems approach to event investigation, confusion about the role of the patient as a contributing factor, hospitals have been building capacity in quality improvement for over a decade in response to expectations from accreditation bodies, CMS and other industry pressures.

* Includes about 20 event types (serious and less serious) such as hemorrhage/hematoma, post-op wound infection, death, wrong-site procedure and more. See quarterly and annual reports for more detail: <http://health.state.tn.us/IPS/quarterly.htm>

- *Assessment: Low baseline quality of ASC reports*
- *Recommendations: Provide frequent and constructive feedback to reporting ASCs about quality of submissions. Make quality improvement tools and resources readily available to all ASC participants. Work with professional organizations to provide root cause analysis training. Set expectations for report submissions. Review the program participation agreements with all ASCs to determine if the obligations are being met. Dedicate additional time and resources to assisting ASCs.*

Adverse Event Report Review

All submitted ASC reports were reviewed for completeness, thoroughness, credibility and acceptability using the same internal criteria for hospital and nursing home reports, Table 3.

- *Assessment: All submitted adverse event reports were reviewed by the Commission staff using standardized review criteria.*
- *Recommendations: Continue to review all reports and share the assessment and possible improvements with reporting participants.*

Feedback to ASCs

There was no formal feedback or quarterly reports from the Commission to ASC participants during 2008. The field coordinator for the ASC program did, however, provide specific report feedback to ASCs for 19 of the 86 reports.

- *Assessment: Specific report feedback for 22% of the submitted reports. No aggregate feedback or quarterly reports to all participants.*
- *Recommendations: Provide all participants with summary of reporting received in 2009.*

Action Plan Follow-up

The action plan follow-up is waived until 2010.

Written Notification

When a serious adverse event is reported, ASC participants are also required to notify patients and their families in writing in a timely and consistent manner. Post-procedure care and communication varies across ASCs depending on their scope of practice and geographic location. Patients sometimes receive care at the ASC and then follow-up care is provided at a location closer to home. The variation raises some challenges in providing written notification to patients. The statute allows ample flexibility about how this requirement may be satisfied.

The Commission and ASCs are still developing customized solutions to meet this patient-centered accountability feature of the reporting program. Participants have access to solutions and recommendations for hospitals.

The PHO Certification will expect 100% written notification for each reported serious adverse event, while accepting that there may be rare exceptions.

- *Assessment: None of the six serious adverse events reported by ASCs in 2008 informed the patient or family in writing.*

- *Recommendations: Continue to support ASCs with written notification and identify the best solution to fit their unique environment of care. Set expectations for completion of written notification.*

Retail Pharmacies

The retail pharmacy world divides itself broadly into two main categories: chain drug stores and independent pharmacies. There are also several subcategories: hospital-associated serving internal populations or outpatient populations, compounding pharmacies, mail order only, closed pharmacies serving limited populations by contract (such as nursing homes, home health or other), radiographic contrast media only and parenteral drugs only.

The retail pharmacy environment has traditionally been one of high accuracy performance requirements and individual pharmacist responsibility for any errors or failures. The systems view of patient safety is mostly an emerging approach. With continually changing external pressures (Medicare Part D, trend toward chain drug stores, expectations about clinical pharmacy services and much more) the retail pharmacy arena faces similar challenges as other health care providers.

The reporting program for retail pharmacies has been delayed by lack of a critical mass of chain and independent pharmacies to ensure confidentiality of the program. The statutorily-required guarantees of confidentiality are only possible with at least 3 large pharmacy chains participating. Also, after consulting with large and small retail pharmacy representatives, the Commission decided that the most efficient way to report is web-based reporting. Electronic reporting would reduce confusion and excessive paperwork for both participants and the limited staff at the Commission

In 2008, the participating pharmacies received complimentary access to the Institute of Safe Medication Practices Newsletter as an interim step. The Commission has submitted a grant proposal to the Agency for Healthcare Research & Quality to sponsor a "Quality Summit" for retail pharmacies in Oregon.

There are about 700 pharmacies total eligible although this number is constantly evolving with independent pharmacies becoming part of small and large chains. This total breaks down by three categories of participants: 444 belong to large chains, 211 independents/small chains and 45 healthcare associated retail pharmacies. Although recruiting voluntary participants has been an uphill climb, 74 pharmacies agreed to participate in the Commission's reporting program by the end of 2008. Of these, 50 (81%) were large chain drug stores, 24 (19%) were independent retail pharmacies and small chains (<10 stores) and none were healthcare associated pharmacies.

- *Assessment: Slow progress toward reporting program development. The program enrollment rates are currently too low to build reporting program.*
- *Recommendations: The Commission is required to provide regular updates to the Legislature, which includes recommendations about changes to the program and possible implementation of mandatory reporting systems. If no improvement is seen by the end of 2010 it may be necessary to consider a switch to mandatory reporting for retail pharmacies.*

Renal Dialysis Centers

The Commission has formed an ad-hoc expert advisory group to design the specific patient safety program with integrated reporting program and draft administrative rules

Birthing Centers

Due to resource limitations at the Commission the development of this program and administrative rules has been deferred until 2010 or later.

Glossary

Action Plan

The product of the root cause analysis is an action plan that identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions [18].

Adverse Event

An injury caused by medical management rather than the underlying condition of the patient. A preventable adverse event is an adverse event attributable to an error or system failure [3].

Commission Event Report Form for Hospitals

The form designated by the Commission to be used by Hospital Participants for the reporting of Reportable Hospital Adverse Events (Appendix C).

Error

Error is the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning) [1].

Harm Level

A harm scale adapted by the Patient Safety Commission to describe the severity of injury to patients. The scale ranges from levels one (error did not reach the patient) to nine (death) (Fig. 2). A serious adverse event is defined by harm level 7-9 and a less serious adverse event by harm level 1-6.

Hospital Participant

A hospital that has volunteered to participate in the Oregon Patient Safety Reporting Program. Hospital pharmacies and ambulatory surgery departments are considered to be part of the hospital.

Joint Commission (also Joint Commission on Accreditation of Healthcare Organizations)

Private, non-profit organization with the mission to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations.

Less serious Adverse Event

An adverse event with a harm level of one to six, see also Harm Level, Serious Adverse Event and Reportable Adverse Event.

Oregon Patient Safety Commission (also “Commission” and “Patient Safety Commission”)

A semi-independent state agency established to improve patient safety by reducing the risk of serious adverse events occurring in Oregon's health care system and by encouraging a culture of patient safety in Oregon. (Oregon Laws 2003, c. 686]

Oregon Patient Safety Reporting Program

The Patient Safety Reporting Program, as defined in Oregon Laws 2003, Chapter 686, Section 4, and operated by the Commission. The Program collects adverse event data from six types of health care facilities: hospitals, retail pharmacies, ambulatory surgery centers, nursing homes, freestanding renal dialysis facilities and freestanding birthing centers. Program activities include broadly: receiving

adverse event reports and other patient safety data, analyzing the patient safety data, providing technical assistance, auditing participant reporting, overseeing action plans, creating incentives to improve participation and distributing written reports and communication.

Patient Safety

Freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximizes the likelihood of intercepting them when they occur [3].

Public Health Officer Certification, (PHO Certification)

Annual certification of the completeness, thoroughness and credibility of participant reporting and the overall integrity of the Patient Safety Reporting Program. The Public Health Officer uses an established certification tool to perform the review. [Appendix A]

Report Form, see Commission Event Report Form (Appendix B)

Reportable Adverse Event - Hospitals

Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury, including the events described in Appendix A of the OAR 325-010-0001 to 325-010-0060. (Appendix C)

Root Cause Analysis

Root Cause Analysis is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls. RCAs have the following characteristics:

- The review is interdisciplinary in nature with involvement of those closest to the process.
- The analysis focuses primarily on systems and processes rather than individual performance.
- The analysis digs deeper by asking *what* and *why* until all aspects of the process are reviewed and all contributing factors are identified (progressing from looking at special causes to common causes).
- The analysis identifies changes that could be made in systems and processes through either redesign or development of new processes or systems that would improve performance and reduce the risk of event or close call recurrence [19].

Serious Adverse Event

An objective and definable negative consequence of patient care, or the risk thereof, that is unanticipated, usually preventable and results in, or presents a significant risk of, patient death or serious physical injury. (Oregon Laws 2003 c.686 §1)

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Appendix A

Oregon Patient Safety Reporting Program for Hospitals 2008 Public Health Officer Certification Criteria and Standards*

Criteria for Annual Public Health Officer Certification

1. What is the Reporting Program enrollment?
 - Number and percentage of hospitals enrolled in the Reporting Program
 - Distribution by hospital size
 - Percentage of statewide discharges represented by enrolled hospitals

2. What are the rates of serious adverse event reporting compared to expected levels?
 - Total number of submitted adverse event reports in 2008
 - Distribution of reports by harm-level determination
 - Distribution of reports by event type
 - Reporting Program – Reports Submitted
 - Number and percentage of participating entities submitting at least one report
 - Distribution by hospital size
 - Percentage of statewide annual discharges represented by reporting hospitals

3. Are the submitted reports complete, thorough, credible, and acceptable?

For Serious Adverse Events:

 - Is the Event Description acceptable?
 - Does the event narrative fully explain the event by including the sequence of actions and relevant environmental conditions in the description?
 - Met/partially met/not met (met: all included, partially met: some included, not met: none included)
 - Is the Serious Adverse Event Analysis acceptable?
 - Does the analysis primarily identify system-level contributing factors most directly associated with the event?
 - Met/not met
 - Does the analysis identify at least one relevant root cause?
 - Met/not met
 - Does the analysis identify additional root or proximal causes?
 - Met/not met
 - Was the senior management notified about the event analysis and recommendations?
 - Met/not met
 - Is the analysis internally consistent? (i.e. does not contradict itself or leave obvious questions unanswered)
 - Met /not met (met: less than 3 inconsistencies, not met: more than 3 inconsistencies)
 - Are the Action Plans acceptable?
 - Do the action plans emphasize strong and system-level solutions that would decrease the likelihood of such events in the future?
 - Met/ not met

* The revised Certification Elements will apply beginning in the report year 2008

- Do the action plans address the identified root and proximate causes?
 - Met/ not met

For Less Serious Adverse Events:

- Same criteria as for serious adverse events with the exception of the question about notification to senior management. This item is not submitted for reports of less serious events.
4. Does the Commission have an accountability plan for the quality and quantity of reports submitted by participants:
 - Does the Commission review a representative sample of submitted reports from each hospital with a systematic and consistent review tool?
 - Percentage met/not met
 - Does the Commission share feedback about the quality and quantity of reports with participants on an annual basis?
 - Percentage of participants that received feedback
 5. Does the Commission annually survey hospitals to get information about follow-up on implementation and effectiveness of their action plans for serious adverse events?
 - Percentage of met/not met
 6. Does the Reporting Program provide useful information about learning and sharing of best practices to hospitals?
 - Percentage of hospitals that find Commission patient safety information useful for their internal quality improvement? (data will come from survey by PHO)
 7. Does the Reporting Program demonstrate patient-centeredness with
 - Acceptable rates of written disclosure for serious adverse events?
 - Percentage of met/not met
 - With the exception of inability to locate appropriate recipient

Minimum standards* for certification of the hospital reporting program:

1. Program Enrollment: maintain participants that represent $\geq 90\%$ of statewide annual discharges
2. Report quantity: Reduce the proportion of cumulatively non-reporting hospitals to $\leq 20\%$ after 3 full years of report submissions (2007-2009)
3. Total Report quality: $\geq 90\%$ in the high quality category
4. 100% hospitals have a representative sample of submitted reports reviewed by Commission
5. 100% of participating hospitals received feedback about reporting at least once per year
6. Action Plan follow-up: Commission completed follow-up for $\geq 90\%$ of serious adverse events
7. Written Notification: 100% for all serious adverse events by 2012 (interim goals: at least 10% increase each year compared to previous year)

Overall Certification levels:

- Certified with no reservations – 6-7 standards achieved
- Certified with reservations – 4-5 standards achieved
- No certification – 3 or less standards achieved

* The proposed standards will apply beginning in the report year 2009.

Oregon Patient Safety Reporting Program for Nursing homes Public Health Officer Certification Criteria 2008*

1. What is the Reporting Program enrollment?
 - Number and percentage of nursing homes enrolled in the Reporting Program
 - Distribution by nursing home size
 - Percentage of statewide annual beds represented by enrolled nursing homes

2. What are the rates of serious adverse event reporting compared to expected levels?
 - Total number of submitted adverse event reports in 2008
 - Distribution of reports by harm-level determination
 - Distribution of reports by event type
 - Reporting Program – Reports Submitted
 - Number and percentage of participating entities submitting at least one report
 - Distribution by nursing home size
 - Percentage of statewide annual beds represented by reporting nursing homes

3. Are the submitted reports complete, thorough, credible, and acceptable?

For Serious Adverse Events:

 - Is the Event Description acceptable?
 - Does the event narrative fully explain the event by including the sequence of actions and relevant environmental conditions in the description?
 - Met/partially met/not met (met: all included, partially met: some included, not met: none included)
 - Is the Serious Adverse Event Analysis acceptable?
 - Does the analysis primarily identify system-level contributing factors most directly associated with the event?
 - Met/not met
 - Does the analysis identify at least one relevant root cause?
 - Met/not met
 - Does the analysis identify additional root or proximal causes?
 - Met/not met
 - Was the senior management notified about the event, analysis and recommendations?
 - Met/not met
 - Is the analysis internally consistent? (i.e. does not contradict itself or leave obvious questions unanswered)
 - Met/partially met/not met (met: less than 3 inconsistencies, not met: more than 3 inconsistencies)
 - Are the Action Plans acceptable?
 - Do the action plans emphasize strong and system-level solutions that would decrease the likelihood of such events in the future?
 - Met/not met
 - Do the action plans address the identified root and proximate causes?
 - Met/not met

* The revised Certification elements will apply beginning in the report year 2008.

4. Does the Commission have an accountability plan for the quality and quantity of reports submitted by participants:
 - Does the Commission review a representative sample of submitted reports from each nursing home with a systematic and consistent review tool?
 - Percentage met/not met
 - Does the Commission share feedback about the quality and quantity of reports with participants on an annual basis?
 - Percentage of participants that received feedback
5. Does the Commission annually survey nursing homes to get information about follow-up on implementation and effectiveness of their action plans for serious adverse events?
 - Percentage of met/not met
6. Does the Reporting Program provide useful information about learning and sharing of best practices to nursing homes?
 - Percentage of nursing homes that find Commission resident safety information useful for their internal quality improvement?
7. Does the Reporting Program demonstrate resident-centeredness with
 - Acceptable rates of written disclosure for serious adverse events?
 - Percentage of met/not met
 -
 - With the exception of inability to locate appropriate recipient

<p>Oregon Patient Safety Reporting Program for Ambulatory Surgery Centers Public Health Officer Certification Criteria 2008*</p>

1. What is the Reporting Program enrollment?
 - Number and percentage of ambulatory surgery centers enrolled in the Reporting Program
 - Distribution by ambulatory surgery center annual procedure volume and specialty area
 - Percentage of statewide annual procedures and specialty area represented by enrolled ambulatory surgery centers
2. What are the rates of serious adverse event reporting compared to expected levels?
 - Total number of submitted adverse event reports in 2008
 - Distribution of reports by harm-level determination
 - Distribution of reports by event type
 - Distribution of reports by specialty area
 - Reporting Program – Reports Submitted
 - Number and percentage of participating entities submitting at least one report
 - Distribution by ambulatory surgery center annual procedure volume and specialty area
 - Percentage of statewide annual procedures represented by reporting ambulatory surgery centers

* The revised Certification Elements will apply beginning in the report year 2008

3. Are the submitted reports complete, thorough, credible, and acceptable?

For Serious Adverse Events:

- Is the Event Description acceptable?
 - Does the event narrative fully explain the event by including the sequence of actions and relevant environmental conditions in the description?
 - Met/partially met/not met (met: all included, partially met: some included, not met: none included)
- Is the Serious Adverse Event Analysis acceptable?
 - Does the analysis primarily identify system-level contributing factors most directly associated with the event?
 - Met/not met
 - Does the analysis identify at least one relevant root cause?
 - Met/not met
 - Does the analysis identify additional root or proximal causes?
 - Met/not met
 - Was the senior management notified about the event, analysis and recommendations?
 - Met/not met
 - Is the analysis internally consistent? (i.e. does not contradict itself or leave obvious questions unanswered)
 - Met/not met (met: less than 3 inconsistencies, not met: more than 3 inconsistencies)
- Are the Action Plans acceptable?
 - Do the action plans emphasize strong and system-level solutions that would decrease the likelihood of such events in the future?
 - Met/not met
 - Do the action plans address the identified root and proximate causes?
 - Met/not met

For Less Serious Adverse Events:

- Same criteria as for serious adverse events with the exception of the question about notification to senior management. This item is not submitted for reports of less serious events.

4. Does the Commission have an accountability plan for the quality and quantity of reports submitted by participants:

- Does the Commission review a representative sample of submitted reports from each ambulatory surgery center with a systematic and consistent review tool?
 - Percentage met/not met
- Does the Commission share feedback about the quality and quantity of reports with participants on an annual basis?
 - Percentage of participants that received feedback

5. Does the Commission annually survey ambulatory surgery centers to get information about follow-up on implementation and effectiveness of their action plans for serious adverse events?

- Percentage of met/not met

6. Does the Reporting Program provide useful information about learning and sharing of best practices to ambulatory surgery centers?

- Percentage of ambulatory surgery centers that find Commission patient safety information useful for their internal quality improvement?

7. Does the Reporting Program demonstrate patient-centeredness with acceptable rates of written disclosure for serious adverse events?

- Percentage of met/not met
 - With the exception of inability to locate appropriate recipient

Oregon Patient Safety Reporting Program for Retail Pharmacies Public Health Officer Certification Criteria 2008*

1. What is the Reporting Program enrollment?
 - Number and percentage of retail pharmacies enrolled in the Reporting Program
 - Distribution by retail pharmacy size

2. What are the rates of serious adverse event reporting compared to expected levels? (Standards for reporting expectations account for the development stage of the program.)
 - Total number of submitted adverse event reports in 2008
 - Distribution of reports by harm-level determination
 - Distribution of reports by event type
 - Reporting Program – Reports Submitted
 - Number and percentage of participating entities submitting at least one report
 - Distribution by retail pharmacy size

3. Are the submitted reports complete, thorough, credible, and acceptable?

For Serious Adverse Events:

 - Is the Event Description acceptable?
 - Does the event narrative fully explain the event by including the sequence of actions and relevant environmental conditions in the description?
 - Percentage of met/partially met/not met (met: all included, partially met: some included, not met: none included)
 - Is the Serious Adverse Event Analysis acceptable?
 - Does the analysis primarily identify system-level contributing factors most directly associated with the event?
 - Percentage of met/not met
 - Does the analysis identify at least one relevant root cause?
 - Percentage of met/not met
 - Does the analysis identify additional root or proximal causes?
 - Percentage of met/not met
 - Did senior management participate in the analysis?
 - Percentage of senior management participation/notification
 - Is the analysis internally consistent? (i.e. does not contradict itself or leave obvious questions unanswered)
 - Percentage of met/partially met/not met (met: less than 3 inconsistencies, not met: more than 3 inconsistencies)
 - Are the Action Plans acceptable?
 - Do the action plans emphasize strong and system-level solutions that would decrease the likelihood of such events in the future?
 - Percentage of met/ not met for system-level action plans
 - Percentage of met/ not met for strong action plans
 - Do the action plans address the identified root and proximate causes?

* The revised Certification Elements will apply beginning in the report year 2008

- Percentage of met/ not met
4. Does the Commission have an accountability plan for the quality and quantity of reports submitted by participants:
 - Review a representative sample of submitted reports from each retail pharmacy with a systematic and consistent review tool?
 - Percentage met/not met
 - Share feedback about the quality and quantity of reports with participants on an annual basis?
 - Percentage of participants that received feedback
 5. Does the Commission annually survey retail pharmacies to get information about follow-up on implementation and effectiveness of their action plans for serious adverse events?
 - Percentage of met/not met
 6. Does the Reporting Program provide useful information about learning and sharing of best practices to retail pharmacies?
 - Percentage of retail pharmacies that find Commission resident safety information useful for their internal quality improvement?
 7. Does the Reporting Program demonstrate resident-centeredness with
 - Acceptable rates of written disclosure for serious adverse events?
 - Percentage of met/not met
 - With the exception of inability to locate appropriate recipient

Appendix B

Reportable Adverse Events by facility type*

Reportable Hospital Serious Adverse Events

Type of Events	Additional Specifications
1. GENERAL CATEGORY	
Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury.	<p>Category includes:</p> <ul style="list-style-type: none"> • Any unanticipated, usually preventable event that results in serious physical injury, even if the harm is temporary. • Only events that are not related to the natural course of the patient's illness or underlying condition. • Healthcare acquired infections that result in patient death or serious physical injury.
2. SURGICAL EVENTS	
A. Surgery performed on the wrong body part.	<p>Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient.</p> <p>Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.</p> <p>Surgery includes endoscopies and other invasive procedures.</p>
B. Surgery performed on the wrong patient.	<p>Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.</p> <p>Surgery includes endoscopies and other invasive procedures.</p>
C. Wrong surgical procedure performed on a patient.	<p>Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient.</p> <p>Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.</p> <p>Surgery includes endoscopies and other invasive procedures.</p>

* All facility types may submit lower harm level or other events in addition to the required events in the lists.

D. Retention of a foreign object in a patient after surgery or other procedure.	Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
E. Intraoperative or immediately post-operative death in an ASA Class I patient. (ASA is the American Society of Anesthesiologists. Class I means a healthy patient, no medical problems.)	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.
3. PRODUCT OR DEVICE EVENTS	
A. Patient death or serious physical injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility.	Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.
B. Patient death or serious physical injury associated with the use or function of a device in patient care in which the device is used or functions other than as intended or is difficult to use as intended.	Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.
C. Patient death or serious physical injury associated with intravascular air embolism that occurs while being cared for in a healthcare facility.	Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
4. PATIENT PROTECTION EVENTS	
A. Infant discharged to the wrong person	
B. Patient death or serious physical injury associated with patient elopement (disappearance) for more than four hours.	Excludes events involving competent adults.
C. Patient suicide, or attempted suicide resulting in serious physical injury while being cared for in a healthcare facility.	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.
5. CARE MANAGEMENT EVENTS	
A. Patient death or serious physical injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration).	Excludes reasonable differences in clinical judgment on drug selection and dose.
B. Patient death or serious physical injury associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.	
C. Maternal death or serious physical injury associated with labor or delivery in a low-risk pregnancy while being cared for in	Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.

a healthcare facility.	
D. Patient death or serious physical injury associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.	
E. Death or serious physical injury (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	Hyperbilirubinemia is defined as bilirubin levels >30 mg/dl. Neonate refers to the first 28 days of life.
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.	Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
G. Patient death or serious physical injury due to spinal manipulative therapy.	
H. Any perinatal death or serious physical injury unrelated to a congenital condition in an infant having a birth weight greater than 2500 grams.	
6. ENVIRONMENTAL EVENTS	
A. Patient death or serious physical injury associated with an electric shock while being cared for in a healthcare facility.	Excludes events involving planned treatments such as electric countershock.
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.	
C. Patient death or serious physical injury associated with a burn incurred from any source while being cared for in a healthcare facility.	
D. Patient death or serious physical injury associated with a fall while being cared for in a healthcare facility.	
E. Patient death or serious physical injury associated with the use of restraints or bedrails while being cared for in a healthcare facility.	

Reportable Nursing Home Serious Adverse Events

Type of Events	Additional Specifications
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.

Reportable Ambulatory Surgery Center Adverse Events

Type of Events	Additional Specifications
1. SURGICAL EVENTS	
A. Unplanned admission to the hospital within 48 hours of discharge from an ambulatory surgery center	This includes any admission to the hospital or emergency department for symptoms related to the recent ASC procedure
B. Postoperative nausea that requires hospital admission	This includes both immediate post-operative and post-discharge hospital admission for symptoms of nausea within 24 hours
C. Any blood products transfusion	Defined as the use of any blood products for a patient during stay at ASC
D. Immediate postoperative bleeding that requires surgical treatment in the operating room (before discharge)	Includes all postoperative bleeding following the procedure and/or anesthesia that requires surgical treatment prior to discharge
E. Deep vein thrombosis with or without pulmonary embolism	Includes deep vein thrombosis or pulmonary embolism within 30 days of surgery
F. Unplanned retention of a foreign object in a patient after surgery or other procedure	Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
G. Death postoperatively directly attributable to surgical procedure	
H. Intraoperative or immediately postoperative death	Includes all ASA Class I-IV patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.

I. Surgery performed on the wrong body part.	Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.
J. Surgery performed on the wrong patient.	Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures.
K. Wrong surgical procedure performed on a patient.	Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies, anesthesia and other invasive procedures.
2. HEALTHCARE-ASSOCIATED INFECTIONS	
A. Surgical site infection up to 30 days postoperatively	Surgical site infections directly attributable to care provided in ASC
3. EQUIPMENT/PRODUCT/DEVICE EVENTS	
A. Patient death or serious physical injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility.	Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.
B. Patient death or serious physical injury associated with the use or function of a device in patient care in which the device is used or functions other than as intended or is difficult to use as intended.	Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.
C. Patient death or serious physical injury associated with intravascular air embolism that occurs while being cared for in a healthcare facility.	Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
4. CARE MANAGEMENT EVENTS	
A. Patient death or serious physical injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration).	Excludes reasonable differences in clinical judgment on drug selection and dose.

B. Patient death or serious physical injury associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.	
C. Patient death or serious physical injury associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.	
5. ENVIRONMENTAL EVENTS	
A. Patient death or serious physical injury associated with an electric shock while being cared for in a healthcare facility.	Excludes events involving planned treatments such as electric countershock.
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.	
C. Patient death or serious physical injury associated with a burn incurred from any source while being cared for in a healthcare facility.	
D. Patient injury associated with a fall while being cared for in a healthcare facility.	
E. Patient death or serious physical injury associated with the use of restraints or bedrails while being cared for in a healthcare facility.	
6. OTHER CATEGORY	
A. Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury.	Includes: <ul style="list-style-type: none"> • Any unanticipated, usually preventable event that results in serious physical injury, even if the harm is temporary. • Only events that are not related to the natural course of the patient's illness or underlying condition