Patient Safety Surveillance and Improvement Program R380-200

2016 – Definitions

Section	Item	Definition	Interpretative Guidelines
R380-200-1	**Purpose**	These rules establish a Patient Safety Surveillance and Improvement program (PSSIP) which extends the past Sentinel Event Reporting program and consists of two components. The first component includes a reportable events program intended to meet public accountability and transparency needs at a state-wide level. The second component uses the data obtained from the reportable events requirement as a foundation intended to develop state-wide patient safety related improvement solutions	Components Public Accountability and Transparency State-wide patient safety improvement
R380-200-2.(1)	**Adverse Events**	an injury associated with healthcare processes rather than the underlying patient condition or disease itself and that prolongs medical intervention or results in harm, disability or death.	Definition
R380-200-2.(2)	**Causal Analysis**	a process for identifying the basic or causal factor(s) that underlie variation in performance, resulting in the occurrence or possible occurrence of a patient safety event, which may include a Root Cause Analysis, a Failure Mode and Effect Analysis, hazards analysis, evidence review, observation or any other relevant analytical process aimed at identifying and understanding contributing factors.	Definition of types of Causal Analysis
R380-200-1(3)	**Meeting National Standards**	The PSSIP intends to be consistent with national regulatory and quality organizational standards to which facilities currently report and may include requirements from the Joint Commission, Agency for Healthcare Research and Quality, American Association of Ambulatory Surgical Centers, DNV Healthcare, Patient Safety Organizations, National Healthcare Safety Network, Centers for Medicaid and Medicare, and the National Quality Forum. As national standards for condition reporting change so may the PSSIP reporting requirements. The quality work output of the PSSIP provides limited access to identifiable health information that facilities report	National Standards

R380-200-2.(3)	**Contaminated**	contamination that can be seen with the naked eye, or with use of detection mechanisms in general use, as they become reported or known to the health care facility	
R380-200-2.(4)	**Harm Scale**	(a) unsafe conditions, (b) near miss which is an event that was stopped prior to reaching the patient, (c) no harm, (d) additional monitoring or treatment to prevent harm, (e) temporary harm requiring intervention, (f) temporary harm requiring hospitalization, (g) permanent patient harm, (h) intervention to sustain life, or (i) patient death.	Harm Scale A-J See
R380-200-2.(5)	**Health care facility" as defined in Title 26, Chapter 21 Part 1, Section 2, (13)(a)**	Acute Care Hospitals Ambulatory Surgical Centers Hospital owned clinics Skilled Nursing Facilities	Approximately 200
R380-200-2.(6)	**Incident facility**	a facility where the patient safety event occurred while in the facility or immediately following discharge within a certain time period defined by specifically by the type of event from that facility	Incident Facility
R380-200-2.(7)	**Medication Error**	medication administration: (a) of a drug other than as prescribed or indicated; (b) of a dose other than as prescribed or indicated; (c) to a patient who was not prescribed the drug; (d) at a time other than prescribed or indicated; (e) at a rate other than as prescribed or indicated; (f) of an improperly prepared drug; (g) by a means other than as prescribed or indicated; or (h) unintentional administration of a drug to a patient who has a known allergy or drug interaction to the prescribed medication	Medication error
R380-200-2.(8)	**Patient safety Event Types**	compilation of serious, largely preventable, and harmful clinical adverse events that includes but are not limited to surgical events, product or device events, patient protection events, care management events, environmental events and criminal events	Patient Safety event types
R380-	**Reporting time period**	(1) Each facility shall report to the Department all patient safety events within	72 hours from

200-3		seventy-two hours of the facility's determination that a patient safety event may have occurred	determination
R380-200-3	**Patient Safety Categories**	(a) Reportable Events with outcome assessed by harm scale; (b) Reportable Events resulting in permanent patient harm, intervention to sustain life, or patient death; (c) Reportable Events referenced by other reporting rules	Harm Scale (A-I) Harm Scale (G, H, I) Annual Reports
R380-200-4.	**Causal Analysis**	(1) The incident facility shall establish a causal analysis process. (2) The incident facility shall designate a responsible individual to be the facility lead for each patient safety event. (3) The incident facility may request the Department representative to participate in the facility's causal analysis in a consultative role to enhance the reliability and thoroughness of the causal analysis. (4) The Department shall notify the facility's lead within 72 hours of receiving the patient safety event report whether the Department intends to participate in the facility's root cause analysis. (5)Participation in the facility's causal analysis by the Department representative shall not be construed to imply Department endorsement of the facility's final findings or action plan. (6) The incident facility and the Department shall each make reasonable accommodations when necessary to allow for the Department representative's participation in the causal analysis. (7) If, during the review process, the Department representative discovers problems with the facility's processes that limit either the thoroughness or credibility of the findings or recommendations, the representative shall report these to the designated responsible individual orally within 24 hours of discovery and in writing within 72 hours. (8) The facility shall conduct a causal analysis which is timely, thorough and credible to determine whether reasonable system changes would likely prevent a patient safety event in similar circumstances. (9) The causal analysis shall: (a) focus primarily on systems and processes, not individual performance; (b) progress from specific, direct causes in clinical processes to contributing	Establish a process Identify a lead May invite UDOH Patient safety or other staff If UDOH sees problems must notify lead orally within 24 hours and in writing within 72 hours Timeliness Thoroughness Credible Focused on system changes including

		causes in organizational processes; (c) seek to determine related and underlying causes for identified causes; (d) identify changes which could be made in systems and processes, either through redesign or development of new systems or processes, that would reduce the risk of such events occurring in the future; and (e) may include a 'Known Complication Test Revision' set of questions to be utilized when requesting a more thorough response from a unit or physician on evaluation of a known complication related to a procedure, treatment or test. These questions should address: (i) Whether the procedure/treatment/test was appropriate and Warranted and based on nationally recognized standards of care; (ii) Whether the complication is a known risk, was anticipated before the procedure and that the standard of care applied to mitigate the risk; (iii) Whether the complication was identified in a timely manner (i.e. at the time of the occurrence); (iv) Whether the complication treatment was according to the standard of care and in a timely manner; and (v) Whether the treatment of the complication follows a nationally recognized standard of care. (10) The Department shall determine the causal analysis to be complete if it: (a) involves a complete review of the patient safety event including interviews with all readily identifiable witnesses and participants and a review of all related documentation; (b) identifies the human and other factors in the chain of events leading to the final patient safety event, and the process and system limitations related to the occurrence; (c) searches readily retrievable records to analyze the underlying systems and processes to determine where redesign might reduce risk; (d) makes reasonable attempts to identify and analyze trends of similar events which have occurred at the facility in the past; (e) identifies risk points and their potential contributions to this type of event; (f) determines potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or that no such improvement opportunities exist; and	systems and processes Completeness Human factors and chain of events with processes and system issues Trends Improvement options and recommendations

		(g) is based on the evidence from the research literature, data from other sources, or is derived from a formal organizational improvement strategy. (11) The Department shall determine the causal analysis to be credible if it: (a) is led by someone with training in causal analysis processes and who was not involved in the patient safety event; (b) involves any necessary consultation with either internal or external experts in the processes in question who were not involved in the patient safety event; (c) includes participation by the leadership of the organization; (d) includes individuals most closely involved in the processes and systems under review; (d) is internally consistent, does not contradicting itself or leave obvious questions unanswered; (e) provides an explanation for all findings of "not applicable" or "no problem"; and (f) includes consideration of relevant, available literature	Evidence based Credibility
R380-200-4 (9)	**Causal Analysis Process**	Facility will conduct a causal analysis which is timely, thorough and credible to determine whether reasonable system changes would likely prevent a patient safety event in similar circumstances; **The causal analysis shall:** (a) focus primarily on systems and processes, not individual performance; (b) progress from specific, direct causes in clinical processes to contributing causes in organizational processes; (c) seek to determine related and underlying causes for identified causes; (d) identify changes which could be made in systems and processes, either through redesign or development of new systems or processes, that would reduce the risk of such events occurring in the future; and (e) may include a Known Complication Test Revision set of questions to be utilized when requesting a more thorough response from a unit or physician on evaluation of a known complication related to a procedure, treatment or test <u>These questions should address:</u> (i) Whether the procedure/treatment/test was appropriate and Warranted and based on nationally recognized standards of care; (ii) Whether the complication is a known risk, was anticipated before the procedure and that the standard of care applied to mitigate the risk;	Process

		(iii) Whether the complication was identified in a timely manner (i.e. at the time of the occurrence); (iv) Whether the complication treatment was according to the standard of care and in a timely manner; and (v) Whether the treatment of the complication follows a nationally recognized standard of care.	
R380-200-4.(10)	**Causal Analysis Determined to be Complete if it:**	(a) involves a complete review of the patient safety event including interviews with all readily identifiable witnesses and participants and a review of all related documentation; (b) identifies the human and other factors in the chain of events leading to the final patient safety event, and the process and system limitations related to the occurrence; (c) searches readily retrievable records to analyze the underlying systems and processes to determine where redesign might reduce risk; (d) makes reasonable attempts to identify and analyze trends of similar events which have occurred at the facility in the past; (e) identifies risk points and their potential contributions to this type of event; (f) determines potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or that no such improvement opportunities exist; and (g) is based on the evidence from the research literature, data from other sources, or is derived from a formal organizational improvement strategy	Completeness Criteria
R380-200-4.(11)	**Causal Analysis Determined to be Credible if it:**	(a) is led by someone with training in causal analysis processes and who was not involved in the patient safety event; (b) involves any necessary consultation with either internal or external experts in the processes in question who were not involved in the patient safety event; (c) includes participation by the leadership of the organization; (d) includes individuals most closely involved in the processes and systems under review; (d) is internally consistent, does not contradicting itself or leave obvious questions unanswered; (e) provides an explanation for all findings of "not applicable" or "no problem"; and (f) includes consideration of relevant, available literature	Credibility Criteria

R380-200-5.	**Causal Reports and Action Plans**	(1) Within 60 calendar days of determination of the patient safety event, the incident facility shall submit to the department a final report with an action plan that: (a) identifies changes that can be implemented to reduce risk or formulates a rationale for not implementing changes; and (b) where improvement actions are planned, identifies who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated. (2) The incident facility shall provide a final report to the facility's administration and the Department in a Department-approved electronic format that includes: (a) type of harm; (b) contributing factors; (c) preventability; and (d) actions taken	Final report is due 60 post date of determination unless notification to UDOH Patient Safety director REDCAP reporting site
	Advisory Panel	(1) The Department shall establish a multi-disciplinary advisory panel to assist in carrying out the Department's responsibilities under this rule. (2) At least one representative from each healthcare system that is required to report under this rule shall be invited to be members of the advisory panel. (3) Representatives from other Department patient safety initiatives and Health Care Associations shall be invited to participate and include but are not limited to: (a) infection control, (b) maternal and infant mortality, (c) women and infant care, and (d) other participants, as identified. (4) Members of the advisory panel will complete confidentiality documents. (5) The advisory panel will meet at least quarterly in person or via electronic meeting. (6) An annual report will be provided to the panel one month prior to public release for review and corrections.	Representatives will be asked to complete a confidentiality agreement. Any data identified is with the permission of the facility. All internal analysis will be de-identified unless representatives agree to share amongst them selves
	State Reporting	(1) The Department will report at a minimum one time a year in March on all events occurring in the state the previous year. (2) This report will be de-identified and publicly available.	Annual report de-identified providing state wide trends.

		(3) Internal reports may be generated for quality improvement initiatives and shared with members of the advisory panel. (4) An annual report of events will be requested from the governing program and incorporated in the annual March Patient Safety Report.	Data presented to users group in February and public release in March
	Penalties	An entity that violates any provision of this rule may be assessed a civil money penalty not to exceed the sum of $5,000 or be punished for violation of a class B misdemeanor for the first violation and for any subsequent similar violation within two years for violation of a class A misdemeanor as provided in Section 26-23-6.	Never used
	Authority	Authorizing, and Implemented or Interpreted Law: 26-1-30(2)(a); 26-1-30(2)(b); 26-1-30(2)(d); 26-1-30(2)(e); 26-1-30(2)(g); 26-3-8	Quality product – not subject to GRAMA – protected information