

**R380. Health, Administration.**

**R380-200. Patient Safety Surveillance and Improvement Program (PSSIP).**

**R380-200-1. Purpose and Authority.**

(1) 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.

(2) The rule requires certain health care facilities to report patient safety events specified in this rule as determined by PSSIP in consultation with the patient safety quality work group.

(3) Reporting requirements for this rule will provide an annual state-wide report released in March of each year for public accountability and transparency. Additionally, data obtained from the reporting requirements will be used to help the Utah Department of Health and Health Care Providers understand patterns of failures, identify and implement state-wide improvement interventions, and evaluate state-wide interventions for improved outcomes. 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.

(4) This rule is authorized by Utah Code Subsections "Utah Code Ann. Subsections 26-1-30(3), (4), (6), (7), (8), and (9)".

**R380-200-2. Definitions.**

(1) "Adverse event" is 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.

(2) "Causal analysis" means 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.

(3) "Contaminated" means 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.

(4) "Harm Scale" is a systematic method to designate a patient's level of harm that includes;

(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.
- (5) "Health care facility" as defined in Title 26, Chapter 21 Part 1, Section 2, (13)(a).

(6) "Incident facility" means 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.

- (7) "Medication Error" means 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.

(8) "Patient safety events" are a 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.

**R380-200-3. Reporting of Patient Safety Events.**

(1) Each facility shall report to the Department all patient safety events within seventy-two hours of the facility's determination that a patient safety event may have occurred.

(2) Patient safety events are categorized as:

- (a) Reportable Events with outcome assessed by harm scale;
- (b) Reportable Events resulting in permanent patient harm, intervention to sustain life, or patient death; and
- (c) Reportable Events referenced by other reporting rules.

(3) Patient Safety Events include:

- (a) Reportable Events required to be reported through the reporting portal and with the outcome level assessed by a harm scale:
  - (i) Surgery or procedures requiring consent performed on the wrong body part;
  - (ii) Surgery or procedures requiring consent performed on the wrong patient;
  - (iii) Incorrect surgery or procedures requiring consent performed on a patient;

- (iv) Unintended retention of a foreign object in a patient after surgery or other procedures requiring consent;
  - (v) Infant discharged to the wrong person;
  - (vi) Neonatal hyperbilirubinemia, where bilirubin is greater than 25 milligrams per deciliter;
  - (vii) Stage 3 or 4 pressure ulcers acquired after admission to the facility, except for pressure ulcers that progress from Stage 2 to Stage 3, if the Stage 2 ulcer was documented upon admission;
  - (viii) 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 a toxic substance;
  - (ix) Unexpected flame or unanticipated smoke during an episode of care;
  - (x) Any care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed or certified health care provider;
  - (xi) Abduction of a patient of any age;
  - (xii) Non-consensual sexual contact on a patient, staff member, or visitor by another patient, staff member or unknown perpetrator while on the premises of the facility; or
  - (xiii) Elopement or disappearance of a patient with cognitive impairment for more than 4 hours;
- (b) Reportable Events resulting in permanent patient harm, intervention to sustain life, or patient death required to be reported to the reporting portal;
- (i) Arising from Intraoperative or immediately post-operative death of a patient who the facility classified prior to surgery as Anesthesia Surgical Assessment Class I or discharged home from an Ambulatory Surgical Center. "Intraoperative" means literally during surgery. "Immediately post-operative" means within 24 hours after surgery, or other invasive procedure was completed, or after induction of anesthesia if surgery not completed;
  - (ii) Arising from the use of contaminated drugs, devices, or biologics provided by the facility;
  - (iii) Arising from the use or function of a device in patient care in which the device is used for an off-label use, except where the off-label use is pursuant to informed consent;
  - (iv) Arising from intravascular air embolism that occurs while being cared for in the facility, except for intravascular air emboli associated with neurosurgical procedures;
  - (v) Arising from Patient suicide or unsuccessful attempt while in the facility or ER within 72 hours of discharge;
  - (vi) Arising from a medication error;
  - (vii) Arising from a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products;
  - (viii) Arising from hypoglycemia, the onset of hypoglycemia which occurs while the patient is being cared for in the facility;
  - (ix) Arising from the irretrievable loss of an irreplaceable

biological specimen;

(x) Arising from failure to follow up or communicate laboratory, pathology, or imaging test results;

(xi) Arising from an unintended electric shock while being cared for at a health care facility, excluding emergency defibrillation in ventricular fibrillation and electroconvulsive therapies;

(xii) Arising from a burn incurred from any source while being cared for in a facility;

(xiii) Arising from the use of restraints or bedrails while being cared for in a facility;

(xiv) Arising from a fall while being cared for in a health care facility;

(xv) Arising from a criminal assault or battery that occurs on the premises of the health care facility;

(xvi) Arising from the introduction of a metallic object into the MRI area;

(xvii) Arising from labor or delivery while being cared for in a facility; or

(xviii) Of an infant born at gestation equal to or greater than 32 weeks excluding congenital causes.

(c) Reportable events required by other reporting rules:

The following set of reportable events is governed by other existing Utah law or rule and facility reporting to the reporting portal under this rule is not needed.

(i) Prolonged fluoroscopy with cumulative dose greater than 1500 rads to single field (R313-20-5);

(ii) Radiology to the wrong body region (R313-20-5);

(iii) Radiotherapy greater than 25% above the prescribed radiotherapy dose(R313-20-5);

(iv) Death or permanent loss of function related to a healthcare acquired infection (R386-705); and

(v) Provider Preventable Conditions (R414-1-29).

(4) If a facility suspects that a patient safety event may have occurred to a patient who was transferred from another facility, the receiving facility shall report the suspected patient safety event to the transferring facility.

(5) All facility required reports will be submitted through a secured reporting portal and consist of the following:

(a) facility information;

(b) patient information;

(c) condition information

(d) type of occurrence;

(e) analysis findings; and

(f) corrective actions.

#### **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 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

(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.

#### **R380-200-5. Reports and Action Plan.**

(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.

(3) The Department representative may submit a separate written dissenting report to the administrator of the incident facility and the Department if the Department representative identifies problems with the processes that limit the thoroughness or credibility of the findings and recommendations and that have not been corrected after reporting them to the designated responsible individual.

(4) The incident facility may seek review of the dissenting report by filing a request for agency as allowed by the Utah Administrative Procedures Act and Department rule.

(5) If a dissenting report is not challenged or is upheld on review:

(a) the facility shall include it in the facility's records of the causal analysis; and

(b) the Department may forward it, together with the facility's report, to the appropriate state agencies responsible for licensing the facility.

#### **R380-200-6. Confidentiality.**

(1) Information that the Department holds under this rule is confidential under the provisions of Title 26, Chapter 3. Because of the public interest to foster health care systems improvements, the Department may exercise its discretion under Section 26-3-8 and shall not release information collected under this rule to any person pursuant to the provisions of Subsections 26-3-7(1) or (8).

(2) Information produced or collected by a facility is confidential and privileged under the provisions of Title 26, Chapter 25.

#### **R380-200-7. Extensions and Waivers.**

(1) The Department may grant an extension of any time requirement of this rule if the facility demonstrates that the delay is due to factors beyond its control or that the delay will not adversely affect the required root cause analysis and the purposes of this rule.

(2) A facility requesting a waiver must submit the request to the Department representative prior to the deadline for the required action.

(3) The Department may grant a waiver of any other provision of this rule if the facility demonstrates that the waiver will not adversely affect the required root cause analysis and the purposes of this rule.

#### **R380-280-8. 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.

**R380-200-9. 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.

(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.

**R380-200-10. 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.

**KEY: hospital, sentinel event, quality improvement, patient safety**

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**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**