

Interpretive Guidelines for Standards of Care Determinations Including Involved Provider (Individual/Entity) Accountability

These Standards of Care interpretive guidelines have been developed to assist hospital and ambulatory surgical center risk managers, and others who fall under the Kansas risk management statutes and regulations, in their deliberations when reviewing quality of care issues. These guidelines provide examples of events which fall under each standard of care level and will assist those who complete risk management documentation for internal and external use. *(The examples and scenarios listed in these guidelines are not all inclusive of clinical events which may take place in a facility and may not reflect all thought processes that take place in defining the “involved provider” or the SOC designation)*

Kansas Administrative Regulation 28-52-4

K.A.R. 28-52-4. Standard-of-care determinations. (a) Each facility shall assure that analysis of patient care incidents complies with the definition of a “reportable incident” set forth at K.S.A. 65-4921. Each facility shall use categories to record its analysis of each incident, and those categories shall be in substantially the following form:

- (1) Standards of care met;
- (2) Standards of care not met, but with no reasonable probability of causing injury;
- (3) Standards of care not met, with injury occurring or reasonably probable;
- (4) Possible grounds for disciplinary action by the appropriate licensing agency.

(b) Each reported incident shall be assigned an appropriate standard-of-care determination under the jurisdiction of a designated risk management committee. Separate standard-of-care determinations shall be made for each involved provider and each clinical issue reasonably presented by the facts. Any incident determined by the designated risk management committee to meet category (a)(3) or (a)(4) shall be considered a “reportable incident” and reported to the appropriate licensing agency in accordance with K.S.A. 65-4923.

(c) Each standard-of-care determination shall be dated and signed by an appropriately credentialed clinician authorized to review patient care incidents on behalf of the designated committee. In those cases in which documented primary review by individual clinicians or subordinate committees does not occur, standard-of-care determinations shall be documented in the minutes of the designated committee on a case-specific basis. Standard-of-care determinations made by individual clinicians and subordinate committees shall be approved by the designated risk management committee on at least a statistical basis. (Authorized by and implementing K.S.A. 65-4922; effective Feb. 27, 1998.)

Interpretive Guidelines for Standards of Care Determinations and Involved Provider (Individual/Entity) Accountability

The purpose of the Kansas risk management statutes - to protect patient safety and improve the quality of healthcare - should be foremost as facilities investigate events and assign a Standard of Care (SOC). To this end the following guidelines are proposed:

An Involved Provider(s) to which a SOC is assigned is the person/provider/individual/entity who caused the event, committed the error or had the potential to significantly impact the outcome of the event. (Please note that the results of investigations regarding whether the event was preventable and whether facility policies were followed will impact the SOC assigned.)

The person who did not make the error or cause the event but discovers and reports the error/event is not generally assigned a SOC. Possible exceptions include- if this person's action had the potential to significantly impact the outcome. In the example of the fall below--if the patient found on the floor by staff suffered a fracture, did the person finding the patient perform an appropriate assessment of possible injuries and notify the physician/family according to the facility's policy/protocol? In the case of the fire situation below, were the actions of the first responder(s) appropriate?

The examples and scenarios listed below are not all inclusive of clinical events which may take place in a facility and may not reflect all thought processes that take place in defining the "involved provider" or the SOC designation.

In general, a few examples of involved providers are as follows:

- A patient found on the floor by staff – the SOC is assigned to the person(s) responsible for the patient prior to the fall.
- Medication error – the SOC is assigned to the person(s) making the error.
- Near miss, i.e., the error is discovered before actually reaching the patient – the SOC is assigned to the person(s) committing the error, even though the error did not reach the patient.
- Sponge left in patient – the SOC is assigned to the staff responsible for the sponge counts as well as to the surgeon.
- Unplanned laceration/perforation of an organ – the SOC is assigned to the person who made the laceration/perforation (generally the surgeon.)
- Fire – the SOC is assigned to the person(s) present at the start of the fire. If no staff were present consider the first responder(s) -- i.e., were the actions of the responder(s) appropriate according to the facility's policies/protocols? Also consider the person whose actions or inactions may have allowed the fire to happen. For example: Staff allows a patient on oxygen to have cigarettes and lighter within reach or allows a child receiving oxygen to have a friction toy.
- Nosocomial infection or pressure ulcer – After extensive review it may not be possible to identify the person(s) responsible for the infection or ulcer. If this is the case, determine whether policies on prevention, assessment and documentation were followed and assign the SOC to the hospital/entity. Do consider documentation and treatment issues in the

review process between the time the patient exhibited no injury and the first documented sign of injury—is there a failure to assess? To report? To use preventative measures?

- Poor surgical or medical outcome resulting in repeat surgery, transfer to higher level of care due to complications, death, etc. Consideration of the following factors will assist in the determination of the appropriate SOC (1 vs. 2 vs. 3) as well as the determination of the “involved provider”---- Consider the following in the decision: timely surgery/treatment performed, appropriate and timely consultation obtained, appropriate patient selection for surgery performed, appropriate and timely tests performed, timely notification of patient condition by nursing to physician. Lack of active involvement in the time out process may have led to the poor outcome as well. Involved Provider could be only the surgeon or may be a combination of attending physician and surgeon plus nurse and anesthesia for example. Some facilities may find that the assistance of ‘outside peer review’ may be helpful in this determination.

Below are scenarios specific to the SOC listed along with additional examples of involved providers (individual/entity) Again—this is not an exhaustive list of examples.

(1) Standards of care met.

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- (1) Standards of care met, even if an injury occurred to the patient. Care provided met the standards of care. Policies, if applicable, were followed.

Examples:

- Patient found on the floor; all appropriate precautions were in place, i.e., call light in place, non-skid footwear in use, etc.
The possible involved provider(s): Staff responsible for direct care and supervision at time of incident.
- Patient given medication and had an allergic reaction. Patient had been asked allergy history. Allergy bracelet was checked. Medication given was not listed as an allergy by the patient.
The possible involved provider: the person giving the medication, pharmacist, physician ordering medication.
- Patient presents to ED with fever. Antibiotics started. Patient returns 48 hours later and is placed on a new medication due to change in condition.
The possible involved provider: the ED physician/provider of the first ED visit.
- Patient and/or family manipulated equipment after being told to keep their hands off the equipment.

The possible involved provider(s): the person(s) accountable for providing patient/family education or staff responsible for patient's care at time of incident.

- A patient with no identified allergies has an allergic reaction to a prescribed medication.

The possible involved provider: the person giving the medication.

(2) Standards of care not met, but with no reasonable probability of causing injury.

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- (2) Standards of care not met, but with no reasonable probability of causing injury.

No reasonable probability means may be possible but is not probable.

Injury is defined to mean an incident that requires significant medical intervention, or causes disability or death.

Significant medical intervention may include a more intensive level of care, surgical intervention, significant change in medications and/or increased length of stay due to unexpected additional diagnostic or treatment measures.

Examples:

- Patient was given the wrong medication. Medication administration process was not followed. Minor medical intervention needed. Minor medical intervention that could be provided by a healthcare provider, for example: nurse, physician, allied health, etc.

The possible involved provider: the person giving the medication. Consider also the pharmacist who may have sent the wrong medication or the person who stocked the medication dispensing unit such as Omnicell, Pyxis, etc in error.

- Patient at risk for falls fell out of bed resulting in some bruising. Fall precautions had not been implemented.

The possible involved provider: Staff responsible for direct care and supervision at the time of the incident.

- A near miss occurred when a pharmacist dispensed the wrong medication and the nurse caught the error before the medication was administered.

The possible involved provider: the pharmacist dispensing the medication.

- Physician orders indicated patient was to ambulate only with assistance. Patient was allowed to get up and was not accompanied as ordered. Patient fell, sustaining minor laceration to knee.

The possible involved provider: the person who allowed the patient to be up without the ordered assistance. Consider possible inappropriate delegation of care or inadequate staffing.

- Incorrect medication dispensed by pharmacy and administered to the patient. No harm occurred to the patient and there was no reasonable probability of harm.

The possible involved providers: the pharmacist dispensing the medication and the nurse giving the medication.

- Critical lab value results were not reported to the physician. On review of the event, knowledge of the critical lab would not have resulted in a change in treatment.

The possible involved provider: the person responsible for timely reporting of critical lab values.

(3) Standards of care not met, with injury occurring or reasonably probable.

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- (3) A **reportable standard of care not met** means a deviation from the standard of care that has a known and direct adverse outcome / impact on patient care *and* causes injury or there is a **reasonable probability** (more likely than not) of causing injury to that patient.

Injury is defined to mean an incident that requires significant medical intervention, or causes disability or death.

Significant medical intervention may include a more intensive level of care, surgical intervention, significant change in medications and/or increased length of stay due to unexpected additional diagnostic or treatment measures.

Examples:

- Following incorrect medication administration during surgery, the patient suffers neurological damage.
The possible involved provider: the person giving the medication. Consider the person who gave the medication; the physician—was the order/ dosage correct; and the role of the pharmacy if any in dispensing---should the pharmacist have questioned the order. If such an error occurred outside of the OR also consider the person transcribing the order.
- Patient is given a medication for which they have a stated allergy and patient experiences severe anaphylactic reaction.
The possible involved provider: the person giving the medication. Consider the pharmacist who may have dispensed the medication and should have known of the allergy. Was the physician aware/notified of the allergy prior to

administration? Was the appropriate allergy documentation and warning bracelet in place?

- Orders for a confused, combative patient stated the patient was to have 1:1 care while the patient was up in the chair. After the patient was assisted to the chair, the assigned caregiver left the room. While the caregiver was gone, the patient fell from the chair and fractured a hip.
The possible involved provider: the assigned caregiver who left the room against orders. Consider the appropriate delegation of care and staffing.
- Failure to report significant changes in patient condition, causing patient injury.
The possible involved provider(s): the person(s) who were responsible for the care and who should have identified and reported the changes.
- Failure of healthcare provider to respond to significant changes in patient condition, causing patient injury.
The possible involved provider: person(s) who did not respond appropriately or timely to changes in the patient's condition. Consider the appropriate use of the chain of command. Was the correct person notified? Was the appropriate call method/notification used?
- A critical radiological finding was missed that resulted in a delay of surgery or other treatment (missed fracture, missed abdominal abscess, etc)
The possible involved provider: Consider the following---radiologist of the initial reading, ED Physician, attending or other physician, radiologist of the final reading, whether the correct finding was communicated to a physician but the physician did not take timely action.
- Critical lab value results were not reported to physician with reasonable probability of injury occurring as a result---a review of the event noted that medical treatment would have been changed if critical results had been communicated.
The possible involved provider: the person responsible for timely reporting of critical lab values.

(4) Possible grounds for disciplinary action by the appropriate licensing agency.

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- (4) A **reportable** incident with possible grounds for disciplinary action by the appropriate licensing agency.
(Note that this applies to licensed healthcare professionals. May be limited for certified healthcare personnel such as CNA, CMA, etc. SOC 4 does not apply to personnel who are not licensed or certified in healthcare.)

Examples: For all of the following examples, the involved provider would be the person/provider who committed the act. Consider all involved individuals, system problems, etc. Although the provider who committed the act may receive an SOC 4, any other involved individual may receive the same or lesser SOC determination. If systemic failure was a factor in the incident, the facility should receive an SOC determination for the facility. For example in the case of drug diversion were narcotic counts performed? Did staff log out of the medication dispensing machine prior to the next person's use? Were reports periodically run to monitor possible drug misuse?

- Practicing without a current license.
- Working under the influence of drugs/alcohol.
- In the course of providing patient care, a healthcare worker is verbally abusive.
- Trended incidents identifying quality or performance issues.
- Violations of a licensing agency's disciplinary codes.
- Falsification of the medical record.
- Practicing outside the scope of one's license.
- Drug diversion.
- Theft of hospital/patient property by staff member.
- Intentional viewing of a patient's protected health information by a staff member or physician without authorization.
- Willful discussion of a patient's protected health information by a staff member or physician without authorization. (HIPAA violations may need to be evaluated in risk management as well as by the facility compliance/privacy officer.)

NCI – Non-Clinical Incident. Used for internal trending purposes. Does not meet requirements for reporting to regulatory agencies.

Examples: (Note that the investigation of these events may cause the event to be considered a clinical event and to need SOC assigned.)

- Theft of hospital or personal property by non-staff persons. Consider if staff took appropriate precautions to prevent the theft.
- Lost patient articles, i.e., watch, ring, etc. Consider staff responsibility for the loss of the items—were policies followed? Was the patient informed of his responsibility in the care of his possessions?
- Visitor closes door on finger. Consider known equipment/door malfunctions that should have been repaired.
- Visitor falls in parking lot. Consider hospital responsibility to timely repair crumbling asphalt or adequate ice removal.

Additional Resources are available through KDHE
on the KDHE website: http://www.kdheks.gov/bhfr/state_ach_licensure_forms.html

or by calling the Risk Management Specialist at 785-291-3552

Resources used in the development of the guidelines include

- A. JCAHO Sentinel Event Policy and Procedures, Oregon Association of Hospitals and Health Systems
- B. JCAHO, January 25, 2006, Sentinel Event Alert
- C. Florida Statute 766.102 Medical Negligence: Injury
- D. General Information for Panel Members: Utah, Division of Occupational & Professional Licensing A3. Proximate Cause
- E. Robert I. Simon, MD Commentary: Medical Errors, Sentinel Events, and Malpractice, *Journal of American Academy of Psychiatry Law* 34:99-100, 2006

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