Health Services
LOS ANGELES COUNTY

POLICIES AND PROCEDURES

SUBJECT: ADVERSE EVENT REPORTING

POLICY NO: 311.202

PURPOSE:

To comply with the mandated reporting requirements of Health and Safety Code § 1279.1(b) and to support the improvement of patient safety and quality improvement initiatives.

SCOPE:

This policy applies to all Los Angeles County, Department of Health Services (DHS) facilities.

POLICY:

All DHS health care facilities shall report adverse events that are urgent or emergent threats to the welfare, health, or safety of patient, personnel, or visitors to the DHS Chief Medical Officer or DHS Director, via phone or e-mail not later than twenty-four (24) hours after the adverse event has been detected. For after-hours phone numbers, please consult the Director's Staff Roster. Facilities shall report all other adverse events within 5 days to the DHS Director of Quality Improvement and Patient Safety. It is our policy that events are investigated to determine the source(s) of the events and initiate any mitigation actions that may be indicated. Investigations are to be completed according to the attached "Procedures for Compliance with Los Angeles County Ordinance 2.76.590 Risk Management Protocol – Quality Improvement Program." Facilities shall also report all adverse events using the Patient Safety Net (PSN). Reportable non-clincal events must be reported in accordance with DHS Policy No. 311, "Incidents Involving Potential Claims Against the County."

Acute care hospitals and outpatient settings where anesthesia, (except local anesthesia, or peripheral nerve blocks, or both), is administered in doses that, when administered have the probability of placing a patient at risk or loss of the patient's life-preserving protective reflexes, are required to report adverse events to the California Department of Public Health (CDPH). Adverse events, as defined within Health and Safety Code §1279.1, must be reported to CDPH no longer than 5 days after the event has been detected; or, if the event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than twenty-four (24) hours after the adverse event has been detected. The report shall be completed using the "DHS Reporting Form – Adverse Events" (attached) and will include a brief narrative

describing the event and a facility identification number. The report shall be sent concurrently to CDPH and to the DHS Director of Quality Improvement and Patient Safety.

It is our policy to cooperate fully with the CDPH throughout the process.

If the facility is uncertain whether an event should be reported to CDPH, the DHS Chief Medical Officer or the DHS Director shall be contacted by phone and the decision to report or not to report to CDPH will be made jointly between the facility and Health Services Administration. If after discussion with Health Services Administration there is still uncertainty about reporting, the facility's General Counsel may be consulted. For after-hours consultation with the DHS Chief Medical Officer, DHS Director, or General Counsel, consult the Director's Staff Roster for contact information.

DEFINITIONS:

"Adverse event" includes *any* of the following:

1. Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.
2. Surgery performed on the wrong patient.
3. The wrong surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. A reportable event does not include a situation requiring prompt action that occurs in the course of surgery, or a situation that is so urgent as to preclude the obtaining of informed consent.
4. Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.
5. Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.
6. Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product. (See also DHS Policy No. 311.1)
7. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes, but is not limited to, a catheter,

drain, or other specialized tube, infusion pump, or ventilator. (See also DHS Policy No. 311.1)

8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
9. An infant discharged to the wrong person.
10. Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decision-making capacity.
11. A patient suicide or attempted suicide resulting in serious disability due to patient actions after admission, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the health facility.
12. A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.
13. A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
14. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy, including events that occur within 42 days post-delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.
15. Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a health facility.
16. Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. "Hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.
17. A Stage 3 or 4 ulcer, acquired after admission, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
18. A patient death or serious disability due to spinal manipulative therapy performed at the health facility.
19. A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric countershock. (See also DHS Policy No. 311.1)
20. 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.
21. A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.

22. A patient death associated with a fall. (See also DHS Policy No. 920)
23. A patient death or serious disability associated with the use of restraints or bedrails.
24. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
25. The abduction of a patient of any age.
26. The sexual assault on a patient within or on the grounds of the facility.
27. The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds.
28. An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor. (See also DHS Policy No. 920)

"Serious disability" means a physical or mental impairment that substantially limits one or more of the major life activities of an individual, or the loss of bodily function, if the impairment or loss lasts more than 7 days or is still present at the time of discharge from the health care facility, or the loss of a body part.

“Sentinel event” is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

Such events are called “sentinel” because they signal the need for immediate investigation and response.

The terms “sentinel event” and “medical error” are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events.

DISCLOSURE

The patient, or the party responsible for the patient, will be notified of the nature of the adverse event by the time the report to the DHS/CDPH is made. Such disclosure shall be reflected in the patient’s record. The patient or the party responsible for the patient shall **not** be provided with a copy of the PSN/DHS/CDPH report. These reports will not be placed in the medical record. (See also DHS Policy No. 311.201).

INVESTIGATION

An investigation into the cause of the event shall be undertaken, using root cause analysis, intensified review or other approved investigative process. The investigation shall be conducted according to the *Procedures for Compliance with Los Angeles County Ordinance 2.76.590 Risk Management Protocol – Quality Improvement Program.* The investigation will be conducted for the purpose of the evaluation and improvement of the quality of care in the facility.

REFERENCES:

Health and Safety Code §1279.1(b)
Los Angeles County Ordinance §2.76.590
Joint Commission standards

DHS Policies

311	Incidents Involving Potential Claims Against the County
311.1	Medical Device Reporting Program
311.201	Communication of Unanticipated Outcomes
311.203	Reportable Non-Clinical Events
920	Accident/Injury Reporting

Procedures for Compliance with Los Angeles County Ordinance 2.76.590 Risk Management Protocol – Quality Improvement Program

PROCEDURES FOR COMPLIANCE WITH LOS ANGELES COUNTY ORDINANCE 2.76.590 RISK MANAGEMENT PROTOCOL – QUALITY IMPROVEMENT PROGRAM AND BOARD OF SUPERVISORS' MOTION OF DECEMBER 10, 1996 FOR CORRECTIVE ACTION PLANS

EFFECTIVE APRIL 15, 2007

This document shall describe the procedures required to comply with the Los Angeles County Ordinance 2.76.590 Risk Management Protocol – Quality Improvement Program (Attachment A). This document shall also describe the Department of Health Services (DHS) procedures required to comply with the Board of Supervisor's motion of December 10, 1996 to ensure that complete and appropriate corrective action plans accompany recommendations for settlement to the Board of Supervisors.

The goal of this protocol is to improve the delivery of medical services and reduce risks of county liability by assuring the prompt reporting, complete investigation, and timely implementation of corrective action regarding events involving patient safety, quality of care, potential liability, claims, and lawsuits as they arise out of the provision of medical services.

These procedures, as described below, will supercede any existing practices related to completion of reviews related to incidents, claims or lawsuits, and are proposed to support the timely review, analysis and promulgation of corrective actions for events involving patient safety, quality of care, potential liability, claims and lawsuits as they may arise out of the provision of medical services.

PROCEDURES

Each facility maintains an online event reporting system, the Patient Safety Net (PSN) which accepts and stores events and near misses reported by facility staff. The Risk Manager, or designee, is responsible for reviewing and screening the events reported in the PSN to determine whether further investigation or follow up is required. In the event that the Risk Manager, or designee, determines that no follow up is required, the event is maintained in the PSN database for use in tracking and trending events and near misses.

In the event that the Risk Manager, or designee, determines that follow up is required, the Risk Manager shall set up a risk management file. The Risk Manager shall inform the Quality Improvement and Patient Safety Program (QIPS) that a risk management file has been set up. **This notification should be via e-mail to QIPS@dhs.lacounty.gov no later than 72 hours of the event and within 24 hours of a sentinel event to inform the director that PSN event (#0000) has been identified for further investigation.**

New Claim Files

Upon receipt of a notice of a new claim file, QIPS shall send the facility a form letter **(Attachment B**) requesting that the facility identify whether the claim meets the criteria for a sentinel event or non-sentinel event. QIPS will send this notice via e-mail requesting a response within 10 business days. If no response is received within 10 business days, and the facility has not requested and been granted an extension, then the Senior Medical Director, DHS shall notify the Facility Chief Medical Officer and Chief Executive Officer of the delinquency and request an

appropriate response within 3 (three) business days. Requests for extensions shall be forwarded to QIPS and will be granted only in extreme emergency situations.

Event Review

If the Risk Manager, or designee determines that the event meets the criteria for a sentinel event review (Joint Commission criteria or SB1301), **the Risk Manager or designee shall begin an immediate investigation.** Within 45 calendar days from the date of the event, the facility shall complete a root cause analysis and develop a corrective action plan. For non-sentinel events, facilities shall complete an initial investigation and complete a corrective action plan within 45 days of the event. The corrective action plan for either a sentinel event or a non-sentinel event shall be submitted to QIPS for review upon completion by facility. Facilities shall use **Attachment B**-template to report their planned and completed corrective actions.

Facilities shall ensure that appropriate peer review and/or personnel review, as applicable, is completed on all events, either sentinel or non-sentinel within 45 days of the event. This peer review and/or personnel review shall include a determination of the individual's performance as related to this event as well as implementation of any necessary corrective actions. This personnel review should be conducted outside of the performance of a root cause analysis (RCA) process.

Upon receipt of the initial corrective action plan, QIPS will review the facility's plan and submit the facility's plan at the next available Executive Peer Review Committee for review. The Executive Peer Review Committee shall determine whether all appropriate corrective actions have been identified, make recommendations for additional corrective actions, and make recommendations for DHS-wide corrective actions, as applicable.

If the corrective action plan is not received within 45 calendar days of the date of notification to QIPS and the facility has not requested and been granted an extension, then the Senior Medical Director, DHS will notify the Facility Chief Medical Officer and Chief Executive Officer of the delinquency and request an appropriate response within 3 (three) business days. Requests for extensions shall be forwarded to QIPS and will be granted only in extreme emergency situations.

Within **135** calendar days of the event, the facility shall submit notification of completion of the corrective actions identified on the initial corrective action plan using the **Attachment B** template. Facilities shall also ensure that the information related to the investigation and corrective actions are entered into the PSN system.

Lawsuits

If a lawsuit is filed, County Counsel chairs a roundtable meeting which is held within six (6) months of the lawsuit being filed. Prior to the roundtable meeting, QIPS staff, together with facility staff, shall review facility and DHS corrective actions taken to date. After the roundtable meeting, should the need for additional corrective actions be identified, either at the individual facility or for the DHS system, the facility and DHS shall have 45 calendar days to complete those actions.

If the corrective action plan is not received within the 45 calendar day time frame and no request for extension has been received and approved by QIPS, the Senior Medical Director, DHS shall notify both the Chief Medical Officer and the Chief Executive Officer of the delinquency and

request an appropriate response within 3 business days. Requests for extensions shall be forwarded to QIPS and will be granted only in extreme emergency situations.

Review of Procedures

The procedures defined in this protocol shall be reviewed by the Risk Management Committee annually and updated as necessary to ensure timely initiation of investigation and completion of corrective actions related to events, claims and lawsuits.

Compliance Monitoring

QIPS staff shall monitor compliance with this protocol and report on activities and compliance with this protocol to the Executive Peer Review Committee monthly.

Compliance monitoring shall include the following:

- Percent compliance with timely reviews to be calculated as follows:
    - # open case files with completed corrective action plans within 45 days / # of open case files in that quarter
    - # new claim files with completed corrective action plans within 45 days / # new claim files in that quarter
        - NOTE: Date for these metrics will be collected 45 days after the end of the quarter to ensure accurate reporting of completed corrective actions.
- A quarterly report of cases scheduled for Executive Peer Review
- A quarterly report of cases pending Executive Peer Review (until the backlog of cases is completed).

DEPARTMENT OF HEALTH SERVICES COUNTY OF LOS ANGELES

Reporting Form – Adverse Events

[PLEASE PLACE ON FACILITY LETTERHEAD]

[Date of report]

California Department of Health Services
Licensing and Certification District Office
[Street Address]
[City]. CA **[ZIP]**

To Whom It May Concern:

This (hospital/outpatient setting) believes it may have detected the adverse event indicated below as defined in Health and Safety Code Section 1279.1, and is hereby reporting pursuant to Health and Safety Code Section 1279.1 as well as Title 22, California Code of Regulations, Section 70737 (the "unusual occurrence" reporting requirement).

Due to the short timeframe required for reporting in the law, the information this facility has may be incomplete. If further investigation shows that no adverse event as defined in this law took place, you will be notified. However, in order to comply with the law's short timeframe, this facility is taking a precautionary measure and reporting accordingly.

This facility may have detected the adverse event checked below:

☐ 1. Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. This does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.

☐ 2. Surgery performed on the wrong patient.

☐ 3. The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. This does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.

☐ 4. Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

☐ 5. Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

☐ 6. Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.

☐ 7. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes but is not limited, to a catheter, drain, or other specialized tube, infusion pump, or ventilator.

☐ 8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical purposes known to present a high risk of intravascular air embolism.

☐ 9. An infant discharged to the wrong person.

☐ 10. Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decision making capacity.

☐ 11. A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, excluding deaths resulting from self-inflicted injuries that were the reason for the admission to the health facility.

☐ 12. A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.

☐ 13. A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

☐ 14. A maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days post delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

☐ 15. Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a health facility.

☐ 16. Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. For purposes of this subparagraph, "hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.

☐ 17. A Stage 3 or 4 ulcer, acquired after admission to a health facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.

☐ 18. A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

☐ 19. A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric countershock.

☐ 20. 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.

☐ 21. A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.

☐ 22. A patient death associated with a fall while being cared for in a health facility.

☐ 23. A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

☐ 24. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
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☐ 25. The abduction of a patient of any age.

☐ 26. The sexual assault of a patient within or on the grounds of a health facility.

☐ 27. The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility. *[Note: if this item is checked because a staff member suffered death or significant injury due to a physical assault on the grounds of the facility, please indicate the staff member's name at the bottom of the form, rather than a patient's name or code.]*

☐ 28. An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor. *[Note: An "adverse event" is defined as the incidents described in items 1 through 27, above. If for some reason an adverse event report is made about an event not listed in items 1 through 27 above, a brief description of the event should be included on this form. If a hospital has an adverse event that causes the death or serious disability of a patient, personnel, or visitor but is not listed above in items 1 through 27, legal counsel should be consulted to determine whether it should be reported. A different reporting requirement may apply.}*

Facility's code to link this report to its file regarding this potential adverse event: **[facility's code]**

Brief Description of the event:

Date facility detected the adverse event:

Please contact me at [phone number] if you require further information.

Sincerely,

[Name]
[Title]

c: DHS Senior Medical Director
DHS Director of Quality Improvement and Patient Safety

Note: *"Serious disability" means:*

(a) A physical or mental impairment that substantially limits one or more of the major life activities of an individual, if the impairment lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or

(b) The loss of bodily function, if the loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or

(c) The loss of a body part.

* *Generally this report must be made within five days of detection. However, if the adverse event is an ongoing or urgent threat to the welfare, health, or safety of patients, personnel or visitors, a report must be made within 24 hours of detection.*