VOLUME 3: QUALITY MANAGEMENT	Effective Date: 11/26/2012
CHAPTER 7: PATIENT SAFETY	Revision Date: 05/2017
3.7.5: PATIENT SAFETY PROGRAM PROCEDURE: INSTITUTION RESPONSE TO A HEALTH CARE INCIDENT	Attachments: Yes ☒ No ☐

I. PROCEDURE OVERVIEW

This procedure provides a standardized process for institution response to a health care incident, including:

- Immediate actions to address the event;
- Notification of institution staff and reporting to headquarters;
- Review of reporting requirements;
- Development and implementation of a Plan of Action to mitigate risk of a similar event occurring in the future; and
- Development and implementation of activities, resources, or technical support that shall be put in place to sustain improvements.

II. DEFINITIONS

Adverse Drug Reaction: Any undesired, unintended, or unexpected response to a medication administered in doses recognized as appropriate in accepted health care practice which results in one or more of the following: changing, stopping, or reducing the medication, or admission to a higher level of care. An adverse drug reaction includes any undesired experience with the appropriate use of a medication product in a patient.

Adverse/Sentinel Event: An event or series of events that cause the death or serious disability of a patient, personnel, or visitor. "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 lasts more than seven calendar days or is still present at the time of discharge, or unintentional loss of a body part.

Blameworthy Act/Reckless Behavior: A criminal act, a purposefully unsafe act, act involving patient abuse of any kind, or a situation in which an individual takes a substantial and unjustifiable risk that may result in patient harm.

Health Care Incident: An unusual or unexpected occurrence in the clinical management of a patient or patients, such as an error, adverse/sentinel event, near miss, accident, or medication event that has or may have adverse health consequences for patients and/or personnel, and requires submission of a written description of the event to the Statewide Health Care Incident Review Committee (HCIRC). For the purposes of this policy, health care incidents include events as described in the Health and Safety Code Section 1279.1; unusual occurrences as described in Title 22, Division 5, Chapter 12, Article 5, Section 79787; adverse drug reactions submitted to the Food and Drug Administration (FDA) MedWatch Reporting Program; and Potential Quality Issue Referrals.

Medication Event: A medication-related health care incident resulting in an adverse drug reaction, medication error, near miss, omission error or sentinel event. Medication events may include, but are not limited to, medication prescribing, verification and dispensing, administration and documentation.

Medication Severity Rating: A system to categorize the degree of harm associated with medication-related events, adapted from the National Coordinating Council for Medication Error Reporting and Prevention, to assist in defining and prioritizing medication events, mitigation strategies, and interventions:

- Level 0 – Event did not reach patient; near miss; no error
- Level 1 – Event reached the patient but did not result in harm
- Level 2 – Increased monitoring but no change in vital signs and no harm
- Level 3 – Increased monitoring and change in vital signs but no harm
- Level 4 – Need for treatment or hospitalization
- Level 5 – Permanent patient harm
- Level 6 – Error caused death

Near Miss: An event or situation that could have resulted in a health care incident but did not, either by chance or through timely intervention.

Root Cause Analysis: A structured and standardized process by which a multidisciplinary team analyzes a health care incident, near miss, or adverse/sentinel event, determines the fundamental reasons why the event occurred, and designs and implements a Plan of Action to prevent similar events from occurring in the future.

III. PROCEDURE

A. Identification of Health Care Incidents and Duty to Report

1. While many health care incidents will be initially detected by institution health care staff, health care incidents may also be identifed by other stakeholders.
2. All California Department of Corrections and Rehabilitation/California Correctional Health Care Services (CCHCS) staff have a duty to report health care incidents using the centralized electronic Health Care Incident Reporting (eHCIR) system within 24 hours of occurrence or discovery. The eHCIR is available to all staff on CCHCS Lifeline and allows health care incidents to be submitted anonymously.
3. Program leads or any person with a leadership role or authority shall not prohibit or create any physical or process barriers that prevent or delay staff from reporting health care incidents to the centralized reporting system.

B. Immediate Action Following a Health Care Incident

1. Mitigate Risk

   Upon realizing that a health care incident has occurred, institution health care staff shall immediately take steps to ensure patient safety, including:
   a. Stabilizing the patient by providing all necessary and appropriate care;
   b. Removing all unsafe devices, equipment, and medications; and
   c. Determining whether the health care incident places other patients, staff, or visitors at immediate risk of harm, and addressing those risks appropriately.
2. Document Care
   a. Health care staff shall ensure that information related to the health care incident, such as treatment provided and communication with the patient and/or family, is documented appropriately in the patient health record.
   b. For health care incidents involving specific patients, progress note documentation shall include preceding events, observations, examination findings, and assessment of the patient (e.g., vital signs, neurological checks, pain assessment).

3. Notify Area Supervisors, the Patient, and Institution Executives
   a. During regular business hours, staff who have identified a health care incident shall immediately notify their direct supervisor.
   b. After regular business hours, staff who have identified a health care incident shall immediately notify the nursing program lead on duty.
   c. For all deaths and sentinel events as defined in policy, including medication events with medication severity rating levels of 4-6, the notified supervisor or nursing program lead shall immediately contact the Chief Executive Officer (CEO), who shall determine which additional institution staff must be apprised of the situation and within what timeframes.
   d. When appropriate, notification of the CEO shall include, at a minimum, the following information:
      - Name of patient, staff and/or visitor involved;
      - Nature of the health care incident (what occurred);
      - Location of the health care incident;
      - Time of the health care incident;
      - Actions taken, treatment provided, and effects;
      - Current condition of patient, staff, and/or other individual; and
      - Any other pertinent information.
   e. Institution staff shall document notification of patients as required by State law.
4. Preserve Materials, Supplies, and Other Related Items
   a. To ensure that physical materials are readily accessible during the health care incident review process and remain in the condition applicable at the time of the health care incident, staff shall collect and secure samples of physical items involved in the event, which may require examination by qualified personnel to safely handle and store any controlled substances or potentially hazardous materials. Examples of collectable physical items may include, but are not limited to:
      - Medical devices and equipment;
      - Retained foreign objects;
      - Medications, containers, package labels, or inserts;
      - Intravenous bags and tubing;
      - Syringes;
      - Supply containers and packaging;
      - Laboratory and pathology specimens; and
      - Any other applicable physical items.
   b. Tampering with, cleaning, or otherwise modifying any physical items could result in inaccurate review findings and is prohibited. Health care staff shall work with custody staff to obtain necessary camera equipment, and take pictures where appropriate.
   c. Health care staff shall work with information technology staff to preserve all electronic data affiliated with the health care incident, including mechanisms to back up or otherwise store data. Health care staff shall obtain paper copies of electronic data if there is a risk that the information may be overwritten or lost.

5. Report the Health Care Incident to Headquarters for Initial Review and Assessment
   a. All health care incidents must be reported as soon as possible, and no later than 24 hours of the occurrence or its discovery, using the eHCIR system.
   b. Licensed facilities have an obligation to report certain health care incidents to the California Department of Public Health. Reporting requirements to external agencies may differ for each institution and must be verified by the facility; all institutions shall comply with health care incident reporting requirements in departmental policy and state and federal law. Refer to Reportable Health Care Incidents in Policy and Current Law (Attachment I) for current reporting mandates and required timeframes.
   c. The pharmacy program lead shall be notified of an adverse drug reaction and shall ascertain whether the reaction warrants the completion of an FDA MedWatch Form FDA 3500, based on FDA criteria (Attachment I).
   d. Upon receiving information about the health care incident, Health Care Incident Review Executives (HCIRE) designated by the Statewide Patient Safety Committee shall perform a review of all health care incidents which are deemed potential adverse/sentinel events, medication errors with an assigned severity level 4 through 6, or any other anomalous health care incident. The HCIREs shall determine the appropriate disposition, and document their findings of the health care incident, which may include assignment of a Root Cause Analysis (RCA), referring to the hiring authority, referring to the appropriate peer review body to address clinical practice issues, and providing institutions with technical assistance as described in the Inmate Medical Services Policies and Procedures, Volume 3, Chapter 7.4, Patient Safety Program Procedure: Initial Review and Assessment of Health Care Incidents.
   e. Any identified possible blameworthy acts or reckless behavior shall be referred to the hiring authority for investigation and response. Health care incidents assigned an RCA where a referral is made to the hiring authority shall have the RCA continue without delay or deferral; however, the staff person(s) referred shall be excluded from the RCA process.
   f. Health care incidents assigned an RCA that result in a peer review referral or temporary redirection of health care staff from direct patient care shall have the RCA continue without delay or deferral.
6. Provide Relief and Support to Caregivers
   a. The nursing program lead managing the health care area where the health care incident occurred and the appropriate clinical program leads shall immediately evaluate the impact of the health care incident on all involved staff and shall provide support to health care staff as appropriate, including addressing staffing and redistributing patients loads to allow caregivers time to cope with the situation.
   b. Caregivers should be assured that any review of the health care incident shall be focused primarily on process and system breakdowns.

C. Deaths

Health care incidents that are deaths shall receive a separate death review per current policy, which covers a different scope than the RCA process, but may still lead to the assignment of an RCA. Refer to Inmate Medical Services Policies and Procedures, Volume 1, Chapter 29.2, Death Reporting and Review Procedure and the Mental Health Services Delivery System Program Guide, Chapter 10, Suicide Prevention and Response.

D. Root Cause Analysis

1. Assigning an RCA and Convening the RCA Team.
   a. Health care incidents may require an RCA as assigned by the Statewide HCIREs. All health care incidents identified as an adverse/sentinel event require an RCA.
   b. As soon as possible and no later than 24 business hours after the RCA is assigned, the CEO shall convene a multidisciplinary team to conduct the RCA. This team shall be responsible for identifying and analyzing the primary system or process lapses that contributed to the adverse/sentinel event and develop a detailed Plan of Action to prevent similar events from occurring in the future.
   c. The CEO shall determine the scope and membership of the RCA Team.
   d. The institution Quality Management Committee or designated subcommittee shall provide oversight of the RCA process and preliminary review of the RCA Report.
2. Understanding the Context of the RCA
   a. Prior to beginning the RCA process, the RCA Team shall review the CCHCS Performance Improvement Culture Statement (Attachment II) to ensure that all members understand the context of the adverse/sentinel event review process.
   b. The primary emphasis of the RCA is focused on system lapses, not the behavior of individual staff.
3. Completion of the RCA and Interim Reports
   a. The RCA Team shall adhere to reporting and timeframe requirements in the CCHCS RCA Tool Kit.
   b. The CEO may request assistance with the RCA process from headquarters staff at any time by contacting the HCIRC or by speaking to any of its committee members or designees.
   c. If at any point during the RCA the team determines that the circumstances surrounding the health care incident meet criteria for a blameworthy act/reckless behavior and referral to the hiring authority, the RCA process shall continue without delay or deferral; however, the staff person referred shall be excluded from the RCA process.
   d. If the RCA Team identifies clinical practice issues that may merit a peer review referral, the team shall elevate this information to the appropriate program lead and the CEO for consideration and referral to headquarters as appropriate per current policy. The RCA process shall continue without delay or deferral.
   e. During the RCA process and pending a final report, the institution shall implement any immediate and concurrent improvements as determined by the RCA Team to be appropriate.
   f. The HCIRC may request concurrent documentation from all RCA Team meetings as interim reports of institution activities.

4. Submission of the RCA and Implementation of the Plan of Action
   a. The RCA Report, including internal review and approval by the CEO and submission of the report to the HCIRC, shall be completed within 45 calendar days from the date the RCA was assigned.
   b. Additional reporting to the California Department of Public Health may be required (Attachment I).
   c. At a minimum, the RCA Report shall contain the following elements per the RCA Tool Kit (additional elements may be included at the discretion of the RCA Team):
      - RCA Team Roster - Classification and titles of staff who served on the RCA Team;
      - Summary of Events - A description of relevant facts and chronology of events, including immediate actions taken per this procedure to stabilize the patient, preserve documentation and physical materials, and support health care staff;
      - Brainstorming Session Documentation - An overview of the process used to conduct the RCA, including documentation and community/industry literature reviewed, physical materials examined, staff interviewed, and tools and techniques applied during analysis and findings from the brainstorming session, including local system and process lapses and appropriate referrals;
      - Identify a Root Cause Worksheet - Identification of the root causes of the health care incident; and
      - Plan of Action - A detailed plan to address the root causes and prevent similar incidents from occurring in the future, including a specific timeframe for implementation of the Plan of Action, measurable objectives, and the activities, resources, or technical support to sustain improvements.
   d. The RCA Report shall be approved by the CEO prior to submission to the HCIRC.
   e. The Institution Quality Management Committee or designated Subcommittee may share results of the RCA, as appropriate, with all institution health care staff (e.g., the Plan of Action and best practices).
   f. Unless otherwise instructed by the HCIRC, the institution shall begin implementation of the Plan of Action as soon as practicable, but no later than upon submission of the RCA Report to headquarters. Changes to local practices and procedures shall be made as appropriate to reduce the likelihood that a similar health care incident will occur in the future.
5. Revisions to the RCA Report
   If upon review of the RCA Report the HCIRC requests clarification or revision of the report, the institution shall make necessary clarifications or revisions and submit the revised report to the HCIRC within 15 calendar days of the request.
6. Post-Submission Plan of Action Status Updates
   a. On a monthly basis, the institution shall submit an updated RCA Monthly Reporting form to the HCIRC describing the progress of activities conducted pursuant to the Plan of Action described in the RCA Tool Kit and this procedure. The status update shall also include performance measurement data and an

analysis of the extent to which local systems or processes have improved upon implementation of the Plan of Action.

b. The institution shall submit monthly status updates to the HCIRC for at least four months following submission of the RCA Report, and until the HCIRC deems the case process closed.

E. Confidentiality

Protected Proceedings and Records

1. All records of proceedings of the health care incident review process shall be maintained as confidential quality management deliberative process documents.
2. All staff participating in the health care incident review process discussed in this procedure shall adhere to these provisions regarding confidentiality.

IV. ATTACHMENTS

- Attachment I: Reportable Health Care Incidents in Policy and Current Law
- Attachment II: Performance Improvement Culture Statement

V. REFERENCES

- California Code of Regulations, Title 22, Division 5, Chapter 12, Article 5, Section 79787, Reporting
- California Health and Safety Code, Division 2, Chapter 2, Article 1, Section 1250
- California Health and Safety Code, Division 2, Chapter 2, Article 3, Sections 1279, 1279.1, and 1279.2
- California Correctional Health Care Services, Inmate Medical Services Policies and Procedures, Volume 1, Chapters 29.1 and 29.2, Death Reporting and Review Program Policy and Procedure
- California Correctional Health Care Services, Inmate Medical Services Policies and Procedures, Volume 3, Chapter 7:
  - 3.7.1 Patient Safety Program Policy
  - 3.7.2 Health Care Incident Reporting Policy
  - 3.7.3 Patient Safety Program Procedure: Statewide Patient Safety Committee
  - 3.7.4 Patient Safety Program Procedure: Initial Review and Assessment of Health Care Incidents
  - 3.7.6 Patient Safety Program Procedure: Statewide Health Care Incident Review Committee
- California Correctional Health Care Services, Inmate Medical Services Policies and Procedures, Volume 9, Chapter 27, Reporting of Medication Errors and Adverse Drug Reactions
- California Department of Corrections and Rehabilitation, Mental Health Services Delivery System Program Guide, Chapter 10, Suicide Prevention and Response
- Food and Drug Administration, MedWatch: The FDA Safety Information and Adverse Event Reporting Program (http://www.fda.gov/safety/medwatch/default.htm)
- The Joint Commission (www.jointcommission.org)
- National Commission on Correctional Health Care 2008 Standards for Health Services in Prisons

- National Coordinating Council for Medication Error Reporting and Prevention
- United States Department of Veterans Affairs - Veterans Affairs National Center for Patient Safety (NCPS) (http://www.patientsafety.va.gov/);
- Veterans Health Administration Vision 2020 http://www.va.gov/healthpolicyplanning/vision2020.pdf

Attachment I
Reportable Health Care Incidents in Policy and Current Law

Reportable Health Care Incidents Defined in Patient Safety Program Policy IMSP&P Vol. 3, Ch. 7.1

Health Care Incident

An unusual or unexpected occurrence in the clinical management of a patient or patients, such as an error, adverse/sentinel event, near miss, accident, or medication event that has or may have adverse health consequences for patients and/or personnel, and requires submission of a written description of the event to the Statewide Health Care Incident Review Committee. For the purposes of this policy, health care incidents include events as described in the Health and Safety Code Section 1279.1; unusual occurrences as described in Title 22, Division 5, Chapter 12, Article 5, Section 79787; and Potential Quality Issue Referrals.

Adverse/Sentinel Event

An event or series of events that cause the death or serious disability of a patient, personnel, or visitor. "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 lasts more than seven calendar days or is still present at the time of discharge, or unintentional loss of a body part.

Medication Event

A medication-related health care incident resulting in an adverse drug reaction, medication error, near miss, omission error or sentinel event. Medication events may include, but are not limited to, medication prescribing, verification and dispensing, administration and documentation.

Adverse Drug Reaction

Any undesired, unintended, or unexpected response to a medication administered in doses recognized as appropriate in accepted health care practice which results in one or more of the following: changing, stopping, or reducing the medication, or admission to a higher level of care. An adverse drug reaction includes any undesired experience with the appropriate use of a medication product in a patient.

Near Miss

An event or situation that could have resulted in a health care incident but did not, either by chance or through timely intervention.

Definitions of Health Care Incidents in Law

California Health and Safety Code Section 1279.1

1279.1. (b) For purposes of this section, "adverse event" includes any of the following:

(1) Surgical events, including the following:

(A) **Surgery performed on a wrong body part** that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph 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.

(B) **Surgery performed on the wrong patient.**

(C) **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. A reportable event under this subparagraph 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.

(D) **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.

(E) **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.

(2) Product or device events, including the following:

(A) **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.

(B) **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.

(C) **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.

(3) Patient protection events, including the following:

(A) An infant discharged to the wrong person.

(B) 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.

(C) **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 admission to the health facility.

(4) Care management events, including the following:

(A) **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.

(B) A patient death or serious disability associated with hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(C) **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 postdelivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

(D) **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.

(E) 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.

(F) **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.

(G) **A patient death or serious disability due to spinal manipulative therapy** performed at the health facility.

(5) Environmental events, including the following:

(A) **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.

(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 a toxic substance.**

(C) **A patient death or serious disability associated with a burn** incurred from any source while being cared for in a health facility.

(D) **A patient death associated with a fall** while being cared for in a health facility.

(E) **A patient death or serious disability associated with the use of restraints or bedrails** while being cared for in a health facility.

(6) Criminal events, including the following:

(A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.

(B) The abduction of a patient of any age.

(C) **The sexual assault on a patient** within or on the grounds of a health facility.

(D) **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.

(7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.

Title 22, Division 5, Chapter 12, Article 5, Section 79787

(c) Events constituting an unusual occurrence shall include, but not be limited to:

(1) Poisonings.

(2) Fires or explosions.

(3) Death of an inmate-patient, employee, or visitor because of unnatural causes.

(4) Sexual acts involving inmate-patients who are minors, non-consenting adults, or persons incapable of consent.

(5) Physical assaults on inmate-patients, employees, or visitors.

(6) All suspected criminal acts involving inmate-patients, employees, or visitors.

(7) All suspected incidents of physical or sexual abuse to an inmate-patient.

(8) Unexplained or illicit disappearance or loss of an inmate-patient or inmate-patient remains.

(9) Disruption of services of the licensed correctional treatment center.

Other Reporting Requirements Under State Law

California Health and Safety Code

1279.1. (a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.

(b) omitted – see definitions of adverse/sentinel events from Health and Safety Code in previous section.

(c) The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made.

(d) "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 seven days or is still present at the time of discharge from an inpatient health care facility, or the loss of a body part.

(e) Nothing in this section shall be interpreted to change or otherwise affect hospital reporting requirements regarding reportable diseases or unusual occurrences, as provided in Section 70737 of Title 22 of the California Code of Regulations. The department shall review Section 70737 of Title 22 of the California Code of Regulations requiring hospitals to report "unusual occurrences" and consider amending the section to enhance the clarity and specificity of this hospital reporting requirement.

1279.2. (a) (1) In any case in which the department receives a report from a facility pursuant to Section 1279.1, or a written or oral complaint involving a health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250, that indicates an ongoing threat of imminent danger of death or serious bodily harm, the department shall make an onsite inspection or investigation within 48 hours or two business days, whichever is greater, of the receipt of the report or complaint and shall complete that investigation within 45 days.

(2) Until the department has determined by onsite inspection that the adverse event has been resolved, the department shall, not less than once a year, conduct an

unannounced inspection of any health facility that has reported an adverse event pursuant to Section 1279.1.

(b) In any case in which the department is able to determine from the information available to it that there is no threat of imminent danger of death or serious bodily harm to that patient or other patients, the department shall complete an investigation of the report within 45 days.

(c) The department shall notify the complainant and licensee in writing of the department's determination as a result of an inspection or report.

(d) For purposes of this section, "complaint" means any oral or written notice to the department, other than a report from the health facility, of an alleged violation of applicable requirements of state or federal law or an allegation of facts that might constitute a violation of applicable requirements of state or federal law.

(e) The costs of administering and implementing this section shall be paid from funds derived from existing licensing fees paid by general acute care hospitals, acute psychiatric hospitals, and special hospitals.

(f) In enforcing this section and Sections 1279 and 1279.1, the department shall take into account the special circumstances of small and rural hospitals, as defined in Section 124840, in order to protect the quality of patient care in those hospitals.

(g) In preparing the staffing and systems analysis required pursuant to Section 1266, the department shall also report regarding the number and timeliness of investigations of adverse events initiated in response to reports of adverse events.

Title 22, Division 5, Chapter 12, Article 5, Section 79787– Pertaining to Correctional Treatment Centers

(a) Reportable communicable diseases shall be reported to the local health officer and all unusual occurrences shall be reported to the Department by the licensed correctional treatment center within twenty-four (24) hours, either by telephone with written confirmation or by telephone facsimile (FAX).

(b) The reporting of communicable diseases and outbreaks shall be in conformance with Sections 2500, 2502, 2503 and 2504 of Title 17, California Code of Regulations.

(c) omitted – see definitions of adverse/sentinel events from Health and Safety Code in previous section.

(d) The licensed correctional treatment center shall furnish other pertinent information related to such occurrences as the local health officer or the Department shall require.

(e) All reports required in this Section shall be retained on file by the licensed correctional treatment center for three (3) years.

(f) Every fire or explosion that occurs in or on the premises shall be additionally reported immediately to the local fire authority, or in the areas not having an organized fire service, to the State Fire Marshal.

(g) The local health officer of the county to which an inmate-patient is to be released shall be notified at least one day in advance before an inmate-patient on any tuberculosis medication is released from the correctional facility.

Reporting Adverse Drug Reactions

Adverse drug reactions shall be reported to the Food and Drug Administration (FDA) via the FDA MedWatch Form FDA 3500 for the following outcomes:

Death	Report if you suspect that the death was an outcome of the adverse event and include the date if known.
Life-threatening	Report if suspected that the patient was at substantial risk of dying at the time of the adverse event, or use or continued use of the device or other medical product might have resulted in the death of the patient.
Hospitalization (initial or prolonged)	Report if admission to the hospital or prolongation of hospitalization was a result of the adverse event.
Disability or Permanent Damage	Report if the adverse event resulted in a substantial disruption of the ability to conduct normal life functions, i.e., the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.
Congenital Anomaly/Birth Defect	Report if you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.
Required Intervention to Prevent Permanent Impairment or Damage	Report if you believe that medical or surgical intervention was necessary to preclude permanent impairment of a body function or prevent permanent damage to a body structure, either situation suspected to be due to the use of a medical product.
Other Serious (Important Medical Events)	Report when the event does not fit the other outcomes, but the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples include allergic bronchospasm requiring treatment in an emergency room, serious blood disorders or seizures/convulsions that do not result in hospitalization. The development of drug dependence or drug abuse would also be examples of important medical events.

Examples of Reportable Health Care Incidents

Below are examples of categories of events/actions/incidents that can lead to patient harm. Often times, health care incidents fall into more than one category.

Category	Sub-Category	Examples
Coordination/ Continuity of Care	Communication/ Handoffs	• Missed/poor communication between health care worker and the patient or another health care worker (internal or external)
	Documentation	• Document missing or delayed in the chart • Wrong document scanned to chart • Document scanned to wrong patient chart • Illegible or incomplete document in chart
	Scheduling/ Follow-Up	• PCP appointment – not scheduled and completed adequately, cancelled, or delayed • Specialty referral or appointment – not scheduled and completed adequately, cancelled, or delayed • Follow-up by PCP or specialist – not scheduled and completed adequately, cancelled, or delayed • Inadequate or delayed follow-up related to diagnostics (laboratory/radiology) – not scheduled and completed adequately, cancelled, or delayed
Clinical Management	Diagnosis	• Error in diagnosis • No diagnosis • Delay in diagnosis
	Treatment	• Failure to identify or react to test results • Failure to follow clinical guidelines • Failure to recognize, evaluate, or manage symptoms • Failure to monitor patient • Delay in appropriate treatment
	Procedure	• Procedure not performed or delayed • Procedure incomplete • Procedure performed on the wrong patient • Wrong procedure/process applied • Procedure performed on the wrong body part/side
	Screening/ Preventive	• Screening/preventive care not performed when indicated • Delayed or incomplete screening/preventive care • Screening/preventive care performed on wrong patient • Wrong screening/preventive care process applied

Attachment I
Reportable Health Care Incidents in Policy and Current Law

Category	Sub-Category	Examples
Medication Event	Missing or Delayed Dose Wrong Patient Wrong Med Wrong Dose Wrong Route	• Ordering and prescribing process (providers) • Verification and dispense process (pharmacy) • Medication administration process (nursing) • Related to the transfer of a patient from any health care setting (e.g., inpatient to outpatient, between institutions)
	Adverse Drug Reaction	• Drug-drug interactions • Drug-disease interactions • Adverse reaction from a heat medication
Miscellaneous	Medical Device/ Equipment Malfunction	• Non-operational or malfunctioning equipment needed for direct patient care • Lack of appropriate medical devices or equipment needed for direct patient care
	Patient Accident	• Patient delay or refusal resulting in harm • Patient fall
	Patient Self-Harm	• Suicide attempt • Completed suicide • Other non-lethal self-harm
	Credentialing	• Non-credentialed professional providing patient care
	Unusual Occurrences	• Physical/sexual assault • Electric shock • Wrong gas/toxic substance • Burn/fire/explosion • Poison
	Undefined/ Unknown	• An undefined event or series of events that led to patient harm or death
Near-Miss		• An event or situation that could have resulted in a health care incident event but did not, either by chance or through timely intervention

Attachment II

California Correctional Health Care Services

Performance Improvement Culture Statement

Patient safety is the fundamental responsibility of every individual in the correctional health care delivery system. To promote an effective performance improvement program, California Correctional Health Care Services (CCHCS) actively cultivates a culture of continuous learning and improvement where all staff focus on making health care delivery processes and outcomes as safe and effective as possible and developing and implementing systems that support sustainable, high-quality performance. At CCHCS, leadership teams foster a culture of trust, which enable staff to report and elevate problems and encourages all staff to be actively involved in improving institution and organization-wide systems.

CCHCS recognizes that . . .

- Human error is inevitable and we continually strive to monitor and improve systems to prevent errors.
- Most incidents of unfavorable variances from expected patient care involve process or system breakdowns that must be addressed before performance can reliably improve.
- A punitive environment does not fully take into account systems issues, nor does a blame-free environment hold individuals appropriately accountable.
- A culture of learning and improvement recognizes that people operate within processes and systems and can make mistakes; acknowledges that even competent people can develop erroneous patterns of behavior, yet has zero tolerance for reckless behavior, blameworthy acts and delayed reporting of health care incidents.
- To effectively identify opportunities for improvement and resolve system problems, CCHCS staff at all reporting levels must be able to report health care incidents without being subject to unjust punitive investigation and penalties.

CCHCS staff will . . .

- Support a learning environment that encourages and fosters the reporting and review of all errors, near misses, adverse events, and system weaknesses.
- Critically analyze existing processes to proactively identify potential problem areas and opportunities for improvement.
- Proactively analyze processes, design and improve systems to support a safe patient care environment.
- Promote collaboration across ranks and disciplines to find sustainable solutions to patient safety issues.
- Respond quickly and reasonably to actions, decisions, and behaviors that may result in unsafe acts, realizing that most actions, decisions, and behaviors do not warrant corrective or adverse action. The most severe penalties, such as demotion, reduction in pay, suspension with or without pay, and termination, are reserved for reckless behavior and blameworthy acts and, as warranted, delayed reporting.
- Report discovered health care incidents within the timeframes prescribed in relevant policies and procedures.
- Use standardized algorithms based upon learning and improvement concepts to determine individual accountability.

A Blameworthy Act . . .

CCHCS maintains a code of conduct for acceptable behavior and behaviors that undermine patient safety. Although performance improvement processes will primarily target the identification and resolution of process breakdowns, reckless behavior and blameworthy acts discovered in this context will be appropriately addressed to ensure patient and staff safety. Reckless behavior includes situations in which an individual takes a substantial and unjustifiable risk that may result in patient harm. A blameworthy patient care act possesses one of the following three characteristics: it involves a criminal act, a purposefully unsafe act, or events involving patient abuse of any kind. Reckless behavior, a blameworthy act, intentionally withholding information, or providing misleading or false information may result in adverse action in accordance with the Disciplinary Matrix.