1.2.7 Institution Patient Safety Program

(a) Procedure

(1) Institution Patient Safety Oversight

The Institution Quality Management Committee or other designated local committee shall provide oversight of patient safety and improve the local health care delivery system by:

(A) Reviewing local patient safety surveillance data, including the Patient Safety Dashboard and Health Care Incident Reporting Registry trends, to identify problematic health care processes and establish priority areas for intervention and patient safety risk mitigation activities, and when appropriate, recommend the addition of patient safety priorities to the Institution Performance Improvement Work Plan.

(B) Coordinating and collaborating with other committees and program areas as appropriate to redesign local health care processes to improve patient safety.

(C) Ensuring oversight and timely completion and monitoring of Root Cause Analysis (RCA), including coordination with Regional Health Care Support Teams and the Statewide Health Care Incident Reporting Committee.

(D) Ensuring health care staff have access to patient safety training and decision support tools (e.g., tool kits, job aids, guides, forms, checklists, and flowcharts) to support patient safety surveillance, health care incident reporting and review, RCAs, and process redesign.

(E) Supporting outreach and other activities that encourage reporting of all health care incidents including near misses, medication events, and sentinel events by institution health care staff.

(F) Communicating patient safety alerts, issues, and RCA recommendations and actions to institution staff.

(G) Identifying local Patient Safety Champions and promoting an organizational culture of continuous learning and improvement.

(2) Identification of Health Care Incidents and Duty to Report

(A) 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 via Lifeline and allows health care incidents to be submitted anonymously.

(B) While many health care incidents will be initially detected by institution health care staff, health care incidents may also be identified by other stakeholders.

(C) Institutions with licensed beds, including Correctional Treatment Centers, Mental Health Crisis Beds, Psychiatric Inpatient Program/Intermediate Care Facilities, Skilled Nursing Facilities, Dialysis, or Hospice are required 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 federal and state law.

(D) Institution leadership, program leads, unit supervisors, and other required health care staff as identified shall monitor the Health Care Incident Reporting Registry and associated Incident Summaries daily for reported health care incidents at their institution and take appropriate action as required by federal and state law; for example, Pharmacy Quality Assurance reviews for medication errors, Professional Practice Reviews, and Psychiatric Inpatient Program incident review and referrals to regulatory agencies.

(E) 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 eHCIR.

(3) Immediate Action Following a Health Care Incident

(A) Mitigate Risk

Upon realizing that a health care incident has occurred, institution health care staff shall immediately take steps to ensure patient safety including, but not limited to:

1. Stabilizing the patient by providing all necessary and appropriate care.
2. Removing all unsafe devices, equipment, and medications.
3. Determining whether the health care incident places other patients, staff, or visitors at immediate risk of harm and addressing those risks appropriately.

(B) Document Care

1. 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 health record.
2. 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).

(C) Notification

1. During regular business hours, staff who have identified a health care incident shall immediately notify their direct supervisor.
2. After regular business hours, staff who have identified a health care incident shall immediately notify the unit supervisor or nursing program lead on duty.
3. For all deaths and sentinel events as defined in policy, including medication events with an assigned severity level of 4 through 6, the notified supervisor or nursing program lead shall immediately contact the Chief Executive Officer (CEO), who shall then determine which additional institution staff must be apprised of the situation and within what timeframes.
4. When appropriate, notification to the CEO shall include, at a minimum, the following information:
   a. Name of patient, staff, and/or visitor involved.
   b. Nature of the health care incident (what occurred).
   c. Location of the health care incident.
   d. Time of the health care incident.
   e. Actions taken, treatment provided, and effects.
   f. Current condition of patient, staff, and/or other visitor.
   g. Any other pertinent information.
5. Institution staff shall document notification of patients as required by state law.
6. The supervisor shall notify the Pharmacy program lead of an adverse drug reaction. The Pharmacy program lead shall complete a United States Food and Drug Administration (FDA) MedWatch Form FDA 3500 if appropriate per FDA instructions.

(D) Preserve Materials, Supplies, and Other Related Items

1. 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:
   a. Medical devices and equipment
   b. Retained foreign objects
   c. Medications, containers, package labels, or inserts
   d. Intravenous bags and tubing
   e. Syringes
   f. Supply containers and packaging
   g. Laboratory and pathology specimens
2. 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 when appropriate.
3. 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.

(E) Provide Relief and Support to Caregivers

1. The unit supervisor or nursing program lead managing the 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 patient loads to allow caregivers time to cope with the situation.

2. Caregivers should be assured that any review of the health care incident shall be focused primarily on process and system breakdowns.

(4) Deaths

(A) Health care incidents that result in deaths shall receive a separate death review pursuant to the Health Care Department Operations Manual, Section 1.2.10, Death Reporting and Review Program and the Mental Health Services Delivery System Program Guide, Chapter 10, Suicide Prevention and Response, which covers a different scope than the RCA process.

(B) Findings from the death review process may result in the assignment of an RCA.

(5) Root Cause Analysis

(A) Assigning an RCA and Convening the RCA Team

1. The CEO shall determine the scope and membership of the RCA Team.
2. As soon as possible, and no later than 24 business hours after an RCA is assigned by the Statewide Health Care Incident Review Committee (HCIRC), 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 sentinel event and developing a detailed Plan of Action to prevent similar events from occurring in the future.
3. The respective Regional Health Care Support Team shall provide oversight of the local RCA process and conduct preliminary review of the RCA Report.
4. An institution may elect to initiate/self-assign an RCA if the leadership team deems it appropriate to inform continuous improvement of the local health care delivery system.
   a. Self-assigned RCAs are not required to be reported to the HCIRC, but if requested, the Regional Health Care Support Team or HCIRC shall provide feedback and recommendations as appropriate.
   b. In the event that a health care incident leading to a self-assigned RCA is identified as a sentinel event and formally assigned an RCA by the HCIRC, the institution shall meet all RCA requirements described in this procedure.

(B) Understanding the Context of the RCA

Prior to beginning the RCA process, the RCA Team shall review the CCHCS Performance Improvement Culture Statement (Appendix 1) to ensure that all members understand the context of the RCA process and that the primary emphasis of the RCA is focused on system lapses, not the behavior of individual staff.

(C) Completion of the RCA and Interim Reports

1. The RCA Team shall adhere to reporting and timeframe requirements in the CCHCS RCA Tool Kit, which is found on Lifeline.
2. 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.
3. The Regional Health Care Support Team may request concurrent documentation from all RCA Team meetings as interim reports of institution activities.

(D) The Submission of the RCA Report and Implementation of the Plan of Action

1. The RCA Report, including review and approval by the CEO and Regional Health Care Executive, shall be completed and submitted to the HCIRC within 45 business days from the date that the RCA was assigned.
2. At a minimum, the RCA Report shall contain required elements per the CCHCS RCA Tool Kit.
3. 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.

(E) 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 business days of the request.

(F) Post-Submission Plan of Action Status Updates

The institution shall submit a monthly Plan of Action status update by the last day of the reporting month for a minimum of four consecutive months following submission of the RCA Report, or until the HCIRC closes the case.

(6) Confidentiality

Protected Proceedings and Records

(A) It is critical that the proceedings and records of the health care incident review process be maintained as confidential and not be made available to unauthorized persons or organizations.
(B) All staff participating in the health care incident review process discussed in this procedure shall adhere to these provisions regarding confidentiality.
(C) The records of the committees and staff responsible for the evaluation and improvement of the quality of patient care shall be maintained as confidential and protected from discovery to the extent permitted by law.

Appendices

- Appendix 1: Performance Improvement Culture Statement

References

- 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 Department of Corrections and Rehabilitation, Department Operations Manual, Chapter 3, Article 2, Health and Safety Program
- California Department of Corrections and Rehabilitation, Department Operations Manual, Chapter 5, Article 11, Section 51110.11, Written Reports
- California Department of Corrections and Rehabilitation, Mental Health Services Delivery System Program Guide, Chapter 10, Suicide Prevention and Response
- Health Care Department Operations Manual, Chapter 1, Article 2, Section 1.2.6, Statewide Patient Safety Program
- Health Care Department Operations Manual, Chapter 1, Article 2, Section 1.2.10, Death Reporting and Review Program
- Health Care Department Operations Manual, Chapter 3, Article 5, Section 3.5.27, Pharmacy Quality Assurance Progam
- 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 https://www.jointcommission.org/topics/patient_safety.aspx
- 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 (http://www.patientsafety.va.gov/)
- Veterans Health Administration Vision 2020
- California Department of Public Health Center for Health Care Quality (https://www.cdph.ca.gov/Programs/CHCQ/Pages/CHCQHome.aspx)

Revision History

Effective: 11/2012
Revised: 11/2018

Appendix 1

Performance Improvement Culture Statement

Patient safety is the fundamental responsibility of every person in the correctional health care delivery system. 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 develop and implement systems that support sustainable, high-quality performance. At CCHCS, leadership teams foster a culture of trust, which enables staff to report problems and encourages all staff to be actively involved in process improvement.

CCHCS recognizes that:

- Human error is inevitable and we continually strive to improve systems to prevent errors.
- Most health care incidents 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 continuous learning and improvement recognizes that people 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 identify opportunities for improvement, 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:

- Report health care incidents within timeframes described in related policies and procedures.
- Encourage and support reporting and review of all health care incidents.
- Critically analyze processes and design improvements to ensure a safe health 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 disciplinary 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.

Reckless Behavior and Blameworthy Acts:

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.