1.2.6 Statewide Patient Safety Program

(a) Policy

California Correctional Health Care Services (CCHCS) shall maintain a Statewide Patient Safety Program to identify and improve problematic health care processes by emphasizing the prevention, reduction, reporting, and analysis of health care incidents that if left unaddressed may result in adverse drug reactions, sentinel events, or preventable patient harm.

(1) The CCHCS Statewide Patient Safety Program encompasses:

(A) Patient safety priorities that are reviewed and revised biennially to identify program objectives for statewide interventions and performance improvement activities.

(B) A comprehensive multidisciplinary health care incident reporting and review process for identifying, reporting, and assessing health care incidents including sentinel events, in accordance with state law and health care industry best practices, to address potential systemic health care process issues and mitigate risk to patients, staff, and visitors.

(C) A committee structure at headquarters to provide oversight to the Statewide Patient Safety Program, review patient safety reports and data, and take action to mitigate patient safety risks and prevent adverse patient outcomes.

(D) A committee structure at each institution that oversees the local implementation of the Patient Safety Program by reviewing patient safety reports and data at the individual institution or care team level to identify and mitigate patient safety risks, and prevent adverse patient outcomes.

(E) Regular communication in the form of patient safety alerts, aggregate reporting of findings and recommendations related to health care incidents or Root Cause Analyses (RCAs) that may be used to inform additional performance improvement efforts, patient safety initiatives, or recommendations to modify statewide policies and procedures.

(F) Technical assistance, decision support tools (e.g., job aids, guides, forms, checklists, and flowcharts), and staff development and education programs to support problem analysis, RCA, and process redesign.

(G) A patient safety culture that encourages staff to proactively identify and report health care incidents to mitigate risk to patients and emphasize continuous learning and improvement.

(b) Purpose

To protect patients, staff, and visitors from poor health outcomes due to flawed health care processes; improve health care quality and cost effectiveness; increase health care process efficiencies and reduce waste; and comply with legal and regulatory requirements.

(c) Responsibility

(1) Statewide

(A) California Department of Corrections and Rehabilitation (CDCR) and CCHCS departmental leadership at all levels of the organization, within the scope of their authority, shall ensure administrative, custodial and clinical systems are in place and appropriate tools, training, technical assistance, and levels of resources are available to ensure appropriate, timely, safe, and cost-effective health care for patients.

(B) The Statewide Patient Safety Committee, a subcommittee of the Statewide Quality Management Committee, is responsible for providing oversight of the Patient Safety Program at the statewide level, identifying and communicating program priorities, and managing implementation of patient safety initiatives.

(C) The Statewide Health Care Incident Review Committee, a subcommittee of the Statewide Patient Safety Committee, is responsible for providing oversight of the health care incident reporting system and RCA process at the statewide level, and identifying and communicating related data and trends.

(2) Regional

(A) Regional Health Care Executives are responsible for implementation of this policy at the subset of institutions within an assigned region.

(B) Regional Health Care Support Teams shall ensure health care staff utilize the centralized electronic Health Care Incident Reporting (eHCIR) system, and use incident data and trends to identify and take action to mitigate patient safety risks within an individual institution or across a region. Regional Health Care Support Teams shall provide oversight, support, and monitoring of RCAs assigned to institutions within their respective region.

(3) Institutional

(A) The Chief Executive Officer (CEO), or designee, is responsible for implementation of this policy at the institution level.

(B) Institution leadership teams including the CEO, Chief Support Executive, Chief Medical Executive, Chief Nurse Executive, Chief of Mental Health, and the Supervising Dentist are jointly responsible for the planning, implementation, evaluation, and monitoring of the local Patient Safety Program and ensuring adherence to the Patient Safety Program policy and procedures. Institution leadership teams are responsible for:

1. Ensuring the institution utilizes the institution Quality Management Committee or other designated local committee to identify and address problematic patient safety trends identified through the eHCIR system.
2. Ensuring staff have access to resources including equipment, supplies, and health information or reporting systems.
3. Encouraging and supporting timely reporting of health care incidents including sentinel events.
4. Identifying Patient Safety Champions to provide subject matter expertise and technical support to staff.

(d) Procedure

(1) Patient Safety Program Committees and Plans

(A) The Statewide Patient Safety Program shall maintain a Statewide Patient Safety Committee to provide oversight of the Patient Safety Program at the statewide level.

(B) The Statewide Patient Safety Program shall identify program priorities on at least a biennial basis that describe the goals and objectives for the Patient Safety Program identified through system surveillance, health care incident reporting trends, root cause analysis findings and recommendations, and/or changes in community best practices.

(2) Statewide Health Care Incident Report Review

The Patient Safety Program shall conduct an initial review of all health care incidents reported to the eHCIR system to determine an appropriate disposition and ensure potential sentinel events or other anomalous health care incidents with an assigned severity level of 4 through 6 are referred for review by the Statewide Health Care Incident Review Committee (HCIRC).

(3) Statewide Patient Safety Committee

(A) Responsibilities

The Statewide Patient Safety Committee (PSC) protects patient safety and improves the health care delivery system by:

1. Designing a surveillance system for the centralized collection and review of data pertinent to patient safety.
2. Maintaining an effective process for assessing, referring, and analyzing or making conclusions regarding reported health care incidents including, but not limited to:
   a. A centralized eHCIR system for identifying and reporting patient safety issues, near misses, sentinel events, and other anomalous health care incidents.
   b. A Health Care Incident Reporting Registry and Incident Summary accessible to select health care staff to ensure that institutions are informed of health care incident reports specific to their individual institution and patient care areas including licensed patient care areas which may require additional mandatory reporting to regulatory agencies.
   c. A standardized process for the identification and examination of sentinel events using the RCA process and CCHCS RCA Tool Kit.
   d. A process for referring health care incidents that involve blameworthy acts/reckless behaviors, including criminal activities, to the appropriate professional practice entities or hiring authority.
3. Reviewing program and surveillance data to identify problematic health care processes and establishing patient safety priorities and program objectives for statewide interventions and performance improvement activities.
4. Establishing a multidisciplinary Statewide HCIRC with headquarters level representation from all health care disciplines (i.e., Medical Services, Nursing Services, Pharmacy Services, Dental Services, and the Mental Health Program including Psychiatry) and custody.
5. Ensuring that Regional Health Care Executives designate Regional Health Care Support Teams to oversee the completion of RCAs assigned to institutions within their region and providing feedback and consultation as needed.

6. Collaborating with other program areas to redesign health care processes to improve patient safety.
7. Developing statewide training programs 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.
8. Coordinating patient safety activities with other committees and programs when appropriate including, but not limited to, the Statewide HCIRC, Death Review Committee, Systemwide Pharmacy and Therapeutics Committee, and Statewide Quality Management Committee (QMC).
9. Issuing a Patient Safety Dashboard at least quarterly that aggregates eHCIR data about health care incident reporting trends to inform continuous process improvement.
10. Issuing statewide patient safety alerts if a health care incident or trend reveal a problem that all institutions should immediately address or be aware of.
11. Supporting outreach and other activities that encourage reporting of all health care incidents including near misses, medication events, and sentinel events; and
12. Promoting an organizational culture of continuous learning and improvement.

(B) Membership, Quorum Requirements, and Meeting Frequency

1. The Deputy Director, Quality Management, or designee, shall serve as chairperson of the Statewide PSC. The chairperson is responsible for ensuring that the statewide PSC meets regularly, the committee agenda reflects the responsibilities described in this procedure, and committee decisions are appropriately documented.
2. The statewide program lead in each respective health care discipline (i.e., Medical Services, Nursing Services, Pharmacy Services, Dental Services, and the Mental Health Program), as well as the program leads in California Correctional Health Care Services Office of Legal Affairs and Health Care Policy and Administration, shall select at least one headquarters designee to serve on the Statewide PSC. Other program representatives may be asked to serve as members at the discretion of the Statewide PSC.
3. All voting members may choose a designee to serve in their stead. Non-voting members, such as presenters and guests, may attend as appropriate and approved by the Statewide PSC.
4. Each member has one vote and a quorum exists when more than one-half of voting members are present.
5. The Statewide PSC shall meet at least quarterly or more often as necessary to carry out its responsibilities.
6. Electronic records of committee proceedings shall be kept in a secure location indefinitely.

(C) Reporting Relationships

The Statewide PSC reports to the Statewide QMC, and provides oversight to the Statewide HCIRC.

(4) Statewide Health Care Incident Review Committee

(A) Responsibilities

The Statewide HCIRC protects patient safety and improves the health care delivery system and shall:

1. Conduct a review of all health care incidents reported to the eHCIR system with an assigned severity level of 4 through 6, potential sentinel events, and any other anomalous health care incidents to determine the appropriate disposition and ensure that any immediate danger to patients, staff, or visitors is addressed.
2. Communicate information about health care incidents to the appropriate regional and institution program leads that are reported by a person or entity not employed at an institution, such as court experts.
3. Refer health care incidents with identified clinical practice concerns or blameworthy acts/reckless behavior to the appropriate peer review committee or hiring authority.
    a. The HCIRC shall coordinate with institution leaders of the appropriate discipline to determine whether clinical staff involved in the health care incident should be removed from providing patient care pending further analysis of the event.
    b. Health care incidents assigned an RCA that result in a referral to peer review or the hiring authority or temporary redirection of health care staff from direct patient care shall have the RCA continue without delay or deferral and the staff person(s) referred shall be excluded from the RCA process.
4. Identify sentinel events and assign RCAs, including collaboration with Regional Health Care Support Teams and institution leadership, to further inform the case prior to assignment, and when appropriate, recommend grouping multiple incidents that are similar in nature into an aggregate RCA.
5. Work with Regional Health Care Support Teams to ensure RCAs are completed, approved, and submitted within 45 business days of assignment.

6. Upon receipt of an RCA Report, coordinate with the institution and Regional Health Care Support Team within 15 business days to provide feedback, including requesting revisions and clarification to the RCA Report if the report does not meet requirements for a thorough and credible RCA.
7. Upon approval of the RCA Report, monitor progress of the RCA Plan of Action for at least four months, and coordinate with the Regional Health Care Support Team to provide additional support or intervene as needed;
8. Advocate for changes to statewide policies and procedures in accordance with findings from patient safety surveillance, health care incident trends, or RCA recommendations.
9. Promote an organizational culture of continuous learning and improvement.

(B) Committee Membership, Quorum Requirements, and Meeting Frequency

1. The statewide program lead in each respective health care discipline (i.e., Medical Services, Nursing Services, Pharmacy Services, Dental Services, and the Mental Health Program including Psychiatry) and custody shall select at least one headquarters designee to serve on the Statewide HCIRC.
2. The Statewide PSC shall elect one or two HCIRC members to serve as chairperson(s). The responsibility of the chairperson(s) is to ensure that the HCIRC meets regularly, the committee agenda reflects the responsibilities described in this procedure, and committee decisions are appropriately documented.
3. All members may choose a designee to serve in their stead. Non-voting members, such as presenters and guests, may attend as appropriate and approved by the HCIRC.
4. Each member has one vote, and a quorum exists when at least three voting members are present.
5. The HCIRC shall meet each business day to carry out its responsibilities.
6. Electronic records of committee proceedings shall be kept in a secure location indefinitely.

(C) Reporting Relationships

The Statewide HCIRC reports to the Statewide PSC.

(5) Regional Health Care Support Teams

(A) Regional Health Care Executives shall designate Regional Health Care Support Teams that include regional representatives from Medical Services, Nursing Services, Pharmacy Services, Dental Services, and Mental Health Program, including Psychiatry, to provide support for institution RCAs as needed and on an individual case-by-case basis.

(B) Regional Health Care Support Teams shall provide RCA consultation, guidance, facilitation, and follow-up to the subset of institutions within their assigned region including, but not limited to:

1. Reviewing health care incidents and collaborating with the Statewide HCIRC and institution leadership on identified sentinel events prior to the assignment of an RCA.
2. Ensuring institution RCA Teams are multidisciplinary and appropriate for the sentinel event under review.
3. Ensuring information is gathered including a chronology of the event before, during, and after the incident, as well as other relevant information, guidelines, best practices, and literature used to inform the brainstorming session and problem analysis.
4. Participating in brainstorming sessions, encouraging thorough discussion of factors contributing to the sentinel event, and ensuring that the fishbone diagram is complete and causal statements are sound.
5. Ensuring the RCA Team identifies root causes.
6. Ensuring that RCA Plans of Action adequately address the identified root causes and associated performance objectives are measurable, realistic, and attainable.
7. Reviewing draft RCA Reports and Plans of Action to ensure they are thorough and credible per CCHCS RCA Tool Kit guidelines.
8. Monitoring Plans of Action submitted by the institution to ensure progress is being made, determining whether additional support or intervention is necessary, and taking action as appropriate.

(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.

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 Code of Regulations, Title 22, Division 5, Chapter 12, Article 5, Section 79787, Reporting
- 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 1.2.7, Institution 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 Program
- 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
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