I. PROCEDURE OVERVIEW
This procedure establishes a Statewide Health Care Incident Review Committee (HCIRC) to:

- Review and assess health care incidents that are submitted through the centralized electronic Health Care Incident Reporting (eHCIR) system or via external stakeholders (e.g., Prison Law Office, Office of the Inspector General, court experts, etc.);
- Provide oversight and support to the Root Cause Analysis (RCA) process at institutions;
- Review RCAs submitted by institutions to ensure that the analyses are thorough and credible and that each Plan of Action adequately addresses the system lapses that led to the health care incident, and provide guidance to institutions as necessary;
- Monitor the progress of RCA Plans of Action and provide assistance where appropriate;
- Issue statewide patient safety alerts if a health care incident reveals a problem or issue that all institutions should immediately address or be aware of;
- Advocate for changes to statewide policies and procedures in accordance with findings from health care incident reviews and trends identified through system surveillance; and
- Issue an aggregate report on all health care incidents including medication events and adverse/sentinel events that may be used to inform performance improvement efforts.

II. DEFINITIONS

**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. For the purposes of this procedure, adverse events include sentinel events as described in the California Health and Safety Code Section 1279.1 and unusual occurrences as described in Title 22, Division 5, Chapter 1, Article 7, Section 70737.

**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; 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.

**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.

**Patient Safety Alert:** A bulletin issued to all institutions informing them of a patient safety issue with statewide implications, which may include actions to mitigate harm to patients. For example, a patient safety alert might be issued when an adverse event is linked to malfunctioning medical equipment used by several institutions.

**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. Statewide Health Care Incident Review Committee

1. **Committee Purpose**
   a. California Correctional Health Care Services (CCHCS) shall maintain a Statewide HCIRC at headquarters as an inter-disciplinary forum to promote patient safety and improvements to the health care services delivery system by:
      - Taking action to address immediate patient safety concerns through the initial review and assessment process, and making referrals to the hiring authority and the peer review process in accordance with current policy;
      - Ensuring that institutions complete assigned RCAs for adverse/sentinel events, which may include events identified by staff at headquarters or by other stakeholder groups;
      - Ensuring that institutions receive consultation, facilitation, and other types of technical support as requested or needed during an RCA;
      - Reviewing and approving RCAs and associated Plans of Action;
      - Monitoring the progress of RCA Plans of Action to ensure that identified institution level system or process breakdowns are resolved and similar adverse/sentinel events are prevented from occurring in the future, and providing additional support as necessary;
      - Identifying system or process lapses that may have a statewide impact and issuing patient safety alerts;
      - Communicating adverse/sentinel event information and RCA findings to program leads and other committees and program areas and coordinating HCIRC activities with the activities or initiatives of other health care committees and programs;
      - Producing a regularly updated Patient Safety Dashboard; and
      - Supporting an organizational culture of continuous learning and improvement.
2. Committee Membership, Quorum Requirements, and Meeting Frequency
   a. The Statewide Patient Safety Committee shall appoint members of the HCIRC as appropriate from headquarters programs and regional health care disciplines to include at least one representative from Medical Services, Nursing Services, Pharmacy Services, the Mental Health Program, and Dental Services. Appointed members shall serve on the committee for a minimum of one year.
   b. Committee members shall nominate and elect one or two committee members to serve as chairpersons for a minimum of one year. The chairperson is responsible for ensuring that the HCIRC meets regularly, the committee agenda reflects the responsibilities and actions described in this procedure, and committee decisions are appropriately documented.
   c. All members may choose a designee to serve in their stead, subject to approval by the HCIRC. Non-voting members, such as presenters and guests, may attend as appropriate and approved by the HCIRC.
   d. Each member has one vote, and a quorum exists when more than one-half of the voting members are present.
   e. The HCIRC shall meet at least monthly, and more often as necessary.

3. Reporting Relationships
   The HCIRC reports to the Statewide Patient Safety Committee.

4. Committee Responsibilities
   a. Oversight and Support of the Health Care Incident Reporting, Review and Response Process
      Most health care incidents will be discovered at the point of care by institution staff; however, some health care incidents may be identified by a person or entity not employed at an institution, such as other stakeholder groups. Upon notification that a health care incident has occurred, the HCIRC shall ensure that:
      1) Information about the health care incident is entered into the centralized eHCIR system;
      2) Institutions requesting assistance with an RCA receive support and technical assistance as appropriate;
      3) Institutions submit RCA Reports and associated Plans of Action in accordance with procedure timeframes and requirements in State law; and
      4) Referrals to the hiring authority, the peer review process, or other program areas have been made as appropriate.
   b. Review and Approval of RCA Reports
      1) The HCIRC shall review all RCA Reports to ensure that:
         - All necessary actions have been taken to stabilize the patient, support health care staff involved, and communicate the incident;
         - Referrals have been made to the hiring authority, peer review bodies, and other program areas when appropriate;
         - The RCA conducted was thorough and credible, in keeping with criteria specified in the CCHCS RCA Tool Kit; and
         - The Plan of Action adequately addresses local system and process lapses.
2) The HCIRC shall request revisions and clarification to RCA Reports if the submitted report does not meet the minimum requirements for a thorough and credible RCA and requires additional action steps or information.

3) Upon approving an RCA Report, the HCIRC shall begin a minimum four-month monitoring period to provide oversight and support to institutions implementing associated Plans of Action.

c. RCA Plan of Action Monitoring

1) For a minimum of four months following the approval of an RCA Report, the HCIRC shall monitor status updates from the institution regarding the Plan of Action implementation and performance results that measure the success of system or progress change improvements.

2) Institutions may be provided technical assistance when appropriate, including on-site support, partnership with institutions that have faced similar issues, and information about best practices within CCHCS and at other health care organizations.

3) At the end of the monitoring period, the HCIRC shall assess whether system or process issues have been adequately addressed and, if appropriate, close the case.

4) In some instances, the HCIRC shall provide additional feedback and support to the institution and extend the monitoring period to allow the institution more time to address system or process issues.

d. Patient Safety Alerts

If a health care incident raises an issue that has statewide implications, such as a problem with commonly used equipment or medications, the HCIRC shall coordinate with the appropriate program area to issue a statewide patient safety alert to all facilities, with a description of the problem and recommendations or instructions for mitigating risk to patients and staff.

e. Recommendations for Changes to Statewide Processes and Policies

1) In the course of reviewing health care incidents and root cause analyses, the HCIRC shall consider whether changes to statewide policy, procedures, processes, information systems or other systems might improve patient safety.

2) The HCIRC shall elevate all recommended changes to statewide systems or processes to the Statewide Patient Safety Committee for consideration and further action, as appropriate.

f. Coordination with Other Committees and Program Areas

In compliance with relevant confidentiality provisions, the HCIRC shall collaborate with other standing committees and program areas to complete health care incident reviews and share information related to health care incidents including, but not limited to:

- Sharing the disposition of health care incidents with relevant committees or program areas;
- Providing information about trends in certain categories with relevant stakeholders, such as reporting medication error trends and system and process concerns to the CCHCS Systemwide Pharmacy and Therapeutics Committee;
• Referring information or making recommendations for program changes to other committees and program areas; and
• Coordinating with other committees or program areas when an initiative under the committee or program’s purview relates to an individual health care incident or a trend in health care incidents.

g. Patient Safety Dashboard
At least quarterly, the HCIRC shall issue a Patient Safety Dashboard that aggregates information about all health care incidents received through the centralized eHCIR system, including any adverse/sentinel events and RCAs that occurred during the reporting period. Health care incident data shall be analyzed and, where possible, trended over time. The Patient Safety Dashboard shall include, but is not limited to:
• Health care incident reporting trends based on the patient safety taxonomy;
• RCAs by region and institution;
• Actions by individual institutions and organization-wide to address common root causes;
• Identified best practices; and
• Summary of any patient safety alerts issued during the reporting period.

B. Confidentiality
1. 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 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 where required by California law.

IV. REFERENCES
• California Code of Regulations, Title 22, Division 5, Chapter 12, Article 5, Section 79787
• 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, Chapter 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:
  o 3.7.1 Patient Safety Program Policy
  o 3.7.2 Health Care Incident Reporting Policy
  o 3.7.3 Patient Safety Program Procedure: Statewide Patient Safety Committee
  o 3.7.4 Patient Safety Program Procedure: Initial Review and Assessment of Health Care
o 3.7.5 Patient Safety Program Procedure: Institution Response to a Health Care Incident

- 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 (http://www.patientsafety.va.gov/)