I. 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.

The CCHCS Statewide Patient Safety Program encompasses:

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

II. 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.

III. DEFINITIONS

Adverse Drug Reaction: Any undesired, unintended, or unexpected response to a medication administered that requires discontinuing or modifying the medication or dose; admission to a
higher level of care; additional treatment with alternative medications; or that results in a physical or cognitive impairment to the patient.

**Health Care Incident:** An unusual or unexpected occurrence in the clinical management of a patient or patients such as an error, sentinel event, near miss, accident, or medication event that has or may have adverse health consequences for patients and/or staff, 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, Section 79787; adverse drug reactions submitted to the Food and Drug Administration MedWatch Reporting Program; incidents reported to the California Department of Public Health; and Potential Quality Issue Referrals.

**Medication Event:** Any preventable event that may cause or lead to inappropriate medication use or patient harm as a result of professional practice, health care products, procedures, and systems. Errors may occur in prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

**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 a sentinel event is linked to malfunctioning medical equipment used by several institutions.

**Potential Quality Issue:** A health care incident, regardless of severity, which occurs during the course of treatment by a Healthcare Provider Network facility or provider and requires submission of a written Potential Quality Issue Referral.

**Root Cause Analysis:** A structured and standardized process by which a multidisciplinary team analyzes a health care incident, near miss, or 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.

**Sentinel Event:** A patient safety event, including adverse events as defined in California Health and Safety Code, not primarily related to the natural course of the patient’s illness or underlying condition that results in death, permanent harm, or a temporary impairment that affects the patient and limits their ability to function normally for a significant amount of time.

### IV. APPLICABILITY

All California Department of Corrections and Rehabilitation (CDCR) and CCHCS staff who observe or discover a health care incident, regardless of severity or absence of harm to a patient, have a duty to report the incident within 24 hours of occurrence or discovery. Failure to comply with policy mandates may, in some cases, result in possible adverse action commensurate with the act or omission.

### V. RESPONSIBILITY

#### A. Statewide

1. 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.

2. 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.

3. 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.

B. Regional

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

2. 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.

C. Institutional

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

2. 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:
   a. 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.
   b. Ensuring staff have access to resources including equipment, supplies, and health information or reporting systems.
   c. Encouraging and supporting timely reporting of health care incidents including sentinel events.
   d. Identifying Patient Safety Champions to provide subject matter expertise and technical support to staff.

VI. 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 CORRECTIONAL HEALTH CARE SERVICES

- California Department of Corrections and Rehabilitation, Department Operations Manual, Chapter 5, Article 11, Section 51110.11, Written Reports
- 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 7.2, Statewide Patient Safety Program Procedure
- California Correctional Health Care Services, Inmate Medical Services Policies and Procedures, Volume 3, Chapter 7.3, Institution Patient Safety Program Procedure
- California Correctional Health Care Services, Inmate Medical Services Policies and Procedures, Volume 9, Chapter 27, Pharmacy Quality Assurance Program Procedure
- 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 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)