VOLUME 3: QUALITY MANAGEMENT	Effective Date: 11/26/2012
CHAPTER 7: PATIENT SAFETY	Revision Date: 05/2017
3.7.2: HEALTH CARE INCIDENT REPORTING POLICY	Attachments: Yes ☐ No ☒

I. POLICY

All health care incidents shall be reported for the purpose of identification and review of adverse/sentinel events that impact patients or staff. During the review of health care incidents including, but not limited to, all medication events regardless of severity rating and adverse/sentinel events, health care staff shall identify and address system failures and utilize this process to prevent similar events from occurring in the future.

California Correctional Health Care Services (CCHCS) shall maintain a centralized system for identifying, reporting, and reviewing all health care incidents including adverse/sentinel events in accordance with State law and health care industry best practices, which includes processes for:

- Mitigating risk to patients and staff after a health care incident has occurred;
- Centralized health care incident reporting;
- Examination of adverse/sentinel events through root cause analysis (RCA).
- Development and implementation of action plans to address system lapses and mitigate risk of similar health care incidents occurring in the future.
- Evaluating the effectiveness of action plans;
- Issuing statewide patient safety alerts if an adverse/sentinel event or other health care incident pattern reveals an issue that all institutions should immediately address or be aware of;
- Recommending modifications to statewide policies and procedures in accordance with findings from health care incident reviews or RCAs;
- Aggregate reporting of findings and recommendations related to health care incidents that may be used to inform performance improvement efforts or patient safety initiatives; and
- Referral to appropriate entities if professional practice issues or blameworthy acts/reckless behaviors are involved.

II. PURPOSE

To define and standardize the process for identifying, reporting, reviewing and managing events determined to be health care incidents in order to reduce the occurrence of preventable deaths and adverse patient outcomes.

III. 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. 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 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.

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 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.

IV. APPLICABILITY

This policy applies to all California Department of Corrections and Rehabilitation (CDCR)/ CCHCS employees as well as individuals contracted to provide health care services to CCHCS patients. Failure to comply with policy mandates may, in some cases, result in possible adverse action commensurate with the act or omission.

V. RESPONSIBILITIES

A. Statewide

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 so that centralized health care incident reporting is accessible to all health care staff.

B. Regional

Regional Health Care Executives are responsible for implementation of this policy at the subset of institutions within an assigned region. Regional executive teams shall provide ongoing support and monitoring to ensure health care staff utilize the centralized electronic Health Care Incident Reporting 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.

C. Institutional

The Chief Executive Officer is responsible for implementation of this policy at the institution level. Institution leadership teams shall ensure that the institution utilizes existing forums such as local quality committees to identify and address local patient safety concerns identified through the centralized health care incident reporting process; support and encourage timely reporting of health care incidents; and identify Patient Safety Champions to provide subject matter expertise and technical support to local staff.

VI. 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, 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:
  - 3.7.1 Patient Safety Program 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
  - 3.7.5 Patient Safety Program Procedure: Institution Response to a Health Care Incident

  - 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 (http://www.patientsafety.gov/)
- Veterans Health Administration Vision 2020 (http://www.va.gov/healthpolicyplanning/vision2020.pdf)