



<b>VOLUME 9: PHARMACY SERVICES</b>	Effective Date: 11/07
<b>CHAPTER 27</b>	Revision Date (s): 9/13
<b>9.27 REPORTING OF MEDICATION ERRORS AND ADVERSE DRUG REACTIONS</b>	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

**I. PROCEDURE OVERVIEW**

Errors in the prescribing, administering, documentation of use of medications, and adverse drug reactions shall be reported immediately to the primary care provider (PCP) or the provider on-call, the Supervising Registered Nurse II (SRN II), and the Pharmacist-in-Charge (PIC) or designee. Medication errors shall be researched to determine the root causes. Health care staff shall monitor patient-inmates for adverse reactions to medication. State and federal agencies shall be notified according to statutory and regulatory requirements.

**II. PURPOSE**

To ensure the following:

- Immediate care of patient-inmates in the case of a medication error or adverse drug reaction.
- Patient-inmate safety by identifying and addressing errors occurring in the prescribing, administration, or documentation of use of medications.
- Continuous quality improvement for future error prevention.
- Proper and timely reporting and documentation of medication errors.
- Identification, reporting, and appropriate action following adverse drug reactions.

**III. DEFINITIONS**

**Adverse Drug Reaction:** Any undesired, unintended, or unexpected response to a medication administered in doses recognized in accepted medical 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 is any undesirable experience with the appropriate use of a medical product in a patient-inmate.

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

**Near Miss:** A medication error that did not reach the patient either by chance or through timely intervention. A near miss shall be reported as a medication error.

**Omission Error:** An error which occurs as a result of an action not taken.

**Sentinel Event:** An event or series of events that cause the death or serious disability of a patient-inmate. "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 functions, if the impairment lasts more than seven days or is still present at the time of discharge, or unintentional loss of a body part. For purposes of this policy, adverse events include sentinel events as described in the California Code of Regulations, Title 22, Division 5, Chapter I, Article VII, Section 70737.

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## IV. PROCEDURE

### A. Medication Errors

1. Stabilize and treat the patient, if applicable.
  - a. Assess the patient-inmate.
  - b. Notify the PCP or the provider on-call of the medication error and the status of the patient.
  - c. Follow care instructions as determined by the PCP or the provider on-call.
  - d. Notify the SRN II on duty.
2. Determine the course of action.
  - a. Omission Error
    - 1) If medication was never dispensed, pharmacy staff shall be notified to dispense the medication as appropriate.
    - 2) Administer the medication to the patient-inmate, if appropriate.
  - b. Administration/Distribution Error
    - 1) Retrieve incorrect Keep-On-Person and Nurse Administered/Direct Observation Therapy medication and return medications to pharmacy.
    - 2) Ensure that the patient-inmate receives the appropriate prescribed medication.
3. Report the error.
  - a. It is the responsibility of the person discovering the error to complete the Medication Error Report form. The form is available at the following link: <http://lifeline/Home/QualityManagement/PatientSafety.aspx>.
  - b. The person completing the Medication Error Report shall submit the completed report to their area supervisor who will forward a copy to the PIC, Chief Nurse Executive, Chief Medical Executive, and Chief Executive Officer (CEO). The PIC and CEO shall determine further distribution of the Medication Error Report, as appropriate.
  - c. The area supervisor and the involved staff shall conduct an initial fact-finding inquiry. The area supervisor shall research the medication error to determine root causes.
4. Errors may be prevented by ensuring the following medication practices:
  - a. Medication is started in a timely manner pursuant to a provider order
  - b. The right drug is prescribed, prepared, and administered;
  - c. At the right time/frequency;
  - d. By the right route;
  - e. In the right dose;
  - f. With the right documentation.
5. The following severity categories shall be used in the reporting of medication errors:

Category	Medication Error Severity
0	Error not reaching the patient-inmate
1	Error reached the patient-inmate but did not result in harm
2	Error resulted in increased monitoring but no change in vital signs and no harm
3	Error resulted in increased monitoring and change in vital signs but no harm

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4	Error resulted in need for treatment or hospitalization
5	Error resulted in permanent patient-inmate harm
6	Error <i>caused death</i>

## 6. PIC Reporting Responsibilities

- a. The PIC shall review the Medication Error Report(s) and complete the CDCR Medication Error Follow-up form within 5 business days of receipt. The CDCR Medication Error Follow-up form is available at the following link: <http://lifeline/Home/AlliedHealthServices/AHSPrograms/PharmacyServices.aspx>.
- b. The PIC shall prepare the CDCR Monthly Medication Error Statistics report to provide monthly statistical data to the Chief of Pharmacy Services, the local Pharmacy and Therapeutics (P&T) Committee/Pharmaceutical Care Committee, and applicable quality improvement committees for recommended changes in procedures and systems to prevent and reduce the recurrence of similar medication-related errors. The CDCR Monthly Medication Error Statistics report form is available at the following link: <http://lifeline/Home/AlliedHealthServices/AHSPrograms/PharmacyServices.aspx>.
- c. The PIC shall provide an incident summary of Level 4, 5, and 6 medication errors to the Chief of Pharmacy Services and the Headquarters Adverse/Sentinel Event Committee (see References). The summary shall include a description of each error, the impact on the patient-inmate, what was done to mitigate the error, and patient-inmate outcome. Level 4, 5, and 6 errors shall be reviewed by the Systemwide P&T Committee.

## 7. Sentinel Event Reporting

Level 4, 5, and 6 medication errors that also meet the criteria for sentinel events shall be reported as described in Inmate Medical Services Policies and Procedures Volume 3, Chapter 7.2, Adverse/Sentinel Event Review Policy.

## 8. Records Maintained as Peer Review

Medication error reports are generated and maintained as a component of the pharmacy's ongoing quality assurance program and are considered peer review documents not subject to discovery in any arbitration, civil or other proceeding as provided under the California Business and Professions Code §4125 and are therefore not part of the patient-inmate medical record.

## **B. Adverse Drug Reactions**

1. Health care staff shall immediately report any suspected adverse drug reaction, regardless of severity, to the PCP/psychiatrist/dentist or to the provider on-call and to the nursing supervisor.
2. The PCP/psychiatrist/dentist or the provider on-call shall document the suspected adverse drug reaction and corrective actions taken in the patient-inmate's Unit Health Record.
3. The health care staff discovering the adverse reaction shall complete the CDCR Suspected Adverse Drug Reaction Report and forward it to their supervisor and the PIC for corrective action. The CDCR Suspected Adverse Drug Reaction Report form is available at the following link: <http://lifeline/Home/AlliedHealthServices/AHSPrograms/PharmacyServices.aspx>.

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4. The PIC shall maintain a record of these reports and provide a summary to the local P&T Committee on a quarterly basis.
5. The PIC shall ascertain whether the adverse drug reaction warrants the completion of an FDA MedWatch Form 3500, based on FDA criteria. If so, the PIC shall submit the form to the FDA, the Chief of Pharmacy Services, the local P&T Committee/Pharmaceutical Care Committee, and applicable quality improvement committees for recommended changes in procedures and systems to prevent and reduce the recurrence of similar adverse drug reactions.
6. Adverse drug reactions shall be reported to the Food and Drug Administration (FDA) for the following outcomes:

<b>Death</b>	Report if you suspect that the death was an outcome of the adverse event, and include the date if known.
<b>Life-threatening</b>	Report if suspected that the patient-inmate was at substantial risk of dying at the time of the adverse event, or use or continued use of the device or other medical product might have resulted in the death of the patient-inmate.
<b>Hospitalization (initial or prolonged)</b>	Report if admission to the hospital or prolongation of hospitalization was a result of the adverse event.
<b>Disability or Permanent Damage</b>	Report if the adverse event resulted in a substantial disruption of the ability to conduct normal life functions, i.e., the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient-inmate's body function/structure, physical activities and/or quality of life.
<b>Congenital Anomaly/Birth Defect</b>	Report if you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.
<b>Required Intervention to Prevent Permanent Impairment or Damage</b>	Report if you believe that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of a medical product.
<b>Other Serious (Important Medical Events)</b>	Report when the event does not fit the other outcomes, but the event may jeopardize the patient-inmate and may require medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples include allergic bronchospasm requiring treatment in an emergency room, serious blood disorders or seizures/convulsions that do not result in hospitalization. The development of drug dependence or drug abuse would also be examples of important medical events.

## V. REFERENCES

- California Business and Professions Code §4125
- California Code of Regulations, Title 22, Division 5, Chapter I, Article VII, Section 70737
- California Health and Safety Code 1279.1

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- Food and Drug Administration, MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- Headquarters Adverse/Sentinel Event Committee: [healthincidentreporting@cdcr.ca.gov](mailto:healthincidentreporting@cdcr.ca.gov)
- <http://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm>
- Inmate Medical Services Policies and Procedures Volume 3, Chapter 7.2, Adverse/Sentinel Event Review Policy
- National Coordinating Council for Medication Error Reporting and Prevention