

DEPARTMENT OF VETERAN AFFAIRS (VA)
SALT LAKE CITY HEALTH CARE SYSTEM
Salt Lake City, Utah

MEMORANDUM 119.02

June 13, 2017

ADVERSE DRUG REACTIONS AND ALLERGIES

1. PURPOSE:

To establish policy and procedure for reporting adverse drug reactions (ADR) in the VA Salt Lake City Health Care System (VASLCHCS).

2. POLICY:

This policy covers the process in which ADRs are identified and documented in order to increase patient safety in drug therapy. All allergic reactions and adverse effects of drugs administered or dispensed to a patient should be documented in CPRS (Computerized Patient's Record System) and should be reported as outlined in this document.

3. DEFINITIONS:

- a. Adverse Drug Reaction (ADR) is a response to a drug which is noxious and unintended and which occurs at doses normally used in individuals for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function. *NOTE: There should be a causal or suspected link between a drug and adverse drug reaction. However, a causality assessment or association of the drug to the adverse drug reaction does not have to be established in order to report an adverse drug reaction or adverse drug event.*
 - i. A historical ADR is a past event or an event that reportedly occurred in the past at another health care setting. A historical ADR is defined in the CPRS system as "reported by the patient as occurring in the past; no longer requires intervention."
 - ii. An observed ADR is defined in CPRS as a reaction that is "directly observed or occurring while the patient was on the suspected causative agent." *NOTE: Observed refers to a newly noted adverse outcome. Although the term implies that the provider of record made the diagnosis, the fact that a provider may not have visually "observed" an adverse drug reaction does not preclude reporting as "observed."*
 - iii. An allergy is an ADR mediated by an immune response (e.g., rash, hives).
 - iv. A serious ADR is a reaction this is life-threatening or fatal, temporarily or permanently disabling, or requires hospitalization, prolongs hospitalization, or results in additional medical therapy.
 - v. An unexpected ADR is a reaction which is not listed in the manufacturer's product information or has not previously been reported in the literature.

- b. Exceptions to ADR definitions listed above:

- i. Reactions caused by blood products need not be reported unless a chemical agent other than the basic substance is suspected of being responsible.
- ii. Minor, temporary, or reversible reactions which are recognized and well known as inherent characteristics of established drugs, and which are identified in the literature as accompanying the product as usual or common side effects, should be documented in CPRS but need not be reported. In case of doubt as to the significance of the drug reaction, it should be reported.

4. RESPONSIBILITIES:

- a. Chief of Staff – Ensure providers are educated on how to verify, document, and report ADRs.
- b. Nursing Service – Ensure that nurses are familiar with this policy, are educated on how to identify, verify, document, and report ADRs, and have been instructed on the proper steps to take when ADRs are identified, not documented, or medications with a documented ADR are ordered for a patient.
- c. Pharmacy Service – Ensure that all pharmacist staff are familiar with this policy, are educated on how to identify, document, verify and report ADRs, and have been instructed on the proper steps to take when ADRs are not documented or medications with a documented ADR are ordered for a patient.
 - i. Pharmacy service is also responsible for collecting reported ADRs, assessing reports to determine which ADRs are truly serious or unexpected, and reporting compiled ADR information to the Pharmacy and Therapeutics (P&T) Committee quarterly.
- d. Health Information Management Service – Ensure patient names are forwarded to Pharmacy service when an ADR is identified or described on patients' discharge summaries or where visits are coded with clinical diagnosis of adverse drug effect.
- e. P & T Committee – Ensure ADR reports are evaluated monthly for patterns or trends or the need for peer review of ADRs reported.
- f. All health care providers – Ensure any suspected or actual serious or unexpected ADRs are reported through the delineated mechanisms in this memorandum.

5. PROCEDURES:

- a. The responsibility for identifying and verifying patient ADRs ultimately rests with the prescribing provider.
- b. Ancillary staff, including nursing and dispensing pharmacy, are responsible for ascertaining and documenting ADRs in patient care documents and verifying that patients do not receive, inadvertently, medication(s) to which they have a known documented ADR.
 - i. Providers, pharmacists, nurses, or anyone ordering, dispensing, or administering medications are responsible for verifying the patient's ADRs and documenting the ADR and associated reaction in CPRS if not already been documented. If the patient does not have any ADRs, the abbreviations

- no known allergies (NKA) or no known drug allergies (NKDA) should be used to document.
- ii. If the patient develops an ADR, the allergy/ADR and reaction identified must be entered in the patient's electronic chart by one of the treating team members at that time.
- c. The order processing pharmacist must ensure the patient's ADR status is documented in CPRS and review that information against any medication orders for appropriateness.
- i. Pharmacists must review the patient's profile for allergy/ADR information.
 - ii. If no ADR assessment is present in CPRS, the pharmacist must contact the patient or provider to confirm and enter appropriate allergy information into patient chart.
 - iii. If a medication is ordered that the patient has had an ADR to or has a high likelihood of cross-reactivity with the patient's allergies, the pharmacist must notify the provider.
 - iv. Patient profiles that indicate no entry (No Allergy Assessment) in the computerized allergy documentation field are considered to be incomplete, and serve as an indicator of inadequate patient counseling.
- d. On inpatient and clinic units, the nurse must ensure the patient's ADR status is documented prior to administering medications.
- i. The clerk will print the Allergy Bracelet Band, and the nurse will then ensure that the band is affixed to the patient with all known drug allergies/ADRs documented on it.
 - ii. The nurse caring for the patient will ask the patient about any known drug allergies/ADRs and document the medication as well as the reaction in the unit appropriate nursing notes and on the patient's CPRS cover sheet.
 - iii. When administering medications, administration of any medications listed on the Allergy Bracelet Band or in CPRS should be avoided unless specific instructions to do so come from the provider (see section e below).
- e. The decision to administer a medication to which the patient has a documented ADR ultimately rests with the provider; however, it is the responsibility of ancillary staff to ascertain that the medication is not being ordered inadvertently.
- i. In the rare instance when a provider writes an order for a patient to receive a medication to which an ADR has been documented, the nurse caring for the patient must notify the provider of this fact before the medication is administered. If the patient is hospitalized or in clinic, and the pharmacist must notify the provider before the medicine is dispensed.

- ii. If the provider still deems it necessary to give a medication to which the patient has a documented ADR, arrangements for the appropriate monitoring and equipment for treating anaphylaxis must be made by the provider, and the rationale for giving the medications should be in the providers documentation in CPRS.
 - iii. Nurses may decline to administer any medication, and pharmacists may decline to dispense any medication which, in their professional judgment, is contraindicated. However, it is then the responsibility of that nurse or pharmacist to notify the patient's provider immediately and seek alternative resolution of the problem. In these rare instances, the nurse may alternatively request the provider to administer the ordered medication.
- f. In the instance where an ADR is observed, the healthcare professional who observed the reaction is responsible for ensuring the reaction is entered into CPRS as above, as well as reporting the ADR in the appropriate manner:
 - i. VA ADERS is a national reporting system that tracks ADRs through a national review committee and forwards reports to MedWatch when deemed appropriate. Pharmacy service ensures all observed ADRs entered into CPRS are entered into VA ADERS.
 - 1) Reports for all ADRS should be entered through the MedSafe Portal located at https://vaww.cmop.med.va.gov/MedSafe_Portal/.
 - 2) Confirmed serious or unexpected ADRs should be forwarded to MedWatch with the VA ADERS report by selecting that option when filling out the electronic form.
 - ii. If an ADR was the result of an error in patient care, a Patient Incident Report should also be filed through the following link <https://vaww.per.r01.med.va.gov/>.
- g. In the instance that a patient denies or cannot confirm a certain ADR that has been documented in CPRS, review the documented ADR with the patient as well as attempt to verify source of documentation in CPRS notes. If after chart review, the provider deems it appropriate to remove the ADR from the patient's chart, the provider will verify that the patient is amenable to this action. If so, the ADR may then be removed by marking as "Entered in Error" with a description of why the ADR is being removed.
 - i. This process should also be used when a re-challenge of a medication does not resulting in any adverse reaction.
- h. In the event of computer malfunctions:
 - i. Providers are responsible for writing outpatients allergy status on the Doctor's Orders.
 - ii. Nurses and/or unit coordinators are responsible for transcribing drug allergies onto written MARs.

- iii. Orders identifying a new allergy are faxed by the unit coordinator to the Inpatient Pharmacy.
- i. ADRs are subject to peer review process if deemed necessary or resulted in patient death or serious harm.
 - i. Peer review will take place by the Care Team Manager of the provider involved.
 - ii. Peer review should include review of the patient's medication and medical history, results of drug discontinuation and re-challenge, assessment of temporal relationships with drug administration and occurrence of suspected reaction, alternative explanations for the reaction and literature review when necessary.
- j. ADRs will be monitored monthly in P&T committee. Pharmacy will compile all reported ADRs and present this information. This report will be used to detect any trends in ADRs and ADR reporting, guide development and implementation of medication use evaluations (MUEs), guide ongoing professional education within the facility, and otherwise help to assure the safe and appropriate use of drugs within the facility.

6. REFERENCES:

- a. The Joint Commission 2017 Medication Management MM 05.01.01, 06.01.01, 07.01.03
- b. VHA Directive 1070 – Adverse Drug Event Reporting and Monitoring

7. RESCISSION:

- a. Center Policy Memorandum 119.29, "Identification and Documentation of Patient Drug Allergies," dated April 8, 2014.
- b. Center Policy Memorandum 119.02 "Adverse Drug Reactions," dated April 8, 2014.

8. RECERTIFICATION DATE: This policy is scheduled for recertification on or before the last working day of June 2020.

9. FOLLOW-UP RESPONSIBILITY: Chief, Pharmacy Service (119)

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Director