RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

POLICY AND PROCEDURE MANUAL		CODE:	1.15.0
PHARMACY SERVICES		DATE:	1/5/82
		REVISED:	4/19/22
SECTION:	**DEPARTMENT OF PHARMACY**	APPROVED:	Thinh Tran, Pharm. D
		MEC APPROVED:	7/28/10,2/22/12,11/19/14,10/28/15, 6/22/16
SUBJECT:	**ADVERSE DRUG REACTION REPORTING**	**Page**	**1 of 3**

POLICY

It is the responsibility of all disciplines to immediately initiate a "REPORT OF ADVERSE DRUG REACTION" and notify the responsible practitioner whenever a patient experiences a undesirable response to a medication(s), based on the following definition:

Definition of an Adverse Drug Reaction: An Adverse Drug Reaction (ADR) is defined as an: undesirable, unintended, or unexpected reaction to a medication within therapeutically acceptable doses.

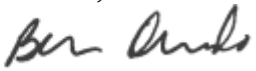
The following would qualify as adverse drug reactions:

A. Intolerance of expected side-effects (e.g. anticholinergic effects with tricyclic antidepressants)
B. Adverse events due to medication withdrawal (e.g. seizures from phenobarbital weaning)
C. Hypersensitivity reactions (e.g. angioneurotic edema with penicillin drugs)
D. Toxic reactions (e.g. hepatic damage from isoniazid)
E. Idiosyncratic reactions (e.g. hemolytic anemia from primaquine)
F. Unexpected drug incompatibilities.

In addition, the use of a **severity index** would assist the practitioner in tracking and defining the adverse event:

A. Near Miss (does not apply to ADRs):
    1. Unsafe.
    2. Near Miss
B. Reached the Patient:
    3. No harm
    4. Emotional distress or inconvenience
    5. Additional treatment
C. Harm
    6. Temporary harm
    7. Permanent harm
    8. Severe permanent harm
    9. Death

Reviewed: 7/17/15bdk, 7/31/2018bdk, 4/19/2022 TT

Approved By: 

REPORTING PROCEDURE

1. The ADR will be reported by entering the required information into the Safety Intelligence system located on the Rancho intranet. Alternatively, you may leave your name and phone number at extension 56129 to report the ADR.
2. The following will be documented in the Safety Intelligence report:
    a. Patient identification
        i. First and last name of patient
        ii. MRUN
        iii. Date of birth
        iv. Gender
        v. Patient location
    b. Date admitted or ambulatory encounter
    c. Date/time of ADR
    d. Event detail
        i. What type of reaction
        ii. What organ system was affected
        iii. What action was taken to relieve the adverse reaction
    e. Medication information
        i. Name of medication
        ii. Dose
        iii. Route
        iv. Frequency
3. The adverse drug reaction will be reported to the patient's primary practitioner and nurse as soon as possible by the individual who initiated the report.
4. The Safety Intelligence Report will be review by the Medication Safety Committee (see below).
5. The practitioner and nurse will document their ADR assessment in the patient's medical record. The "Allergy" section of the patient's medical record will be updated due to the reported reaction.

MEDICATION SAFETY COMMITTEE RESPONSIBILITY

1. Monthly analysis, trends, and recommendations of adverse drug reactions, which are reported to the P&T Committee.

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2. Follow-up and ensure that medical records are updated with new allergy status or adverse drug reaction as applicable.

PHARMACY AND THERAPEUTICS COMMITTEE RESPONSIBILITY

1. Review monthly report presented to the Committee by the Medication Safety Committee and act on the recommendations.
2. The Committee Chair will delegate to the necessary committee activities as follows:

    a. Facility inservices as necessary
    b. Intervening in ADR prevention if patterns develop, which indicate certain medication(s) are culprits
    c. Recommend new or changes to order sets, protocols, or policies and procedures.
3. Review quarterly reports, including identifying those moderate to severe reactions that require reporting to the Food and Drug Administration via the MedWatch Online Voluntary Submission Form 3500 and an analysis of severe adverse drug reactions.