RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

POLICY AND PROCEDURE MANUAL		CODE:	1.16.0
PHARMACY SERVICES		DATE:	1/5/83
		REVISED:	4/19/22
SECTION:	**DEPARTMENT OF PHARMACY**		
		APPROVED:	Thinh Tran, Pharm. D
SUBJECT:	**DRUG DEFECT REPORT**	PAGES:	1 of 1

PURPOSE

To provide uniform procedures to report product quality problems to the Food and Drug Administration (FDA) so that Pharmacy staff participates in ensuring the safety of drugs, biologicals, medical devices, and other products once they have been introduced into the market.

POLICY

Pharmacists shall report all defective drug products received by the Pharmacy Department on the FDA MedWatch form when a defect in labeling, packaging, or other issues of drug integrity is noted or suspected.

PROCEDURE

1. Staff pharmacists shall initiate the MedWatch form to document a drug product problem they encounter or a problem which is brought to their attention.
2. Product problems reportable shall include issues of quality, performance or safety, and may include occurrences of:
   a) suspected contamination
   b) questionable stability
   c) defective components
   d) poor packaging or labeling
3. FDA MedWatch Form 3500 (Attachment 1) shall be completed and forwarded to the Food and Drug Administration. MedWatch may be called at 1-800-FDA-1088 or 1-800-332-1088. Use of MedWatch fax number 1-800-FDA-0178 expedites the reporting process.
4. A copy of the completed FDA MedWatch Form shall be maintained in the Pharmacy Department files.
5. Defective products shall be segregated from regular Clinic and Pharmacy stock and the manufacturer contacted.

Reviewed: 4/1/16bj, 7/31/2018bdk, 4/19/2022 TT

Approved By: Ben Ando