



**POLICY AND PROCEDURE MANUAL  
PHARMACY SERVICES**

SECTION: **DEPARTMENT OF PHARMACY**  
SUBJECT: **BLACK BOX WARNINGS**

CODE: 1.42.0  
DATE: 7/22/08,4/26/16  
REVISED: 4/19/22  
MEC APPROVED: 8/27/08,6/22/16  
APPROVED: Tinh Tran, Pharm. D  
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**POLICY**

A black box warning is a type of warning that appears on the package insert for prescription drugs that may cause serious adverse effects. It is so named for the black border that usually surrounds the text of the warning.

A black box warning is warranted when a drug presents one of the following:

- 1 unique risk to benefit concern compared with other drugs in the same class
- 2 the potential adverse reaction is extremely significant above the drug's benefit
- 3 when adverse reactions can be prevented or reduced by restricted use or observance of defined cautions.

High priority black box warning medications and guidelines will be disseminated to Medical, Nursing, and Pharmacy staff and the list reviewed annually.

**PROCEDURE**

- 1 Each Medical, Nursing, and Pharmacy department will receive an electronic list of the FDA Black Box Warnings and an Acknowledgement Form that also educates staff on how to find additional information on any medication that has a FDA Black Box Warning. Each department is required to print and distribute the FDA Black Box Warnings and an Acknowledgement Form to each clinical staff member.
- 2 Each department will be responsible for having their respective clinical staff read and sign off the Acknowledgement Form. Each department will be required to keep on file the Acknowledgement Form for the various regulatory agencies that may survey RLANRC for compliance to this safety standard.
- 3 Each department must have all clinical staff comply with acknowledgement of the black box warning.
- 4 In addition, the following will be provided:

Reviewed: 9/30/15, 11/14/2018bdk, 4/19/2022 TT

Approved By: *Ben Arndt*



**RANCHO LOS AMIGOS**  
NATIONAL REHABILITATION CENTER

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- a A list of high priority black box warning medications on the patient care units and their guidelines.
- b Black box warning on the Pyxis MedStations.