RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

POLICY AND PROCEDURE MANUAL		CODE:	1.29.0
PHARMACY SERVICES		DATE:	1/04/01
		REVISED:	4/19/22
SECTION:	**DEPARTMENT OF PHARMACY**	APPROVED:	Thinh Tran, Pharm.D.
		MEC APPROVED:	4/28/10
SUBJECT:	**OFF-LABEL USE OF DRUGS**	Page:	1 of 3

BACKGROUND:
The Food and Drug Administration (FDA) provides a barrier to market entry and use of unproven *and* unsafe products. For prescription drugs, the FDA approval process requires substantial evidence of efficacy and safety for specific clinical situations. Although approval is indication-specific, the FDA has a limited role once a drug is on the market. The Food, Drug and Cosmetics Act does not limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses that are not included in the approved labeling, i.e. “off–label” use. Unapproved or off-label uses may be appropriate and rational in certain circumstances, and may reflect approaches to drug therapy that have been extensively reported in the medical literature, or are considered community standard of care. To ensure that off-label indications are safely prescribed, this policy outlines system wide standards and requirements for use of off-label medications throughout DHS. This policy applies to all practitioners with medication prescribing privileges.

DEFINITIONS:
FDA approved labeled indication: Indications for use that have been approved by the FDA
Off-label indication: Indications for use that have not been approved by the FDA.

PURPOSE:
- Describe procedures when a medication is prescribed for off-label indications
- Outline minimum requirements for supporting literature references

POLICY:
- Medications may be prescribed for off-label indications when supported by currently available drug information resources and scientific literature. Off-label prescribing may be considered MEDICALLY NECESSARY when **all** of the following conditions are met and/or the therapy is generally accepted as community standard practice for a particular indication:
    - The drug is approved by the FDA.
    - The drug will be prescribed to treat a specific medical condition, including life-threatening conditions or chronic and seriously debilitating conditions.
    - The drug is recognized as appropriate for the stated indication by one of the following:
        - The FDA (including listing on the FDA Orphan Drug Approval web

Reference: DHS Policy Number: 329.XXX
Reviewed: 4/4/16bj, 11/14/2018bdk, 4/19/2022 TT
Approved By:

- American Hospital Formulary Service (AHFS) Drug Information reference
- MICROMEDEX Healthcare Drug resources (online drug information reference)
- United States Pharmacopeia Dispensing Information, Vol. I
- The Sanford Guide to Antimicrobial Therapy

- FDA approvals of medications are commonly based on clinical trials conducted in adult study populations. A drug is recognized as appropriate for pediatric use if the drug is FDA-approved in the pediatric age group, or the therapeutic use and appropriate dose is included in either of the following pediatric drug information references:
  - Lexi-Comp Pediatric Dosage Handbook
  - The Harriet Lane Handbook
- In the absence of being listed in the above named reference sources, supporting material may be used to validate the proposed use for the specific medical condition as safe and effective. Scientific and medical information that concerns the safety or effectiveness of an approved drug for an unapproved new indication that is not included in the product's approved labeling is often published in peer-reviewed journals or reference publications.
- References should be published by an organization that has an editorial board that utilizes experts who have demonstrated expertise in the subject of the article under review by the organization and who are independent of the organization to review and objectively select, reject, or provide comments about proposed articles; and that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors, contributors, or editors associated with the journal or organization.
- Material should be peer-reviewed and published in accordance with the peer-review procedures of the organization.
- The material should not be in the form of a special supplement or publication that has been funded in whole or in part by one or more of the manufacturers of the product that is the subject of the article.
- Material should not be written, edited, excerpted, or published specifically for, or at the request of, a drug manufacturer; or edited or significantly influenced by a drug manufacturer or any individuals having a financial relationship with the manufacturer.
- Information contained in the scientific or medical journal article or reference publication should address adequate and well-controlled clinical investigations that are considered scientifically sound by experts with scientific training and experience to evaluate the safety or effectiveness of the drug.

- Off-label prescriptions shall be reviewed for appropriateness by a pharmacist. Order review shall include evaluation of the following:
    - Appropriate dosage, frequency, and route of administration
    - Therapeutic duplications
    - Potential allergies or sensitivities
    - Drug-drug interactions, drug-food interactions, drug-disease interactions, druglab interactions
    - Formulary status
    - Age-specific criteria such as renal function
    - Other clinical issues or concerns

Off-label prescriptions that are deemed inappropriate will be re-evaluated by the prescriber and the pharmacist and may require submission of additional supporting references, and escalated to the medical director (or designee) as appropriate.

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