



MONTANA STATE HOSPITAL POLICY AND PROCEDURE

DIETARY SUPPLEMENT POLICY

Effective Date: April 10, 2020

Policy: PH-02

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- I. PURPOSE:** To establish a mechanism to ensure patients at Montana State Hospital (MSH) receive medications which are proven to be both safe and effective as set forth by Food and Drug Administration (FDA) standards.
- II. POLICY:**
 - A. Dietary supplements come in many forms, including tablets, capsules, powders, softgels, gelcaps, and liquids. Though commonly associated with health food stores, dietary supplements also are sold in grocery, drug and national discount chain stores, as well as through mail-order catalogs, TV programs, the Internet, and direct sales.
 - B. Dietary supplements are not drugs. A drug, which sometimes can be derived from plants used as traditional medicines, is an article that, among other things, is intended to diagnose, cure, mitigate, treat, or prevent diseases. Before marketing, drugs must undergo clinical studies to determine their effectiveness, safety, possible interactions with other substances, and appropriate dosages. The FDA must review this data and authorize the drug's use before they are marketed. FDA does not authorize or test dietary supplements.
 - C. MSH has no way of determining priority, safety, or effectiveness of substances not FDA approved.
- III. DEFINITIONS:**
 - A. **Dietary Supplements:** Dietary supplements refer to products made of one or more of the essential nutrients, such as vitamins, minerals and protein. The Dietary Supplement Health and Education Act (DSHEA) broadens the definition to include, with some exceptions, any product intended for ingestion as a supplement to the diet. This includes vitamins; minerals; herbs; botanicals and other plant-derived substances; amino acids (the individual building blocks of protein), and concentrates, metabolites, constituents and extracts of these substances.
- IV. RESPONSIBILITIES:**
 - A. Licensed Independent Practitioners and nursing staff are responsible for abiding by this policy.

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V. PROCEDURE:

A. The use of dietary supplements not approved by FDA is typically prohibited at MSH, except in rare circumstances when approved by the Pharmacy or Medical Staff.

VI. REFERENCES: FDA Guidelines.

VII. COLLABORATED WITH: Pharmacy Director, Dietitian.

VIII. RESCISSIONS: PH-02, Dietary Supplement Policy dated February 24, 2014; PH-02, *Dietary Supplement Policy* dated June 30, 2009; PH-02, *Dietary Supplement Policy* dated September 11, 2006; PH-02; PH-02, *Dietary Supplement Policy* dated March 31, 2003; PH-02; *Dietary Supplement Policy* dated February 14, 2000; HOPP PH-08-97-N, Herbal Policy, dated March 7, 1997.

IX. DISTRIBUTION: All hospital policy manuals.

X. ANNUAL REVIEW AND AUTHORIZATION: This policy is subject to annual review and authorization for use by either the Administrator or the Medical Director with written documentation of the review per ARM § 37-106-330.

XI. FOLLOW-UP RESPONSIBILITY: Medical Director.

XII. ATTACHMENTS: None.

Signatures:

Kyle Fouts
Hospital Administrator

Thomas Gray, MD
Medical Director