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| Name of Policy: <u>Herbal and Nutraceuticals</u> Policy Number: 3364-133-42 Department: Pharmacy Approving Officer: Senior Hospital Administrator Responsible Agent: Director of Pharmacy Scope: University of Toledo Medical Center |  Effective Date: 4/25/2022 Initial Effective Date: January, 2002 |
| <input type="checkbox"/> New policy proposal <input type="checkbox"/> Major revision of existing policy | <input type="checkbox"/> Minor/technical revision of existing policy <input checked="" type="checkbox"/> Reaffirmation of existing policy |

(A) Policy Statement

Herbal and nutraceuticals shall not be purchased and/or dispensed by the University of Toledo Medical Center (UTMC) Department of Pharmacy unless approved by the Pharmacy and Therapeutics (P&T) committee.

(B) Purpose of Policy

To define and delineate the use of herbal and nutraceuticals for inpatients at UTMC.

(C) Procedure

1. The use of herbal and nutraceuticals is rising. Consistent, clinically proven information, which has been reviewed by the FDA regarding product safety, effectiveness, and interactions with medication, other supplements, or foods, may not be known or available. The FDA does not regulate the manufacturing of alternative medicines. Consequently, it is not possible to routinely purchase standardized quality products, and it is often not possible to verify potency or lack thereof. Furthermore, it is known that some of these products can interfere or interact with medical therapies rendering medical treatments less effective and may even place the patient at potential risk.
2. According to the Food and Drug Administration (FDA) in the Dietary Supplement Health and Education Act of 1994, dietary supplements are defined as:

“Products (other than tobacco) that are intended to supplement the diet that bear or contain one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total daily intake; or a concentrate metabolite, constituent, extract, or combinations of these ingredients.”¹

The FDA has not approved dietary supplements for any use. Dietary supplements are not drugs and are not regulated by the FDA. Additionally, dietary supplements are not intended to “diagnose, mitigate, treat, cure, or prevent disease.”²

3. The UTMC P&T Committee does not consider nutraceuticals (i.e., herbals, nutritionals, etc.) as medicinal drugs, and does not endorse the procurement of nutraceuticals not recognized by well-established medical evidence. For those nutraceuticals that have medical evidence to support their use, P&T will review those agents for addition to the formulary. The only exceptions are vitamins, minerals, oral nutritional drink/food products, and nutraceuticals already on the UTMC formulary or approved by P&T for use (e.g., multiple vitamins, vitamin E, Boost Plus, etc.).
4. Patients may only use their own if product is prescribed by a physician and appropriately labeled to comply with 3364-133-40

