

The Center for Medicine and Healing Arts

KARYN SHANKS MD

Heart, Hope, Healing

Informed Consent Regarding Nutritional and Herbal Supplements

According to the Federal Food, Drug, and Cosmetic Act, as amended, Section 201(g)(1), the term *drug* is defined as an “article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.” Technically, vitamins, minerals, trace elements, amino acids, herbs, or homeopathic remedies are not classified as drugs. However, these substances can have significant effects on physiology and must be used rationally. In this office, we provide nutritional counseling and make individualized recommendations regarding use of these substances in order to upgrade the quality of foods in a patient’s diet and to supply nutrition to support the physiological and biomechanical processes of the human body. Although these products may also be suggested with a specific therapeutic purpose in mind, their use is chiefly designed to support given aspects of metabolic function. Use of nutritional supplements may be safely recommended for patients already using pharmaceutical medications (drugs), but some potentially harmful interactions may occur. For this reason, it is important to keep all of your healthcare providers fully informed about all medications and nutritional supplements, herbs, or hormones you may be taking.

Sale of Nutritional Supplements at The Center for Medicine and Healing Arts

You are under no obligation to purchase nutritional supplements at our clinic.

As a service to you, we make nutritional supplements available in our office. We purchase these products only from manufacturers who have gained our confidence through considerable research and experience. We determine quality by considering: (1) the quality of science behind the product; (2) the quality of the ingredients themselves; (3) the quality of the manufacturing process; and (4) the synergism among product components. The brands of supplements that we carry in our facility are those that meet our high standards and tend to produce predictable results.

While these supplements may come at a higher financial cost than those found on the shelves of pharmacies or health food stores, the value must also include assurance of their purity, quality, bioavailability (ability to be properly absorbed and utilized by the body), and effectiveness. The chief reason we make these products available is to ensure quality. You are not guaranteed the same level of quality when you purchase your supplements from the general marketplace. We are not suggesting that such products have no value; however, given the lack of stringent testing requirements for dietary supplements, product quality varies widely.

If you have concerns about this issue, please discuss them with our staff.

I, _____, have read and understand the above statement on

_____ (date), witnessed by _____, _____ (date).