

LEGISLATIVE RESEARCH REPORT

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OTHER STATES' POLICIES REGARDING NURSES ADMINISTERING PRESCRIBED DIETARY SUPPLEMENTS

PREPARED FOR REPRESENTATIVE MIKE KELLY

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You asked if Boards of Nursing in other states have policies in place that allow nurses to administer dietary supplements. You were also interested in whether or not these supplements must be prescribed by a physician in order for a nurse to administer them.

We asked the Boards of Nursing in 19 randomly selected states whether it was within the scope of practice for nurses to administer dietary supplements. We received responses from 13 states, and none replied that it was always outside of the scope of practice for nurses to administer dietary supplements. However, Board representatives from two states, Texas and Wyoming, expressed reservations about the practice. Staff from nine states noted that supplements would need to be prescribed by an individual authorized to prescribe medication in order for a nurse to administer these products.

BACKGROUND

As you know, the "dietary supplement" category includes a range of substances, such as, vitamins, minerals, herbs, enzymes, and amino acids. Although some of these substances are commonly used, the U.S. Food and Drug Administration (FDA) does not approve dietary supplements. Manufacturers are responsible for properly labeling the contents of these products.

The Alaska Board of Nursing has determined that it is "outside of the scope of practice for nurses to administer remedies that are not FDA approved."¹ The Board has addressed this issue three times, in 1998, 1999, and 2002, and each time reached this same decision. Dorothy Fulton,

¹ "Board of Nursing Minutes of Meeting", December 10-11, 1998, p.8.

Executive Administrator for the Alaska Board of Nursing, stated that the decisions were based in part on concerns that nurses are not trained in the use of these types of supplements and that interactions between supplements and prescribed medications can be dangerous.²

Although the Board has determined that administering supplements is outside of the scope of practice for nurses, at least one organization in the state has a policy that allows, but does not require, nurses to administer supplements. The Alaska Pioneer Homes "Policy and Procedures Manual" permits nurses to administer supplements under certain conditions, including that the supplement is prescribed and the nurses are willing to perform this task.³

DIETARY SUPPLEMENTS

The Dietary Supplement Health and Education Act (DSHEA) of 1994 defined the term "dietary supplement," and established the relationship between the U.S. Food and Drug Administration (FDA) and these products. According to the FDA's website, a *dietary supplement* is a product containing a *dietary ingredient* taken by mouth to supplement the diet. *Dietary ingredients* can include one or more of the following substances: vitamins, minerals, herbs, botanicals, amino acids, enzymes, organ tissues, glandulars, and metabolites. A *dietary supplement* may include a number of different *dietary ingredients*, for example, a number of products are marketed as multi-vitamins or contain combinations of herbal substances. The *dietary supplement* category includes a broad range of products, from commonly used vitamins pills to more obscure, and potentially controversial, supplements. Although some of these products may be recognized as safer than others within the medical community, no *dietary supplements* are FDA-approved.⁴

The DSHEA makes a distinction between dietary ingredients that were sold in the U.S. prior to October 15, 1994, and "new dietary ingredients" that were not sold in the U.S. until after this date. Manufacturers who wish to sell products containing new dietary ingredients must typically provide the FDA with some safety data prior to marketing these products. Manufacturers who develop supplements containing dietary ingredients that are not considered new do not need to provide this information to the FDA. For example, a manufacturer could create a new product using a combination of dietary ingredients that were sold prior to 1994 without submitting information to the FDA. However, if the manufacturer wished to include any new dietary ingredient, then the company would be responsible for submitting the necessary safety information.

The FDA's regulation of dietary supplements focuses on ensuring that products meet certain labeling requirements and identifying and removing illegal or unsafe products from the market. The FDA requires that supplement labels contain several pieces of information, including a complete list of ingredients and the net contents of the product. Manufacturers are responsible for ensuring that dietary supplements are safe and contain the ingredients listed on the label.

² Personal communication from Dorothy Fulton, Executive Administrator, Alaska Board of Nursing. Ms. Fulton can be reached at (907) 269-8194.

³ "Alaska Pioneer Homes Policy and Procedure Manual," 3-B-13 to 3-B-17, provided by Virginia Smiley, Director, Division of Alaska Pioneer Homes, Department of Health and Social Services. Ms. Smiley can be reached at (907) 465-4422. We include this document as Attachment A.

⁴ Personal communication from Dr. Robert Moore, Team Leader, Compliance and Enforcement Team, Division of Dietary Supplement Programs, U.S. Food and Drug Administration. Dr. Moore can be reached at (301) 436-1441.

Unlike drug manufacturers, producers of dietary supplements are not required by law to record, investigate, or inform the FDA of complaints about adverse reactions to their products. There is no regulatory mechanism through which the FDA may “approve” these supplements before they reach the market. Instead, the FDA must show that a supplement that is being distributed is unsafe, and take steps to have the product removed from the market. According to Dr. Robert Moore, with the FDA, the only dietary supplements that have been banned to date are those that contain ephedrine alkaloids. The FDA has a MedWatch hotline and website to allow health care providers and patients to report problems that they believe may be related to dietary supplements, drugs, or other medical devices.⁵

OTHER STATES’ POLICIES AND POSITIONS

We received information about whether administering dietary supplements is considered within the scope of practice for nurses from the Boards of Nursing in the following 13 states—Alabama, Arizona, California, Colorado, Delaware, Maine, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Texas, and Wyoming. None of these states responded that it was always outside the scope of practice for nurses to administer dietary supplements; however, none stated that they required nurses to do so. Nine of the Boards replied that nurses could only administer these products if they are prescribed. In an advisory opinion, the Vermont State Board of Nursing noted that nurses have the right to refuse to administer substances that they believe may harm the patient, or if there is insufficient information available about a particular substance.⁶ It appears unlikely that a Board of Nursing would require a nurse to administer any substance that was prescribed; however, it is possible that nurses would be more or less willing to administer these supplements depending on the position of their state Board.

Responses from a number of Boards of Nursing reflected the importance of nurses being able to exercise discretion and professional judgment. Board of Nursing staff from some states, including Colorado, New York, and Oregon, noted that the nurse should have the necessary knowledge, competency, or information to administer a dietary supplement. The Pennsylvania State Board of Nursing responded with a letter including questions that a nurse should consider when trying to determine if administering a supplement, or any other practice, is within the scope of practice.⁷

Of the 13 Boards that responded, two expressed reservations about nurses administering dietary supplements. A representative from the Wyoming State Board of Nursing noted that although the Board does not have a direct advisory opinion on the topic, they generally have not allowed nurses to administer non-FDA approved medications, particularly without a prescription. A staff member of the Texas Board of Nurse Examiners expressed concern that dietary supplements

⁵ “Overview of Dietary Supplements,” U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, January 3, 2001. We include this document as Attachment B.

⁶ Vermont State Board of Nursing Advisory Opinion, Board Approved May 8, 2000, available at <http://vtprofessionals.org/opr1/nurses/>. We include this document as Attachment C.

⁷ Letter from Colleen Rosborough, Nursing Practice Advisor, Pennsylvania State Board of Nursing, February 17, 2006. We include this letter as Attachment D.

can be risky, especially when combined with other medications, and noted that a nurse would likely have difficulty supporting a decision to administer a supplement.

Table 1 details the responses that we have received from the Boards of Nursing in other states.

I hope you find this information to be useful. Please do not hesitate to contact us if you have questions or need additional information.

Table 1: Responses from Selected States' Boards of Nursing Regarding Nurses Administering Dietary Supplements

State	Response	Source
Alabama	A nurse (either an LPN or an RN) could administer the supplements if an order exists from an authorized prescriber. In long-term care, the physician or nurse practitioner would have to order the supplement, but once the order existed the nurse could administer it. The issue of FDA approval has never come up to the knowledge of the responder.	N. Genell Lee, MSN, RN, JD, Executive Officer, Alabama Board of Nursing, (334) 242-4184, Genell.Lee@abn.alabama.gov.
Arizona	In order to administer supplements in a long-term care setting, a nurse would have to have an order from a health care provider. Anything administered to a patient would have to be given by someone licensed to administer medications, i.e. an RN or LPN.	Sydney M. Munger, RN, MS, Nurse Practice Consultant, Arizona State Board of Nursing, smunger@azbn.org.
California	RNs in California can only give prescribed medications. The Business & Professions Code Section 2725(b) (1) allows RNs the administration of medications and therapeutic agents, necessary to implement a treatment, disease prevention, or rehabilitative regimen ordered by and within the scope of licensure of a physician, dentist, podiatrist, or clinical psychologist.	Maria Bedroni, California Board of Registered Nursing, brnmaria@sbcglobal.net.
Colorado	The Colorado Nurse Practice Act, Board of Nursing Rules and Policies do not specifically address whether it is within the scope of practice for RNs to administer non-FDA approved dietary supplements. I assume that these supplements are "over-the-counter". Therefore, if it is within the knowledge, judgment, and skill of the RN to administer such supplements, doing so would not be prohibited.	Linda Metzner, Nurse Practice Consultant, Colorado Board of Nursing, (303) 894-2150, linda.metzner@dora.state.co.us
Delaware	The Delaware Nurse Practice Act requires that all medications, whether legend or over-the-counter, be ordered by an authorized prescribing practitioner in order for the RN and LPN to administer. Currently there is no language that speaks to non-approved FDA medications that the prescribing practitioner may order.	Iva J. Boardman, RN, MSN, Executive Director, Delaware Board of Nursing, (302) 744-4517, iva.boardman@state.de.us.
Maine	Any medications, including dietary supplements, that nurses would administer in Maine must be prescribed by a physician.	Virginia E Delorimier, Assistant Executive Director, Maine State Board of Nursing, Virginia.E.Delorimier@maine.gov
New Mexico	Nurses who have prescriptive authority can prescribe. If the supplements are for nursing home patients, then nurses would need an order from a health care provider. The New Mexico Board of Nursing does not differentiate between FDA and non-FDA approved products.	Debra Werner, Assistant Director/Practice, New Mexico Board of Nursing, Debra.Werner@state.nm.us.
New York	The New York State Board of Nursing usually allows the nurse or facility to decide on a non-FDA approved supplement, as long as there is a written order for it and the appropriate dosage. We advise the nurse or the facility to request from the prescriber the research data that supports the usage, and any accompanying data regarding negative effects and side effects.	Laurene C. O'Brien, MS, RN, Nursing Associate to the Executive Secretary, New York State Board of Nursing, (518) 474-3817 ext. 120, LOBRIEN@MAIL.NYSED.GOV.
North Carolina	<p>The North Carolina Board of Nursing has a statement relative to over-the-counter (OTC) drugs and such supplements would be considered as such.¹ If a facility allowed the RN to recommend supplements to the client, the employing facility policy and procedures should support this as being acceptable.</p> <p>Although the statement says the RN "recommends" this is interpreted by the Board to also include that the nurse may administer the OTC product if the person agrees. The RN could not do this unless the employing facility had written policies which allowed the nurse to do this. Of course, if a medical doctor ordered OTC medications, the nurse could administer them.</p>	Linda C. Thompson, Director-Education/Practice, North Carolina Board of Nursing, LINDA@ncbon.com.

**Table 1: Responses from Selected States' Boards of Nursing Regarding Nurses Administering Dietary Supplements--
Continued**

State	Response	Source
Oregon	The Board of Nursing in Oregon does not have a specific policy regarding this issue. However, with a doctor's order and appropriate knowledge and competency a nurse could administer supplements.	Marilyn L. Hudson, RN, MSN, CNS, Nursing Practice Consultant, Oregon State Board of Nursing, (971) 673-0656, Marilyn.Hudson@state.or.us.
Pennsylvania	The Pennsylvania State Board of Nursing is not authorized to issue advisory opinions and cannot pre-approve a specific nursing practice. The Board responded with a letter describing regulations that a nurse might want to consider before engaging in a nursing practice. ²	Colleen Rosborough, RN, MSN, CRNP, Nurse Practice Advisor, PA State Board of Nursing, crosboroug@state.pa.us.
Texas	<p>The Texas NPA and Rules are not prescriptive to specific nursing procedures or practice settings. Texas nurses have a duty to protect the client (Rule 217.11(1)(B); this duty cannot be superseded by a physician order or by facility policy--see Position Statement 15.14 Duty of a Nurse in Any Setting.³</p> <p>Rule 217.11 Standards of Nursing Practice, further requires the nurse to "know and comply" to the NPA and rules, as well as other applicable laws in the nurse's practice setting. This includes "knowing the rationale for and effects of medications and treatments, and correctly administer the same"[217.11(1)(C)]. The basis for this knowledge is typically based on FDA approval/classification and information on dose, route, side effects, over dosage, etc. Given that manufacturers of non-FDA approved substances rarely adhere to the same strict standards as the FDA (supporting body of research literature, known side effects, or a list of ingredients), a nurse would likely find it difficult to support a decision to administer a medication or substance that did not carry FDA approval.</p> <p>Dietary supplements, herbal remedies, etc. are not without risks, especially when combined with other medications a client is receiving. The nurse may use Rule 217.11, the position statement, and the 6-step decision making model for determining nursing scope of practice (in the above practice section, look under "Scope of Practice") to help him/her make a decision regarding whether or not the nurse wants to engage in the task.</p>	Carol Marshall MSN RN, Lead Nursing Consultant for Practice, Board of Nurse Examiners for the State of Texas, (512) 305-6841, Carol.Marshall@bne.state.tx.us.
Wyoming	Although Wyoming does not have a direct advisory opinion regarding non-FDA approved medications, the Board has generally not allowed persons to administer non-FDA approved medications. The Board does have an advisory opinion related to medications prescribed by a herbalist that relates to this issue. ⁴ The opinion states that a nurse may administer medications prescribed by any person authorized by state law to prescribe, but not medications prescribed by individuals that lack this authority.	Cheryl Ksoki, Executive Director, Wyoming State Board of Nursing, CKOSKI@state.wy.us.

Notes: Some responses have been edited for length, clarity and grammar.

- 1) We include this statement as Attachment E.
- 2) We include this letter as Attachment D.
- 3) We include this document as Attachment F.
- 4) We include this opinion as Attachment G.

LIST OF ATTACHMENTS

Attachment A

“Alaska Pioneer Homes Policy and Procedure Manual,” 3-B-13 to 3-B-17

Attachment B

“Overview of Dietary Supplements,” U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, January 3, 2001, available at <http://www.cfsan.fda.gov/~dms/ds-oview.html>

Attachment C

Vermont State Board of Nursing Advisory Opinion, Board Approved May 8, 2000, available at <http://vtprofessionals.org/opr1/nurses/>

Attachment D

Letter from Colleen Rosborough, Nursing Practice Advisor, Pennsylvania State Board of Nursing, February 17, 2006

Attachment F

“Position Statement 15.14 Duty of a Nurse in any Practice Setting,” Board of Nurse Examiners for the State of Texas, Adopted January, 2005, available at <http://www.bne.state.tx.us/position.htm>

Attachment G

“Administering Medications Ordered by a Herbalist-RN,” Wyoming State Board of Nursing, Reviewed January 2004, available at <http://nursing.state.wy.us/>

Attachment A

“Alaska Pioneer Homes Policy and Procedure Manual,” 3-B-13 to 3-B-17

Becky Taylor

3908

5 pages

M. Smiley

3B3. Administration of Dietary Supplements Which Are Not FDA-Approved

1.0-Purpose(s): To define procedures by which a resident who is unable to self-administer dietary supplements might receive them

2.0-Revision History: Rewritten from previous P&P manual

3.0-Applicable Staff Members: nurses, administrators.

4.0-Policy:

- Under the conditions defined in this P&P, Pioneer Homes nursing staff might administer physician-prescribed dietary supplements to residents requiring and requesting assistance with administration. Administration is subject to the completion by the resident or representative of all requirements in this policy and procedure *and* voluntary agreement by Pioneer Homes nurses to administer the supplement(s), as considered on a case-by-case basis.
- Nursing staff members are not required to administer non-FDA approved supplements



Background information pertinent to this policy:

- Herbal and homeopathic remedies and other dietary supplements are not FDA approved. Because these substances are not FDA approved they cannot be marketed as medications, only as dietary supplements. They also cannot claim

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to cure or prevent any medical conditions. Since the FDA does not approve these supplements, they are not subject to standardized, scientific testing within the United States for potency, purity, or effectiveness. Therefore, no certainty can be established regarding the actual contents of a product, the absence of harmful impurities, or the amount that should be taken. In addition, some of these substances can have harmful effects, side effects, or interactions with medications or foods. Because of the above, the Pioneers' Home pharmacy does not carry dietary supplements.

- The board of nursing has issued statements regarding the administration of non-FDA approved supplements by nurses. In December 1998, the board determined that "it is outside the scope of practice for nurses to administer remedies that are not FDA approved." In September 2002, the board resolved that it "does not support nurse administration of dietary supplements at this time." These statements are neither regulations nor statutes, but do represent the board's concern for the current lack of regulation and safety controls inherent in the manufacture and administration of non-FDA approved supplements.

5.0-Definitions:

- **Dietary supplements**—A product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and other substances such as enzymes, organ tissues, glandular tissues, and metabolites.

6.0-Responsibilities:

6.1-The administrator is responsible for:

- Ensuring compliance with this policy and all applicable procedures
- Designating at least one nurse to receive and consider residents' requests for assistance with administration of dietary supplements

6.2-The designated nurse is responsible for:

- Considering a resident's request for assistance with dietary supplement administration
- Ensuring that the resident or representative requesting the supplement administration has carried out all the required procedural steps indicated on the release form, and that the release form is signed.

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- **Determining whether a sufficient number of nurses voluntarily agree to administer the supplement(s)**

7.0-Procedure

7.1-Procedure for requesting that Pioneer Homes nursing staff administer supplements:

In order for Pioneer Homes nursing staff to consider administering non-FDA approved supplements to a resident, the following must occur:

- **A written order is obtained from the resident's primary prescribing practitioner, who indicates the name, brand, and dosage of supplement(s) to be administered.**
- **A release form is completed and signed by the resident or his/her representative, informing the resident/responsible party of the possible risks in using non-FDA approved supplements and releasing the Pioneer Homes from legal liability for negative effects which could occur from the use of these substances (see form on following pages).**
- **The resident or his/her representative privately purchases and obtains the supplement(s).**
- **Supplements are supplied to the Pioneer Home packaged in original packaging, and labeled with the following information: Name of supplement, brand, lot number, expiration date, resident's name, room number, dosage and frequency of administration.**
- **The pharmacy is informed of any nutritional supplements that a resident is currently taking in order to monitor drug:supplement and/or disease:supplement interaction.**

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Administration of Non-FDA Approved Supplements

Request/Release Form

Resident's name: _____ Date: _____

Pioneer Home: _____

I am the above-named resident or the legal guardian, conservator, or medical power of attorney of the above-named resident. I request that the Pioneer Home staff administer the following non-FDA approved supplement(s) to the above resident, as ordered by the resident's primary health care practitioner (please include the brand name ordered):

By signing this form, I acknowledge my understanding that:

- Because these supplements are not approved by the Food and Drug Administration (FDA), they cannot be marketed as medication, only as dietary supplements;
- Supplement manufacturers cannot claim that their products cure or prevent any medical conditions;
- Since the FDA does not approve these supplements, they are not subject to standardized, scientific testing within the United States for potency, purity, or effectiveness, and therefore no certainty can be established regarding the actual contents of a product, the absence of harmful impurities, or the amount which should be taken;
- Some of these substances can have harmful effects, side effects, or interactions with medications or foods, and the producers of these supplements are not required to list these harmful side effects or interactions;

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- The elderly may be at greater potential risk for harm from these substances simply because of their age-related changes in physiology.

I agree to the following requirements:

- Prior to the administration of any supplement by Pioneer Home staff, I must have obtained a written order for the supplement (which indicates the brand name of the supplement) from the resident's primary health care practitioner and provide a copy of the order to the Pioneer Homes;
- I must purchase and deliver any supplement(s) to the Pioneer Home, or arrange for such purchase and delivery;
- Supplement(s) must be delivered to the Pioneer Home in original, sealed packaging;
- The label of the package must contain the name of the supplement, lot number, expiration date, resident's name, room number, dosage and frequency of administration.

By signing this form I release the Pioneer Homes and their employees from liability should the above-named resident experience negative effects from administration of the above-listed supplements.

Signature of Resident
(or guardian, conservator or
medical power of attorney)

Date

Attachment B

“Overview of Dietary Supplements,” U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, January 3, 2001, available at <http://www.cfsan.fda.gov/~dms/ds-overview.html>

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
January 3, 2001

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Overview of Dietary Supplements

What is a dietary supplement?

Congress defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (DSHEA) of 1994. A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of "foods," not drugs, and requires that every supplement be labeled a dietary supplement.

What is a "new dietary ingredient" in a dietary supplement?

The Dietary Supplement Health and Education Act (DSHEA) of 1994 defined both of the terms "dietary ingredient" and "new dietary ingredient" as components of dietary supplements. In order for an ingredient of a dietary supplement to be a "dietary ingredient," it must be one or any combination of the following substances:

- 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 dietary intake (e.g., enzymes or tissues from organs or glands), or
- a concentrate, metabolite, constituent or extract.

A "new dietary ingredient" is one that meets the above definition for a "dietary ingredient" and was not sold in the U.S. in a dietary supplement before October 15, 1994.

What is FDA's role in regulating dietary supplements versus the manufacturer's responsibility for marketing them?

In October 1994, the Dietary Supplement Health and Education Act (DSHEA) was signed into law by President Clinton. Before this time, dietary supplements were subject to the same regulatory requirements as were other foods. This new law, which amended the Federal Food, Drug, and Cosmetic Act, created a new regulatory framework for the safety and labeling of dietary supplements.

Under DSHEA, a firm is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. This means that dietary supplements do not need approval from FDA before they are marketed. Except in the case of a new dietary ingredient, where pre-market review for safety data and other information is required by law, a firm does not have to provide FDA with the evidence it relies on to substantiate safety or effectiveness before or after it markets its products.

Also, manufacturers do not need to register themselves nor their dietary supplement products with FDA before producing or selling them. Currently, there are no FDA regulations that are specific to dietary supplements that establish a minimum standard of practice for manufacturing dietary supplements. However, FDA intends to issue regulations on good manufacturing practices that will focus on practices that ensure the identity, purity, quality, strength and composition of dietary supplements. At present, the manufacturer is responsible for establishing its own manufacturing practice guidelines to ensure that the dietary supplements it produces are safe and contain the ingredients listed on the label.

When must a manufacturer or distributor notify FDA about a dietary supplement it intends to market in the U.S.?

The Dietary Supplement Health and Education Act (DSHEA) requires that a manufacturer or distributor notify FDA if it intends to market a dietary supplement in the U.S. that contains a "new dietary ingredient." The manufacturer (and distributor) must demonstrate to FDA why the ingredient is reasonably expected to be safe for use in a dietary supplement, unless it has been recognized as a food substance and is present in the food supply.

There is no authoritative list of dietary ingredients that were marketed before October 15, 1994. Therefore, manufacturers and distributors are responsible for determining if a dietary ingredient is "new", and if it is not, for documenting that the dietary supplements it sells, containing the dietary ingredient, were marketed before October 15, 1994. For more detailed information on new dietary ingredients, go to:

<http://www.cfsan.fda.gov/~dms/ds-ingrd.html>.

What information must the manufacturer disclose on the label of a dietary supplement?

FDA regulations require that certain information appear on dietary supplement labels. Information that must be on a dietary supplement label includes: a descriptive name of the product stating that it is a "supplement;" the name and place of business of the manufacturer, packer, or distributor; a complete list of ingredients; and the net contents of the product.

In addition, each dietary supplement (except for some small volume products or those produced by eligible small businesses) must have nutrition labeling in the form of a

"Supplement Facts" panel. This label must identify each dietary ingredient contained in the product.

Must all ingredients be declared on the label of a dietary supplement?

Yes, ingredients not listed on the "Supplement Facts" panel must be listed in the "other ingredient" statement beneath the panel. The types of ingredients listed there could include the source of dietary ingredients, if not identified in the "Supplement Facts" panel (e.g., rose hips as the source of vitamin C), other food ingredients (e.g., water and sugar), and technical additives or processing aids (e.g., gelatin, starch, colors, stabilizers, preservatives, and flavors). For more details, see: <http://www.cfsan.fda.gov/~lrd/fr97923a.html>.

Are dietary supplement serving sizes standardized or are there restrictions on the amount of a nutrient that can be in one serving?

Other than the manufacturer's responsibility to ensure safety, there are no rules that limit a serving size or the amount of a nutrient in any form of dietary supplements. This decision is made by the manufacturer and does not require FDA review or approval.

Where can I get information about a specific dietary supplement?

Manufacturers and distributors do not need FDA approval to sell their dietary supplements. This means that FDA does not keep a list of manufacturers, distributors or the dietary supplement products they sell. If you want

more detailed information than the label tells you about a specific product, you may contact the manufacturer of that brand directly. The name and address of the manufacturer or distributor can be found on the label of the dietary supplement.

Who has the responsibility for ensuring that a dietary supplement is safe?

By law (DSHEA), the manufacturer is responsible for ensuring that its dietary supplement products are safe before they are marketed. Unlike drug products that must be proven safe and effective for their intended use before marketing, there are no provisions in the law for FDA to "approve" dietary supplements for safety or effectiveness before they reach the consumer. Also unlike drug products, manufacturers and distributors of dietary supplements are not currently required by law to record, investigate or forward to FDA any reports they receive of injuries or illnesses that may be related to the use of their products. Under DSHEA, once the product is marketed, FDA has the responsibility for showing that a dietary supplement is "unsafe," before it can take action to restrict the product's use or removal from the marketplace.

Do manufacturers or distributors of dietary supplements have to tell FDA or consumers what evidence they have about their product's safety or what evidence they have to back up the claims they are making for them?

No, except for rules described above that govern "new dietary ingredients," there is no provision under any law or regulation that FDA enforces that requires a firm to disclose to FDA or consumers the information they have about the safety or purported benefits of their dietary supplement products. Likewise, there is no prohibition against them making this information available either to FDA or to their customers. It is up to each firm to set its own policy on disclosure of such information. For more information on claims that can be made for dietary supplements, see (<http://www.cfsan.fda.gov/~dms/hclaims.html>).

How can consumers inform themselves about safety and other issues related to dietary supplements?

It is important to be well informed about products before purchasing them. Because it is often difficult to know what information is reliable and what is questionable, consumers may first want to contact the manufacturer about the product they intend to purchase (see previous question "Where can I get information about a specific dietary supplement?"). In addition, to help consumers in their search to be better informed, FDA is providing the following sites: *Tips For The Savvy Supplement User: Making Informed Decisions And Evaluating Information* -- <http://www.cfsan.fda.gov/~dms/ds-savvy.html> (includes information on how to evaluate research findings and health information on-line) and *Claims That Can Be Made for Conventional Foods and Dietary Supplements* -- <http://www.cfsan.fda.gov/~dms/hclaims.html>, (provides information on what types of claims can be made for dietary supplements).

What is FDA's oversight responsibility for dietary supplements?

Because dietary supplements are under the "umbrella" of foods, FDA's Center for Food Safety and Applied Nutrition (CFSAN) is responsible for the agency's oversight of these products. FDA's efforts to monitor the marketplace for potential *illegal* products (that is, products that may be unsafe or make false or misleading claims) include obtaining information from inspections of dietary supplement manufacturers and distributors, the Internet, consumer and trade complaints, occasional laboratory analyses of selected products, and adverse events associated with the use of supplements that are reported to the agency.

Does FDA routinely analyze the content of dietary supplements?

In that FDA has limited resources to analyze the composition of food products, including dietary supplements, it focuses these resources first on public health emergencies and products that may have caused injury or illness. Enforcement priorities then go to products thought to be unsafe or fraudulent or in violation of the law. The remaining funds are used for routine monitoring of products pulled from store shelves or collected during

inspections of manufacturing firms. The agency does not analyze dietary supplements before they are sold to consumers. The manufacturer is responsible for ensuring that the "Supplement Facts" label and ingredient list are accurate, that the dietary ingredients are safe, and that the content matches the amount declared on the label. FDA does not have resources to analyze dietary supplements sent to the agency by consumers who want to know their content. Instead, consumers may contact the manufacturer or a commercial laboratory for an analysis of the content.

Is it legal to market a dietary supplement product as a treatment or cure for a specific disease or condition?

No, a product sold as a dietary supplement and promoted on its label or in labeling* as a treatment, prevention or cure for a specific disease or condition would be considered an unapproved--and thus illegal--drug. To maintain the product's status as a dietary supplement, the label and labeling must be consistent with the provisions in the Dietary Supplement Health and Education Act (DSHEA) of 1994.

*Labeling refers to the label as well as accompanying material that is used by a manufacturer to promote and market a specific product.

Who validates claims and what kinds of claims can be made on dietary supplement labels?

FDA receives many consumer inquiries about the validity of claims for dietary supplements, including product labels, advertisements, media, and printed materials. The responsibility for ensuring the validity of these claims rests with the manufacturer, FDA, and, in the case of advertising, with the Federal Trade Commission.

By law, manufacturers may make three types of claims for their dietary supplement products: health claims, structure/function claims, and nutrient content claims. Some of these claims describe: the link between a food substance and disease or a health-related condition; the intended benefits of using the product; or the amount of a nutrient or dietary substance in a product. Different requirements generally apply to each type of claim, and are described in more detail at the following site: (<http://www.cfsan.fda.gov/~dms/hcliams.html>).

Why do some supplements have wording (a disclaimer) that says: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease"?

This statement or "disclaimer" is required by law (DSHEA) when a manufacturer makes a structure/function claim on a dietary supplement label. In general, these claims describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the body. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not approved by FDA. For this reason, the law says that if a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated this claim. The disclaimer must also state that this product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim.

How are advertisements for dietary supplements regulated?

The Federal Trade Commission (FTC) regulates advertising, including infomercials, for dietary supplements and most other products sold to consumers. FDA works closely with FTC in this area, but FTC's work is directed by different laws. For more information on FTC, go to: <http://www.ftc.gov/bcp/menu-health.htm>. Advertising and promotional material received in the mail are also regulated under different laws and are subject to regulation by the U.S. Postal Inspection Service.

How do I, my health care provider, or any informed individual report a problem or illness caused by a dietary supplement to FDA?

If you think you have suffered a serious harmful effect or illness from a product FDA regulates, including

dietary supplements, the first thing you should do is contact or see your healthcare provider immediately. Then, you and your health care provider are encouraged to report this problem to FDA.

Your health care provider can call FDA's MedWatch hotline at 1-800-FDA-1088, submit a report by fax to 1-800-FDA-0178 or on-line at: <http://www.fda.gov/medwatch/report/hcp.htm>. The [MedWatch program](#) provides a way for health care providers to report problems believed to be caused by FDA-regulated products such as drugs, medical devices, medical foods and dietary supplements.

You, or anyone, may report a serious adverse event or illness directly to FDA if you believe it is related to the use of any of the above-mentioned products, by calling FDA at 1-800-FDA-1088, by fax at 1-800-FDA-0178 or reporting on-line at: <http://www.fda.gov/medwatch/report/consumer/consumer.htm>. FDA would like to know when you think a product caused you a serious problem, even if you are not sure that the product was the cause, or even if you do not visit a doctor or clinic. In addition to communicating with FDA on-line or by phone, you may use the postage-paid MedWatch form available from the FDA Web site.

NOTE: The identity of the reporter and/or patient is kept confidential.

For a general, not serious, complaint or concern about food products, including dietary supplements, you may contact the consumer complaint coordinator at the local FDA District Office nearest you. See the following Web address for the telephone number: <http://www.fda.gov/opacom/backgrounders/complain.html>.

For more recent information on Dietary Supplements
See <http://www.cfsan.fda.gov/~dms/supplmnt.html>

[Dietary Supplements](#) | [Women's Health](#) | [Q & A](#)

[Foods Home](#) | [FDA Home](#) | [Search/Subject Index](#) | [Disclaimers & Privacy Policy](#) | [Accessibility/Help](#)

Hypertext updated by cjm/dms/ear/kwg 2002-JAN-04

Attachment C

Vermont State Board of Nursing Advisory Opinion, Board Approved May 8, 2000,
available at <http://vtprofessionals.org/opr1/nurses/>

**VERMONT STATE BOARD OF NURSING
ADVISORY OPINION**

QUESTION

The Board received a request for an Advisory opinion on the role of the nurse in the administration of homeopathic remedies and/or food additives.

BOARD OPINION

The Board believes that in the administration of any substance, the nurse must be aware of and have access to current valid information regarding the action, desired effects, side effects, toxic effects and possible chemical and drug interactions with other substances.

Information on homeopathic and food additives may be obtained from a monograph written by a physician or naturopath if published data is not available.

Validation in writing from the medical physician should be obtained if the client is receiving medication, indicating that the homeopathic substances are not contraindicated.

Nurses have the right to refuse to administer substances if they feel that the substances may harm the client or if information regarding the substance is unknown.

This opinion is advisory only and is subject to change as changes in nursing practice occur.

Board Approved May 8, 2000

Attachment D

Letter from Colleen Rosborough, Nursing Practice Advisor, Pennsylvania State
Board of Nursing, February 17, 2006



PENNSYLVANIA STATE BOARD OF NURSING
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February 17, 2006

Rebecca Taylor, Legislative Analyst
Legislative Research Services
State Capitol
Juneau, AK 99801

Dear Ms. Taylor:

I would like to address your questions recently sent via email concerning nurses' scope of practice related to dietary supplements.

The PA State Nursing Board's jurisdiction and authority is limited to licensees of the Board and nursing education programs. Under state law, as interpreted by the Commonwealth Court, the Board is not authorized to issue advisory opinions and cannot pre-approve a specific nursing practice. It is the responsibility of the nurse to practice in accordance with the nursing practice acts and the Board's regulations, to ascertain whether a practice is acceptable to the professional nursing community and to exercise professional judgment in the treatment of patients. The Board's authority to decide whether a nurse has adhered to accepted ethical and quality standards arises only in the context of a disciplinary action.

The following section of the Act is relevant to your inquiry and should be considered by any nurse before the nurse undertakes the performance of any alternative or complementary therapy, such as dietary supplements:

The Professional Nursing Law, Section 2. Definitions.

The "Practice of Professional Nursing" means diagnosing and treating human responses to actual or potential health problems through services such as case finding, health teaching, health counseling, and provision of care supportive to or restorative of life and well-being, and executing medical regimens **as prescribed by** a licensed physician or dentist. The foregoing shall not be deemed to include acts of medical diagnosis or prescription of medical therapeutic or corrective measures, except as may be authorized by rules and regulations jointly promulgated by the Board."

Before the nurse contemplates the performance of an alternative or complementary therapy, such as dietary supplements, the nurse should also consider the following series of questions. These questions are intended as a suggested guideline to help the nurse determine whether a specific practice might be consistent with the nursing practice acts and regulations of the Board. It does not constitute legal advice and does not constitute Board approval or disapproval of any practice.

1. Is the practice or therapy permitted or prohibited by the PA nursing practice acts or regulations?
2. Does the practice or therapy require you to have, and do you in fact have, the specialized nursing knowledge, preparations, experience, skill and competency? Could the practice be considered negligence or incompetence in the practice of nursing?
3. Is the practice or therapy consistent with the ethical and quality standards embraced by the professional nursing community in the Commonwealth?
4. Is the practice or therapy contained in standards of practice developed by appropriate nursing associations?
5. Could the practice or therapy be considered fraud or deceit in the practice of nursing?
6. Is the practice or therapy taught as part of a nursing curriculum in an approved nursing education program?
7. Is the nurse prepared to accept full responsibility for his/her action and be accountable to the client or patient?

In conclusion, the Board cannot, by law, pre-approve a specific practice or issue advisory opinions. Regulations and published policy statements of the board may provide guidance. It is the responsibility of the nurse to practice in accordance with the nurse practice acts and regulations and ascertain whether a practice is acceptable to the professional nursing community and to exercise professional judgment in the treatment of patients. The Board's authority to decide whether a nurse has adhered to accepted ethical and quality standards arises only in the context of a disciplinary action. Answers to inquiries are not intended to be legally enforceable against a licensee and are not binding upon the Board in issuing adjudications.

Thank you for your inquiry.

Sincerely,

Colleen Rosborough, RN, MSN, CRNP
Nursing Practice Advisor
PA State Board of Nursing

Attachment E

“The Role of the RN in Recommending the Use of Over-The-Counter
Pharmaceutical Products and Non-Prescription Devices,”
North Carolina Board of Nursing, Revised May 2000,
available at <http://www.ncbon.com/prac-rnystate.asp>

THE ROLE OF THE RN IN RECOMMENDING THE USE OF OVER-THE-COUNTER PHARMACEUTICAL PRODUCTS AND NON-PRESCRIPTION DEVICES.

Legend drugs, prescription devices, and controlled substances must be prescribed by a licensed physician, nurse practitioner, certified nurse midwife, physician assistant or other person authorized by State law to prescribe such treatment regimens. Neither the registered nurse nor the licensed practical nurse have the legal authority to prescribe legend drugs or controlled substances. However, the licensed nurse (RN or LPN) does have the authority to implement the order for a legend drug or controlled substance prescribed by a person authorized to prescribe such a regimen as long as such an activity is within the legal scope of practice for the licensed nurse and he/she has the knowledge and skill to safely implement the activity.

Over-the-counter pharmaceutical products and non-prescription devices such as, but not limited to, splints, point stimulators/electro-stimulation units, positioning assists, blood glucose machines, and take-home blood pressure machines, are not subject to the prescribing and dispensing regulations of North Carolina. Consistent with G.S. 90-171.20 (7) of the Nursing Practice Act and Administrative Rule 21 NCAC 36.0224 (a) - (h), the registered nurse may recommend the use of an over-the-counter pharmaceutical product and non-prescription device for an identified health-related need of a client as part of his/her nursing practice. The registered nurse who makes such a recommendation is held accountable for having the knowledge to make such nursing care decisions safely and to monitor the outcomes of his/her actions . The practice of recommending over-the-counter pharmaceutical products and non-prescription devices must also be consistent with the established policies of the system in which the registered nurse practices as well as consistent with the client's overall health-related plan of care.

Because the licensed practical nurse does not have the authority to make independent nursing decisions, he/she does not have the authority to recommend the use of over-the-counter products and non-prescription devices as part of a health-related plan of care. However, the licensed practical nurse may participate in implementing an established plan of care consistent with G.S. 90-171.20 (8) of the Nursing Practice Act and Administrative Rule 21 NCAC 36.0225.

Approved October, 1996

Revised: May, 2000

Attachment F

“Position Statement 15.14 Duty of a Nurse in any Practice Setting,” Board of Nurse Examiners for the State of Texas, Adopted January, 2005, available at <http://www.bne.state.tx.us/position.htm>

15.14 Duty of a Nurse in any Practice Setting

In a time when cost consciousness and a drive for increasing productivity have brought about the reorganization and restructuring of health care delivery systems, the effects of these new delivery systems on the safety of clients/patients have placed a greater burden on the licensed vocational nurse (LVN) and the registered professional nurse (RN) to consider the meaning of licensure and assurance of quality care that it provides.

In the interest of fulfilling its mission to protect the health, safety, and welfare of the people of Texas through the regulation of nurses, the Board of Nurse Examiners (BNE), through the Nursing Practice Act and Board Rules, emphasizes the nurse's responsibility and duty to the client/patient to provide safe, effective nursing care.

Specifically, the following portions of the Board Rules underscore the duty and responsibilities of the LVN and/or the RN to the client/patient:

- The Standards of Nursing Practice differentiate the roles of the LVN and the RN in accepting nursing care assignments, assuring a safe environment for patients, and obtaining instruction and supervision as needed (Rule 217.11); and
- In *Lunsford v. Board of Nurse Examiners*, 648 S.W. 2d 391 (Tex. App.--Austin, 1983), the court in affirming the disciplinary action of the Board, held that a nurse has a duty to the patient which cannot be superseded by hospital policy or physician's order.
- The Board's Disciplinary Sanction Policies discuss expectations of all nurses regarding behaviors that are consistent with the Board's rules on Good Professional Character, §§213.27-213.29. These policies explain the client's vulnerability and the nurse's "power" differential over the client by virtue of the client's status (with regard to age, illness, mental infirmity, etc) and by the nature of the nurse:client relationship (where the client typically defers decisions to the nurse, and relies on the nurse to protect the client from harm).
- The delegation rules guide the RN in delegation of tasks to unlicensed assistive personnel who are utilized to enhance the contribution of the RN to the client's/patient's well being. When performing nursing tasks, the unlicensed person cannot function independently and functions only under the RN's delegation and supervision. Through delegation the RN retains responsibility and accountability for care rendered (Rules 224 and 225). The Board may take disciplinary action against the license of a RN or RN administrator for inappropriate delegation
- RNs with advanced practice authorization from the Board must comply with the same rules applicable to other RNs. In addition, rules specific to advanced practice nursing Chapters 221 & 222 must also be followed.
- Each nurse must be able to support how his/her clinical judgments and nursing actions were aligned with the NPA and Board Rules. The Board recommends nurses use the Six-Step Decision-Making Model for Determining Nursing Scope of Practice when trying to determine if a given task is within the individual nurse's abilities. Congruence with standards adopted by national nursing specialty organizations may further serve to enhance and support the nurse's decision to perform a particular task.

The nurse, by virtue of a rigorous process of education and examination leading to either LVN or RN

licensure, is accountable to the Board to assure that nursing care meets standards of safety and effectiveness.

Therefore, it is the position of the Board that each licensed nurse upholds his/her duty to maintain client safety by practicing within the parameters of the NPA and Board Rules as they apply to each licensee.

(Adopted 01/2005)

Attachment G

“Administering Medications Ordered by a Herbalist-RN,”
Wyoming State Board of Nursing, Reviewed January 2004,
available at <http://nursing.state.wy.us/>

WYOMING
STATE BOARD OF NURSING
ADVISORY OPINION

ADMINISTERING MEDICATIONS ORDERED BY A HERBALIST–RN

Advisory Opinion Number: 99-93
Board Meeting Date: April 14-16, 1999

The Board reviewed a requesting asking if a school nurse give medicines prescribed by a certified herbalist and teaching non-nurses to administer medication?

- After deliberation, and by consensus, the Board stated that a nurse may administer medications prescribed by any person authorized by state law to prescribe. {The Nursing Practice Act, 33-21-120,(viii),(ix)}.
- The Board of Pharmacy was contacted and it was ascertained that herbalists do not have prescriptive authority; therefore, nurses cannot take orders from herbalists to administer medications (July 7-9,1999).

What liability of the school nurse in teaching non-nurses to (1) mix/inject glucagon prn; and (2)administer epinephrine in ANA Kits or Epi Pens?

- By consensus, the Board directed the school nurse to the delegation policy found in Chapter 7, Section 6 of the Administrative Rules and Regulations. The Board stated that non-nurses may be taught to administer glucagon or epinephrine in an emergency situation, as long as clear policies and procedures on delegation are followed, and said policies are approved by the school board. Furthermore, the Board directed glucagon be purchased in pre-mixed syringes.

Approved: 4/1999
Reviewed: 01/2004
Revised: