HB

467

STATE OF ALASKA

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REPRESENTATIVE MIKE KELLY
HOUSE DISTRICT 7

Member
House Finance Committee

MEMORANDUM

To: Senator Dyson
Chair, HESS Committee
From: Representative Mike Kelly
Date: April 25, 2006
Re: Committee Hearing Request – CS HB 467(HESS)

Attached you will find the bill packet for CS HB 467(HESS) – "*An Act relating to the administration of prescribed remedies and dietary supplements by a nurse.*" The packet contains the following:

- Current version of the bill
- Sponsor Statement
- Fiscal Note
- Legislative Research Report
- Background Information

Thank you for your time and attention to this request. If I can provide any other relevant information or answer any immediate questions you might have, feel free to contact me directly at extension 4976 or my staff, Derek Miller at extension 6890.

Alaska State Legislature

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Member
House Finance Committee

Representative Mike Kelly

House District 7

"An Act relating to the administration of prescribed remedies and dietary supplements by a nurse."

HB 467 will give Registered Nurses licensed in Alaska the authority to administer prescribed remedies or dietary supplements within the manufacturers' recommended dosage when certain requirements are met. We believe the current Board of Nursing policy is too restrictive and the intention of this bill is to allow nurses to administer prescribed remedies and dietary supplements when they believe it is safe and appropriate to do so.

Due to the Board of Nursing determination that "it is outside of the scope of practice for nurses to administer remedies that are not FDA approved," nurses who desire to provide the requested patient care are prevented from administering these prescribed remedies. We believe the decision by the Board of Nursing ignores the patients' preference, undermines doctors' power to prescribe and treat patients, and frustrates the desire of the institutions to provide a patient service under reasonably controlled circumstances.

Legislative Research Report # 06.139 concluded in its research, that of the 13 states that responded to its request for information, none replied that it was always outside the scope of practice for nurses to administer dietary supplements. Some states provide guidelines for nurses to consider before administration of non FDA-approved prescribed dietary supplements. This legislation will bring Alaska into the mainstream.

FISCAL NOTE

STATE OF ALASKA
2006 LEGISLATIVE SESSION

Fiscal Note Number:
Bill Version: CSHB 467(HES)
() Publish Date:

Revision Date/Time (Note if correction):
Dept. Affected: Commerce
Title: Administration of Medication by a Nurse
RDU: Corp, Bus & Prof Licensing (117)
Component: Corp, Bus & Prof Licensing
Sponsor: Reps. Kelly, Anderson, Seaton
Requester: House Rules
Component No.: 2360

Expenditures/Revenues (Thousands of Dollars)
Note: Amounts do not include inflation unless otherwise noted below.

OPERATING EXPENDITURES	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Personal Services						
Travel	22.0	22.0	0.0	0.0	0.0	0.0
Contractual	8.0	8.0	0.0	0.0	0.0	0.0
Supplies						
Equipment						
Land & Structures						
Grants & Claims						
Miscellaneous						
TOTAL OPERATING	30.0	30.0	0.0	0.0	0.0	0.0
CAPITAL EXPENDITURES						
CHANGE IN REVENUES (1156)	30.0	30.0	0.0	0.0	0.0	0.0

FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts						
1003 GF Match						
1004 GF						
1005 GF/Program Receipts						
1037 GF/Mental Health						
Other 1156 - Receipt Supported Services	30.0	30.0	0.0	0.0	0.0	0.0
TOTAL	30.0	30.0	0.0	0.0	0.0	0.0

Estimate of any current year (FY2006) cost: 0.0
Mark this box (X) if funding for this bill is included in the Governor's FY 2007 budget proposal:

POSITIONS

Full-time						
Part-time						
Temporary						

ANALYSIS: *(Attach a separate page if necessary)*
CSHB 467 (HES) mandates the Board of Nursing to establish standards for nurses to administer a prescribed remedy or dietary supplement to a patient. The controversial nature of this mandate will require at least one special joint meeting of the Nursing, Pharmacy, and Medical regulatory boards to establish the standards. The contractual funding will cover writing the regulations, attorney review time, and public noticing costs to establish the standards in regulations. Funding is shown for FY07 and FY08 to provide sufficient coverage depending on when the bill become law.

Prepared by: Jennifer Strickler, Chief
Division: Corporations and Licensing
Phone: (907) 465-2144
Date/Time: 4/14/06 12:00 AM
Approved by: William C. Noll, Commissioner
Agency: Commerce, Community and Economic Development
Date:

(Revised 9/7/2004 OMB)

FISCAL NOTE

STATE OF ALASKA
2006 LEGISLATIVE SESSION

Fiscal Note Number: 1
Bill Version: CSHB 467(HES)
(H) Publish Date: 4/12/06

Revision Date/Time (Note if correction):
Dept. Affected: Commerce
Title: Administration of Medication By A Nurse
RDU: Corp, Bus & Prof Licensing (117)
Component: Corp, Bus & Prof Licensing
Sponsor: Kelly
Requester: Health, Education and Social Services
Component No.: 2360

Expenditures/Revenues (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below.

OPERATING EXPENDITURES	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Personal Services						
Travel						
Contractual						
Supplies						
Equipment						
Land & Structures						
Grants & Claims						
Miscellaneous						
TOTAL OPERATING	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
CAPITAL EXPENDITURES						
CHANGE IN REVENUES (1156)	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts						
1003 GF Match						
1004 GF						
1005 GF/Program Receipts						
1037 GF/Mental Health						
Other 1156 - Receipt Supported Services						
TOTAL	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Estimate of any current year (FY2006) cost: 0.0
Mark this box (X) if funding for this bill is included in the Governor's FY 2007 budget proposal:

POSITIONS

Full-time						
Part-time						
Temporary						

ANALYSIS: *(Attach a separate page if necessary)*

This legislation amends AS 08.68.396 Section 1 to permit a licensed RN to administer prescribed remedies or dietary supplements to patients. It has no fiscal impact on the operations of the division.

Prepared by: Katherine Mason, Administrative Manager
Phone: (907) 465-2572
Division: Corporations and Licensing
Date/Time: 3/31/06 3:32 PM
Approved by: William C. Noll, Commissioner
Date: 3/31/2006
Agency: Commerce, Community, and Economic Development

(Revised 9/7/2005 OMB)

RICK J. SCHIKORA
CERTIFIED PUBLIC ACCOUNTANT

1418 GILLAM WAY
FAIRBANKS, ALASKA 99701

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March 20, 2005

Representative Mike Kelly
State Capitol, Room 434
Juneau, AK 99801

Dear Mike:

As we discussed, here are some papers I received from the Pioneer's Home here in Fairbanks regarding the policy of their nurses not administering non-FDA approved supplements to the residents – they won't do it even with orders or prescriptions from the doctors. In my case, my grandmother (97 years old) has bad knees and dementia. She lives in the Homestead section of the Fairbanks Pioneer's Home where she is taken care of very well. After the staff discontinued administering glucosamine and fish oil pills for her knees, she started failing. I could see it happening each of the three days roughly that I would go by in a week. She started complaining about her knees, she was having real problems getting up from her chair and not walking as much as she liked for exercise. Her knees were "just killing me". On one of my visits one day a nurse took me aside and said that Grandma had gone downhill rapidly in the month since the supplements had been stopped. She suggested that I consider getting the non-FDA medications for Grandma, but that they could not administer them, nor would they let Grandma have them in her room (due to other residents wandering in and out, and Grandma not knowing if she took them that day or not). When I told her that I would only be by 3 days a week, if that, with tax season getting cranked up, she said three days a week was better than nothing. I got the pills that afternoon and have been by every day since to administer them. She has improved wonderfully, and though she still mentions her knees, they are no longer "just killing me". When her knees were bothering her, it would take a couple of CNAs or staff members to help her up. Now, if she needs help, it only takes one.

It just doesn't make sense that we would need a new law allowing doctor prescribed supplements to be administered by nurses to our aged nursing home residents, but maybe it does. Please see what you can do to help in this. I know the Pioneer's Home staff would appreciate it. I have had several of them tell me "Grandma is lucky to have you – just think of the all the residents that have no one that comes by at all". In their final years, why should they have to suffer when the alternative is so simple? Does the nursing board think that these supplements are going to kill the residents?

Please see what you can do. I would appreciate it and will talk with any other Representative or Senator you suggest. I will travel to Juneau to do so. Thanks.

Sincerely,

Rick Schikora

Enclosures

ASHNHA
Alaska State Hospital and Nursing Home Association
Rod L. Betit, President/CEO

To: Representative Mike Kelly
Re: Committee Substitute for House Bill 467 (HES)
Date: April 20, 2006

I have learned that certain parties are contacting House members to express their opposition to CSHB 467(HES). I wanted to provide this letter of support from my membership to make it clear that there is strong support for this bill from a broad cross section of health care providers in the State.

Please feel free to circulate this letter amongst your colleagues in the House as you further debate this bill for passage.

The ***Alaska State Hospital and Nursing Home Association*** represents 23 acute care hospitals, 2 behavioral health facilities, 6 assisted living facilities (Alaska Pioneer Homes), and 5 nursing facilities. Nine of our 23 acute care hospitals also include nursing home beds. ASHNHA's rich composition of private, federal, state, and tribal health care facilities provides a balanced viewpoint on important health care policy matters. ASHNHA's Legislative Committee evaluates health care legislation weekly and authorizes the position expressed in this testimony.

ASHNHA has carefully reviewed CSHB 467 and believes it to be important legislation. CSHB 467 would make it clear that a licensed registered nurse may administer a prescribed remedy or dietary supplement to a patient under his/her care in a nursing facility, assisted living home or an Alaska Pioneer's Home.

However, CSHB 467 also provides that a nurse who is uncomfortable administering these products could choose not to.

ASHNHA's membership believes this language will serve to clarify that administering these products is not outside the scope of practice for a licensed registered nurse, and should eliminate nurses' concerns about liability and scope of practice if they choose to administer these prescribed products to their patients.

➲Other points to consider:

- Keep in mind we are talking only about products prescribed by a person authorized under state law.

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- CSHB 467 passage should reduce the 'practice' of family & friends providing supplements often without the knowledge of caregivers.
- CSHB 467 will allow nurses, pharmacists & physicians to participate in administering these supplements and thereby be aware of what is being taken on top of other medicines, and to note this in the patient record.
- If we generally believe that most people do not know if their supplements are harmful relative to other medications they are taking or to their present medical condition, we should support CSHB 467 as it will insure this is being monitored as part of the patient's overall treatment plan.
- Most facilities have policy & procedures in place to address how the handling of supplements will be handled to insure that nursing staff have a 'safe harbor' in which to operate.
- Finally, at any time a nurses feels the safeguards are not adequate, that the patient is not in a position to understand the risks, that the supplement is not safe in their judgment or for any other reason, that nurse can simply say 'no' to administering the supplement if they are uncomfortable doing so.

ASHNHA believes the provisions found in CSHB 467 improve the safe delivery of healthcare and urge passage of this bill.

If ASHNHA can provide any additional information, please contact our main office at 586-1790 in Juneau.

Sincerely,

Rod Betit

Rod Betit
President/CEO

ASHNHA Represents the Following Alaska Health Care Providers

Alaska Regional Hospital, Alaska Native Medical Center, Alaska Pioneer Home System, Alaska Psychiatric Institute, Bartlett Regional Hospital, Bassett Army Community Hospital, Central Peninsula General Hospital, Cordova Community Medical Center, Denali Center Nursing Home, Fairbanks Memorial Hospital, Heritage Place Nursing Home, Kanakanak General Hospital, Ketchikan General Hospital, Maniilaq Health Center, Mary Conrad Center, Mat-Su Regional Hospital, Mt. Edgecumbe Hospital SEARHC, North Star Behavioral Health, Norton Sound Regional Hospital, Petersburg Medical Center, Providence Alaska Medical Center, Providence Extended Care Center, Providence Kodiak Island Medical Center, Providence Seward Medical & Care Center, Providence Valdez Medical Center, Sitka Community Hospital, South Peninsula Hospital, USAF 3rd Medical Group-Elmendorf, Wrangell Medical Center, Wildflower Court Nursing Home, Yukon Kuskokwim Delta Regional Hospital.

To: Representative Mike Kelly
Re: Committee Substitute for House Bill 467 (HES)
Date: April 20, 2006

I have reviewed CSHB 467 and believe the proposed legislation clarifies when a licensed registered nurse may administer a prescribed remedy or dietary supplement to a patient in a nursing facility, assisted living home or an Alaska Pioneer's Home.

I also believe language in CSHB 467 would eliminate nurses' scope-of-practice concerns should they choose to administer these products to residents of these facilities. Clearly, this legislation relates to products prescribed by persons authorized under state law, and would allow nurses, pharmacists and physicians to participate in administering these supplements. Furthermore, this legislation provides a clear and important record of administration required to enhance care to the resident.

As some of the most highly regulated facilities in the country, care givers in long-term care facilities are circumspect about ensuring safe and efficient handling of these dietary supplements and remedies. I believe CSHB 467 helps advance the quality of life for the residents of our long term care and assisted living facilities, and the vitally important family support people that augment our care to their family members.

Please call if you have any questions about my position.

Sincerely,

Mike Powers
CEO/Administrator
Fairbanks Memorial Hospital & Denali Center

AaNA Alaska Nurses Association

c/ 907-274-0827
f/ 907-272-0292
3701 E. Tudor Rd. Suite 208
Anchorage, AK 99507
www.aknurse.org

April 3, 2006

Honorable Mike Kelly
State Capitol Bldg., Rm. 434
Juneau, AK 99801-1182

Dear Representative Kelly,

Thank you for your letter of March 27, 2006 soliciting the Alaska Nurses Association's position on the administration of dietary supplements to patients by Registered Nurses.

As with many issues in medicine, the issue of the safety and efficacy of dietary supplements is complex. While the general public views dietary supplements and herbal preparations as different from prescription medications, health care professionals treat both of these groups as substances that affect the human body in ways that can be both beneficial and harmful. When administering any substance to alter the body's functioning, one needs to know the possible beneficial effects, the potential interactions with other medications the patient is taking, the potential adverse or side effects, and the effect of the substance on any illnesses the patient might have. When patients suffer from a chronic illness, the process involved in making decisions about the safety of these substances is far more complex than reading the label on the container they come in.

An example of the potential deleterious effects of dietary supplements and herbal preparations comes from my practice in the operating room. We ask all patients to list dietary supplements or herbal medications they are taking as part of our pre-operative assessment. If the patient is taking St. John's wort, we have to delay surgery for two weeks because this supplement increases the risk of bleeding during surgery.

There is an additional concern with these dietary supplements and herbal medications in that there is poor regulation of their manufacturing. Numerous studies have shown that the ingredients listed on the label of the bottle corresponds poorly with the what scientists find when they evaluate their actual contents. I know from experience that these pills are unmarked, and when a family brings in a container there is no way to confirm that the pills are actually what the label states they are. Prescription/legend medications have a identifier number imprinted on them.

The public generally thinks that if a physician prescribes a medication or dietary substance then the nurse has no liability if the patient becomes ill or suffers damage from taking that substance.

This is not the case. The courts have repeatedly upheld that the nurse is legally and ethically responsible to confirm the safety of any substance they are directly administering to a patient.

EXCELLENT STATEMENT

This being said, we do feel that dietary supplements and herbal preparations can be beneficial to patients. There is a growing body of scientific research on these substances and over time we have been better able to differentiate which substances are truly beneficial and which have the potential for serious side effects. There has also been steps taken to improve the oversight of production of these substances. As of this writing the United States Pharmacopeia (USP) has a verification process for supplements. This is a voluntary process, and many manufacturers have submitted their products for verification (http://www.usp.org). As manufacturing oversight improves, our position on safety of administration will no doubt change as well.

You can tell from the above discussion that this issue is very complex. I have asked the Alaska Nurses Association's (AaNA) Professional Practice Committee to investigate this issue in light of recent advances and come up with a policy recommendation before the AaNA Board meeting. We would be happy to share these recommendations with you.

If you want to discuss this issue with me directly feel free to call me at 907-278-1070 in the evening. Thank you again for requesting our input on this important issue.

Sincerely,

Debbie Thompson

Debbie Thompson, RN, BSN
President
Alaska Nurses Association

LICENSED NURSE ADMINISTRATION OF NON-FDA APPROVED OVER THE COUNTER DRUGS AND NUTRITIONAL SUPPLEMENTS

A licensed nurse employed by an assisted living facility, may, without repercussion from the Alaska Board of Nursing, administer non-FDA approved over the counter drug products or nutritional supplements provided:

1. The over the counter drug or nutritional supplement is prescribed under a written order by the resident's primary prescribing practitioner, including the brand name of the product, the dosage, and frequency of administration,

2. That administration of the over the counter drug or nutritional supplement is requested in writing by the resident of the long-term care facility or his or her responsible representative. A request/release form may be used for this written request.

3. That the over the counter drug or nutritional supplement is provided by the resident or responsible party to the long-term care facility in its original, sealed, undamaged packaging, which is to include manufacturer's information as to name of the supplement, brand, lot number, expiration date, resident's name, room number, dosage and frequency of administration,

4. That any related pharmacy is informed of any over the counter drugs or nutritional supplements that a resident is taking in order to monitor drug/supplement and/or disease/supplement interaction,

5. That the licensed nurse may not be required by the long-term care facility to administer any over the counter drugs or nutritional supplements in question,

6. That the licensed nurse may question the prescription of an over the counter drug or nutritional supplement without repercussion of the long-term care facility or primary prescribing practitioner, and

7. That the licensed nurse may at any time decline to administer or discontinue administration of an over the counter drug or nutritional supplement without repercussion, but with appropriate notice to the long-term care facility administrator and the resident or the resident's responsible party.

-Rick Schikora
CPA, Warwick & Schikora
Fairbanks, AK

LEGISLATIVE RESEARCH REPORT

FEBRUARY 27, 2006

REPORT NUMBER 06.139

OTHER STATES' POLICIES REGARDING NURSES ADMINISTERING PRESCRIBED DIETARY SUPPLEMENTS

PREPARED FOR REPRESENTATIVE MIKE KELLY

BY BECKY TAYLOR, LEGISLATIVE ANALYST

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.

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[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

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[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, bmmaria@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 for Nursing, (518) 474-3817 ext. 120, LOBRIEN@MAIL.NYSED.GOV.
North Carolina	The North Carolina Board of Nursing has a statement relative to over-the-counter (OTC) drugs and such supplements would be considered as such. If a facility allowed the RN to recommend supplements to the client, the employing facility policy and procedures should support this as being acceptable. 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.	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	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] 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. 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.	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

6 pages

V 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

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.

- 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.

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;

- 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-oview.html*

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

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 its 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, occaisional 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/hclaims.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
P.O. BOX 2649
HARRISBURG, PA 17105-2649

PHONE: (717) 783-7142
www.dos.state.pa.us

FAX: (717) 783-0822
email: st-nurse@state.pa.us

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-rnistate.asp

THE ROLE OF THE RN IN RECOMMENDING THE USE OF OVER-THE-COUNTER PHARMACEUTICAL PRODUCTS AND NON-PRESCIPTION 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 th cense 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:

DEPARTMENT OF
COMMERCE
COMMUNITY AND
ECONOMIC DEVELOPMENT
Division of Corporations, Business and Professional Licensing

Frank H. Murkowski, Governor
William C. Noll, Commissioner
Rick Urion, Director

April 21, 2006

The Honorable Ben Stevens
President, Senate
State Capital, Room 111
Juneau, AK 99801-1182

Dear Senator Stevens:

As requested by the Board of Nursing, the Board of Pharmacy would like to comment on CSHB 467 concerning administration of "remedies and dietary supplements" by nurses to patients in nursing homes and assisted living situations.

The Board of Pharmacy concurs with the Board of Nursing's opposition to the bill. A major factor with the agents is potential interactions with prescribed therapeutic medicine that is well documented in pharmacy literature and not necessarily familiar to prescribers.

Although CSHB 467 does not mandate that a nurse administer the agents, it would allow an institution to mandate the practice.

We urge the senate to take into account public safety when considering CSHB 467.

Sincerely,

Cindy Bueler, Chair
Alaska Board of Pharmacy

PO Box 110806, Juneau, AK 99811-0806
Telephone: (907) 465-2534 Fax: (907) 465-2974 Website: www.commerce.state.ak.us/occ

RICK J. SCHIKORA
CERTIFIED PUBLIC ACCOUNTANT

1416 GILLAM WAY
FAIRBANKS, ALASKA 99701

(907) 456-1566
FAX: (907) 456-1569
EMAIL: schikora@gci.net

April 25, 2006

VIA FAX - #907-465-4587

Senator Fred Dyson
Alaska State Senate
State Capitol, Room 121
Juneau, AK 99811

RE: CS HB467

Dear Senator:

We met last month in your office on a different matter than the subject of this letter – I am the Chairman of the Golden Valley Board of Directors.

CS HB467 is the result of my grandmother's residency at the Fairbanks Pioneers Home and her need for dietary supplements or prescribed remedies. My interest in this bill is not in its benefit to my grandmother, but similarly situated residents in facilities. My grandmother is 98 and odds are she won't be with us much longer.

My grandmother has been taking Cosamin DS and Tri-omega 3 fish oil pills for the past few years. We would purchase the pills and the Pioneers Home would administer them. Due to some conflicting statements by the Alaska State Board of Nursing, the Pioneers Homes decided to discontinue the practice of administering supplements. Despite a policy allowing voluntary continuance of administration, the nurses there are afraid to continue due to fear of actions that may be taken by the Board.

CS HB467 will allow registered nurses to administer prescribed remedies or dietary supplements under regulations adopted by the Board. I stand ready to assist the Board in their efforts to draft such regulations, and already have the June meeting on my schedule to attend for this purpose.

I urge you to give CS HB467 positive consideration and to pass it out of your committee to the floor so that it may pass this session. If you have any questions, please call me at the number above. Even if I am traveling, I will be in contact.

Sincerely,

Rick Schikora

STATE OF ALASKA
DEPARTMENT OF COMMERCE
COMMUNITY AND ECONOMIC DEVELOPMENT

DIVISION OF OCCUPATIONAL LICENSING

April 24, 2006 *Frank H. Murkowski, Governor*

Senator Ben Stevens, President
Alaska State Senate
State Capitol Building
Juneau, Alaska 99801

Subject: HB 467, administration of prescribed remedies

Dear Senator Stevens,
I am the chair of the Alaska Board of Nursing. I am writing to you about HB 467, which may soon be transmitted to the Senate. This bill requires the Alaska Board of Nursing to overrule a longstanding policy by mandating the enactment of regulations.

During the House Committee process, changes were made to the bill that created a fiscal impact upon the Board of Nursing. These changes were adopted in the House Health, Education and Social Services Committee on April 11, and then the bill was waived through House Finance on April 13.

HB 467 has a significant cost associate with it. The Fiscal Note was being prepared as the bill was waived through House Finance. I am writing primarily to request that the Senate Committee process respectfully consider the fiscal note prepared by the Board of Nursing on this bill.

There are other important considerations that should be made regarding HB 467.

The Board is entrusted with ensuring public safety through the regulation of safe nursing practice. As you are aware, the Board is composed of members of the nursing profession who bring years of experience, at all levels of nursing, to discussion and deliberation of professional issues. The Board considers the ramifications of decisions on the broad range of Alaska residents.

The Board of Nursing carefully considered the question of administering non-FDA approved substances to our most vulnerable and debilitated people, residing in assisted living homes. The Board found overwhelming evidence demonstrated that this would not be a safe practice and therefore upheld its prior decisions that this would be outside the scope of practice for a Registered Nurse. The Board's Position Paper outlines the deliberations and decision of the Board, and accompanies this letter.

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Email: license@commerce.state.ak.us Website: http://www.commerce.state.ak.us/occ/

The Board of Pharmacy has agreed with the Board of Nursing position on this matter.

There should be preponderance of evidence to justify the passage of legislation overruling a regulatory board comprised of professionals in healthcare and nursing. An issue of that gravity deserves the same level of careful examination as was given by the Board of Nursing to this issue.

Please know that I am fully prepared to provide testimony regarding both the fiscal impacts and the public policy concerns to the proper Standing Committees of the Senate.

Thank you for your attention to this matter.

Respectfully,

Cathy Giessel, MS, RN, ANP
Board of Nursing, Chair

Cell 242 5450

cc: Senators Dyson, Green and Wilken

Alaska Board of Nursing
Position Paper
March 2006

Administration of Nutritional supplements, Herbal and Homeopathic Preparations and other Non-FDA Approved Medications by Registered Nurses

Background
The Alaska Board of Nursing is charged with the regulation of nursing practice to ensure public safety. The Board of Nursing enacts regulations to implement safe nursing practice, reviews and validates license application credentials and oversees nursing education. The Board of Nursing also reviews issues, utilizing scientific findings and best practices recommendations, to ensure that the Alaska public receives safe nursing care.

The Alaska Board of Nursing has considered the issue of nurse licensee administration of nutritional supplements, herbal and homeopathic preparations and other non-FDA approved medications several times over the last decade. Each time the Alaska Board of Nursing has maintained that the administration of nutritional supplements, herbal and homeopathic preparations and other non-FDA approved medications is an unsafe practice and outside the scope of practice for nurses in Alaska.

Deliberations
The Board of Nursing reviewed the issue of administration of herbal preparations in December 1998. The case brought to the Board related to a resident of an assisted living home whose physician prescribed a number of ingested therapies, including St. John's Wort and over-the-counter Tylenol. (1) The Board determined that "it is outside the scope of practice for nurses to administer remedies that are not FDA-approved". Rationale was based on the unknown interactions of these substances with pharmaceutical medications and the fact that education about these substances was not part of the nursing education curriculum. The Board underscored the fact that a licensed nurse must practice within their scope of practice, regardless of the presence of a prescription by a licensed physician.

The Board of Nursing again discussed the issue in March 1999 when it was asked to reconsider its decision. This time the question related to the administration of homeopathic remedies. The Board reviewed the contents of a reference book, *Nursing Responsibility Regarding Herbal Remedies*, by the National Organization for Homeopathic Remedies. This reference did not indicate that it was within the nurse's responsibility to administer supplements or homeopathic remedies. The Board upheld its previous position statement that the administration of non-FDA approved substances and nutritional supplements is an unsafe practice and outside the scope of practice for nurses in Alaska. (2)

On March 15, 2002 the Board was approached by a member of the Alaska Mental Health Trust, to review the position on administration of non-FDA substances. At that time the Board of Nursing reviewed a document from the North Carolina Board of Nursing, "The Role of the Registered Nurse in recommending the use of over-the-counter pharmaceutical products and non-prescription devices". This reference stated, "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." (3)

The Board also reviewed an article summarizing opinions of other Boards of Nursing who approve alternative therapies administered by Registered Nurses. Therapies discussed in the research article were alternative therapies that were non-invasive. (4) This was not relevant to the administration of non-FDA approved supplements or substances.

On September 26, 2003 the Board of Nursing was asked to approve nurse administration of a non-FDA approved substance, memantine, to a resident in a Pioneer Home. The substance, memantine, was a medication used in Europe and currently undergoing FDA scrutiny. The Board queried the other sixty one (61) Boards of Nursing concerning their position on the administration of non-FDA approved medications which have been used in clinical trials and are awaiting FDA approval, and specifically memantine. Thirty-one state boards responded with 14 banning the practice, 5 allowing it if the nurse is knowledgeable and the administration was in conjunction with medical research, and 12 states responding with no specific position on this. After discussion, the Board tabled the topic for the March 2004 Board meeting. (5) In the interim, the FDA approved the substance as the medication, Namenda.

The Board was asked to approve administration of nutritional supplements to a Pioneer Home resident on March 8, 2006. After more than two hours of discussion with a family member and thoughtful deliberation, over a two-day period, the Board reiterated and continued the position that administration of nutritional supplements, herbal and homeopathic preparations and other non-FDA approved medications is unsafe and therefore outside the scope of practice for a licensed nurse in Alaska.

Basis of the Board of Nursing position

The Board of Nursing is charged with ensuring public safety by the regulation of nursing practice (AS 08.68.100). There exist grounds for the Board to deny, suspend or revoke the license of a nurse in Alaska for several reasons, one of which includes intentionally or negligently engaging in conduct that has resulted in a significant risk to the health or safety of a client or in injury to a client (AS 08.68.270 (1) – (10)). Unprofessional conduct (12 AAC 44.720 (9)) includes assuming duties and responsibilities, on repeated occasions, without sufficient preparation or for which competency has not been maintained (12 AAC 44.770 (2)).

The Food and Drug Administration (FDA), through the Center for Drug Evaluation and Research (CDER), reviews and approves pharmaceuticals in the United States for efficacy, safety, purity and other quality assurance markers. This rigorous review attempts to assure safety for the American public but, even then, some pharmaceuticals are withdrawn from the market after approval, due to safety concerns that arise with increased use by a diverse population.

There is widespread use by Americans of nutritional supplements, herbal preparations, and vitamins, as well as pharmacologic agents obtained from foreign countries via the Internet. (6) There have been increasing reports of interactions, potentiation of effect and adverse reactions between nutritional supplements, herbal and homeopathic preparations and other non-FDA approved medications and pharmaceuticals.

The FDA does not regulate the production of nutritional supplements because they are classified as food products. In addition, the Dietary Supplement Health and Education Act of 1994 (DSHEA) restricts the FDA from regulating any product that is labeled as a "supplement" and makes no disease treatment claims. There is no regulatory oversight of production in quality, purity, or contents of these products or official monitoring of adverse events; this responsibility is left to the manufacturer. There have been adverse events resulting in injury and even death with the use of these ingested products. (7, 8, 9,10,11,12.13)

The United States Pharmacopeia (USP) is an independent, nonprofit organization that establishes public standards of quality for medicines, dietary supplements, and related products. In October 2001, the United States Pharmacopeial Convention, Inc. (USP) launched a verification program for dietary supplements in order to evaluate the ingredients listed on the label. The program provides independent testing and review to verify ingredient and product integrity, purity, and potency for manufacturers who choose to participate. However, USP does not comprehensively address the issue of safety.

Two references are available to the medical community that contain information on some nutritional supplements: the PDR for Herbal Medicines (1998) and the German Commission E Therapeutic Monographs. These documents contain limited information on indications, contraindications, side effects, interactions with other drugs and dosage.

Nurses are not educated in the use of nutritional supplements, herbal and homeopathic preparations and other non-FDA approved medications in bachelor's or diploma Registered Nurse programs or Licensed Practical Nurse programs. This testimony was given by Dr. Carolyn Keil, University of Alaska Anchorage faculty, on December 10, 1998, and affirmed on March 10, 2006 by Terri Olson, MSN, University of Alaska Anchorage faculty.

The populations of clients in Alaska's long-term care facilities and assisted living facilities are a vulnerable population with multiple disease diagnoses and prescribed pharmaceutical medications. This group of people is highly susceptible to adverse events and interactions between nutritional supplements, herbal and homeopathic preparations and other non-FDA approved medications and prescribed pharmaceuticals. Nurses administering pharmaceuticals have a wealth of experience, knowledge and resources to draw upon to safely administer these medications to the clients. This is not the case with administration of non-FDA approved substances, about which little information may be known or available to the nurse.

The licensed nurse is accountable for her actions and has a duty to the patient that cannot be supplanted by healthcare provider prescription or facility policy. This responsibility applies even when a healthcare practitioner has ordered a certain therapy. The nurse is held responsible to understand the implications of any therapy administered to the patient.

Conclusion

It is incumbent on the Board of Nursing to review the medical evidence and make objective judgments to protect public safety. The Board is aware that its decisions have widespread impact on vulnerable, dependent persons of all ages in a variety of healthcare settings, who expect and trust in safe nursing care. Nurse licensees in Alaska look to the Board for evidence-based, best practices guidelines.

The Board of Nursing considered all the above facts. Based on impartial, objective review of the facts, the Board of Nursing for the State of Alaska finds that it is unsafe and therefore outside the scope of practice for a licensed nurse to administer nutritional supplements, herbal and homeopathic preparations and other non-FDA approved medications

The Board of Nursing acknowledges the rights of patients and their families to make the decision to self-administer these supplements or substances to themselves or their family members.

References

1. Alaska Board of Nursing minutes, December 10-11, 1998, pg. 8-9.
2. Alaska Board of Nursing minutes, March 4-5, 1999, pg. 8.
3. http://www.ncbon.com/prac-rnistate.asp
4. Sparber, Andrew RN, MS, CS (August 31, 2001) "State Boards of Nursing and Scope of Practice of Registered Nurses Performing Complementary Therapies" Online Journal of Issues in Nursing, 6 (3), Manuscript 10. Available: http://www.nursingworld.org/ojin/topic15/tpc15_6.htm.
5. Alaska Board of Nursing minutes, September 26, 2003, pg. 13.
6. Eisenberg, D.M., et.al. (1998). Trends in alternative medicine use in the United States, 1990-1997. Journal of the American Medical Association, 280, 1569-1575.
7. Larrey, D. (1997). Hepatotoxicity of herbal remedies. Journal of Hepatology, 16 (suppl.1), 47-51.
8. Sheehan, D.M. (1998). Herbal medicines, phytoestrogens and toxicity: Risk:benefit considerations. Proceedings of the Society for Experimental Biology and Medicine, 217(3), 379-385.
9. Shaw, D., et.al., (1997). Traditional remedies and food supplements. A 5-year toxicological study (1991-1995). Drug Safety, 17(5), 342-356.
10. McGuire, J.K., et.al., (2000). Fatal hypermagnesemia in a child treated with megavitamin/megamineral therapy. Pediatrics, 105(2), 414.
11. Borowitz, S.M. (1998). Alternative therapy: Focus on herbal products. Pediatric Pharmacotherapy, 4(5), 405.
12. Gardiner, P., & Kemper, K.J. (2000). Herbs in pediatric and adolescent medicine. Pediatrics in Review, 21(2), 44-57.
13. Abbot, N.C., et.al., (1998). Uncovering suspected adverse effects of complementary and alternative medicine. International Journal of Risk and Safety in Medicine, 11, 99-106.
14. Atwater, et.al. (2005). The USP Dietary Supplement Verification Program: Helping Pharmacists and Consumers Select Dietary Supplements. US Pharmacist. 6:61-64. (http://www.uspharmacist.com/index.asp?show=article&page=8_1500.htm)

Jason Hooley

From: Bueler, Cindy [Cindy.Bueler@providence.org]
Sent: Wednesday, April 26, 2006 11:14 AM
To: Sen. Fred Dyson
Cc: Jason Hooley; sher_zinn@commerce.state.ak.us
Subject: message #2-HB 467

Senator Dyson,

It would appear that I did not have the most current information when I sent you my letter from the Board of Pharmacy earlier today. The main point of concern would appear to be moot, as I now realize the bill has been amended to prevent MANDATING nurse dispensing of alternative medicine. HB 467 as amended on April 24th, appears to address concerns of the Board of Pharmacy.

Thank-you.

Cindy Bueler, R.Ph.
Chair, Alaska Board of Pharmacy

AMENDMENT

OFFERED IN THE SENATE

TO: CSHB 426(FIN) (title am)

Page 9, line 16, following "in":

Insert "mental health treatment facilities located in the state and outside the state, including"

Page 9, line 18, following "receiving":

Insert "services provided by mental health treatment facilities located in the state and outside the state, including"

Page 9, line 19:

Delete "center"

Insert "centers"

Delete "services"

Page 9, line 20, following "of":

Insert "services provided by mental health treatment facilities located in the state and outside the state, including"

Page 9, line 21:

Delete "center"

Insert "centers"

Delete "services"

Insert ","

24-LS1602\XA.2
Mischel
5/1/06

AMENDMENT

OFFERED IN THE SENATE BY SENATOR DYSON

TO: CSHB 426(FIN) (title am)

Page 1, line 10, through page 2, line 9:

Delete all material and insert:

"* **Section 1.** AS 21.09 is amended by adding a new section to read:

Sec. 21.09.240. Cooperation with the Department of Health and Social Services. An insurer, including a pharmacy benefits manager, with respect to medical assistance programs under AS 47.07, shall cooperate with the Department of Health and Social Services to

(1) provide, with respect to an individual who is eligible for or is provided medical assistance under AS 47.07, on the request of the department, information to determine during what period the individual or the individual's spouse or dependents may be or may have been covered by the insurer and the nature of the coverage that is or was provided by the insurer, including the name and address of the insurer and the identifying number of the health care insurance plan;

(2) accept the department's right of recovery and the assignment to the department of any right of an individual or other entity to payment from the party for an item or service for which payment has been made under AS 47.07;

(3) respond to any inquiry by the department regarding a claim for payment for any health care item or service that is submitted not later than three years after the date of the provision of the health care item or service; and

(4) agree not to deny a claim submitted by the department solely on the basis of the date of submission of the claim, the type or format of the claim form, or a failure to present proper documentation at the point-of-sale that is the basis of the claim if

(A) the claim is submitted by the department within the three-year period beginning on the date on which the item or service was furnished; and

(B) any action by the department to enforce its rights with respect to the claim is commenced within six years after the department's submission of the claim."

Page 10, following line 6:

Insert a new bill section to read:

"* **Sec. 15.** Section 1 of this Act takes effect July 1, 2007."

Renumber the following bill section accordingly.

Page 10, line 7:

Delete "sec. 14"

Insert "secs. 14 and 15"

24-LS1602\XA.3
Mischel
5/1/06

AMENDMENT

OFFERED IN THE SENATE BY SENATOR DYSON

TO: CSHB 426(FIN) (title am)

Page 3, lines 26 - 28:

Delete "Before pursuing an action or claim on behalf of a medical assistance recipient for care or services for an injury or illness for which medical assistance was received, an"

Insert "An"

Page 3, line 29, following "representing":

Delete "the"

Insert "a"

Page 4, line 17:

Delete "An"

Insert "Except for payments under AS 23.30, an"

Page 4, line 19:

Delete "all proceeds"

Insert "any lump sum settlement or judgment"

Page 4, lines 23 - 29:

Delete all material and insert:

"(e) An attorney who fails to comply with this section is not entitled to the pro rata reduction under AS 47.05.070(c). If the attorney has already received payment for the attorney's services through the pro rata reduction as provided in AS 47.05.070(c), the attorney is civilly liable to the department for the amount of that payment."

Page 6, following line 1:

Insert a new subsection to read:

"(h) Notwithstanding (a) - (g) of this section, a third-party payor shall be held harmless if it settles or compromises a dispute in good faith and without knowledge that the individual is a recipient of medical assistance."

April 3, 2006

Honorable Mike Kelly
State Capitol Bldg., Rm. 434
Juneau, AK 99801-1182

Dear Representative Kelly,

Thank you for your letter of March 27, 2006 soliciting the Alaska Nurses Association's position on the administration of dietary supplements to patients by Registered Nurses.

As with many issues in medicine, the issue of the safety and efficacy of dietary supplements is complex. While the general public views dietary supplements and herbal preparations as different from prescription medications, health care professionals treat both of these groups as substances that affect the human body in ways that can be both beneficial and harmful. When administering any substance to alter the body's functioning, one needs to know the possible beneficial effects, the potential interactions with other medications the patient is taking, the potential adverse or side effects, and the effect of the substance on any illnesses the patient might have. When patients suffer from a chronic illness, the process involved in making decisions about the safety of these substances is far more complex than reading the label on the container they come in.

An example of the potential deleterious effects of dietary supplements and herbal preparations comes from my practice in the operating room. We ask all patients to list dietary supplements or herbal medications they are taking as part of our pre-operative assessment. If the patient is taking St. John's wort, we have to delay surgery for two weeks because this supplement increases the risk of bleeding during surgery.

There is an additional concern with these dietary supplements and herbal medications in that there is poor regulation of their manufacturing. Numerous studies have shown that the ingredients listed on the label of the bottle corresponds poorly with the what scientists find when they evaluate their actual contents. I know from experience that these pills are unmarked, and when a family brings in a container there is no way to confirm that the pills are actually what the label states they are. Prescription/legend medications have a identifier number imprinted on them.

The public generally thinks that if a physician prescribes a medication or dietary substance then the nurse has no liability if the patient becomes ill or suffers damage from taking that substance.

This is not the case. The courts have repeatedly upheld that the nurse is legally and ethically responsible to confirm the safety of any substance they are directly administering to a patient.

This being said, we do feel that dietary supplements and herbal preparations can be beneficial to patients. There is a growing body of scientific research on these substances and over time we have been better able to differentiate which substances are truly beneficial and which have the potential for serious side effects. There has also been steps taken to improve the oversight of production of these substances. As of this writing the United States Pharmacopeia (USP) has a verification process for supplements. This is a voluntary process, and many manufacturers have submitted their products for verification (http://www.usp.org). As manufacturing oversight improves, our position on safety of administration will no doubt change as well.

You can tell from the above discussion that this issue is very complex. I have asked the Alaska Nurses Association's (AaNA) Professional Practice Committee to investigate this issue in light of recent advances and come up with a policy recommendation before the AaNA Board meeting. We would be happy to share these recommendations with you.

If you want to discuss this issue with me directly feel free to call me at 907-278-1070 in the evening. Thank you again for requesting our input on this important issue.

Sincerely,

Debbie Thompson, RN, BSN
President
Alaska Nurses Association

ASHNHA Testimony on CSHB 467 (HES)am Before Senate HESS
Presented by: Linda Fink, Vice President
May 1, 2006

The ***Alaska State Hospital and Nursing Home Association*** represents 23 acute care hospitals, 2 behavioral health facilities, 6 assisted living facilities (Alaska Pioneer Homes), and 5 nursing facilities. None of our 23 acute care hospitals also include nursing home beds. ASHNHA's rich composition of private, federal, state, and tribal health care facilities provides a balanced viewpoint on important health care policy matters. ASHNHA's Legislative Committee evaluates health care legislation weekly and authorizes the position expressed in this testimony.

ASHNHA has carefully reviewed CSHB 467 (HES) am and believes it to be important legislation. CSHB 467, if passed, would make it clear that a licensed registered nurse may administer a prescribed remedy or dietary supplement to a patient under his/her care in a nursing facility, assisted living home or an Alaska Pioneer's Home. However, this bill also provides that a nurse who is uncomfortable administering these products could choose not to.

ASHNHA's membership believes this language will serve to clarify that administering these products is not outside the scope of practice for a licensed registered nurse, and should eliminate nurses' concerns about liability and scope of practice if they chose to administer these prescribed products to their patients.

➲Other points to consider:

- Keep in mind we are talking only about products prescribed by a person authorized under state law.
- CSHB 467 passage should reduce the 'practice' of family and friends providing supplements often without the knowledge of caregivers.
- CSHB 467 will allow nurses, pharmacists and physicians to participate in administering these supplements and thereby be aware of what is being taken on top of other medicines, and to note this in the patient's record.
- If we generally believe that most people do not know if their supplements are harmful relative to other medications they are taking or their present medical condition, how can we then advocate that the taking of these supplements should not be administered by caregivers as part of the patient treatment plan? Which approach presents the greater risk to the patient's overall health
- Most facilities have policies and procedures in place to address how the supplements will be handled to insure that nursing staff have a 'safe harbor' in which to operate.

Alaska State Hospital and Nursing Home Association, 426 Main Street, Juneau, AK 99801 (907) 586-1790

- Finally, at any time a nurse feels the safeguards are not adequate, that a patient is not in a position to understand the risks, that the supplement is not safe in their judgment or for any other reason, that nurse can simply say 'no' to administering the supplement if they are uncomfortable doing so.

ASHNHA believes the provisions found in CSHB 467 improve the safe delivery of healthcare and urge this Committee to vote to move it forward to its next Committee assignment.

If ASHNHA can provide any additional information, please contact our main office at 586-1790 in Juneau.

ASHNHA Proudly Represents the Following Alaska Health Care Providers

Alaska Regional Hospital, Alaska Native Medical Center, Alaska Pioneer Home System, Alaska Psychiatric Institute, Bartlett Regional Hospital, Bassett Army Community Hospital, Central Peninsula General Hospital, Cordova Community Medical Center, Denali Center Nursing Home, Fairbanks Memorial Hospital, Heritage Place Nursing Home, Kanakanak General Hospital, Ketchikan General Hospital, Maniilaq Health Center, Mary Conrad Center, Mat-Su Regional Hospital, Mt. Edgecumbe Hospital SEARHC, North Star Behavioral Health, North Sound Regional Hospital, Petersburg Medical Center, Providence Alaska Medical Center, Providence Extended Care Center, Providence Kodiak Island Medical Center, Providence Seward Medical and Care Center, Providence Valdez Medical Center, Sitka Community Hospital, South Peninsula Hospital, USAF 3rd Medical Group-Elmendorf, Wrangell Medical Center, Wildflower Court Nursing Home, Yukon Kuskokwim Delta Regional Hospital.

Gayle Keller

From: Cathleen Winfree [crwinfree@yahoo.com]
Sent: Tuesday, April 25, 2006 9:55 AM
To: Sen. Fred Dyson
Subject: HB 467 referred to Senate

Dear Senator Dyson,

I have been an RN, practicing in Alaska for 27years. I am currently on the Board of Nursing and support the decision the Board made in the March 2006 in Juneau. I am opposed to HB 467 for a number of reasons.

As a Registered Nurse I was not educated in the use of nutritional supplements, herbal and homeopathic preparations and other non-FDA approved medications. I believe this is still true today in the education of RNs and LPNs.

I am accountable for my actions and have a duty to my patients that cannot be supplanted by health care provider prescription or facility policy. This responsibility applies even when a health care practitioner has ordered a certain therapy. I am responsible to understand the implications of any therapy administered to the patient.

The populations of clients in Alaska's long-term care facilities and assisted living facilities are a vulnerable population with multiple disease diagnoses and prescribed pharmaceutical medications. This group of people is highly susceptible to adverse events and interactions between nutritional supplements, herbal and homeopathic preparations and other non-FDA approved medications and prescribed pharmaceuticals. When administering pharmaceuticals, RNs have a wealth of experience, knowledge and resources to draw upon to safely ad minster these medications to the clients. This is not the case with administrations of non-FDA approved substances, about which little information may be known or available to the nurse.

The Board of Nursing is entrusted with ensuring public safety through the regulation of safe nursing practice. The Board considerd the ramifications of our decision on the broad range of Alaska residents. As an RN, that is my job also.

I urge you to vote no on HB 467.

Thank you for your time and consideration

Cathy Winfree RN

24-LS1265\YA.3
Mischel
5/1/06

AMENDMENT

OFFERED IN THE SENATE

TO: CSHB 467(HES) am

Page 1, lines 8- 10:

Delete ". The board shall adopt regulations that include safeguards that prevent the administration of a prescribed remedy or dietary supplement if"

Insert "unless"

HB 467 Amendment 05/05/06

The amendment takes out the requirement for the board to adopt regulations and simply states that a nurse may, but is not required to administer a prescribed dietary supplement or remedy as long as it is not outside the manufacturer's recommended dosage. This puts the nurse in her professional capacity as the decision maker.

-----Original Message-----
From: Mike Pat Grandinetti [mailto:mikepat@gci.net]
Sent: Monday, May 01, 2006 7:59 PM
To: Sue Nikodym-Nelson; Ann Fama; Barbara Berner; C Clouse; Christine Dittrich; Debbi Kiley; Debbie Thompson; Dianne O'Connell; Donna Phillips; Elsa DeHart; Gail Holtzman; Judy & George Petersen; Kay Lahdenpera; Lynn Hartz; Margie Draskovich; Pat Senner; Patricia Hong; Patti Hong; Shirley LaForge
Subject: Recap of May 1 Meeting

We had a productive meeting tonight, thanks to everyone who attended.

We reviewed the charge to the Professional Practice Committee: "...develop a position paper providing guidelines for nurses on recommending, providing counseling regarding and on safe administration of dietary/herbal supplements." (AaNA General Assembly, 2002)

Lynn Hartz brought several examples of dietary supplements (vitamins, minerals). One had the USP Verified symbol on it, and also had the USP website so consumers could review material there.

We discussed several resources:
MedlinePlus Herbs and Supplements: http://www.nlm.nih.gov/medlineplus/
US Food and Drug Administration; Overview of Dietary Supplements: http://www.cfsan.fda.gov/~dms/ds-oview.html
US Food and Drug Administration; Dietary Supplement Health and Education Act of 1994:
http://www.cfsan.fda.gov/~dms/dietsupp.html
USP Verified: http://www.usp.org/USPVerified
Natural Medicines Comprehensive Database: http://www.naturaldatabase.com (this is a subscription only database, included with ePocrates)
Legislative Research Report: Other States' Policies Regarding Nurses Administering Prescribed Dietary Supplements, February 2006
http://www.akrepublicans.org/kelly/leg-kelly.php#Legislation (Follow link for HB 467, and look for this document)

Other resources: Rita Grenier, pharmacist at Mary Conrad, has indicated she would be willing to assist. Ann Thrall, ANP, is also willing to assist

We agreed to use the following questions as a framework for the main body of a position paper to forward to the AaNA Board of Directors:

1. 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? *Barb Berner and Patti Hong, point people*
2. Is the practice or therapy consistent with the ethical and quality standards embraced by the professional nursing community in the state? *Judy Petersen to draft definitions of ethics and standards*
3. Is the practice or therapy contained in standards of practice developed by appropriate nursing associations? *Elsa de Hart and Margie Draskovich, point people*
4. Is the practice or therapy taught as part of a nursing curriculum in an approved nursing education program? *Patti Hong to summarize*
5. Does the workplace support access to resources that nurses can use to research the practice? *Lynn Hartz to summarize* (Lynn, I may have mis-written this item)
6. Is the nurse prepared to accept full responsibility for his/her action and be accountable to the client or patient? *Shirley LaForge to research cases where nurses may have been accused of negligence or malpractice.*

We agreed to meet again at 5 p.m. on Monday, May 8, 2006. Those who agreed to research the above items will circulate their drafts to everyone.
We will also meet at 5 p.m. on Monday, May 15, 2006 to further craft a statement.

Goal: Bring draft position paper to AaNA Board of Directors on June 2, 2006.

Patti Hong

Jason Hooley

From: Bueler, Cindy [Cindy.Bueler@providence.org]
Sent: Wednesday, April 26, 2006 11:14 AM
To: Sen. Fred Dyson
Cc: Jason Hooley; sher_zinn@commerce.state.ak.us
Subject: message #2-HB 467

Senator Dyson,

It would appear that I did not have the most current information when I sent you my letter from the Board of Pharmacy earlier today. The main point of concern would appear to be moot, as I now realize the bill has been amended to prevent MANDATING nurse dispensing of alternative medicine. HB 467 as amended on April 24th, appears to address concerns of the Board of Pharmacy.

Thank-you.

Cindy Bueler, R.Ph.
Chair, Alaska Board of Pharmacy

Jason Hooley

From: Bueler, Cindy [Cindy.Bueler@providence.org]
Sent: Wednesday, April 26, 2006 10:04 AM
To: Sen. Fred Dyson
Cc: Jason Hooley
Subject: concerning HB 467

Attachments: bop letter.doc

bop letter.doc (558 KB)

Honorable Senator Dyson,

Enclosed is a letter concerning HB 467 from the Alaska Board of Pharmacy. Please include this letter in your consideration of the bill. I can be reached at Providence Hospital in the in-patient pharmacy 261-3633 if you have questions.

Sincerely,

Cindy Bueler, Registered Pharmacist
Chair, Alaska Board of Pharmacy

<<bop letter.doc>>

Gayle Keller

From: Cathy Giessel [cgiessel@mac.com]
Sent: Tuesday, May 02, 2006 9:39 PM
To: Sen. Fred Dyson
Subject: HB 467 considerations

Dear Senator Dyson
I know that time is short and you have all worked very hard this session on some very weighty issues. HB 467 is being reviewed at the last minute, with little time allowed to ponder the ramifications. Some considerations as you deliberate this bill:

HB 467 does NOT serve public safety:

Many potential unintended consequences:
It opens the door to an unlimited myriad of substances. Salvia divinorum (SB 313) is an herb included in the substances described in HB 467. This bill needs more time and scrutiny, rather than a rush through the Legislature.

Alaska's most vulnerable, debilitated population

Residents of assisted living homes are the most ill members of our communities, with multiple diseases processes and numerous medications, with impaired liver and kidney function. Adverse events and interactions with non-FDA approved substances are a significant risk.

Facility waiver does NOT protect the patient

The waiver that patients are required to sign at the Alaska Pioneer Home serves only to protect the facility, NOT the patient.

Overrule the findings of a regulatory board composed of healthcare professionals

The Board of Nursing has considered this question several times over the last 8 years, with many different members on the Board. The Board has always reached the same conclusion – this is not a safe practice. Why do regulatory boards exist, if the Legislature so quickly overrules the judgment and expertise of the Board of Nursing?

Powerful marketing

Two weeks ago I had a patient bring me a homeopathic that she purchased based on a late night infomercial. She wanted me to approve it for her muscle pain. I explained that I did not know what was in it and there was no proof that it would help her. She seemed very puzzled but seemed to accept that I could not validate the product or its efficacy. Then she said, " I have just one more question. Cathy, the instructions say I should put this in my mouth for 10 seconds t' en swallow it. So, on the clock there is that hand that goes around kind of fast. Is it 10 seconds when the hand goes from the 6 to the 7?"

I did not have the heart to ask my patient how much she paid for the product, for fear of embarrassing her.

Thank you for giving this bill careful consideration.

5/5/2006

Cathy Giessel, MS, RN, ANP
cgiessel@mac.com

Alaska Board of Nursing
chair

April 11, 2006

Dear Representative Wilson,

I am writing in regards to HB 467 which addresses administration of "remedies and dietary supplements" by nurses to patients in assisted living and other nursing facilities. While I am the Director of Pharmacy of Alaska Regional Hospital, I am expressing my personal professional opinion.

The terms remedies, dietary supplements, natural remedies, homeopathic and herbal products encompass a very broad spectrum of products available to the consumer. While some of these products are very widely used such as vitamin supplements, other products are often imported with extremely vague if non-existent safety and efficacy information. Labels often contain terms such as "proprietary blend" which may list 10-20 obscure ingredients. Since these products are not regulated by the FDA as prescription or even over the counter drugs, adverse effects and hazards are only identified retrospectively, after affecting consumers. In addition, the potency of this broad basket of products varies significantly with little or no standardization and often conflicting dosage information.

I would encourage a careful consideration of the necessity and broad impact or ramifications of passing HB 467. I do not think this bill adequately addresses the professional concerns identified by health professionals such as nurses and pharmacists and does not serve the public in this form.

Sincerely

Chris Coursey
8612 Lassen St.
Eagle River, AK 99577
Registered Pharmacist

11 April, 2006

Dear Representative Wilson,

I am a pharmacist writing in regards to HB 467 concerning administration of "remedies and dietary supplements" by nurses to patients in nursing homes and assisted living situations. Although I sit on the Alaska Board of Pharmacy, I am writing not in that capacity, but as an Alaskan pharmacist. I urge you to exercise caution in proceeding with this bill for reasons of patient safety. Let me explain.

There exists a myriad of over-the-counter "remedies", dietary supplements, herbal remedies, "natural" remedies and supplements, diet aids, etc. Although generally these agents are benign, that is not always the case. Warnings from the FDA periodically come out concerning safety of these agents, often from products originating in other countries and imported and sold in the U.S. They may contain toxic contaminants or may indeed contain pharmaceutical ingredients that are prescription-only in the U.S. and toxic if not used correctly. Product labeling does not reveal these minefields.

Aside from the issues of toxic contaminants, there is the issue of potency of the agent. There is little or no standardization of content of these agents, and potency may vary greatly between manufacturers or even from batch to batch...regardless of the labeled potency. There is no FDA oversight for these products.

The other major factor with these agents is potential interactions with prescribed therapeutic medicine. This is well documented in pharmacy literature and not necessarily familiar to prescribers.

Although HB 467 does not mandate that a nurse administer these agents, it would allow an institution to mandate the practice.

Please consider the safety ramifications to the public when considering HB 467.

Sincerely,

Cindy Bueler, Registered Pharmacist

May 5, 2006

Senate HESS committee

I serve in the Licensed Practical Nurse position for the Alaska State Board of Nursing.

I am testifying in opposition to HB 467.

The Board of Nursing is charged with protecting public safety through safe nursing practice. HB 467 does not allow that to happen.

Every nurse has standards of practice that they follow when giving nursing care. One of those standards pertains to administration of medications and it is called the five rights.

1. Right patient, are you the person this medication was order for.
2. Right drug. the nurse is educated about this drug and it is what was ordered
3. Right dose, knowing what are recommended dosages and this is the appropriate dose
4. Right route, knowing the proper routes of administration for this drug
5. Right time, it is being given at the appropriate time. Once a day, twice a day etc.

This is a foundation from which nurses practice safely when administering medications to patients in all health care settings and what you should expect as a patient.

Let me provide an example: You are my patient and an injection has been ordered. My patient load is very heavy and someone else draws up the injection for me out of my site, brings the syringe to me and says "here is your patient's injection"
It would be neglegent of me to accept that syringe and inject you with it because I do not know what is in the syringe. I did not see it drawn, I cannot be sure of anything about the contents of that syringe and you should not want me to give you that injection.

That level of unknown exists with dietary supplements and remedies. Because of the lack of oversite during production and lack of testing of the products there is no way to know what these remedies really contain.

If you are thinking it is adding another level of safety to an unsafe situation, by your own admission these products are not safe. Asking one person to prescribe an unknown and another to administer an unknown does not make it right or more safe.

It is not surprising that there are some nurses willing to administer these remedies to patients, it is in a nurses nature to want to help. I heard the nurse from Denali Center here in Fairbanks say it would be a shame if the patients there could not have cranberry tablets administered to ward off urinary tract infections, but would she feel the same if when cranberries were being collected by the manufacturer poisonous bainberries were mistakenly collected and put into the mix.She would have no way of knowing that.

I am sure that when the day comes that nurses can be assured that these remedies and dietary supplements contain what the label says they contain and that they have been tested to be pure and safe that the Board of Nursing will gladly step forward and change their ruling.

Please know that when you are being taken care of by a nurse that every effort has been made to give you the good and safe care that you deserve.

Please vote no on this bill so that level of care can continue.

Thank you for your time.

Mary Weymiller, LPN
907-479-4395
907-479-7432 fax
907-322-0111

April 25, 2006

VIA FAX - #907-465-4587

Senator Fred Dyson
Alaska State Senate
State Capitol, Room 121
Juneau, AK 99811

RE: CS HB467

Dear Senator:

We met last month in your office on a different matter than the subject of this letter – I am the Chairman of the Golden Valley Board of Directors.

CS HB467 is the result of my grandmother's residency at the Fairbanks Pioneers Home and her need for dietary supplements or prescribed remedies. My interest in this bill is not in its benefit to my grandmother, but similarly situated residents in facilities. My grandmother is 98 and odds are she won't be with us much longer.

My grandmother has been taking Cosamin DS and Tri-omega 3 fish oil pills for the past few years. We would purchase the pills and the Pioneers Home would administer them. Due to some conflicting statements by the Alaska State Board of Nursing, the Pioneers Homes decided to discontinue the practice of administering supplements. Despite a policy allowing voluntary continuance of administration, the nurses there are afraid to continue due to fear of actions that may be taken by the Board.

CS HB467 will allow registered nurses to administer prescribed remedies or dietary supplements under regulations adopted by the Board. I stand ready to assist the Board in their efforts to draft such regulations, and already have the June meeting on my schedule to attend for this purpose.

I urge you to give CS HB467 positive consideration and to pass it out of your committee to the floor so that it may pass this session. If you have any questions, please call me at the number above. Even if I am traveling, I will be in contact.

Sincerely,

Rick Schikora

'Mr. Chairman, members of the committee, my name isMerritt Andruss. I am a gerontological nurse practitioner and I have been practicing here in Juneau for the last 8 years. I strongly support house bill 467 for several reasons:

First, I would respectfully disagree with the nurse from the BON who stated, "this is not about glucosamine" the fact is – It IS about glucosamine, it IS about cranberry chews, it IS about viactiv (a calcium and vit. D supplement within a soft chocolate candy), it IS about acidophilus – these are supplements that older folks have been using successfully and with very effective and helpful results for a number of years. Without these supplements, many older adults would have to be taking more and much stronger FDA approved drugs to help them with their problems.

For example, I have several residents with severe OA AND histories of GI bleeds. These people cannot take many NSAIDS because they increase risk of GI bleed and are hard on the livers and kidneys of older folks. These people suffer greatly from the pain of OA and would be suffering much more if nurses were not able to give them the glucosamine they have taken for years to help with their arthritis pain. I have many residents who suffer from chronic UTIs which are very painful. Several of these residents are no longer able to take the cipro and nitrofurantoin originally prescribed for them daily as a prophylaxis for recurrent UTIs because their kidneys can no longer handle these harsh antibiotics. If they couldn't get their cranberry chews three times a day, they would be suffering from UTIs almost all the time. The gigantic horse pills of calcium and Vit D. required to be taken by all my patients with osteoporosis are extremely difficult for most people to swallow – the viactiv is a much gentler and kinder way to take their calcium. If families had to come in 2-3 times a day to administer these supplements it would create a hardship not only for the families, but for the residents who already feel too often a burden on their loved ones.

Secondly, as nurses we should be advocates for our patients. Just as we are obligated to have some understanding of the drugs we are asked to administer, we should also have some understanding of the supplements we are asked to administer. If we don't know about the supplements, we can go to the "natural medicines comprehensive database and look them up. The database lists any theoretical harm that is deemed significant, such as dangerous interactions with medications.It also lists significant studies that have been done on supplements which help show whether they are efficacious or not. Many pts and their families do not have all this information and as nurses it is our responsibility to educate our pts and their families about the pros and cons of each supplement they want to take so that they can make informed choices. For any nurse to simple bury their head in the sand and rigidly say to their patients, "No, I will not administer ANY supplement to you is not only wrong it is irresponsible.

Lastly, I support this bill b/c even though I feel strongly that nurses owe it to their patients to find out all they can about supplements their pts are taking or wish to take, this bill still allows those nurses who do NOT feel as I do, to simply refrain from giving them. The argument that they could be fired for this doesn't wash, as all nurses always have the

right to refuse to give any treatment to a pt. that they think will harm them. I have myself refused to give medication and was never fired for it.
I therefore, urge you to pass this bill and assist the older adults of Alaska who are unable to take their medications and supplements by themselves to get the complete care they need and deserve. Thank you.

washingtonpost.com

'Natural' Guidance

Better Safety, Efficacy Data on Natural Medicines Are Now Available for a Fee, as Public Use Grows

By Sandra G. Boodman
Washington Post Staff Writer
Tuesday, May 2, 2006; HE01

Consumer Reports, the bible of independent consumer ratings, has introduced a new database of information on thousands of herbs, dietary supplements and other natural medicines, a response to the enormous growth in the use of these products.

The new database -- unveiled last week and believed to be the most comprehensive of its kind -- contains detailed and easily accessible information on the safety, effectiveness and possible harmful interactions of nearly 14,000 supplements. It is available for a $19 annual fee, which also gives users access to Consumer Reports guides to prescription drugs and medical treatments.

The database, officially known as the Natural Medicines Comprehensive Database, is the product of the Therapeutic Research Center in Stockton, Calif., which analyzes prescription and over-the-counter drugs. Like Consumers Union (CU), which publishes the monthly Consumer Reports magazine and does not accept advertising, the center receives no funding from pharmaceutical companies, according to its chief, Jeff Jellin.

Jellin, a former professor of pharmacy, said that the center is funded by subscriptions to two newsletters it publishes: the Prescriber's Letter and the Pharmacist's Letter. The consumer database is adapted from these newsletters, which circulate to medical schools, hospitals, doctors and pharmacists, according to Jellin, who is the editor-in-chief.

'It looks like there's a tremendous amount of useful information here," said Allen J. Vaida, executive director of the Institute for Safe Medication Practices (ISMP), a nonprofit group that promotes drug safety, of the new CU database.

For several years CU has provided information to subscribers about prescription drugs through a partnership with the Bethesda-based American Society of Health-System Pharmacists.

'We decided to do this because we get calls all the time" about natural medicines, said CU project manager Nancy Metcalf.

A 2002 survey found that an estimated 19 percent of Americans take at least one supplement-- ranging from ginkgo to improve memory to St. John's wort to treat depression.

Many users erroneously regard these products as safe because they are "natural" and do not consider them to be drugs, Metcalf noted. In fact, the efficacy of many products is untested, their purity unknown and their safety uncertain because they are largely exempt from the scrutiny of the Food and Drug Administration.

Even so, demand for natural medicines seems insatiable: Americans now spend an estimated $20 billion annually on herbal remedies for weight loss or to treat back pain, dementia or cancer, studies have found. Because of growing demand, the number of products has skyrocketed.

Yet credible information about supplements remains scarce and what exists may require parsing complicated scientific studies. Although many Web sites and guides offer information about such medicines, much of it is produced by groups

hat have a financial interest in selling the products, experts say.

'CU does a good job," said Candy Tsourounis, an associate professor of pharmacy at the University of California, San Francisco. Tsourounis, an expert in the use of herbs and natural medicines, called the natural medicine guide nformative and "very user-friendly."

\ Difference in Detail

The National Institutes of Health sponsors two databases -- through its Office of Dietary Supplements (http://dietary-upplements info.nih.gov/) and its National Center for Complementary and Alternative Medicine http://www.nccam.nih.gov/). Both provide safety and effectiveness information about supplements that is free of commercial influence. But neither site contains as much detailed or easily accessible information as the CU database, vhich allows consumers to check which natural medicines might be effective for specific health problems.

Search "colds," for example, and information on 17 supplements pops up. Among them are echinacea, which the guide classifies as "possibly effective" in reducing cold symptoms based on published studies, and ginseng, for which it says here is "insufficient evidence."

CU's database (http://www.consumerreportsmedicalguidc.org/) lists approximately 100 brands of supplements that contain garlic, often taken to reduce cholesterol or blood pressure, for which it is rated "possibly effective." The site varns users that garlic supplements could interfere with the effectiveness of birth control pills because they speed the breakdown of estrogen and may interact with statins, which are broken down by the liver.

/aida of ISMP said he hopes the detailed safety information won't lead users to self-medicate. "The important thing is hat people should not go on this site and decide for themselves whether to tell their doctor or pharmacist" they are aking a supplement, he said.

\lternative medicine specialist Adriane Fugh-Berman, an associate professor of complementary medicine at Georgetown University School of Medicine, said that while the CU directory is " much more accurate than many other esources," it fails to distinguish between theoretical risks various supplements may pose at a cellular level and actual iarm seen in human studies.

Extreme caution can work against public health outcomes," said Fugh-Berman, who has written about the benefits of ome herbal medicines. If consumers are told "everything interacts with everything, people will just stop listening."

ellin said that such distinctions appear on the professional version of the database, but not on the consumer Web site.

We put forward what we think is the best advice," he said. If a theoretical harm is deemed potentially significant, such is increased bleeding associated wit.. ginkgo ingestion, it is posted in the interest of consumer protection.

\ distinctive feature of the database is its ability to quickly check interactions between herbal supplements and prescription drugs.

The listing for the popular antidepressant Zoloft, for example, shows interactions with more than 80 supplements and ierbs, including vitamin E, which is often taken to protect the heart.

ellin said his employees combed through 1,450 scientific studies of supplements last year, and he expects the number o be higher this year because of growing scientific research in herbal medicine. Like the newsletter database, the guide s continuously updated.

5/5/06

Talking Points-HB 467 May 3, 2006

For the record I am Virginia Smiley, director of the Division of Pioneer Homes for the Department of Health and Social Services. Mr. Chairman, I would like to give you a very brief overview of the division's position on RNs involvement in administering dietary supplements.

The Pioneer Homes has a procedure for administering supplements that includes a written order from the primary prescribing practitioner, who indicates brand name and dosage. We require a release form signed by the resident or his representative, privately purchased supplements by the family in original, sealed, packaging whose label must include brand name, lot number, expiration date, resident's name, resident's room number, dosage and frequency.

In addition, our pharmacy is informed of any supplement so they can add it into the resident's medication profile and monitor it in reference to diagnosis, disease or possible drug interaction.

Finally our policy includes voluntary agreement by an RN to administer supplements reviewed on a case-by-case basis.

We prefer to have a RNs involvement in supplement administration for the very same reasons we have their involvement in medication administration. If a nurse is unsure about something that has been ordered, the nurse has an obligation to get in touch with the prescriber and ASK questions: why it is being ordered, or could it interfere with other meds?

We expect our nurses to (1) know their residents, and (2) know the risk/benefit of each medication ordered by a prescriber and administered by the nurse. We expect they will treat supplements accordingly.

We would much rather have a nurse involved with a well planned procedure for supplement administration than have a family member bringing in a zip-lock bag full of unknown, unmarked pills, dispensing them in an unsupervised, unstructured manner.

And I would disagree that administering something ordered by a care provider violates any code of ethics or is outside the scope of nursing practice. Practitioners have an obligation to try to do everything they can to improve the quality of life for their patients. And that may include monitoring and administering a supplement that has shown a benefit to an individual patient.

The Board of Nursing has, by their own admission, been grappling with this issue since 1998 yet there is still nothing in statute or their regulations that direct nurses on how to handle this specific issue; there have only been Board of Nursing opinions or positions.

If this legislation does not pass, residents will continue to take supplements in an unsupervised manner, so we are not protecting the public health by eliminating the RN in the process. In fact, for the Pioneer Homes, we could just ask housekeepers or dietary personnel to pass supplements and circumvent the whole issue. But that is not in the best interest of the patient. Having RN involvement is.

In conclusion, the Pioneer Homes support the passage of HB 467.

SENATE COMMITTEE REPORT

DATE: 4/25/06

FURTHER:

DATE TURNED IN TO OFFICE: 5.5.06

Health, Education & Social Services Committee considered CS FOR HOUSE BILL NO. 467(HES) am

HB 467 ADMINISTRATION OF MEDICATION BY A NURSE

"An Act relating to the administration of prescribed remedies and dietary supplements by a nurse."

and recommends:

[ ] be **replaced** with _____ **CS** _____ (_____)

[ ] adopt **previous** _____ **CS** _____ (___ ___)

[ ] attached amendment(s)

[ ] adopt Letter of Intent by _____ Committee

[ ] further referral to _____ Committee

CS Senate Bill:
[ ] Same Title
[ ] New Title

SCS House Bill:
[ ] Same Title
[ ] Technical Title Change
[ ] New Title w/ SCR #_____

NEW FISCAL NOTE(S):

Department	Date	Fiscal	Indet.	Zero	FN#

PREVIOUS FISCAL NOTE(S):

Department	Date	Fiscal	Indet.	Zero	FN#
CED	3/31			x	

[ ] **APPROPRIATION - no fiscal note**

SIGNATURES AND RECOMMENDATIONS:	DO PASS	DO NOT PASS	NO REC	AMEND
~~HRO~~			✓	
Gene Wilken			✓	
Lyda Green			✓	
Donald C. Olson			✓	
CHAIR: Fred Dyson	✓			