

Administration of Dietary Supplements by Registered Nurses in Alaska

A Report and Position Paper by

The Alaska Nurses Association Professional Practice Committee¹

Adopted by: Alaska Nurses Association (AaNA) Board of Directors

Date: June 5, 2006

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¹ A list of committee members is included as Attachment A. Vitae are on file at the AaNA office.

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June 7, 2006

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Background

The 2002 the Alaska Nurses Association (AaNA) General Assembly passed a resolution that directed the AaNA Professional Practice Committee to develop a position paper providing guidelines for nurses on recommending, providing counseling regarding and on safe administration of dietary/herbal supplements.

In April of 2006, AaNA President Debbie Thompson, in response to a letter from a legislator again requested the committee to “investigate the issue in light of recent advances and to come up with a policy recommendation before the AaNA Board meeting.”²

Scope of Issue

It’s estimated that more than 70% of Americans have used an alternative medical therapy in their lives. (retrieved May 17, 2006 from <http://naturalstandard.com>)

More than \$30 billion is spent on herbs/supplements, etc. per year in the U.S. (retrieved May 17, 2006 from <http://naturalstandard.com>)

Dietary supplements are regulated but not approved as drugs by the Food and Drug Administration (FDA); however, the Dietary Supplement Health and Education Act of 1994 (DSHEA) was enacted to help ensure that safe and appropriately labeled products continue to be available to individuals who wish to use them. A dietary supplement is defined as: (retrieved April 19, 2006 from <http://www.cfsan.fda.gov/>)

- *A product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.*
- *Is intended for ingestion in pill, capsule, tablet, or liquid form.*
- *Is not represented for use as a conventional food or as the sole item of a meal or diet.*
- *Is labeled as a ‘dietary supplement.’*
- *Includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision).*

² Letter from Debbie Thompson, President Alaska Nurses Association, to Rep. Mike Kelly, April 3, 2006. We include this letter as Attachment B..

A relative lack of regulatory oversight remains problematic for consumers and health care providers regarding dietary supplements. The majority of dietary supplements in the United States:

- do not require proof of safety,
- are not required to meet any standards of manufacturing,
- do not need to have any proof of efficacy;
- do not need to notify the FDA in cases of harm they may have caused to consumers
- have been shown repeatedly to contain ingredients that are not on the label.³

lynn e. hartz

Comment: This relates to pre and post 1994 and the grandfathering in of all ingredients before 94. Those introduced after 94 are subject to modestly stricter requirements. See consumer report article for specifics. Or fda site. LH

The impact of increasing use of dietary supplements on nursing practice includes but is not limited to:

- Long term care residents taking one or more dietary supplements prior to admission to the facility who wish to continue taking them
- Individuals admitted to an acute care facility taking dietary supplements;
- Known interactions between dietary supplements and prescription drugs; these interactions may be harmful to the individual (e.g., ginkgo biloba and aspirin, warfarin)
- Suddenly stopping some dietary supplements having a negative effect on an individual⁴
- Medication reconciliation is one of the 2006 National Patient Safety Goals set by JCAHO, and many individuals regularly take dietary supplements at home

Currently, the Alaska Pioneers' Home has a policy: Administration of Dietary Supplements Which Are Not FDA-Approved. This policy establishes that:

- Nursing staff members are not required to administer non-FDA approved supplements
- The pharmacy of the Pioneers' Home does not carry dietary supplements
- There is a specific procedure for residents who wish to receive dietary supplements, which includes a release form⁵

The Legislative Research Services of the Alaska Legislature surveyed boards of nursing in nineteen randomly selected states. Responses were received from 13 state boards of nursing, and are summarized in the legislative research report included as attachment C.

- Seven boards of nursing do not prohibit the practice of administering dietary supplements as long as there is a legal order for the supplement.
- Four boards of nursing would not prohibit this practice as long as the nurse or facility have either
 - Obtained appropriate support for supplement use and information about adverse effects in the form of research data
 - Adopted policies and procedures that guide the use of dietary supplements

³ Consumer Reports, 5/04 p.12-17

⁴ personal communication Rita Grenier, RPh, Mary Conrad Center and Providence Extended Care, Anchorage, May 2006.

⁵ Taken from Other States' Policies Regarding Nurses Administering Prescribed Dietary Supplements.

Legislative Research Report Feb. 27, 2006. We include this as Attachment C.

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- Have a legal provider order and demonstrate appropriate knowledge and competency
- Two boards of nursing express reservation about the administration of dietary supplements by a registered nurse and advocate the use of a decision-making model for any nurse considering this practice.⁶

Guiding Principles

The profession of nursing is a dynamic discipline with practice boundaries shifting and growing with the expansion and change of knowledge in response to health care needs of the consumer and health care industry. A determination of whether a particular practice or technique falls within the practice of nursing must therefore rely on qualitative criteria rather than a set list of tasks as any particular list would be rapidly out of date. The profession of nursing is impacted and defined by four main institutions:

- nursing education curricula
- state and national professional nursing association standards, scope of practice statements and certification bodies
- state nurse practice acts
- workplace job requirements.

It is not unusual in American nursing history for one institution to move ahead of the rest creating for a short time a lack of concordance on what is or is not within the practice of nursing. A relatively recent example is that of the role of nurse practitioner. In 1965 an educational institution in Colorado headed by Loretta Ford EdD, FAAN and the late Dr. Henry Silver created a curricula and new role for the registered nurse prior to there being any state nursing board approval, professional scope of practice statement, or job description: these all came later as the other entities caught up.⁷ The role of nurse practitioner seems to functionally be falling well within nursing practice as each institution: education, state practice act, professional association and workplace job description now place the practice of nurse practitioner as being within the practice of nursing.

Therefore, the AaNA position on whether administration of dietary supplements by nurses in Alaska should be considered within the practice of the registered nurse depends on the evidence regarding the current status and trend in practice in the four main institutions in Alaska: education, regulation, professional association and the workplace.

The AaNA Professional Practice Committee reviewed available background information that addresses the current status of nurse administration of dietary supplements related to the following:

⁶ “Nursing Practice Guide RN” from the Pennsylvania State Board of Nursing is included as attachment D.

⁷ Comments from Loretta Ford, “Thursday Night Live with Loretta Ford”, Alaska Nurse Practitioner 20th Annual Conference, 9/11/2003.

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- Administration of dietary supplements in educational nursing curricula in Alaska
- AaNA and ANA Standards of Practice, Scope of Practice Statement, Ethics
- Alaska Nurse Practice Act
- Alaska State Board of Nursing statements/motions/minutes related to nurse administration of dietary supplements
- Workplace job requirements, resources

Findings- Alaska RN Curricula

Education

In 2006, there are three Registered Nursing education programs in Alaska, all offered by the University of Alaska Anchorage:

- Associate of Applied Science (AAS), Nursing Program
- Bachelor of Science (BS), Nursing Program
- Master of Science (MS), Nursing Program
- Separate pharmacology courses are taught in the three RN curricula.
- The AAS and MS pharmacology courses contain objectives that speak directly to dietary supplements and alternative therapies. The BS program intends to include objectives about dietary supplements and alternative therapies.
- Required texts for the AAS, BS, and MS pharmacology courses all include chapters about herbal/dietary supplements and alternative therapies.
- Drug handbooks and a PDA with nursing software are now required for all nursing students in the AAS and BS programs. Both of these resources contain monographs about dietary supplements, charts that summarize uses, interactions, and adverse effects of dietary supplements, and supplement-drug, supplement-food, and supplement-supplement interactions.⁸

Findings- Professional Scope of Practice

AaNA, ANA Scope of Practice, Standard of Practice, Ethics

Is the practice or therapy consistent with the ethical and quality standards embraced by the professional nursing community in the State?

- Standards of care are the skills and learning commonly possessed by members of a profession.
- Standards of Nursing Practice are guidelines for providing high-quality nursing care and criteria for evaluating care.
- Ethics is the science or study of moral values or principles that guide right conduct.
- In Alaska, the ANA Scope and Standards of Practice provide the framework for nursing practice. The ANA Code of Ethics for Nurses provides the framework for conduct of nurses.

⁸ Attachment E includes more specific information on curricula on dietary supplements at the UAA School of Nursing.

Is the practice or therapy contained in standards of practice developed by appropriate nursing associations?

- The ANA Standards of Nursing Practice describes responsibilities for which nurses are held accountable. These standards reflect the values and priorities for the profession, provide direction for professional nursing practice, and is a framework for evaluation of nursing practice (Scope & Standards of Practice, American Nurses Association, 2003, p. 1). Of the 15 Standards, the following are important when making a decision about a particular action:
 - Standard 2. The registered nurse analyzes the assessment data to determine the diagnoses or issues.
 - Standard 3. The registered nurse identifies expected outcomes for a plan individualized to the patient or the situation.
 - Standard 4. The registered nurse develops a plan that prescribes strategies and alternatives to attain expected outcomes.
 - Standard 5. The registered nurse implements the identified plan.
 - Standard 6. The registered nurse evaluates progress toward attainment of outcomes.
 - Standard 7. The registered nurse systematically enhances the quality and effectiveness of nursing practice.
 - Standard 8. The registered nurse attains knowledge and competency that reflects current nursing practice.
 - Standard 9. The registered nurse evaluates one's own nursing practice in relation to professional practice standards and guidelines, relevant statutes, rules, and regulations.
 - Standard 13. The registered nurse integrates research findings into practice.
 - Standard 14. The registered nurse considers factors related to safety, effectiveness, cost, and impact on practice in the planning and delivery of nursing services.

Is the nurse prepared to accept full responsibility for his/her action and be accountable to the client or patient?

- The degree of responsibility for a nurse's actions is dependent on the nurse's preparation, knowledge and skill, and demonstrated competence. The Alaska Board of Nursing approves all nursing education programs in the State, and such approval is evidence that the curriculum is satisfactory. All registered nurses in Alaska have either successfully passed the NCLEX-RN or been granted licenses upon presentation of a valid license in another state.
- The practice of registered nursing is guided by the Code of Ethics (American Nurses Association, 2001). Item #4 of the Code of Ethics states,
 - The nurse is responsible and accountable for individual nursing practice and determines the appropriate delegation of tasks consistent with the nurse's obligation to provide optimum patient care. (American Nurses Association, *Code of Ethics for Nurses with Interpretative Statements*, 2002, p. 16.)

- When a nurse is **accountable**, he/she is answerable to themselves and others for his/her actions. Accountability for actions is independent of health care facilities' policies or provider orders.
- When a nurse accepts **responsibility** for practice, he/she continually assesses his/her competence. When a situation calls for qualifications and competencies beyond that of the nurse, he/she seeks consultation, support, and education to advance his/her competence prior to performing duties.

Findings-Alaska Nurse Practice Act

In 2006, there are no statutes or regulations that permit or prohibit administration of dietary supplements by a registered nurse. Under the statutory definition of “practice of registered nursing”, two statutes could broadly be interpreted to relate: Sec. AS.68.410 (9) (D) “execution of a medical regimen as prescribed by a person authorized by the state to practice medicine, and (E) performance of other acts that require education and training that are recognized by the nursing profession as properly performed by registered nurses.” The last statement in the statute is of interest, as it appears to give some statutory authority for the nursing profession to “recognize” acts as “properly performed by registered nurses” which is at the crux of this committee’s task.

Findings-Alaska State Board of Nursing

In 1998 the Alaska Board of Nursing published an opinion that it was “outside the scope of nursing practice to administer remedies that are not FDA approved.” (Board of Nursing minutes, December 10-11, 1998, p. 8) The Board’s position remained unchanged in 1999. In September of 2002 the Alaska Board of Nursing passed a motion regarding dietary supplements which stated, “The Board of Nursing having considered the current lack of regulatory oversight of dietary supplements in regard to ingredients, potency and contaminants view dietary supplement administration as incurring unknown risks to clients, therefore the Board does not support nurse administration of dietary supplements at this time.”⁹ Although not in support, the Board’s position in 2002 no longer contained the statement that administration was “outside the scope of nursing practice” and appeared to leave the door open for change at some future “time”.

Findings-Alaska Workplace Survey Summary

An informal workplace survey was sent by email to nurses at various facilities in the state. Results were received from eight facilities representing all areas of the state including acute

⁹ Alaska State Board of Nursing Minutes. September 2002 page.....
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care as well as long-term care. No assisted living facilities were included. A copy of the email explanatory note and survey are included in the attachments.¹⁰

- Prescribed vitamins and minerals are administered by nurses in 100% of the 8 responding facilities.
- Prescribed herbs are administered by nurses in 50% of facilities although it was noted by respondents in two facilities that those circumstances were rare.
- In three out of the eight facilities nurses administer prescribed botanicals, amino acids, enzymes, organ tissues, glandulars or metabolites.
- Seven out of eight facilities have a pharmacist available to consult regarding dietary supplements though one comment was that the pharmacist might refer on to the dietician if needed.
- Information on dietary supplements is available to nurses at all facilities, usually through more than one modality. The Internet was most commonly listed in 7 out of 8 facilities followed by intranet (6:8), books (6:8) and drug databases (4:8).
- The final question in the survey had to do with what, if any dietary supplements were administered in the facility and asked the person completing the survey to list the supplements in order of frequency. In this case, the supplements might be given by family or other caregivers as is was not stipulated that the nurse was administering the dietary supplement. Other than multivitamins, Ensure, calcium and iron, no other supplements listed were the same from respondent to respondent. A number of supplements were listed which include; Peptamen products, potassium, glucosamine, senna, saw palmetto, black cohosh, garlic, ginkgo, thiamine, folate, pancreatic enzymes, vitamin C, zinc and magnesium.

Findings-Workplace Job Requirements/Resources

Are there sufficient resources in the workplace to support this practice?

- Although dietary supplements are not approved by the FDA, the United States Pharmacopoeia (USP, <http://www.usp.org>) has established a voluntary third-party evaluation process to ensure that good manufacturing processes are used in the production of supplements that have been submitted. Examples of manufacturers that participate in this program are NatureMade, Kirkland, and Schiff. Products that have been through this process carry the label, USP-Verified. The USP will not verify products that contain ingredients known to have safety concerns, such as ephedra.
- ConsumerLab.com is another independent evaluator of dietary supplements.
- In 2006, most acute care and long term care facilities in Alaska have access to MicroMedex, a Web-based database of prescription and over-the-counter drugs. This database is updated regularly, and contains a description of indications, mechanism of action, dose range, interactions, side effects, and adverse reactions.
- The pharmacy that serves Providence Extended Care Center and the Mary Conrad Center use an OTC formulary, a generic drug formulary, and a legend drug formulary when dispensing drugs to residents.

¹⁰ Attachments F and G

- The Natural Standard is an international multidisciplinary consortium that reviews scientific studies about herbal/dietary supplements and analyzes the evidence for efficacy. This resource requires registration and is available to health care providers in Alaska through the University of Alaska Consortium Library's Health Sciences Information Services (HSIS, <http://lib.uaa.alaska.edu/hsis/index.php>).
- Medline Plus (<http://www.nlm.nih.gov/medlineplus/druginformation.html>) is a public resource that also lists a summary of available scientific evidence about dietary supplements.

Conclusions

- **Education- Nursing education curricula in Alaska now includes dietary supplements in all three Registered nursing programs that are offered.**
- **Professional Association- Administration of medications is a core skill commonly possessed by members of the profession. Administration of vitamins and minerals are the standard of care in Alaska with limited administration of other dietary supplements. With the ready availability of basic education or continuing education in these subjects and the workplace resources available, nurses choosing to administer dietary supplements in Alaska should be able to perform this practice within the guidelines of the ANA Scope and Standards of Practice and the ANA Code of Ethics.**
- **Alaska Nurse Practice Act- Does not preclude. Other nurse practice acts have been interpreted to incorporate new therapies. " A number of complementary therapeutic modalities have long been incorporated into standard nursing practice to assist patient in meeting identified health needs and goals." [retrieved from Texas <http://www.bne.state.tx.us/position.htm#15.23>]**
- **State Board of Nursing- Most recent motion 2002 does not support "at this time".**
- **Workplace requirement- vitamins and mineral administration are a job requirement of the nurse, herbs somewhat, others dietary supplement administration seems to occur but without a pattern.**
- **Resources available –Multiple resources regarding dietary supplements are now available to nurses including nursing textbooks, personal digital assistant databases with weekly updates, facility internet databases and pharmacist consultants.**

The current status and trend of practice in Alaska indicate that limited administration of dietary supplements (vitamins and minerals) by registered nurses is established, ongoing and should be recognized as properly performed by registered nurses. Educational curricula, workplace requirements and demands of the consumer are steadily pushing the boundaries further into the federal definition of dietary supplements including administration of herbs and other prescribed botanicals. The Alaska Nurses Association supports administration of dietary supplements by the registered nurse with the following recommendations:

Recommendations

Administration of Dietary Supplements

- Facilities refrain from creating specific lists of dietary supplements that registered nurses would administer.
- Registered nurses should evaluate provider orders for dietary supplements for appropriateness in the same manner as is done for orders for FDA-approved drugs.¹¹
- When a patient/client wishes to take their own meds, and this includes dietary supplements, a AaNA recommends the following:
 - An authorized provider writes an order.
 - The patient/client must bring in all drugs in their original containers. In the case of a dietary supplement, the container must be unopened and sealed by the manufacturer.
 - Only dietary supplements that are manufactured by companies on the facility formulary and/or those that have been USP-verified will be administered (to ensure quality control of manufacturing).
 - The pharmacist, prescriber, and registered nurse should evaluate the dietary supplement and prescribed drugs for possible interactions.
 - The patient's medications and dietary supplements should be evaluated by a pharmacist, and a designation authorizing use can be placed in the patient/client's chart.
 - The registered nurse has the option to decline to administer the dietary supplements.
 - Documentation of doses taken should follow facility policy. Suggestions include a sheet that the patient/client maintains, or the facility's medication administration record.
 - In facilities without pharmacies, nurses should restrict their recommendations, counseling and administration to USP – verified dietary supplements only. No other organization in the U.S. that tests supplements is recognized in federal law as the nation's official standard-setting body for medicines and supplements. USP standards are enforceable by the FDA. [see Attachment I]
- Continuing education about dietary supplements should be available to nursing staff.
- Nursing staff has 24/7 access to consultation with pharmacists, print materials, Web-based materials, and electronic materials about dietary supplements (indications, mechanism of action, dose ranges, expected outcomes, side effects and adverse reactions).

¹¹ **Suggestions for Resolving Conflicts in Drug Therapy, Institute for Safe Medication Practices included as Attachment H.**

Counseling Patients on Dietary Supplements

When counseling individual about taking dietary supplement, nurses should use guidelines such as “Tips for the Savvy Supplement User” (US Food and Drug Administration, Center for Food Safety and Applied Nutrition: <http://www.cfsan.fda.gov/~dms/ds-savvy.html#basic>) and educate patients on the following:

- Dietary supplements are regulated more like foods than drugs. In many cases there are no data to show how or even if these supplements work as the manufacturer claims.
- Dietary supplements can interfere with medications the patient is already taking and the patient or family should always let the nurse administering and prescriber know all medications and supplements they are taking.
- Many supplements should be stopped 2-3 weeks before surgery, as they could cause unwanted changes in heart function or bleeding.
- Nurses who counsel and recommend dietary supplements must be informed. The Internet is a great site to find information about dietary supplements. Consumers and professionals should be sure to use websites that are run by governmental agencies (.gov), universities (.edu), or reputable health/medical agencies such as the American Heart Association, National Institutes of Health, US Food and Drug Administration).¹²
- Nurses counseling patients regarding dietary supplements should recommend choosing the manufacturer wisely, since the manufacture of dietary supplements is not regulated. Some companies have participated in a voluntary program from the US Pharmacopoeia (USP) that examines the company’s manufacturing processes. Supplements from these companies will be marked with “USP-Verified”. No other organization in the U.S. that tests supplements is recognized in federal law as the nation’s official standard-setting body for medicines and supplements. USP standards are enforceable by the FDA.

¹² See Attachment J for list of suggested websites.

Circulation:

ANA

Governor Murkowski

Rep. Donny Olson?

Alaska State Board of Nursing

AaNA members through Alaska Nurse summary

AaNA Affiliates

Professional Practice Committee members

Representative Mike Kelly

Facility Survey participants

Senate and House HESS Committee members

ASHNA

Attachment A - AaNA Professional Practice Committee Members:

Member	Organization	Position	Contact	City
Chairperson: Patricia Hong MA,RN, CCRN	UAA School of Nursing	Professor Emerita	786-4578	Anchorage
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Attachment B – AaNA Pres. Letter to Rep. Kelly



April 3, 2006

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 health care, 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.

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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 have also been steps taken to improve the oversight of production of these substances. As of this writing the United States Pharmacopoeia (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 to come up with a policy recommendation before the AaNA Board meeting. We would be happy to share these recommendations with you.

Thank you again for requesting our input on this important issue.

Sincerely,
Debbie Thompson, RN, BSN
President, Alaska Nurses Association

**Attachment C – Other States’ Policies Regarding Nurses Administering
Prescribed Dietary Supplements, Legislative Research Report**

[the complete legislative report is at the end of this report]

Attachment D – Nursing Practice Guide Pennsylvania State Board of Nursing

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NURSING PRACTICE GUIDE
RN

The following series of questions is intended as a suggested guideline to help you determine whether a specific practice that you might undertake is 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 permitted or prohibited by the Pennsylvania nursing practice acts or regulations?
2. Does the practice require you to have, and do you in fact have, the specialized nursing knowledge, preparation, experience, skill and competency? (See, Sections 21.11(c) and 18(a)(1) of the Board's regulations, 49 Pa. Code §§21.11(c) and 18(a)(1))
3. Is the practice consistent with the ethical and quality standards embraced by the professional nursing community in the Commonwealth? (See, Section 14(a)(9) of the Professional Nursing Law, 63 P.S. §224(a)(9))
4. Is the practice contained in standards of practice developed by appropriate nursing associations? (Section §21.11(d) of the Board's regulations, 49 Pa. Code §21.11(d))
5. Are you prepared to accept full responsibility for your action and be accountable to the client or patient? (See, Sections 21.11(b) and 21.18 of the Board's regulations, 49 Pa. Code §§21.11(b) and 21.18)

The Board cannot, by law, pre-approve a specific practice. 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.

Adopted September 27, 1999
Amended October 25, 1999

Attachment E – Dietary Supplements in Alaska Nursing Curricula

The AAS Nursing Program

NURS 180, Basic Nursing Pharmacology: taught in the 2nd semester of the AAS Program
Objectives from syllabus: (found in the Outreach syllabus, but not yet in the Anchorage syllabus)

1. Unit 1: Identify the advantages and disadvantages of prescription and over-the-counter (OTC) drugs.
2. Unit 6:
 - Describe the functions of common vitamins and minerals
 - Compare and contrast the properties of water-soluble and fat-soluble vitamins.
 - Identify diseases and conditions that may benefit from vitamin or mineral pharmacotherapy.
 - Describe the nurse's role in the pharmacologic management of nutritional disorders
 - Compare and contrast the properties of macrominerals and trace minerals.
3. Unit 8: Describe the nurse's role in the pharmacologic management of disorders caused by calcium and vitamin D deficiency.

Texts:

- Adams, M.P., D.L. Josephson, L.N. Holland, Jr. Pharmacology for Nurses: A Pathophysiologic Approach
- Chapter 11: Herbal and Alternative Therapies (8 pages). Preparations are found in tables, the text is more broadly focused.
 - the role of complementary and alternative medicine
 - reasons for the popularity of herbals and dietary supplements
 - parts of the herb that contains active ingredients
 - the Dietary Supplement Health and Education Act (DSHEA)
 - adverse effects of herbal preparations
 - role of the nurse in teaching about complementary/alternative therapies
 - common drug-herbal interactions
- Saunders Nursing Drug Handbook, 2006
 - Appendix G, Herbal Therapies and Interactions (see attached)
 - Common herbal preparations included in database (e.g., St. John's wort, ginseng, ginkgo biloba, glucosamine/chondroitin)
 - Action
 - Uses
 - Precautions (Contraindications, Cautions, and Lifespan considerations)
 - Interactions (Drug, Herbal, Food, Lab Values)
 - Availability
 - Indications/Routes/Dosage
 - Side Effects
 - Adverse Reactions/Toxic Effects
- Pepid Student RN (required database program for all generic nursing students)
- Herbal/dietary supplements available on database (e.g., glucosamine sulfate, glucosamine MSM, St. John's wort, St. Mary thistle, ginkgo biloba, goldbloom)
 - Dosing
 - Contraindications
 - Uses

- Mechanism of action
- Adverse drug reactions
- Kinetics/dynamics
- Pregnancy/lactation
- Interactions
- Other names
- Other information
- Evidence-based inquiry

Bachelor of Science, Nursing Program

The pharmacology course has not been assigning the chapter on supplements and herbal preparations. It is being added now.

- The more well-known herbal remedies in the related module in other courses. For example, glucosamine is mentioned in M/S; St John's wort is covered with the anti-depressants, etc.
- Vitamin concerns are often mentioned in the drug modules.

Texts:

- Lehne (2004) (Saunders).
 - It has a chapter entitled: Herbal Supplements.
 - 10 pages
 - Discusses the following herbal supplements: Aloe, black cohosh, Echinacea, feverfew, garlic, gingerroot, ginkgo, goldenseal, kava, ma huang (ephedra), St. John's wort, saw palmetto & valerian.
 - For the supplements listed above the book discusses use, preparations, actions, effectiveness, adverse effects and for some -- drug interactions. It is interesting to note that there is no section on nursing implications in the herbal supplement chapter. This section is standard in other chapters in the book.
 - Includes 4 pages of general concerns regarding herbal supplements in general.
 - Davis' Drug Guide
 - About 20 full monographs on the most commonly used herbals
 - Herbals in a separate class
 - Appendix includes monographs on the most commonly used herbals
 - Pepid software (as above)

Master of Science, Nursing Program

Learning objectives for the Advanced Pharmacology course include

- a statement about dietary and herbal supplements specifically related drug interactions
- herbal and dietary supplements used as treatments in a variety of diseases throughout the course

There is also a three hour lecture on dietary supplements from Bethany Buchanan, FNP, who incorporates dietary supplements into her practice.

Texts

- Edmunds & Mayhew (2004) Pharmacology for the Primary Care Provider, 2nd edition.
 - Chapter 74, Vitamins and Minerals, pp 773-791

- Chapter 75, Complimentary and Alternative Medicine, pp 792-805. Chapter 75, in particular, is specific to the use of herbals

Attachment F - Email attached to survey of health care facilities in Alaska

AaNA Survey Regarding Registered Nurses Administering Dietary Supplements”.

The Professional Practices Committee of the Alaska Nurses Association is conducting this survey. We have been tasked with writing a position paper on RN administration of dietary supplements in facilities in Alaska. Patti Hong is the Chairperson and we have members from around the state who have helped come up with names and contacts who either might have the information themselves or know who to get this survey to who could answer these questions. In order to come up with an official position that we can then share with our Board of Directors, state legislators who have requested our input and the state Board of Nursing, we need to know what resources nurses have available to them where they work. Although the issue of nurses administering dietary supplements seems to have come up primarily in long-term care such as the Pioneer Homes, the committee has added acute care facilities to the survey.

The committee hopes to draft a paper by the end of May. Therefore this survey is short and going out as an email.

Carol Clouse typed up the survey and instructs the following: open the attached survey and save it to your computer; fill it out, I suppose you could do a 'save as' with your city in front of "Survey" at that point so that you know the file you are dealing with is the filled out survey.. Create an email to lhartz@alaska.com, attach your filled out survey and return. I am not a whiz at computers but think it should work. If you run into problems you can also contact Patti Hong at mikepat@gci.net.

Thanks so much,
Lynn Hartz

Attachment G

**AaNA Survey Regarding Registered Nurses Administering
Dietary Supplements ***

Date:
Person completing survey:
Position:
Facility: City:
Contact phone: Email contact:

1. Do nurses in your facility currently administer prescribed vitamins and minerals?
YES ____ NO ____

2. Do nurses in your facility currently administer prescribed herbs?
YES ____ NO ____

3. Do nurses in your facility currently administer other prescribed botanicals, amino acids, enzymes, organ tissues, glandulars or metabolites?
YES ____ NO ____

4. Which of the following do you have available at your facility to obtain information on dietary supplements? Please mark all that apply.
a. books ____ b. internet ____
c. drug databases ____ d. intranet ____

5. Do you have a pharmacist available to consult regarding dietary supplements?
YES ____ NO ____

6. If dietary supplements are administered in you facility, please list the five most common supplements in order of frequency
a. b.
c. d.
e.

*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.

Thank-you for your time! Please return ASAP to lhartz@alaska.com
[5/10/06 C:aANA. Survey Regarding Registered Nurses Administering.rtf]

Attachment H – Suggestions for Resolving Conflicts in Drug Therapy

Institute for Safe Medication Practices [www.ismp.org]
ISMP Medication Safety Alert acute care newsletter
From the May 29, 1998 issue:

“Suggestions for Resolving Conflicts in Drug Therapy”

Many serious medication errors reported to us have involved a drug order that at least one practitioner believed to be unsafe. In some cases, practitioners did not question the order because they were intimidated by the prescriber. More often, practitioners questioned the order by discussing it with a supervisor, pharmacist or physician. Nevertheless, the practitioners’ concerns were not addressed, the order was not changed, and the medication was administered in error. The missing link in preventing these errors is a clear process for handling drug therapy concerns, which concludes only when all practitioners are satisfied that no harm will come to the patient. Although each process may vary to meet the unique needs of the organization, we recommend that you follow these guidelines for handling concerns and conflict with drug therapy orders:

1. If a nurse is concerned that the physician-ordered drug therapy may not be safe, contact the pharmacist. This step is critical, especially when the drug ordered will be removed from unit stock or a patient’s medication supply from home. The pharmacist must take an active role in determining the safety of the drug order and not delegate order clarification to nursing staff. Investigate the safety of the order and contact the practitioner as needed.
2. If the pharmacist suspects that drug therapy is potentially harmful, he/she should pursue the matter until satisfied that the therapy will not harm the patient, or until the order is changed. Completely research the issue before contacting the ordering physician so your concerns can be clearly communicated and based on facts, not your opinion. Confirmation of an order’s safety may come from reviewing the medical record, talking with the patient, researching the matter through reputable drug resources, consulting with other pharmacists or physicians or discussing the order

directly with the prescriber. Request supporting documentation (protocols, journal article, etc.) from the prescriber to verify the safety of the order but read it carefully. Many errors begin with the physician misinterpreting published information, misprints in texts, or ambiguous statements in the reference.

3. If the pharmacist is not satisfied that the patient won't be harmed, and the prescriber will not change the order, consult with the prescriber's chief resident, chief attending physician, department chairperson or a specialist in the area of drug therapy ordered. If the individual consulted agrees that the order may be unsafe, have them contact the ordering physician.
4. If concerns about drug therapy persist despite the above efforts, consider whether more significant harm would result from administering the drug than from withholding it. Refuse to dispense (or administer) the drug if you are reasonably sure that withholding the drug is the safest action. Refer the issue to an ad-hoc group for peer review to determine the order's safety.
5. Do not request or allow the physician to give the drug themselves when a concern for patient safety remains unanswered. Patient safety is not served by attempting to transfer responsibility to the physician for any patient harm resulting from drug administration. There will likely be little legal or emotional absolution for the pharmacist or nurse if the patient is injured.
6. Be sure to document your actions objectively on a standard incident report.

Attachment I USP-Verified Dietary Supplements

Who We Are

The United States Pharmacopeia (USP) is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States. USP sets standards for the quality of these products and works with healthcare providers to help them reach the standards. USP's standards are also recognized and used in more than 130 countries. These standards have been helping to ensure good pharmaceutical care for people throughout the world for more than 185 years.

USP is an independent, science-based public health organization. As a self-sustaining nonprofit organization, USP is funded through revenues from the sale of products and services that help to ensure good pharmaceutical care.

Our Mission

USP promotes the public health by developing and disseminating quality standards and information for medicines, healthcare delivery, and related products and practices. Our standards and information help patients and practitioners maintain and improve health.

What We Do

Product Quality—Standards and Verification

USP establishes public standards to help assure good quality medicines, dietary supplements, and related products used to maintain health and treat disease. Prescription and over-the-counter medicines available in the United States must, by federal law, meet USP's public standards, where such standards exist. Many other countries require the use of high-quality standards such as USP's to assure the quality of medicines and related products. USP disseminates its standards to pharmaceutical manufacturers, pharmacists, and other users through its [USP–NF](#) and other publications, official USP [Reference Standards](#) materials, and [Pharmacopeial Education](#) courses.

USP also conducts [verification programs](#) for dietary supplement ingredients and products. These programs involve independent testing and review to verify ingredient and product integrity, purity, and potency for manufacturers who choose to participate.

Overview – Dietary Supplement Verification Program

In response to increasing consumer concerns about dietary supplements, USP established a rigorous third-party testing program to verify the integrity of dietary supplements submitted by manufacturers voluntarily participating in the program. USP then extended its verification

capabilities by developing a program to verify the quality of ingredients used in the manufacture of dietary supplements. USP's verification programs draw upon its experience of more than 185 years in setting federally recognized public standards for medicines and dietary supplements. USP's independent nonprofit status and its volunteer-based scientific expertise lend authority and credibility to its verification programs.

USP-Verified Dietary Supplements

The USP-Verified mark on a dietary supplement label helps to assure consumers that the supplements they buy provide the expected value. See which [companies are participating](#) in the USP-Verified program. Get a list of [verified supplements](#) and find out where they're available. Learn how USP verifies supplements. Find out how supplement manufacturers can [join the program](#).

USP-Verified Ingredients

USP verifies active and inactive ingredients used in the manufacture of dietary supplement products. The USP-Verified Ingredient mark helps manufacturers recognize that they are buying ingredients of consistent quality for use in the supplements they manufacture. Learn which [companies are participating](#) in the ingredient verification program. Get a list of [verified ingredients](#). Learn [how](#) USP verifies ingredients. Find out how ingredient manufacturers can join t USP-Verified Dietary Supplements program.



What the USP-Verified Mark Means on a Supplement Label

The distinctive USP-verified mark represents that USP has rigorously tested and verified the supplement, to assure the following:

1. What's on the label is in fact in the bottle—all the listed ingredients in the declared amount.
2. The supplement does not contain harmful levels of contaminants.
3. The supplement will break down and release ingredients in the body
4. The supplement has been made under good manufacturing practices.

USP is an independent, not-for-profit organization. No other organization in the U.S. that tests supplements is recognized in federal law as the nation's official standard-setting body for medicines and supplements. USP standards are enforceable by the FDA.

Why it's Important to Know What USP-Verified Assures

1. **Integrity** Tests based on USP standards have shown that contents of many supplements sold in retail stores don't match the label and that some supplements contain significantly less or more than the claimed amount of key ingredients. There may be a serious health risk when supplements taken to prevent a specific health problem do not contain ingredients in appropriate quantities. You must be sure of the identity and amount of ingredients in your supplements if you want to be sure you're getting value for your money.
2. **Purity** Some supplements may contain lead, mercury, other heavy metals, pesticides, bacteria, molds, toxins, or other potentially harmful contaminants. You must be sure these contaminants are not present at levels that can cause health problems.
3. **Dissolution** If a supplement does not break down properly to allow its ingredients to dissolve in the body, it means you won't get the full benefit of its contents. It's important for you to know that the supplement has been tested against recognized standards, as the USP-Verified mark indicates.
4. **Safe manufacturing** Assurance of safe, sanitary, well-controlled, and well-documented manufacturing and monitoring processes is proof that the supplement manufacturer is quality-conscious and concerned for your well-being.

Find out about USP's [professional education program](#) on dietary supplements.

[retrieved from <http://www.usp.org/USPVerified/>]

Attachment J – Website Resources on Dietary Supplements

- Federal Food and Drug Administration: Center for Food Safety and Applied Nutrition <http://www.cfsan.fda.gov/>
- Institute for Safe Medication Practices. A nonprofit organization educating the healthcare community and consumers about safe medication practices. Phone (215) 947-7797. <http://www.ismp.org/about/Default.asp>
- Medline Plus, a service of the National Institute of Health and the National Library of Medicine <http://medlineplus.gov>
- Natural Standard, the Authority on Integrative Medicine (requires registration through the UAA Health Sciences Information Service: <http://lib.uaa.alaska.edu/hsis/>)
- <http://naturalstandard.com>
- US Pharmacopeia <http://www.usp.org> . United States official standard-setting body for medicines and supplements. USP standards are enforceable by the FDA.
- National Sanitation Foundation :www.nsf.org is a not-for-profit, non-governmental organization dealing with standards development, product certification, education, and risk-management for public health and safety. It has relationships with the World Health Organization and FDA.