ALASKA STATE LEGISLATURE
HOUSE HEALTH, EDUCATION AND SOCIAL SERVICES STANDING COMMITTEE
April 6, 2006
3:04 p.m.

MEMBERS PRESENT

Representative Peggy Wilson, Chair
Representative Paul Seaton, Vice Chair
Representative Carl Gatto
Representative Vic Kohring
Representative Sharon Cissna
Representative Berta Gardner

MEMBERS ABSENT

Representative Tom Anderson

COMMITTEE CALENDAR

HOUSE BILL NO. 467
"An Act relating to the administration of prescribed remedies and dietary supplements by a nurse."

- HEARD AND HELD

SENATE BILL NO. 177
"An Act eliminating the requirement that persons using titles or descriptions of services that incorporate the terms 'psychotherapy,' 'psychotherapeutic,' or 'psychotherapist' be licensed by the Board of Psychologist and Psychological Associate Examiners."

- SCHEDULED BUT NOT HEARD

HOUSE BILL NO. 482
"An Act relating to harassment, intimidation, and bullying in schools."

- SCHEDULED BUT NOT HEARD

HOUSE JOINT RESOLUTION NO. 30
Relating to public health and a prevention compact.

- BILL HEARING CANCELED

PREVIOUS COMMITTEE ACTION

BILL: HB 467
SHORT TITLE: ADMINISTRATION OF MEDICATION BY A NURSE
SPONSOR(s): REPRESENTATIVE(s) KELLY

02/13/06	(H)	READ THE FIRST TIME - REFERRALS
02/13/06	(H)	HES, FIN
03/28/06	(H)	HES AT 3:00 PM CAPITOL 106
03/28/06	(H)	<Bill Hearing Postponed to 03/30/06>
03/30/06	(H)	HES AT 3:00 PM CAPITOL 106
03/30/06	(H)	-- Meeting Canceled --
04/04/06	(H)	HES AT 3:00 PM CAPITOL 106
04/04/06	(H)	<Bill Hearing Postponed to 04/06/06>
04/06/06	(H)	HES AT 3:00 PM CAPITOL 106

WITNESS REGISTER

DEREK MILLER, Staff
to Representative Michael “Mike” Kelly
Alaska Legislature
POSITION STATEMENT: Presented HB 467 on behalf of Representative Kelly, sponsor.

CATHERINE GIESSEL, Registered Nurse (RN)
Advanced Nurse Practitioner;
Chairperson, Alaska Board of Nursing
Anchorage, Alaska
POSITION STATEMENT: Testified in opposition of HB 467.

GENA EDMISTON, Registered Nurse (RN)
Associate Administrator
Denali Long-term Care Center
Fairbanks Memorial Hospital
Fairbanks, Alaska
POSITION STATEMENT: Testified in support of HB 467.

RICK SCHIKORA, Certified Public Accountant (CPA)
Fairbanks, Alaska
POSITION STATEMENT: Testified in support of HB 467.

MIKE POWERS, Administrator
Fairbanks Memorial Hospital
Fairbanks, Alaska
POSITION STATEMENT: Testified in support of HB 467.

CHARLOTTE DAVIS, Registered Nurse (RN)
Fairbanks, Alaska
POSITION STATEMENT: Testified in opposition to HB 467.

VIRGINIA SMILEY, Director
Division of Pioneer Homes
Department of Health and Social Services (DHSS)
Juneau, Alaska
POSITION STATEMENT: Testified in support of HB 467.

NANCY DAVIS, Registered Nurse (RN)
Representative
Alaska Nurses Association (ANA)
Juneau, Alaska
POSITION STATEMENT: Testified in opposition to HB 467.

ROD BETIT, President
Alaska State Nursing Home Association (ASNHA)
Juneau, Alaska
POSITION STATEMENT: Testified in support of HB 467.

ACTION NARRATIVE

CHAIR PEGGY WILSON called the House Health, Education and Social Services Standing Committee meeting to order at 3:04:48 PM. Representatives Seaton, Gatto, Cissna, and Wilson were present at the call to order. Representatives Kohring and Gardner arrived as the meeting was in progress.

HB 467-ADMINISTRATION OF MEDICATION BY A NURSE

3:05:40 PM

CHAIR WILSON announced that the first order of business would be HOUSE BILL NO. 467, "An Act relating to the administration of prescribed remedies and dietary supplements by a nurse."

3:06:10 PM

CHAIR WILSON stated that her intention would be to hear and hold HB 467, to allow continued committee discussion.

REPRESENTATIVE SEATON moved to adopt HB 467, Version 24-LS1265\G, as the working document. There being no objection, Version G was before the committee.

3:07:10 PM

DEREK MILLER, Staff to Representative Michael “Mike” Kelly, Alaska Legislature, sponsor, introduced HB 467 on behalf of

Representative Kelly, paraphrasing from a written statement, which read as follows [original punctuation provided]:

> Before you today is HB 467. This bill was introduced with the goal of working out a reasonable solution to the current Board of Nursing policy that prevents most registered nurses in the state of Alaska from administering prescribed remedies and dietary supplements for patients in a nursing facility, an assisted-living home, or an Alaska Pioneers' Home. In recent years the Board of Nursing has determined that it is outside of the scope of practice for a nurse to administer remedies that are not FDA approved even if the patient requests them, the doctor prescribes them, and the facility has approved written procedures for administering them. We believe this is too restrictive and HB 467 would allow nurses to administer such remedies provided that it is a prescribed remedy or dietary supplement administered within the manufacturer's recommended dosage.
>
> This legislation was introduced after Rep. Kelly received a letter from Rick Schikora in Fairbanks. Mr. Schikora's grandmother lives in the Fairbanks Pioneer Home and she has bad knees and dementia. Her doctor prescribed glucosamine and fish oil pills and nurses were willing to administer them, but because of the Board of Nursing decision, the Pioneer Home discontinued their administration. Mr. Schikora was forced to go to the Pioneer Home daily to give her the prescribed remedies.
>
> This seems to just make good sense to fix this problem and we have found many lay and professional folks who agree. We think current policy is not in the best interest of the patient and we propose a common sense solution. Other states have found ways to safely administer these supplements and HB 467 would permit Alaska to do the same.

3:08:55 PM

REPRESENTATIVE SEATON referred to page 1, line 14, and page 2, lines 1-2, and read, "'prescribed remedy or dietary supplement'" includes over-the-counter, herbal, and vitamin remedies prescribed by a person authorized under this title to prescribe the remedy or supplement." He asked who would be authorized

under this title to prescribe remedies or supplements; would more than one category of persons be identified to prescribe; and do supplements generally require prescriptive authority prior to purchase.

MR. MILLER responded that prescriptive authorization would be required for the administration of supplements in this context, and that the prescription would be written by a physician. He stated that there may be other individuals who would be provided prescriptive authority under this statute.

3:10:01 PM

REPRESENTATIVE SEATON asked to have statute checked in this regard to ascertain if a requirement exists for the prescription of supplements. Further, he inquired:

> [Is] ... this bill ... saying that even if [a substance] doesn't need to be prescribed, it ... [could] only be administered by a nurse if it ... [were] prescribed by a physician.

MR. MILLER confirmed that the bill provides for a nurse to administer prescribed substances only, including dietary supplements.

3:10:39 PM

CHAIR WILSON inquired who would have prescriptive authority.

MR. MILLER stated that he would be able to provide the committee with that information at a later time.

3:11:17 PM

CATHERINE GIESSEL, Registered Nurse (RN), Advanced Nurse Practitioner; Chairperson, Alaska Board of Nursing, stated her history of work in the field of health care, and highlighted her care for patients of various ages and facilities. She paraphrased from the following Alaska Board of Nursing Position Paper, March 2006, which read as follows [original punctuation provided]:

> **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.

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.

MS. GIESSEL continued her testimony and explained how some supplements, that may otherwise be considered safe, could cause adverse effects if administered in the company of prescribed medication, and she provided examples. She stressed that nurses are not trained in the area of non-FDA approved drugs, or how to recognize complications from non-regulated supplements. She said that elderly patients are vulnerable, and public safety is a key issue. She underscored that nurses are held accountable for the care provided to a patient and that these types of substances are outside the scope of practice for a nurse. Referring to a research paper provided in the committee packet, she deemed that the sample was insufficient with only 13 of the nation's 61 nursing boards polled. Finally, she highlighted that signed waivers do not provide a nurse with adequate legal protection.

3:24:59 PM

REPRESENTATIVE GARDNER asked what would happen if a physician gave orders, which a nurse considered to be contrary to the patient's welfare.

MS. GIESSEL responded that, in such a situation, it is a nurse's responsibility to decline to carry out a physician's order; not a rare occurrence. Responding to a question, she opined that the research regarding supplements is not highly regarded or publicized, as it is often conducted by the supplement industry, and she stated that information on negative health effects caused by supplements is not commonly available.

3:28:19 PM

REPRESENTATIVE GATTO offered information on two supplements, no longer available on the market as it was alleged that they may have caused negative health effects, thus supporting her concerns.

MS. GIESSEL explained the difference of how the FDA scrutinizes approved drugs versus the accountability standard placed on the supplement industry. She stressed that negative affects of non-regulated supplements are not subject to the same reporting and obligation for recall. Additionally, she said that although the FDA may investigate when a supplement is reported to be injurious, the department is limited in its resources to determine the safety of the majority of substances available from the supplement industry.

3:30:17 PM

REPRESENTATIVE SEATON stated his understanding that a physician's decision would be considered inadequate when recommending a supplement, and that a nurse would be unable to legally administer prescriptions for substances other than FDA approved drugs.

MS. GIESSEL explained that Alaskan law allows physicians, nurse practitioners (NPs), and physician assistants (PAs) prescriptive authority; however, the person on a patient's medical team who administers the prescribed substance is the registered nurse (RN). Further, she stated that the reason non-FDA approved substances are at issue is because of the Alaska Pioneer Nursing Home policy; allowing the administration of over-the-counter substances. She said:

> It's not that [the] physicians are not doing their job, it's that the nurse is responsible to know what she's administering, what side effects to look for, and whether or not this is going to interact with other medications that the individual is taking. ... The nurse is doing ... her or his part in being one of those people that assures patient safety in this whole delivery of health care scheme.

3:33:56 PM

GENA EDMISTON, Registered Nurse (RN), Associate Administrator, Denali Long-term Care Center, Fairbanks Memorial Hospital, stated support for HB 467, and explained the policy of the Denali Center, which provides for the pharmaceutical review of medicinal or supplemental substances which are administered to residents/patients. She explained that this assures an additional level of review, which can be implemented when a pharmacy is available.

3:36:19 PM

CHAIR WILSON asked what the Denali Center's current policy is for having the nurses administer medications.

MS. EDMISTON responded that Denali Center has a pharmacy policy, and she reiterated the review process of every substance that is administered to residents of the center or the hospital. However, she said that in the hospital setting the patient would usually be self administering supplements, which is not the case in the long-term facility. She provided an example of a commonly used supplement that the nurses administer to residents of the Denali Center.

3:38:00 PM

REPRESENTATIVE SEATON inquired whether there are any restrictions placed on non-FDA approved Native foods, made available to facility residents.

MS. EDMISTON stated that she is not aware of any food issues. She opined that it is difficult for her to imagine not being able to provide a patient with a necessary supplement. She pointed out that many of the residents do not have family members nearby who would be able to visit regularly and administer these type of supplemental needs.

3:40:04 PM

REPRESENTATIVE GATTO stated his understanding of the inconsistency in the standardization of many supplements, and asked whether establishing a proper dose has been an issue.

MS. GIESSEL responded:

> That is a difficult question to answer because with a lot of these substances their effects are difficult to quantify. ... I can't really say in my experience that I've seen a lot of variation in terms of response. And yes, you are absolutely right, there is no standardization of any of these products.

3:43:14 PM

RICK SCHIKORA, Certified Public Accountant (CPA), stated support for HB 467, and explained his personal interest in the issue.

He described the situation of his grandmother, as a resident at the local Pioneer's Home, in need of a non-prescribed supplement. Although this supplement had been being administered, he said that he eventually received a letter from the Pioneer's home stating that, due to an inquiry from the Alaska Board of Nursing, the facility would be discontinuing this service. Noting that his grandmother's health began to decline when the supplements were discontinued, he began to administer to her needs, on a daily basis, which he had to provide off of the premises. Although he was able to take up this care for his grandmother, he realized that many nursing home residents do not have the benefit of an outside person who can assist them in this type of situation. His understanding is that, although the nurses do not object to providing this care, because of the stance that the Alaska Board of Nurses has taken, they are fearful of losing their licenses. He said:

> The nursing board has not been specific in their characterization of this and ... I don't have the exact quote but ... [the board's caution to nurses stated] "it's outside of the scope of practice," ... and ... "we may not support you." ... It was for those reasons that the nurses are afraid to participate in this. The Pioneer's Home does have a policy that says that ... they will get a coordinator to handle this and that the nurses can provide this administration to residents if they wish .... Based on that ... I put together a policy that was submitted to the Board of Nursing [available in the committee packet]. ... It doesn't require anybody to do anything that they feel is outside of their scope of practice. ... I think Alaska ... ought to be on the forefront of trying to accommodate in these situations, but we ought to do it in a fashion that doesn't require the nurse to do it, and doesn't punish her if she does. ... There's a lot of older ... [residents] over at the Pioneer's Home, and I'm sure there will be in the future, that won't have somebody that can go over and administer [to them]. ... I'm serious about seeing something happen where the board of nursing either authorizes this or state law gets changed to basically require them to authorize it.

3:52:30 PM

MIKE POWERS, Administrator, Fairbanks Memorial Hospital, stated support for HB 467, and referred to Ms. Giessel's testimony as

being both accurate and erroneous. He concurred that safety is above all the primary concern for hospitals and long-term care facilities. However, a call for reasonableness should be held that would allow for nurses to provide even better care, which may include the administration of some of these supplements. He suggested a meeting of the interested parties, and stressed that common ground must be sought that will improve the entire health system.

3:56:18 PM

REPRESENTATIVE GARDNER asked whether Mr. Schikora's suggestions have been reviewed by the nursing board.

MR. POWERS responded, "I don't know."

CHAIR WILSON interjected that Mr. Schikora testified to having provided the nursing board with his paperwork and that it was reviewed. Additionally, she reported her understanding that the Nursing Board has subsequently provided Mr. Schikora's suggestions to a subcommittee for review.

MR. MILLER added that the Board of Nursing did review Mr. Schikora's document; however, the Alaska Nurses Association (ANA) letter requested that the Nurses Association Professional Practice Committee investigate the issue and provide recommendations to the ANA at large. The ANA will then forward the recommendation that they adopt to the Board of Nursing.

3:57:53 PM

CHARLOTTE DAVIS, Registered Nurse (RN), spoke in opposition to HB 467, and paraphrased from a letter submitted to the committee, which read as follows [original punctuation provided]:

> As a registered nurse, I am urging you to **defeat passage of House Bill # 467** regarding the administration of prescribed remedies and dietary supplements by a nurse. There are numerous reasons this bill should be defeated, however, I will concentrate on the most important reasons. They are as follows with a more complete discussion below:
>
> ❖ Dietary supplements, herbals, and vitamin remedies **are not FDA approved**.

- ❖ These products **are not drugs** (which require FDA approval) and do not require a prescription from a health care provider.

- ❖ Administration of these products **is not an acceptable** standard of nursing care.

- ❖ The State of Alaska Board of Nursing states nurses **shall not administer** these supplements.

- ❖ The manufacturer sets the dosage of supplements **without sound scientific study** on efficacy or safety.

- ❖ Administration by a nurse of supplements **violates the ANA Code of Ethics** regarding safety.

- ❖ Administration of these supplements **is outside the scope of nursing practice**. Malpractice insurance companies may not defend claims made against a nurse's license.

- ❖ The vulnerable residents of these facilities **deserve the same standard of care** as every other citizen from nurses whose licenses **have equal value** with the other 8,000 nurses in Alaska.

Further discussion on these points is as follows:

The short title states *Administration of Medication by a Nurse.* Herbals, vitamin remedies, and dietary supplements are NOT medications. The Food and Drug Administration (FDA) categorizes them as food so the FDA regulatory focus can only be on the product labels and claims by the manufacturers. The FDA does NOT approve food supplements for particular uses, in particular doses, or routes of administration.

The bill states "unless the prescription". The FDA must prove drug products are safe and effective for their intended use BEFORE prescribed by a health care provider and administration by a nurse. A health care provider does not prescribe but only advises use of a remedy or dietary supplement. Health care providers who do advise or prescribe use of dietary supplement could be sued if there were adverse affects, an

unintended side-effect over time, or a carcinogenic effect. The nurse in turn can also be sued for administering the supplement even when prescribed by a health care provider.

A nurse has the duty to provide care and to follow an acceptable standard of care. These standards of care come from different sources including Nurse Practice Acts, American Nursing Association, Joint Commission on Accreditation of Healthcare Organizations, and Case Law. The nurse is accountable for knowing the standard of care, adhering to that standard, and reporting any breaches in that standard of care by others. The administration of non-FDA approved supplements is NOT an acceptable standard of nursing care.

The State of Alaska Board of Nursing has repeatedly taken the position over the years, most recently in March 2006, that nurses shall not administer non-FDA approved supplements. I support my Board of Nursing on this issue.

HB 467 states, “unless the prescription is for an amount of the remedy or supplement that is outside of the manufacturer’s recommended dosage.” The manufacturer sets the dose, route, and frequency of the supplement use. It is the manufacturer who is responsible for the safety of the dietary supplement products but there is no provision for the FDA to approve dietary supplements for safety or effectiveness. These same manufacturers are not required by law to record, investigate or forward to the FDA any reports of injuries, illnesses, or deaths that may be related to the use of the supplement. After the product is on the market, the FDA has the responsibility for showing that a dietary supplement is "unsafe," to restrict its use of remove it from the market. The recall of all ephedra products on the market after injury and deaths is one example of the FDA responsibility.

The American Nurses Association’s Code of ethics states “The nurse promotes, advocates for, and strives to protect the health, safety, and rights of the patient.” Supplements may interfere with other herbals, drugs, or treatment regimens. Combinations cannot only be dangerous by life threatening (kava

beans, ephedra, St. Johns Wort). Supplements may interfere with tests, procedures, and cause complications with surgery. How many more supplements are currently on the market that the manufacturers have determined as "safe"? As a nurse, it is outside my scope of practice to determine the safety of these supplements.

After repeated calls to my malpractice insurance, I could not get a definitive answer to any hypothetical question I posed regarding this issue. They would not state they would defend a claim if I knowingly practiced outside of my scope of practice or outside the acceptable nursing standard of care. They will only defend a claim once it is filed.

Finally, the bill states "a registered nurse ... to a resident of a nursing facility, an assisted living home, or an Alaska Pioneers' Home". Why is this bill intended for only residents of these facilities and not those who live at home or who are in a medical facility? The elderly and disabled (most vulnerable in our society) deserve an even higher standard of safety then those who can advocate for themselves. Why is this bill intended only for a registered nurse caring for those residents? My license is no less valuable then those who work in home health care or medical facilities.

Please defeat passage of this bill. I will be available for any questions. I have listed my home number above or you may reply to this email.

4:03:02 PM

REPRESENTATIVE SEATON clarified that this bill would restrict an RN to the administration of prescribed substances. Additionally, it does not mandate that an RN administer any substance, and further, if a prescription is written to exceed the manufacturer's recommended dose, the RN would be disallowed from its administration. He asked if that was Ms. Davis' understanding of the bill action.

MS. DAVIS stated that her understanding of this bill is to provide facility residents a means to comply with prescription administration policy. She maintained that this would be a mute

issue if the substance were to be self administered by the patient, a family member, or a hired agent. The non-standardization aspect of these products is her primary concern, she said.

4:05:21 PM

VIRGINIA SMILEY, Director, Division of Pioneer Homes, Department of Health and Social Services (DHSS), stated support for HB 467, paraphrasing from a written statement, which read as follows [original punctuation provided]:

> For the record I am Virginia Smiley, director of the Division of Pioneer Homes for the Department of Health and Social Services. Madame chair, 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, lot number, expiration date, resident's name, room number, dosage and frequency.
>
> In addition, our pharmacy is informed of any supplement so they can monitor it in reference to resident 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.

CHAIR WILSON asked who administers the supplements.

MS. SMILEY responded that the RN is the administrator, and she continued with her written statement as follows:

If a nurse is unsure about something that has been ordered, the nurse has an obligation to get in touch with the primary care provider and ASK questions: why it is being ordered, or could it interfere with other meds.

We expect our nurses to 1) know their patients, and 2) know the risk/benefit of each medication ordered. We expect them to 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.

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

4:10:49 PM

NANCY DAVIS, Registered Nurse (RN), Representative, Alaska Nurses Association (ANA), compared the casual use of supplements in the United States to usage in other countries, and opined that this country has not “moved as far forward” on this issue. Self administration of a supplement is certainly different from having a nurse administer it, she cautioned. She reported how the ANA membership across the state is divided on this issue, however, she said that every nurse does have a desire to be informed on safety and developing health concerns held in the profession. The Board of Nursing is the standard bearer for the

ANA, and as such the board is obliged to define nursing practices for the profession. She said that it would be remiss not to look at what is current on the issue of supplements, and for that reason the ANA is convening their Professional Practices Committee. She explained that the U.S. Pharmacopeia (USP) has a process for review and standardization of supplements, if a manufacturer voluntarily submits their product for verification. The product receives a USP stamp on the label for having been subjected to this approval. Reminding the committee that nurses have a professional obligation for the safety of patients, she opined that through joint board discussion a safe, appropriate, reasonable, professionally responsible position would be adopted. Further, she provided suggestions why some supplement companies may not choose to submit their products for verification and review by the USP. She echoed the ANA's stated opposition to HB 467, stressing that it would be preferential to handle this issue through a process whereby the State Board of Nursing would examine and develop standards for professional nursing practices.

4:18:17 PM

REPRESENTATIVE CISSNA described her personal use of supplements under the supportive advice of a Nurse Practitioner (NP). She expressed concern for the quality of life of the elderly who are currently in need of daily administration of supplements, while this issue is in the process of being addressed.

MS. DAVIS conceded that studies are available regarding some substances, and noted that the National Institute of Health's Office of Dietary Supplements provides reports on the efficacy of certain supplements. She cautioned that this bill would be providing standards for the administration of a large variety of supplements, some that are commonly used, and others possibly more obscure. Further, she opined that this issue would be best handled, through the collaborative efforts of the ANA with the Alaska Pharmaceutical Association (AkPhA), and the Alaska Board of Medicine.

REPRESENTATIVE CISSNA asked whether a time-line exists for resolving this issue.

MS. DAVIS responded that the ANA expects to bring this topic before the Board of Nursing, at the June meeting.

4:21:58 PM

ROD BETIT, President, Alaska State Nursing Home Association (ASNHA), stated support for HB 467, and noted the scope and membership of the state facilities which he represents. He agreed that this issue is in need of resolution. Further, he said that the permissive nature of the bill allows latitude for resolution of conflicts. He echoed the need to have supplements made part of the health care decision process.

4:25:27 PM

REPRESENTATIVE GARDNER asked whether specific language was needed in the bill that would clarify a nurse's ability to freely decline to participate in the administration of supplements.

MR. BETIT responded that the bill, as drafted, provides allowance for the nurse to decline and generally implies no repercussion. However, specific language to this effect could be worked out, he said. Responding to a question, he stated that he was not in receipt of the document titled "Licensed Nurse Administration of Non-FDA Approved Over-the-Counter Drugs and Nutritional Supplements," which enumerates a seven point policy.

4:26:40 PM

CHAIR WILSON asked Ms. Giessel, whether pharmacists are more knowledgeable on the effects of supplements than nurses.

MS. GIESSEL opined that pharmacists have access to a wealth of information and can access the FDA website. However, she said, "How many ... truly understand the supplements ..., I couldn't tell you."

4:27:32 PM

CHAIR WILSON closed public testimony and announced that the bill would be held for further discussion. She directed the committee's attention to page 2, lines 1-2, [previously read into the record by Representative Seaton], and she suggested close scrutiny of the language therein.

ADJOURNMENT

There being no further business before the committee, the House Health, Education and Social Services Standing Committee meeting was adjourned at 4:28:57 PM.