Table 1. 12 Common Prescription Drugs: Prices Paid by Uninsured Consumers vs. the Federal Government

	Federal supply price	Average price paid by uninsured nationally	% more paid by uninsured nationally	Average price paid by uninsured in Alaska	% more paid by uninsured in Alaska
Synthroid	$9.20	$24.08	162%	$25.78	180%
Zyrtec	$43.30	$73.37	69%	$73.44	70%
Ambien	$73.13	$103.30	41%	$102.95	41%
Lipitor	$47.05	$80.65	71%	$83.96	78%
Levoxyl	$10.27	$17.70	72%	$18.36	79%
Allegra	$54.77	$93.34	70%	$87.91	61%
Premarin	$15.53	$38.73	149%	$41.90	170%
Norvasc	$45.39	$72.38	59%	$79.61	75%
Singulair	$58.35	$105.19	80%	$106.58	83%
Effexor XR	$51.46	$109.72	113%	$105.21	104%
Ortho Tri-Cyclen	$18.72	$43.24	131%	$42.60	128%
Zithromax	$31.71	$57.30	81%	$57.06	80%
Average	**$38.24**	**$68.25**	**78%**	**$68.78**	**80%**

Table 2. Nine Common Prescription Drugs: Prices Paid by Uninsured American Consumers vs. Canadian Consumers

	Price in Canada	Average price paid by uninsured Americans	% more paid by uninsured Americans	Average price paid by uninsured in Alaska	% more paid by uninsured in Alaska
Synthroid	$5.54	$24.08	335%	$25.78	365%
Zyrtec	$18.54	$73.37	296%	$73.44	296%
Lipitor	$47.40	$80.65	70%	$83.96	77%
Premarin	$6.15	$38.73	530%	$41.90	581%
Norvasc	$50.04	$72.38	45%	$79.61	59%
Singulair	$62.15	$105.19	69%	$106.58	71%
Effexor XR	$50.39	$109.72	118%	$105.21	109%
Ortho Tri-Cyclen	$19.12	$43.24	126%	$42.60	123%
Zithromax	$35.30	$57.30	62%	$57.06	62%
Average	**$32.74**	**$67.18**	**105%**	**$68.46**	**109%**

Policy Recommendations

Although the prescription drug crisis is undeniably complex, simple and readily available policy options do exist and could be immediately implemented. Some of these recommendations have already been employed at the state level. The state PIRGs support the following state and federal strategies to lower the cost of prescription drugs:

Create Prescription Drug Buying Pools

The state PIRGs support creating prescription drug-buying pools at the state level that would allow businesses, the government and individuals of all ages to use their combined buying power to negotiate lower drug prices, similar to what is done by the federal government and big health insurance providers. Specifically, this would:

- Give the state government the ability to negotiate substantial rebates from drug companies and discounts from retailers, then pass those savings along to participants; and
- Provide tools to help persuade drug companies to negotiate prices in good faith, including public disclosure of uncooperative companies.

In May 2000, the Maine legislature passed the Maine Rx Program, which allowed the state to negotiate fairer drug prices for all residents, regardless of income level or age, by using the buying power of its Medicaid program. The Pharmaceutical Research and Manufacturers Association filed a lawsuit on the basis that the program interfered with interstate commerce. In May 2003, the U.S. Supreme Court decided in favor of Maine. Concerned over future legal challenges, the Maine legislature enacted changes to the program in June 2003 that limited participation to Maine residents with incomes under 350% of the federal poverty level and to individuals whose drug expenses exceed 5% of their income.

Interstate Buying Pools

States are banding together to leverage their market power to lower the price of prescription drugs and reduce inefficiencies in the purchase of medication for their residents.

The RxIS Coalition, an arrangement between Delaware, Missouri, New Mexico, West Virginia, and most recently Ohio, negotiates manufacturer discounts for prescription drugs for state employees using a single PBM.

In April 2004 the U.S. Department of Health and Human Services (HHS) Secretary approved plans by five states (Michigan, Vermont, New Hampshire, Alaska, and Nevada) to pool their collective purchasing power to gain deeper discounts on prescription medications for their state Medicaid programs. In 2004, Michigan estimates that it will save $8 million; Vermont $1 million; Alaska $1 million; New Hampshire $250,000; and Nevada $1.9 million. Minnesota and Hawaii have submitted plans to HHS in order to join. Minnesota estimates that it could save $11 million.

Source: "State Purchasing Pools for Prescription Drugs: What's Happening and How Do They Work?" an issue brief from the National Governors Association Center for Best Practices, available at www.nga.org.

Increase Competition from Low Cost Generic Drugs

The state PIRGs support legislation that would close the loopholes in the Hatch-Waxman Act and prevent pharmaceutical companies from using costly tactics to delay the introduction of generic drugs. The state PIRGs also call on FDA to take a more proactive role to prevent the practices commonly used by pharmaceutical companies to extend their patents.

Expand Use of Preferred Drug Lists

The state PIRGs support expanding the use of "preferred drug lists," or PDLs. Panels of experts develop PDLs by evaluating the effectiveness and price of similar medications then placing the equally effective yet lower cost medications on the lists. Health care providers and state governments use these PDLs when making purchasing decisions, ensuring that patients get the most cost-effective drugs available while encouraging drug manufacturers to offer competitive prices. Evidence-based review programs (see box) are a perfect complement to PDLs; experts can rely on research from evidence-based review to make well-informed decisions about which drugs to include on the PDLs.

Regulate the Marketing Practices of the Pharmaceutical Industry

Both consumers and doctors are increasingly inundated with information about brand-name prescription drugs. Neither doctors nor consumers can rely on the information provided by pharmaceutical companies. The state PIRGs support the following strategies to end or limit direct-to-consumer advertising and restrict

Evidence-Based Review

Evidence-based review programs can help health care providers and state governments make well-informed decisions about which drugs to place on Preferred Drug Lists.

With the support of consumer advocacy groups, including OSPIRG, Oregon state lawmakers created "The Drug Effectiveness Review Project" in 2002. The project established a database of unbiased scientific evidence, "evidence-based research," regarding the safety and effectiveness of drugs that treat the same condition. Oregon uses the research to make cost-effective drug purchasing decisions for its Medicaid program, but the information is also available to the public. A central website, www.OregonRx.org, provides consumers with a helpful tool to sort through the available prescription medications to treat their conditions.

Instead of purchasing multiple drugs within the same treatment class (such as competing name brand drugs), government programs can purchase the best and most cost-effective medications. Evidence-based research rewards effective low cost drugs and could reduce the number of high cost drugs that are not an improvement on existing medication options. In many cases, the research has found that the newest and most expensive prescriptions are not any better than older, cheaper medications.

As of April 2004, 10 other states (Alaska, Idaho, Kansas, Michigan, Minnesota, Missouri, North Carolina, Washington, Wisconsin, and Wyoming) had joined with Oregon to fund evidence-based research.

Sources: The Oregon state website on evidence-based research, www.OregonRx.org; AARP, Rx Watchdog Report, Vol. 1, Issue 2, July 2004, "AARP Building a Functioning Market for Prescription Drugs."

pharmaceutical company marketing to doctors:

- *End or Limit Direct-to-Consumer Advertising*

The state PIRGs support legislation to end the practice of direct-to-consumer advertising, which encourages consumers to request the newest and often most expensive treatment regardless of proof about the drug's superiority. Physicians tend to prescribe the requested drug, often despite their ambivalence about the treatment choice.[49] The state PIRGs also support interim steps to close loopholes in the legislation that allows direct-to-consumer advertising. For instance, a drug manufacturer does not have to include information about the side effects of a drug in an advertisement if the advertisement does not explicitly say what the drug is used to treat.

Over the past few years, several states, including Massachusetts, California, Vermont and West Virginia, have introduced legislation to regulate direct-to-consumer advertising or passed resolutions asking Congress to limit prescription drug advertising.[50]

- *Restrict Marketing to Doctors*

The state PIRGs support legislation to limit pharmaceutical promotion to physicians (detailing). Some legislative options that state PIRGs support or have supported in the past include:

✓ Codifying the PhRMA and American Medical Association guidelines for interactions between doctors and pharmaceutical company representatives.

Recently, the state of California enacted legislation, sponsored by CALPIRG, to codify previously unenforceable voluntary guidelines on gift-giving to doctors. The legislation also requires drug companies to make their internal guidelines on gift-giving available on their websites.[51]

✓ Placing strict monetary limits or outright bans on gifts from pharmaceutical companies to doctors.

Minnesota was the first state to cap gift value at $50 per gift, with some exceptions, in 1993. In 2004, the Minnesota legislature introduced but did not pass a bill to lower the cap from $50 to $20.[52]

✓ Improving doctor and drug company disclosure, such as requiring pharmaceutical companies to report the value, nature, and purpose of any gift or economic incentive over a certain value given to a health care provider.

In the past two years, Maine and Vermont have enacted, and more than 15 state legislatures have considered, some disclosure requirements for drug companies or doctors.[53]

Increase the Transparency of PBMs

Pharmacy Benefit Managers (PBMs), the pharmaceutical "middlemen", manage the prescription drug care for millions of Americans. PBMs negotiate deals from pharmaceutical companies on behalf of insurers, state health programs, and large businesses. These deals, however, are shrouded in secrecy and are the basis for allegations that PBMs fail to act in their clients' best interests. The state PIRGs support efforts to increase transparency and accountability for PBMs.

In 2003, South Dakota enacted legislation to regulate PBMs. Under the legislation, a PBM is required to perform its duties in "good faith" and to disclose to its clients the

amount of all rebate revenues and the nature, type and amounts of all other revenues that the PBM receives from each pharmaceutical manufacturer or labeler with whom the PBM has a contract.[54]

Legalize Prescription Drug Importation

To provide consumers with immediate relief from the high cost of prescription drug prices, the state PIRGs support legislation to legalize prescription drug importation as an interim solution for the millions of consumers who cannot afford to purchase their medication. Legalizing prescription drug importation through legislation such as the bi-partisan Dorgan-Snowe proposal in the 108th Congress will give consumers timely access to affordable medication and pressure the pharmaceutical industry to lower the prices of prescription drugs sold in America.

Although federal legislative proposals have stalled, numerous states and cities have implemented programs to help employees and consumers import prescription medication. For example, the state of Rhode Island enacted a law in 2004 to allow pharmacies licensed in Canada to do business in Rhode Island. FDA, however, continues to frustrate states' efforts to help their residents import prescription drugs. Vermont filed a lawsuit against the FDA in August 2004 after the agency rejected the state's request to set up a pilot program to demonstrate how importation could be done safely.[55]

Consumer Tips

✓ **Beware of brand name generics.**

A testimony to the effectiveness of the pharmaceutical industry is the emergence of "brand name generics," generic equivalents of popular brand name drugs made by companies that spend money on advertising to distinguish their products from other generic versions. One of the drugs included in our survey, Levoxyl, is a brand name generic version of another drug in our survey, Synthroid. Both are top sellers, and both are priced higher than equally effective generic versions. See the price comparisons for Synthroid below. The prices represent the cost of a one month's supply (30 tablets); we used Walgreen's website price for 100 tablets to calculate the cost of a month's supply.

Prescription Drug Version	Prescription Drug Name	Average Price in Survey	Price on Walgreen's Website*
Original, Brand Name	Synthroid	$24.08	$19.20
Generic, Brand Name	Levoxyl	$17.70	$15.90
Generic	Levothyroxine	n/a	$11.40

*prices downloaded from www.walgreens.com on October 5, 2004.

✓ **Always ask if there is a generic version of your prescription.**

Ask your doctor or your pharmacist for a generic version of your prescription medication or do some research by looking at an online drugstore. Generic drugs are much cheaper than their brand name counterparts. For example, the price of the most popular brand of birth control in America, Ortho Tri-Cyclen, is much higher than its generic equivalent, Tri-nessa. On Walgreen's website, a month's supply of Ortho Tri-Cyclen costs $41.99. The generic version, Tri-Nessa, costs only $29.99—nearly 30% less.

✓ **Be sure to tell your doctor if you are not able to afford the medication that he or she prescribed you.**

If a doctor writes you a prescription, he or she expects that you will fill it and take it as directed. Your doctor might have free samples available or might be able to prescribe a different medication that is less expensive.

✓ **Shop around; use the phone and the Internet to look for lower drug prices.**

Ask a pharmacist for advice on how to save money on your prescriptions; they might know of discount programs for which you might be eligible. Certain websites also can help consumers compare prices from multiple Internet pharmacies, such as www.pricegrabber.com and www.destinationrx.com. (See tip below about using safe Internet pharmacies.)

✓ **Be careful when purchasing your prescriptions on the Internet.**

Many websites appear legitimate but actually sell counterfeit and unsafe products. The National Association of Boards of Pharmacy developed the Verified Internet Pharmacy Practice Sites (VIPPS) program to certify pharmacies that meet licensing requirements for their state, as well

as for each state to which they dispense pharmaceuticals. For more information on VIPPS, visit http://vipps.nabp.net/.

In general, be sure that any Internet pharmacy is licensed by a government authority. Also, never use an Internet pharmacy that does not require a hard copy (faxed or mailed) of your doctor's prescription. Always look for the online pharmacy's address; if the website does not disclose any address or phone number, it is probably not a legitimate business

✓ **Only import prescription drugs from pharmacies certified by the country in which they are based.**

Several states have set up websites to help their residents import drugs from certified Canadian pharmacies. These websites are generally open to people living outside of the state. The state of Minnesota, for example, maintains www.MinnesotaRxConnect.com to help consumers price Canadian drugs. The Minnesota State Department of Health visited and approved each of the pharmacies included on its website. Another website, www.pharmacychecker.com, is a free service that allows consumers to compare drug prices at a variety of Internet sites. It has rated 44 online pharmacies in the United States, Canada, Mexico, and elsewhere.

Questions to Ask Your Health Care Provider:[56]

✓ **Is this drug more effective than an older, cheaper drug because it is prescribed at a higher dosage? If so, would the older, cheaper drug be as effective if it were given at an equivalent dose?**

Sometimes the best course is simply to increase the dose of an older drug. New drugs are not necessarily better than old ones, and the older the drug, the better its safety record is likely to be.

✓ **Are the benefits worth the side effects, the expense, and the risk of interaction with other drugs I take?**

Every drug has side effects, and the side effects and associated risks may outweigh the benefits of taking a new prescription.

Methodology

The goal of this report was to find out how much uninsured, non-elderly consumers pay for commonly prescribed medications.

How We Selected the Prescription Drugs to Survey

This report surveyed drugs commonly prescribed to Americans under 65. Using data from NDC Health,[57] we developed a list of the 20 brand name prescription drugs most frequently dispensed to anyone in 2003. We included only brand name drugs and brand name generics; we did not include generic versions of drugs manufactured and sold by multiple companies. The data are based upon more than three billion prescriptions dispensed in 2003.[58]

To focus our study on prescription drugs used by people *under 65,* however, we dropped any drug falling on the list of the top 30 brand-name drugs used by the elderly, based on an analysis by Families USA.[59] In doing so, we removed two categories of drugs that many people under 65 require—medication to lower cholesterol and medication to lower blood pressure or treat angina. For this reason, we restored Lipitor (the top prescribed drug for the elderly and the top dispensed drug overall) and Norvasc (the top blood pressure/angina drug prescribed to the elderly and the fourth most frequently dispensed drug overall) to the survey list.

We surveyed pharmacies for the following drugs at the noted quantity and dosage.[60]

Lipitor, 10 mg/30 tablets. Lipitor, or atorvastatin, lowers a patient's cholesterol and triglycerides levels in the blood. Lowering these cholesterol levels reduces the risk of hardened arteries, which leads to heart attacks, strokes and peripheral vascular disease.

Norvasc, 10 mg/30 tablets. Norvasc is a calcium channel blocker that affects the movement of calcium into cells of the heart and blood vessels. It relaxes the blood vessels and increases the supply of blood and oxygen to the heart. Norvasc is prescribed for patients with high blood pressure (hypertension) and can relieve and control angina pectoris (chest pain).

Synthroid, 112 mcg/30 tablets. Levothyroxine sodium is an antineoplastic that is used when a patient's thyroid gland does not produce enough hormone. It also can be used to decrease the size of an enlarged thyroid gland (goiter) and to treat thyroid cancer.

Levoxyl, 112 mcg/30 tablets. Levoxyl is the brand name generic of Synthroid. It too is an antineoplastic that is used when a patient's thyroid gland does not produce enough hormone. It can be used to decrease the size of an enlarged thyroid gland (goiter) and to treat thyroid cancer.

Zithromax, 250 mg/ 6 tablets.[b] Zithromax is used to treat bacterial infections in many different parts of the body, including pneumonia. It functions by killing or preventing the growth of bacteria.

Premarin, 0.3 mg/30 tablets. Premarin is a drug composed of the female hormone estrogen and has a variety of uses. It is prescribed to provide additional hormone

[b] Surveyors asked for either six capsules or the pre-packaged version of the same dosage, called the Z-Pack.

when the body does not produce enough of its own, especially during menopause or when female development is lacking. It can help prevent the weakening of bones (osteoporosis) as well as function as treatment for both breast and prostate cancer.

Zyrtec, 10 mg/30 tablets. Zyrtec, or cetrizine hydrochlorine, is an antihistamine used to relieve the symptoms of hay fever, such as itching, runny nose, watery eyes and itchy hives, especially heightened during allergy season. Zyrtec treats both seasonal and perennial allergy symptoms.

Allegra, 60 mg/60 tablets. Allegra, or fexofenadine, is an antihistamine used to relieve the symptoms of hay fever and hives of the skin. Allegra treats primarily seasonal allergy symptoms.

Singulair, 10 mg/30 tablets. Singulair, or montelkast, is used in mild to moderate asthma treatment. It helps decrease the severity of the symptoms and reduces the number of acute asthma attacks. It also can help treat seasonal allergies.

Ortho Tri-Cyclen, 1 dispense pack/28 tablets. Ortho Tri-Cyclen is a progestin and estrogen combination that is used as an oral contraceptive to prevent pregnancy. Doctors also prescribe it to prevent acne.

Effexor XR, 75 mg/30 capsules. Effexor is an anti-depressant and anti-anxiety agent that treats depression and certain anxiety disorders.

Ambien, 10 mg/30 tablets. Ambien functions on a short-term basis to treat insomnia by helping patients fall asleep faster and sleep through the night.

How We Conducted the Survey and Calculated Average Retail Prices

We surveyed a total of 468 retail pharmacies in 19 states and Washington, DC in August and September of 2004. We chose to survey retail pharmacies—chain pharmacies, grocery store pharmacies, and mass merchant pharmacies—rather than online retailers or other outlets. Although Internet pharmacy sales are growing, the vast majority of Americans purchase their medications from retail pharmacies. Retail pharmacies filled 3.2 billion prescriptions in 2003, with total sales of $203 billion.[61]

We selected the pharmacies at random from an Internet directory website. Surveyors posed as uninsured, non-senior citizen consumers shopping around for the best prices for their prescriptions. The surveyors found that pharmacists were very helpful and often gave the "uninsured" surveyor useful advice about how to save money on their prescriptions.

How We Compared Results to Federal Supply Schedule Pricing

The most favored customer price used for comparison is the Federal Supply Schedule price, provided by the Pharmacy Strategic Benefit Management Group of the Department of Veterans Affairs, which oversees the Federal Supply Schedule prices. We downloaded the Federal Supply Schedule prices from http://www.vapbm.org/PBM/prices.htm on August 10, 2004. The pharmaceutical industry, HMOs, and large insurers do not make public the drug prices paid by most favored private sector customers. The U.S. Government Accountability Office, however, has found that "federal supply schedule prices represent the best publicly available information of the prices that pharmaceutical makers charge their most favored customers."[62]

When multiple Federal Supply Schedule prices were available for a specific drug, we used the highest available price. Because the Federal Supply Schedule prices do not include pharmacy-dispensing fees, we added $4.50 to each price to reflect a generous dispense fee ($4.50 is the average dispense fee paid to pharmacies by state Medicaid programs). Large purchasers, including HMOs and the federal government, negotiate a fixed dispensing fee per prescription. Most purchasers probably pay a higher fee than state Medicaid programs.

How We Compared Results to Prices From a Certified Canadian Pharmacy

We used a website run by the state of Minnesota, www.MinnesotaRxConnect.com, to obtain comparative drug prices in Canada. As described on the Minnesota website, "This website provides information to Minnesotans about the issues surrounding affordable prescription medicines and information about ordering prescription medicines from Canadian pharmacies featured on the website. The Canadian pharmacies featured on this site are licensed by a Canadian province and governed by the laws and regulation of Canada. State officials visited the Canadian pharmacies listed on this site and reviewed the pharmacy's facilities, the protocols used for filling prescriptions and the Canadian regulations governing Canadian pharmacies. Many of the regulations governing the pharmacies are similar to regulations applicable to pharmacies licensed by the State of Minnesota."

The website features four different Canadian pharmacies and gives information about both their prescription prices and their shipping charges. The website finds the lowest price from among the four pharmacies for a specific dosage of the prescription drug. For seven of the drugs we compared, the website listed only one quantity and price available for the dosage specified in our survey. For Zyrtec, we selected the price associated with a 3-month supply of 100 tablets, because most consumers would choose both the savings and convenience of ordering a larger supply of a daily medication; the only other option was for 18 tablets. For Zithromax, we selected the price associated with six tablets, rather than 30 tablets, because that is the quantity generally prescribed to treat most infections.

Appendix A. Average Retail Prices Paid by Uninsured Consumers for a 30-day Supply of Prescription Medication: By Location

Surveyed Area	Synthroid	Zyrtec	Ambien	Lipitor	Levoxyl	Allegra	Premarin	Norvasc	Sirgulair	Effexor XR	Ortho Tri-Cyclen	Zithromax	All 12 Drugs
Alaska (statewide)	$25.78	$73.44	$102.95	$83.96	$18.36	$87.91	$41.90	$79.61	$106.58	$105.21	$42.60	$57.06	**$68.78**
Albuquerque, NM	$24.43	$70.28	$99.71	$79.75	$17.33	$91.49	$41.90	$70.31	$101.82	$108.79	$44.35	$56.28	**$67.20**
Atlanta, GA	$22.96	$73.22	$104.51	$80.26	$17.43	$91.46	$39.04	$71.12	$102.61	$111.16	$42.93	$57.31	**$67.83**
Baltimore, MD	$23.44	$75.33	$105.32	$85.88	$17.61	$95.76	$38.56	$74.74	$104.67	$109.21	$45.09	$56.85	**$69.37**
Boston, MA	$24.15	$78.60	$109.54	$85.02	$18.91	$100.09	$38.95	$78.33	$112.43	$118.80	$44.71	$59.33	**$72.41**
Charleston, WV	$23.80	$74.83	$105.20	$81.93	$18.17	$93.97	$39.33	$74.87	$106.64	$113.88	$41.79	$56.63	**$69.25**
Denver, CO	$23.87	$71.09	$101.80	$77.25	$17.91	$94.71	$38.81	$70.75	$105.55	$110.13	$43.41	$54.96	**$67.50**
Des Moines, IA	$22.88	$70.18	$98.58	$77.80	$17.96	$89.21	$36.50	$69.61	$98.61	$104.62	$42.66	$54.02	**$65.22**
Las Vegas, NV	$25.90	$73.93	$101.98	$79.13	$18.22	$89.91	$44.34	$70.94	$107.90	$114.48	$44.05	$58.81	**$69.13**
Nashville, TN	$23.25	$71.05	$101.51	$79.07	$17.34	$92.88	$35.66	$68.89	$101.90	$106.64	$41.87	$56.22	**$66.36**
Oakland County, MI	$24.42	$73.82	$102.27	$81.56	$15.20	$97.40	$39.85	$71.30	$106.67	$118.54	$41.74	$63.59	**$69.70**
Portland, OR	$25.16	$72.88	$102.89	$76.27	$18.38	$91.66	$39.79	$74.39	$106.15	$107.79	$45.09	$57.74	**$68.18**
Providence, RI	$24.25	$73.94	$105.44	$80.68	$17.18	$96.14	$38.29	$71.76	$106.25	$109.45	$41.59	$56.30	**$68.44**
Raleigh, NC	$24.83	$76.15	$106.71	$85.43	$17.94	$97.29	$39.13	$73.90	$108.75	$107.44	$43.14	$61.71	**$70.20**
San Antonio, TX	$22.67	$68.20	$97.90	$76.27	$17.19	$89.15	$35.29	$70.22	$101.62	$103.34	$42.46	$55.33	**$64.97**
St. Louis, MO	$23.78	$71.98	$101.60	$80.08	$17.30	$101.76	$38.82	$68.43	$102.07	$106.84	$43.01	$55.81	**$67.62**
Tallahassee, FL	$23.88	$71.35	$99.51	$75.46	$17.67	$81.78	$35.09	$67.05	$102.06	$107.30	$42.21	$57.56	**$65.08**
Twin Cities, MN	$21.89	$71.20	$103.27	$76.48	$17.01	$90.61	$34.61	$69.73	$101.99	$103.32	$42.75	$54.37	**$65.60**
Vermont (statewide)	$24.13	$77.52	$108.44	$80.48	$17.13	$95.02	$38.24	$75.36	$109.15	$112.50	$43.45	$55.58	**$69.75**
Washington, DC	$26.06	$78.31	$106.92	$90.24	$19.85	$98.80	$40.44	$76.21	$110.48	$115.03	$45.84	$60.63	**$72.40**
National Average	**$24.08**	**$73.37**	**$103.30**	**$80.65**	**$17.70**	**$93.34**	**$38.73**	**$72.38**	**$105.19**	**$109.72**	**$43.24**	**$57.30**	**$68.25**

End Notes

[1] National Association of Chain Drug Stores, "2003 Community Pharmacy Results," downloaded September 17, 2004, at http://www.nacds.org/user-assets/PDF_files/2003results.PDF.
[2] Dee Mahan, "Sticker Shock: Rising Prescription Drug Prices for Seniors," Families USA, June 2004.
[3] David Gross, "Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2000 through 2003," AARP Public Policy Institute, May 2004.
[4] David Gross, "Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2000 through 2003—First Quarter Update," AARP Public Policy Institute, July 2004.
[5] For an excellent summary of the Medicare Prescription Drug Benefit, see the Kaiser Family Foundation Fact Sheet titled: "The Medicare Prescription Drug Law," Fact Sheet #7044, published in March 2004, available at www.kff.org.
[6] U.S. Census Bureau. Income, Poverty, and Health Insurance Coverage in the United States: 2003.
[7] Kaiser Commission on Medicaid and the Uninsured, "Health Insurance Coverage in America: 2003 Data Update Highlights," issued on September 27, 2004: Figure 6.
[8] Kaiser Commission on Medicaid and the Uninsured, Fact Sheet #1420-06, September 2004.
[9] ibid
[10] Bill Brubaker, "Drug Spending Falls As Co-Payments Rise," *Washington Post,* October 9, 2002: E03.
[11] "Pharmaceuticals Rank as Most Profitable Industry, Again." Public Citizen, April 2002.
[12] "Profiting from Pain: Where Prescription Drug Dollars Go," Families USA, July 2002.
[13] Public Citizen Congress Watch, "2002 Drug Industry Profits: Hefty Pharmaceutical Margins Dwarf Other Industries," June 2003. Available at www.citizen.org/documents/Pharma_Report.pdf.
[14] Pharmaceutical Research and Manufacturers of America, "Intellectual Property Overview," http://www.phrma.org/issues/intprop/.
[15] Pharmaceutical Research and Manufacturers of America, "Why Do Prescription Drugs Cost So Much?... and Other Questions About Your Medicine," available at www.phrma.org/publications/publications/brochure_questions/questions.pdf.
[16] Public Citizen, "Would Lower Prescription Drug Prices Curb Drug Company Research and Development?", http://www.citizen.org/congress/reform/drug_industry/r_d/articles.cfm?ID=7909, accessed October 11, 2004.
[17] Scott Hensley, "Drug Prices Rise at Faster Clip, Placing Burden on Consumers," *Wall Street Journal,* April 15, 2002.
[18] "Profiting from Pain: Where Drug Dollars Go," Families USA, July 2002, 3.
[19] Julie Appleby, "Drugmakers spend more on dividends than research," *USA Today,* October 11, 2004.
[20] Marcia Angell, M.D. *The Truth About Drug Companies: How the Deceive Us and What to Do About It,* Random House, New York, 2004: 179.
[21] Gardiner Harris and Joanna Slater, "Generic Drug Makers Use Altered Copies to Outmaneuver Patients in Legal Battles," *Wall Street Journal,* April 17, 2003.
[22] Wyeth obtained the 6-month extension referenced here legally. Under The Best Pharmaceuticals for Children Act (enacted in 1997 and recently reauthorized until 2007), drug companies that test their drug for use in children are given an additional six months of market exclusivity for that drug. (Pub L. No. 107-109). Wyeth tested Effexor for use in children. Although Wyeth did not find the drug to be more effective for treating pediatric depression than a placebo, the company still received the 6-month exclusivity extension.
[23] From testimony submitted by Congressman Henry Waxman at "Hearing on Publication and Disclosure Issue in Anti-Depressant Pediatric Clinical Trials" in Subcommittee on Oversight and Investigations of the House Energy and Commerce Committee, September 9, 2004
[24] "Generic Drug Entry Prior to Patent Expiration: An FTC Study", Federal Trade Commission, July 2002.
[25] ibid

[26] Patrick Cafferty, "Collusion and Other Anticompetitive Practices: a Survey of Class Action Lawsuits Against Drug Manufacturers," Families USA, April 2002.
[27] ibid
[28] Prescription Access Litigation Project, "Consumers and Third Party Payers Reach $29 Million Settlement With GlaxoSmithKline in Antitrust Drug Lawsuit," press release, July 9, 2004.
[29] David Balto. "Beginning Steps for PBM Reform," The Food and Drug Law Institute, Update Issue 4, July/August 2004.
[30] Milt Freudenheim, "Big Employers Join Forces to Negotiate Lower Drug Prices," *New York Times*, June 12, 2004.
[31] David Balto. "Beginning Steps for PBM Reform," The Food and Drug Law Institute, Update Issue 4, July/August 2004.
[32] "New York, 19 States Settle Deceptive Trade Practices Claims Against Medco Health Solutions," Office of New York Attorney General Eliot Spitzer, April 26, 2004.
[33] ibid
[34] "Express Scripts Accused of Defrauding State and Consumers Out of Millions of Dollars," Office of New York Attorney General Eliot Spitzer, August 4, 2004.
[35] ibid
[36] California Healthline, "Pharmacy Benefit Manager Express Scripts Faces Investigations by 20 States," July 29, 2004. Available at http://www.californiahealthline.org.
[37] "Settlement Sets New Standard for Release of Drug Information," Office of New York Attorney General Spitzer, August 26, 2004.
[38] ibid
[39] ibid
[40] Food and Drug Administration, "FDA Statement on Recommendations of the Psychopharmacologic Drugs and Pediatric Advisory Committees," press release, September 16, 2004.
[41] Mary Duenwald, "One Lesson From Vioxx: Approach New Drugs with Caution," *New York Times*, October 5, 2004.
[42] Julie Appleby and Matt Krantz, "Merck Estimates $2.5B Impact From Pulling Vioxx Plug," *USA Today*, September 30, 2004.
[43] ibid
[44] ibid
[45] "Vioxx creator Merck insists drug is safe," *Columbia Daily Tribune*, August 27, 2004.
[46] Public Citizen Congress Watch, "The Medicare Drug War: An Army of Nearly 1,000 Lobbyists Pushes a Medicare Law that Puts Drug Company and HMO profits Ahead of Patients and Taxpayers," June 2004.
[47] ibid
[48] Robert Pear, "Drug Companies Increase Spending on Efforts to Lobby Congress and Governments," *New York Times*, June 1, 2003.
[49] Barbara Mintzes, et al, "How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA," *Canadian Medical Association Journal*, September 2, 2003.
[50] National Conference of State Legislatures, "2003 Prescription Drug State Legislation" and "2004 Prescription Drug State Legislation," available at http://www.ncsl.org/programs/health/drugdisc04.htm
[51] CALPIRG, "Governor Signs Drug Marketing Bill, Vetoes Bills on Bulk Purchasing and Drugs from Canada," press release, September 30, 2004, www.calpirg.org.
[52] ibid
[53] ibid
[54] South Dakota Board of Pharmacy News, April 2004 issue, www.state.sd.us/doh/pharmacy/April04.htm.
[55] Patricia Barry, "States Defy FDA on Drug Importation," AARP Bulletin, October 2004.
[56] These tips were adapted from the afterword of *The Truth About Drug Companies,* by Dr. Marcia Angell, p. 261.
[57] NDC Health data, available at www.rxlist.com.
[58] ibid

[59] "Sticker Shock: Rising Prescription Drug Prices for Seniors" Families USA, June 2004.
[60] Description information referenced at: http://www.nlm.nih.gov/medlineplus/druginformation.html, a service of the U.S. National Library of Medicine and National Institutes of Health.
[61] National Association of Chain Drug Stores, "2003 Community Pharmacy Results," downloaded September 17, 2004, at http://www.nacds.org/user-assets/PDF_files/2003results.PDF.
[62] Correspondence by William J. Scanlon, Director, Health Financing and Public Health Section, U.S. Government Accountability Office, April 21, 1999.

What is the National Legislative Association on Prescription Drug Prices?

We are a nonpartisan, nonprofit organization founded and directed by state legislators. The Association was incorporated as a 501c4 nonprofit in 2000. Our mission is to assist legislators who seek to work jointly across state lines to make prescription drugs more affordable and accessible to people in the United States, especially by reducing prescription drug prices.

Some of the activities of the Association include:

- Serving as a clearinghouse for research and information relating to the pricing of prescription drugs and other public policies and strategies that may provide greater access to pharmacy benefits at a fair price;
- Providing a forum for the discussion, development and coordination of public policy strategies to reduce prescription drug prices;
- Encouraging and supporting the enactment of legislation to reduce prescription drug prices;
- Initiating and coordinating communication with members of the United States Congress and with Federal agencies to promote federal laws and policies to reduce prescription drug prices; and
- Urging development of federal and state assistance insurance assistance programs offering prescription drug coverage.

The Association has become a leader in the national discussion on reducing prescription drug prices. Information sharing has played a vital role in progress around the region and the country. The Association has regular meetings that have been described as summits which bring together leaders from around the country to learn about the latest strategies to advance the goal of reducing prescription drug prices and making prescription drugs more affordable. We maintain an electronic distribution list of legislators, administrators, members of the media, and interested groups and citizens from around the country, and produce an weekly electronic newsletter which includes relevant media reports, current state activities, model legislation and policy information including statistics and research.

Current membership includes Maine, Vermont, New Hampshire, Connecticut, Massachusetts, Rhode Island, New York, Pennsylvania, the District of Columbia, West Virginia and Hawaii. In addition, legislators from many other states that are not yet members regularly contact the Association for information and participate in our meetings. Efforts are currently underway to expand membership to include all states serious about obtaining fair prescription drug prices for individuals, businesses, and government. Legislators interested in joining should contact our Executive Director Sharon Treat at nlarx@gwi.net for further information.

National Legislative Association on Prescription Drugs Office
P.O. Box 492, Hallowell, ME 04347—Phone: 207-622-5597—Fax: 207-622-3302
Office Location: 226 Water Street, Hallowell, ME—Email: nlarx@gwi.net

JOINING THE ASSOCIATION

There are two forms of participation in the National Legislative Association on Prescription Drug Prices:

. Participation by State Legislatures or Legislative Chambers:
Formal membership by one or more legislative chamber requires a legislative expression of intent such as a resolution or letter from the presiding officer. Membership entitles the presiding officer of each participating chamber to appoint up to three members of the chamber as Directors of the Association. Our bylaws require both political parties to be represented (no more than two legislators may be appointed from each chamber from the majority party), and a vote by the current Directors of the Association to accept a member state or legislative chamber. Legislative Directors from states or chambers that have joined, and who have filed a required annual disclosure and appointment form with the Executive Director, have full voting rights when voting on resolutions, bylaws, and overall management of the organization. The Executive Committee handles personnel and day to day management.

Dues for 2005-06 have been set at $20,000 per state. We recognize that it can be difficult to appropriate this sum every year, and we are willing to work with legislators to help them raise the funds. Some states fund the dues from the legislative budget while others have appropriated dues as part of the state budget. It is also possible that a private foundation from your state could partner with you to provide some or all of the funding. Our only restriction is that we do not accept funding from the pharmaceutical industry. If a state is not current in its dues payments, legislators and legislative staff from that state will be charged a registration fee to attend meetings, and will not be able to serve on the Executive Committee beginning in January 2006.

. Associate Directors:
If you are a legislator from a state or legislative chamber that is not a member, or a state that is a member but you are not one of the appointed directors, you may in the alternative join as an individual Associate Director. Dues for Associate Directors are $250 per year. Associate Directors may not vote but otherwise are included in all of the activities of the Association. Associate Directors must annually file a disclosure form with the Executive Director.

For more information and copies of the required disclosure forms, please contact Sharon Treat at nlarx@gwi.net.

Statement PhRMA

Pharmaceutical Research and Manufacturers of America (PhRMA)
Statement in Opposition to Alaska HB 452
April 24, 2006

Position: PhRMA respectfully opposes Alaska House Bill 452 because it would establish a process to control prescription drug prices, regulate advertising and marketing, determine what information health care practitioners provide to patients, and essentially regulate a private sector industry.

This measure would create a government task force mandated to consider strategies for managing prescription drugs prices, require prescription drug manufacturers to disclose expenditures for advertising and marketing, and create programs to steer health care practitioners to older generic drugs and away from new, cutting-edge brand name prescription drugs. The overall emphasis of the bill is to promote government-dictated price controls.

Price Controls
HB 452 would move Alaska toward government price controls, which PhRMA opposes. PhRMA opposes price controls because they harm the development of new drugs, which can hinder advancement of new cures and ameliorate disease. New medicines are designed to improve patient health and help control costs through decreased hospitalizations, reduced numbers of needed surgeries and lost work productivity.

Advertising, Marketing, And Promotion
Advertising's overarching purpose is to inform and educate consumers about treatable conditions and symptoms and about available therapies. Research shows that communication with the general public about approved drug products through print, broadcast, and electronic media encourages productive dialogue between patients and their physicians. According to Prevention Magazine, it also encourages compliance with physician-prescribed treatment regimens.[1]

If the bill is intended to eventually limit advertising and marketing, it should be noted that advertising is protected commercial speech. The landmark U.S. Supreme Court decision, Central Hudson Gas & Electric Corp. v. Public Serv. Commission Of New York, established a four-part test to be applied by courts in determining the constitutionality of commercial speech restrictions.[2] The government may prohibit commercial speech only if the speech is inherently false or misleading or proposes an unlawful transaction. Not only are advertisements for prescription medicines not false or misleading, they are among the most regulated advertisements of any industry.

Government-Determined Prescription Drugs
The bill contemplates the government determining appropriate prescription drug therapies. This measure provides the task force with the ability to establish programs to educate health care practitioners "about

[1] "the National Survey on Consumer Reaction to DTC Advertising of Prescription Medicines", Prevention Magazine - Men's Health (2005).
[2] Central Hudson Gas & Elec. Corp. v. Public Serv. Commission, 447 U.S. 557 566 (1980).

the relative costs and benefits of various prescription drugs, with an emphasis on generic substitution for brand-name prescription drugs when available and medically appropriate; prescribing older, less costly drugs instead of newer, more expensive prescription drugs, when appropriate; and prescribing lower dosages of prescription drugs, when available and medically appropriate." The determination regarding the appropriate medication to best treat a specific condition should be left to the properly educated, trained and licensed physicians, not government bureaucrats, who have no knowledge of the patient's medical history. Further, the government should not be responsible for determining the appropriate prescription drug or dosage. Patients should have access to cutting-edge, life saving drugs and this bill would undermine this ability.

Bulk Purchasing

The bill also charges the task force with "coordination among the medical assistance program, the labor-union representatives, and, to the extent possible, in-state hospitals and private insurers toward the development of a uniform prescription drug list that is clinically appropriate and that leverages retail prices." PhRMA has concerns with bulk purchasing programs that include vulnerable populations, such as the medical assistance population. Bulk purchasing programs that include multiple patient populations may not meet the medical needs of individual patients. Diverse populations have unique clinical and therapeutic needs that must be met in their own distinctive manner. For instance, because they may have multiple diseases or be disabled, the medical needs of Medicaid patients may differ from those of patients in the public employee system, which may be different from those of prison inmates.

It is for all these reasons, PhRMA respectfully urges Legislators to oppose HB 452.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $39.4 billion in 2005 in discovering and developing new medicines. Industry wide research and investment reached a record $51.3 billion in 2005.

HB

467

D

HOUSE COMMITTEE REPO

4-12-06

(7)

Date Referred to Committee: February 13, 2006 **FURTHER REFERRALS: Finance**

Date of Committee Action: April 11, 2006

The HEALTH, EDUCATION AND SOCIAL SERVICES Committee considered: **HB 467**

HOUSE BILL NO. 467 **ADMINISTRATION OF MEDICATION BY A NURSE**

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

Recommends it be replaced with [ ] HCS *or* [~~4~~CS for HB467 (HES)
For Senate Bills with new title: [ ] Technical Title [ ] New Title: HCR_____ **[~~4~~Same Title [ ] New Title**

[ ] attach amendments
[ ] add new referral to _____Committee
[ ] Letter of Intent_____Committee

List of Abbrev for Depts.:
ADM
CED
COR
CRT
EED
DEC
DFG
GOV
HSS
LEG
LAW
LWF
MVA
DNR
DPS
REV
DOT
UA

NEW **FISCAL NOTES** *Assigned by Chief Clerk's Office				
List by Dept(s):	*FN#	Fiscal	Indet.	Zero
CED	1			X

PREVIOUS **FISCAL NOTES**				
List by Dept(s):	FN#	Fiscal	Indet.	Zero

Signing with recommendations	Printed Last Name	DP	DNP	NR	AM
	CISSNA				✓
Berta Gardner	Gardner		X		
	ANDERSON	X			
	Gatti		X		
Chair: Peggy Wilson	WILSON				✓
Chair:					

STATE OF ALASKA

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Member
House Finance Committee

REPRESENTATIVE MIKE KELLY
HOUSE DISTRICT 7

MEMORANDUM

To: Rep. Wilson, Chair, HESS Committee
Members of the HESS Committee
From: Rep. Mike Kelly
Date: April 10, 2006
Re: Answers to questions posed in April 6, 2006 Committee Hearing for HB 467

1) Would we be permitting nurses to administer non-prescribed dietary supplements based on the language in page 1, line 5?

Answer: No we would not, because the definition of "prescribed remedy or dietary supplement" beginning on page 1, line 14 of the bill addresses this concern.

2) Does this bill only allow the administration of remedies and dietary supplements if an Advanced Practice Nurse (APN) prescribes them, or does it encompass all professionals with prescriptive authority?

Answer: No, under Title 8 Advanced Nurse Practitioners, physicians, physician assistants, dentists and podiatrists can prescribe.

3) How can we insert language into the bill that will ensure that the Board of Nursing and the nursing community at-large incorporate safeguards or a set of guidelines for nurses to follow for administration of dietary supplements?

Answer: Yes, and I will provide a CS for the committee to adopt with the language that would charge the Board of Nursing to establish standards and regulations for the administration of prescribed remedies and dietary supplements.

Derek Miller

From: Williams, Dave (PH) [Dave_Williams@health.state.ak.us]
Sent: Wednesday, March 22, 2006 10:30 AM
To: Derek Miller
Subject: RE: HB467

FYI

Prev | Next

TITLE 42 > CHAPTER 7 > SUBCHAPTER XIX > § 1396r

§ 1396r. Requirements for nursing facilities

Release date: 2005-12-27

(a) **"Nursing facility" defined**
In this subchapter, the term "nursing facility" means an institution (or a distinct part of an institution) which-
(1) is primarily engaged in providing to residents-
(A) skilled nursing care and related services for residents who require medical or nursing care,
(B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons, or
(C) on a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services (above the level of room and board) which can be made available to them only through institutional facilities,
and is not primarily for the care and treatment of mental diseases;
(2) has in effect a transfer agreement (meeting the requirements of section 1395x (l) of this title) with one or more hospitals having agreements in effect under section 1395cc of this title; and
(3) meets the requirements for a nursing facility described in subsections (b), (c), and (d) of this section.
Such term also includes any facility which is located in a State on an Indian reservation and is certified by the Secretary as meeting the requirements of paragraph (1) and subsections (b), (c), and (d) of this section.

-----Original Message-----
From: Derek Miller [mailto:Derek_Miller@legis.state.ak.us]
Sent: Monday, March 20, 2006 11:32 AM
To: Williams, Dave (PH)
Subject: RE: HB467

Nope. I've got one started, but not finished. I'm working on a different bill right now...but I'll try to run something by Mike by the end of the day. If I finish, I'll make sure to get it to you.

thanks,
Derek

From: Williams, Dave (PH) [mailto:Dave_Williams@health.state.ak.us]
Sent: Monday, March 20, 2006 11:27 AM
To: Derek Miller
Subject: HB467

Sec. 47.32.900. Definitions.

In this chapter,

(1) "ambulatory surgical center" means a facility that

(A) is not a part of a hospital or a physician's general medical practice; and

(B) operates primarily for the purpose of providing surgical services to patients who do not require hospitalization;

(2) "assisted living home"

(A) means a residential facility that serves three or more adults who are not related to the owner by blood or marriage, or that receives state or federal payment for services regardless of the number of adults served; the department shall consider a facility to be an assisted living home if the facility

(i) provides housing and food services to its residents;

(ii) offers to provide or obtain for its residents assistance with activities of daily living;

(iii) offers personal assistance as defined in AS 47.33.990; or

(iv) provides or offers any combination of these services;

(B) does not include

(i) a correctional facility;

(ii) an emergency shelter;

(iii) a program licensed under AS 47.10.310 for runaway minors;

(iv) a type of entity listed in AS 47.32.010(b)(5), (8), (9), (10), (11), or (12);

(3) "child placement agency" means an agency that arranges for placement of a child

(A) in a foster home, residential child care facility, or adoptive home; or

(B) for guardianship purposes;

(4) "commissioner" means the commissioner of health and social services;

(5) "department" means the Department of Health and Social Services;

(6) "entity" means an entity listed in AS 47.32.010(b);

24-LS1265\F
Mischel
4/7/06

CS FOR HOUSE BILL NO. 467( )

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-FOURTH LEGISLATURE - SECOND SESSION

BY

Offered:
Referred:

Sponsor(s): REPRESENTATIVE KELLY

A BILL

FOR AN ACT ENTITLED

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

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

*** Section 1.** AS 08.68 is amended by adding a new section to article 6 to read:

Sec. 08.68.396. Administration of prescribed remedies and dietary supplements. (a) The board shall establish standards in regulation that authorize a registered nurse licensed under this chapter to administer a prescribed remedy or dietary supplement to a patient who is a resident of a nursing facility, an assisted living home, or an Alaska Pioneers' Home. The standards must include safeguards that prevent the administration of a prescribed remedy or dietary supplement if the prescription is for an amount of the remedy or supplement that is outside of the manufacturer's recommended dosage for a patient of the same physical condition.

(b) In this section,

(1) "assisted living home" has the meaning given in AS 47.33.990;

(2) "nursing facility" has the meaning given in AS 18.20.390;

(3) "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.

Linda Miller

From: Chris Wyatt [chris_wyatt@gov.state.ak.us]
Sent: Tuesday, April 11, 2006 3:38 PM
To: Linda Miller; Derek Miller
Subject: HB 467

Attachments: HB467-COM-OL-03-31-06.pdf

HB467-COM-OL-03-31-06.pdf (79 ...

Linda,
Here is some information from DCCED on HB 467. I have attached the FN if you did not receive it last week....Chris

Chris--thanks for sending over the draft cs for HB467 which is up in H HSS at 3 pm today. I've had our occ licensing folks look it over and the cs will not change our 3/31 zero fiscal note. Would you please let Rep Kelly's office know this and forward them a copy of our fn. Thanks!

FISCAL NOTE

STATE OF ALASKA
2006 LEGISLATIVE SESSION

Fiscal Note Number:
Bill Version: HB 467
() Publish Date:

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

Expenditures/Revenues (Thousands of Dollars)

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

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

FUND SOURCE (Thousands of Dollars)

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

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

POSITIONS

Full-time						
Part-time						
Temporary						

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

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

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

(Revised 9/7/2005 OMB)

Sponsor Statement

HB 467

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

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

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

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

FISCAL NOTE

STATE OF ALASKA
2006 LEGISLATIVE SESSION

Fiscal Note Number:
Bill Version: HB 467
() Publish Date:

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Personal Services						
Travel						
Contractual						
Supplies						
Equipment						
Land & Structures						
Grants & Claims						
Miscellaneous						
TOTAL OPERATING	0.0	0.0	0.0	0.0	0.0	0.0
CAPITAL EXPENDITURES						
CHANGE IN REVENUES (1156)	0.0	0.0	0.0	0.0	0.0	0.0

FUND SOURCE (Thousands of Dollars)

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

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

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Part-time						
Temporary						

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

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

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

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

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

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

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

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

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

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

Alabama

Ms. Taylor,

The nurses (either LPN or RN) could administer the supplements if an order exists from an authorized prescriber. In long-term care, the physician or nurse practitioner would have to order the supplement but once the order existed, the nurse could administer it. The issue of FDA approval has never come up to my knowledge. Let me know if I can provide further information.

N. Genell Lee, MSN, RN, JD
Executive Officer
Alabama Board of Nursing
P.O. Box 303900
Montgomery, AL 36130-3900
www.abn.state.al.us
334-242-4184
1-800-656-5318
Fax: 334-242-4360

New Mexico

Ms Taylor, thank you for your question to the NM Board of Nursing. Nurses who have prescriptive authority can prescribe. If this is for nursing home patients, then nurses would need an order from a health care provider. We do not differentiate between FDA/vs. non-FDA approval. Have you talked with Board of Pharmacy's about this issue?
Please let me know if you have additional questions.
Debra Werner

Oregon

Hello Ms. Taylor,
The Board of Nursing in Oregon does not have a specific policy regarding this issue. However, with a doctor's order and appropriate knowledge and competency a nurse could administer supplements.

Marilyn L. Hudson, RN, MSN, CNS
Oregon State Board of Nursing
Nursing Practice Consultant
971-673-0656

North Carolina

Ms. Taylor,
We have a statement relative to over-the-counter drugs and such supplements would be considered as such.
the statement is on our website: http://www.ncbon.com/prac-rnistate.asp You will find this statement near the bottom of this list.
If a facility allowed the RN to recommend supplements to the client the employing facility policy and procedures should support this as being acceptable.

Linda C. Thompson, RN, MSN, MBA
Director-Education/Practice

Maine

Any medications that nurses would administer in Maine must be prescribed by a physician, including dietary supplements.

New York

Hi I have a cousin who lives in Manly Springs! We usually allow the nurse or facility to decide on a non FDA approved item such as you mention as long as there is a written order for it and the appropriate dosage. We advise the nurse or the facility to request from the prescriber, the research data that supports the usage, and any accompanying data regarding negative effects and side effects. Does this help? Laurene

Laurene C. O'Brien, MS, RN
Nursing Associate
to the Executive Secretary
New York State Board for Nursing
New York State Board for Respiratory Therapy

telephone: 518-474-3817 ext. 120
e-mail: Nursebd@mail.nysed.gov

Delaware

Hello- The Delaware Nurse Practice Act requires that all medications, whether legend or over the counter, be ordered by an authorized prescribing practitioner in order for the RN and LPN to administer. Currently there is no language that speaks to non-approved FDA medications that the prescribing practitioner may order.

Iva J. Boardman, RN, MSN
Executive Director
Delaware Board of Nursing
861 Silver Lake Blvd., Suite 203
Dover, DE 19904
Phone: (302) 744-4517
Fax: (302) 739-2712
Visit our website at http://www.dpr.delaware.gov

California

I am responding to your inquiry. RNs in California can only give prescribed medications. The Business & Professions Code Section 2725(b) (1) allows RNs the administration of medications and therapeutic agents, necessary to implement a treatment, disease prevention, or rehabilitative regimen ordered by and within the scope of licensure of a physician, dentist, podiatrist, or clinical psychologist

You can access the B&P code at www.rn.ca.gov
If you have any further questions , please do not hesitate to contact this Board.

MBedroni, EdD
CA_BRN

LEGISLATIVE RESEARCH REPORT

FEBRUARY 27, 2006

REPORT NUMBER 06.139

OTHER STATES' POLICIES REGARDING NURSES ADMINISTERING PRESCRIBED DIETARY SUPPLEMENTS

PREPARED FOR REPRESENTATIVE MIKE KELLY

BY BECKY TAYLOR, LEGISLATIVE ANALYST

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

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

BACKGROUND

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

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

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

907-465-3991
907-465-3908 (fax)

Alaska Legislature
Legislative Research Services
w3.legis.state.ak.us/Research/research_home.htm

State Capitol
Juneau, AK 99801

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

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

DIETARY SUPPLEMENTS

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

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

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

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

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

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

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

OTHER STATES' POLICIES AND POSITIONS

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

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

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

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

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

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

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

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

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

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

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

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

Notes: Some responses have been edited for length, clarity and grammar.
1) We include this statement as Attachment E.
2) We include this letter as Attachment D.
3) We include this document as Attachment F.
4) We include this opinion as Attachment G.

LIST OF ATTACHMENTS

Attachment A

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

Attachment B

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

Attachment C

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

Attachment D

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

Attachment F

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

Attachment G

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

Attachment A

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

Becky Taylor 3908

5 pages

V Smiley

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

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

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

3.0-Applicable Staff Members: nurses, administrators.

4.0-Policy:

- Under the conditions defined in this P&P, Pioneer Homes nursing staff might administer physician-prescribed dietary supplements to residents requiring and requesting assistance with administration. Administration is subject to the completion by the resident or representative of all requirements in this policy and procedure *and* voluntary agreement by Pioneer Homes nurses to administer the supplement(s), as considered on a case-by-case basis.

- Nursing staff members are not required to administer non-FDA approved supplements

Background information pertinent to this policy:

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

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

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

5.0-Definitions:

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

6.0-Responsibilities:

6.1-The administrator is responsible for:

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

6.2-The designated nurse is responsible for:

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

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

7.0-Procedure

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

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

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

Administration of Non-FDA Approved Supplements

Request/Release Form

Resident's name:_____ Date:_____

Pioneer Home:_____

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

_____

_____

_____

_____

_____

By signing this form, I acknowledge my understanding that:

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

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

I agree to the following requirements:

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

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

_____ _____

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

Date

Attachment B

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

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

Overview of Dietary Supplements

What is a dietary supplement?

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

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

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

- a vitamin,
- a mineral,
- an herb or other botanical,
- an amino acid,
- a dietary substance for use by man to supplement the diet by increasing the total dietary intake (e.g., enzymes or tissues from organs or glands), or
- a concentrate, metabolite, constituent or extract.

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

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

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

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

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

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

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

There is no authoritative list of dietary ingredients that were marketed before October 15, 1994. Therefore, manufacturers and distributors are responsible for determining if a dietary ingredient is "new", and if it is not, for documenting that the dietary supplements its sells, containing the dietary ingredient, were marketed before October 15, 1994. For more detailed information on new dietary ingredients, go to: http://www.cfsan.fda.gov/~dms/ds-ingrd.html.

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

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

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

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

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

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

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

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

Where can I get information about a specific dietary supplement?

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

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

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

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

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

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

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

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

What is FDA's oversight responsibility for dietary supplements?

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

Does FDA routinely analyze the content of dietary supplements?

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

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

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

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

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

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

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

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

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

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

How are advertisements for dietary supplements regulated?

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

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

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

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

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

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

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

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

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

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

Attachment C

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

VERMONT STATE BOARD OF NURSING
ADVISORY OPINION

QUESTION

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

BOARD OPINION

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

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

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

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

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

Board Approved May 8, 2000

Attachment D

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

PENNSYLVANIA STATE BOARD OF NURSING
P.O. BOX 2649
HARRISBURG, PA 17105-2649

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

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

February17, 2006

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

Dear Ms. Taylor·

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

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

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

The Professional Nursing Law, Section 2. Definitions.

***

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

***

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

1. Is the practice or therapy permitted or prohibited by the PA nursing practice acts or regulations?

2. Does the practice or therapy require you to have, and do you in fact have, the specialized nursing knowledge, preparations, experience, skill and competency? Could the practice be considered negligence or incompetence in the practice of nursing?

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

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

5. Could the practice or therapy be considered fraud or deceit in the practice of nursing?

6. Is the practice or therapy taught as part of a nursing curriculum in an approved nursing education program?

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

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

Thank you for your inquiry.

Sincerely,

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

Attachment E

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

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

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

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

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

Approved October, 1996

Revised: May, 2000

Attachment F

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

15.14 Duty of a Nurse in any Practice Setting

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

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

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

- The Standards of Nursing Practice differentiate the roles of the LVN and the RN in accepting nursing care assignments, assuring a safe environment for patients, and obtaining instruction and supervision as needed (Rule 217.11); and

- In *Lunsford v. Board of Nurse Examiners*, 648 S.W. 2d 391 (Tex. App.--Austin, 1983), the court in affirming the disciplinary action of the Board, held that a nurse has a duty to the patient which cannot be superseded by hospital policy or physician's order.

- The Board's Disciplinary Sanction Policies discuss expectations of all nurses regarding behaviors that are consistent with the Board's rules on Good Professional Character, §§213.27-213.29. These policies explain the client's vulnerability and the nurse's "power" differential over the client by virtue of the client's status (with regard to age, illness, mental infirmity, etc) and by the nature of the nurse:client relationship (where the client typically defers decisions to the nurse, and relies on the nurse to protect the client from harm).

- The delegation rules guide the RN in delegation of tasks to unlicensed assistive personnel who are utilized to enhance the contribution of the RN to the client's/patient's well being. When performing nursing tasks, the unlicensed person cannot function independently and functions only under the RN's delegation and supervision. Through delegation the RN retains responsibility and accountability for care rendered (Rules 224 and 225). The Board may take disciplinary action against the license of a RN or RN administrator for inappropriate delegation

- RNs with advanced practice authorization from the Board must comply with the same rules applicable to other RNs. In addition, rules specific to advanced practice nursing Chapters 221 & 222 must also be followed.

- Each nurse must be able to support how his/her clinical judgments and nursing actions were aligned with the NPA and Board Rules. The Board recommends nurses use the Six-Step Decision-Making Model for Determining Nursing Scope of Practice when trying to determine if a given task is within the individual nurse's abilities. Congruence with standards adopted by national nursing specialty organizations may further serve to enhance and support the nurse's decision to perform a particular task.

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

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

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

(Adopted 01/2005)

Attachment G

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

WYOMING
STATE BOARD OF NURSING
ADVISORY OPINION

ADMINISTERING MEDICATIONS ORDERED BY A HERBALIST–RN

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

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

- After deliberation, and by consensus, the Board stated that a nurse may administer medications prescribed by any person authorized by state law to prescribe. {The Nursing Practice Act, 33-21-120,(viii),(ix)}.

- The Board of Pharmacy was contacted and it was ascertained that herbalists do not have prescriptive authority; therefore, nurses cannot take orders from herbalists to administer medications (July 7-9,1999).

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

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

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

ASHNHA Testimony on HB 467 Before House HESS
Presented by: Rod Betit, President/CEO
April 6, 2006

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

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

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

➲Other points to consider:

- Keep in mind we are talking only about products prescribed by a person authorized under state law.
- HB 467 passage should reduce the 'practice' of family & friends providing supplements often without the knowledge of caregivers.
- HB 67 will allow nurses, pharmacists & physicians to participate in administering these supplements and thereby be aware of what is being taken on top of other medicines, and to note this in the patient record.
- If we generally believe that most people do not know if their supplements are harmful relative to other medications they taking or their present medical condition, how can we then advocate that the taking of these supplements should not be administered by caregivers as part of the patient treatment plan? Which approach presents the greater risk to the patient's overall health?
- Most facilities have policy & procedures in place to address how the handling of supplements will be handled to insure that nursing staff have a 'safe harbor' in which to operate.

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

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

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

ASHNHA Proudly Represents the Following Alaska Health Care Providers

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

Linda Miller

From: Rep. Peggy Wilson
Sent: Tuesday, April 11, 2006 8:29 AM
To: linda_miller@legis.state.ak.us
Subject: FW: Testimony on HB 467 for 4-11-06 3:00pm

Attachments: Letter to HESS Committee HB 467; ATT2150509.txt


Letter to HESS Committee HB 46...


ATT2150509.txt (298 B)

-----Original Message-----
From: Jerry Weymiller [mailto:JWEYMILLER@cinci.rr.com]
Sent: Tuesday, April 11, 2006 8:18 AM
To: Rep. Peggy Wilson
Subject: Testimony on HB 467 for 4-11-06 3:00pm

Dear Rep. Wilson,

Please submit my testimony on HB 467 to committee members for consideration during todays meeting. I am out of state today and unable to testify publicly but would appreciate being able to share my thoughts.

If members have any questions, my cell phone is 322-0111

Respectfully,

Mary Weymiller, LPN
666 11th Ave. #302
Fairbanks, Alaska
907-479-4395
907-479-7432 fax
907-322-0111

April 11, 2006

House HESS Committee
Rep. Wilson, Chair
Rep. Seaton, Co-Chair

Re: HB 467

Committee Members;

I am writing in opposition to HB 467 "An act relating to the administration of prescribed remedies and dietary supplements by a nurse."

As I have listened to the testimony given so far on this bill, I question why remedies and dietary supplements are felt to be the answer to all that ails the elderly.

The fact that this issue has come before our lawmakers demonstrates to me the power of marketing by the manufacturers of these products because , in spite of, the expert testimony given stating that there are dangers and adverse effects to taking some of these remedies some still feel adamant about convincing you that mandating registered nurses to administer them should be a law.

The permisive nature of this bill does not adequately protect the public from the potentially hazardous products that can be put on the market for public consumption.

HB 467 is asking that registered nurses, not educated in dietary supplements and remedies, give them to their patients because someone else prescribed them. How can a registered nurse be expected to administer when she or he may not be aware of all the effects it may have on their patients and has no guarantee the prescriber does either. The public and nurses themselves, hold nurses to a higher standard.

I would caution you, as lawmakers, that the focus has been on only a couple of alternative supplements, one of which has had a lot of media coverage and is fairly well known but there are thousands of other compounds on the market that this bill would allow a professional, untrained in remedies and dietary supplements to administer.

When thinking of safety in medicine ask yourself, would you want your surgeon mandated to use a steak knife or a scalpel when doing your surgery? Both will cut your skin and both will probably get the job done but of course, the scalpel will be much safer.

I urge you to leave this decision up to the experts you have charged with protecting the public and allow this issue to be decided among the professionals.

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

Frank H. Murkowski, Governor

FAX Transmittal

TO: Rep. Peggy Wilson

DATE: 4/11/06

FAX NUMBER: #465-3175

FROM: **Dorothy Fulton R.N. MA**
Executive Administrator
Alaska Board of Nursing
Telephone: (907) 269-8161
Fax: (907) 269-8169

Total # of pages including cover 2

Attachment:

Please give to Representative Wilson ASAP
for 3:00 p.m. hearing on HB 467

550 W. 7th Avenue, Suite 1500, Anchorage, Alaska 99501-3567
Telephone: (907) 269 8160 Fax: (907) 269-8156 Text Telephone: (907) 465-5437
Email: license@commerce.state.ak.us Website: http://www.commerce.state.ak.us/occ/

If this FAX does not transmit properly, please call the number listed immediately

April 11, 2006

Dear Representative Wilson,

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

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

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

Sincerely

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

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

Frank H. Murkowski, Governor

FAX Transmittal

TO: **Rep. Peggy Wilson** ***DATE:*** 4/11/06

FAX NUMBER:

FROM: **Dorothy Fulton R.N. MA**
Executive Administrator
Alaska Board of Nursing
Telephone: (907) 269-8161
Fax: (907) 269-8169

Total # of pages including cover 2

Attachment:

Please give to Representative Wilson ASAP
for 3:00 p.m. hearing on HB 467

Thank you

550 W 7th Avenue, Suite 1500, Anchorage, Alaska 99501-3567
Telephone: (907) 269 8160 Fax: (907) 269-8156 Text Telephone: (907) 465-5437
Email: license@commerce.state.ak.us Website: http://www.commerce.state.ak.us/oce/

If this FAX does not transmit properly, please call the number listed immediately

11 April, 2006

Dear Representative Wilson,

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

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

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

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

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

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

Sincerely,

Cindy Bueler, Registered Pharmacist

HB

468

Alaska State Legislature
House of Representatives

Standing Committees:
Judiciary
State Affairs

Interim Special Committees:
Military & Veterans' Affairs
Ways & Means

Finance Subcommittees:
Courts
Department of Law
Dept. of Military & Veterans' Affairs

Interim:
716 W 4th Avenue
Anchorage, Alaska 99501-2133
Phone: (907) 269-0123
Fax: (907) 269-0124

Session:
Alaska State Capitol
Juneau, Alaska 99801-1182
Phone: (907) 465-4940
Toll Free: (866) 465-4940
Fax: (907) 465-3766

Email:
rep.max.gruenberg@legis.state.ak.us

Representative Max F. Gruenberg, Jr.
House District 20
Anchorage (Mountain View, Russian Jack, East Anchorage)

Sponsor Statement for House Bill 468

"An Act relating to disclosure of employment information on a medical assistance application and a hospital intake report; and requiring the Department of Health and Social Services to prepare and publicize a report pertaining to employers who do not provide health insurance."

This legislation is modeled after bills introduced in other states to deal with the problems of large, profitable employers who do not provide for their worker's basic health care needs. This results in working Alaskans and their families having to seek public assistance to pay their health care costs, or going without adequate health care entirely.

The purpose of this bill is to identify those employers who are taking advantage of the state's welfare system to subsidize their lack of health benefits for their employees. It would mandate that health care providers report annually to the state the name of the employer of any person, as well as the dependents of that person, needing public assistance to pay for the cost of their needed health care. It would also require that those results be reported on a yearly basis to inform lawmakers and the public.

HB 468 will require the state to collect information on those employers who are not paying adequate health care costs for working Alaskans and their families and are instead maximizing their profits at the public's expense.

To: **House HESS Committee members**

From: **Rep. Gruenberg, sponsor**

Re: **Explanation of changes in the CS for House Bill 468 (HES)**

After the last hearing of this bill, Rep. Gruenberg, his staff and staff with Rep. Wilson's office convened a meeting of representatives from the Dept. of H&SS, Dept. of Labor, and the Hospitals.

Together, we have crafted a CS that we are confident will be less expensive, easier to carry out, and still provide valuable information for the legislature and the public to consider how to reduce the state's substantial and rising Medicaid costs.

Comparison between HB 468 G version and CS for HB 468 (HES) version I

HB 468 version G	CS for HB 468 (HES)
Title: Relates to medical assistance applications and hospital intake reports.	Title: Requires DHSS to prepare a report pertaining to certain employers of recipients of medical assistance
Sec. 1: Hospital intake form naming employers of uninsured persons and their beneficiaries would be filled out and reported annually.	Deleted.
Sec. 2 (Sec. 47.07.061): DHSS shall collect "employers of uninsured" data on medical assistance application.	Deleted.
Sec. 2 (Sec. 47.07.062): DHSS shall prepare and publicized a report, by January 20th of each year, to the legislature and the public showing which employers have employees or their beneficiaries applying for the state Medicaid program and/or listed by the hospitals as uninsured.	Sec. 1: A one-time report shall be prepared by January 16, 2007, using DHSS/DOL data from 2005, showing which employers had employees or their beneficiaries who received state Medicaid benefits.
"Employer" is defined as having more than 25 employees.	"Employer" is defined as having had an average monthly employment in 2005 of more than 25 persons.
	Effective immediately
Fiscal Note: $130,000 annually	Fiscal Note: Zero to $7,500 one time

Prepared by Michael Bucy, staff to Rep. Gruenberg
465-2840

FISCAL NOTE

STATE OF ALASKA
2006 LEGISLATIVE SESSION

Fiscal Note Number:
Bill Version:
( ) Publish Date: HB468-DHSS-FMS-03-28-06

Revision Date/Time (Note if correction):

Dept. Affected: Health & Social Services

Title: RELATING TO THE EMPLOYMENT OF PERSONS RECEIVING MEDICAL ASSISTANCE

RDU: Departmental Support Services

Component: Information Technology Services

Sponsor: GRUENBERG

Requester: HOUSE (HES)

Component No.: 2754

Expenditures/Revenues (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below

OPERATING EXPENDITURES	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Personal Services	25.0					
Travel						
Contractual						
Supplies						
Equipment						
Land & Structures						
Grants & Claims						
Miscellaneous						
TOTAL OPERATING	**25.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
CAPITAL EXPENDITURES						
CHANGE IN REVENUES (0)						

FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts	12.5					
1003 GF Match	12.5					
1004 GF						
1037 GF/Mental Health						
Other(Specify Type-do not abbreviate)						
Other(Specify Type-do not abbreviate)						
TOTAL	**25.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Estimate of any current year (FY2006) cost:

Mark this box (X) if funding for this bill is included in the Governor's FY 2007 budget proposal:

POSITIONS

Full-time						
Part-time						
Temporary						

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

This bill would require the department to compile and report to the Legislature (and make public), by January 20 each year, the names and addresses of employers - taken from hospital intake reports and medical assistance applications - with the total number of employees from each business who were uninsured hospital patients, and also the total number of employees (or employee dependents) who applied for or received medical assistance.

The Division of Public Assistance (DPA) collects, however, does not electronically store employer name and address information in its Eligibility Information System (EIS).

The department estimates $25,000 will be needed to make the necessary programming changes to its EIS to allow DPA staff to record employer name and address information, and to generate reports so the information can be compiled with the hospital intake reports to meet the proposed reporting requirement.

Prepared by: Janet Clarke, Assistant Commissioner — Phone 465-1630
Division: Finance and Management Services — Date/Time 03/23/2006
Approved by: Karleen Jackson, Commissioner — Date 03/28/2006
Agency: Department of Health and Social Services

(Revised 9/7/2005 OMB)

FISCAL NOTE

STATE OF ALASKA
2006 LEGISLATIVE SESSION

Fiscal Note Number:
Bill Version:
( ) Publish Date: HB468-DHSS-DPA1-03-28-06
Dept. Affected: Health & Social Services

Revision Date/Time (Note if correction):

Title: RELATING TO THE EMPLOYMENT OF PERSONS RECEIVING MEDICAL ASSISTANCE

RDU: Public Assistance

Component: Public Assistance Field Svcs

Sponsor: GRUENBERG

Requester: HOUSE (HES)

Component No.: 236

Expenditures/Revenues (Thousands of Dollars)

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

OPERATING EXPENDITURES	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Personal Services	130.0	130.0	130.0	130.0	130.0	130.0
Travel						
Contractual						
Supplies						
Equipment						
Land & Structures						
Grants & Claims						
Miscellaneous						
TOTAL OPERATING	**130.0**	**130.0**	**130.0**	**130.0**	**130.0**	**130.0**
CAPITAL EXPENDITURES						
CHANGE IN REVENUES (0)						

FUND SOURCE (Thousands of Dollars)						
1002 Federal Receipts	65.0	65.0	65.0	65.0	65.0	65.0
1003 GF Match	65.0	65.0	65.0	65.0	65.0	65.0
1004 GF						
1037 GF/Mental Health						
Other(Specify Type-do not abbreviate)						
Other(Specify Type-do not abbreviate)						
TOTAL	**130.0**	**130.0**	**130.0**	**130.0**	**130.0**	**130.0**

Estimate of any current year (FY2006) cost:

Mark this box (X) if funding for this bill is included in the Governor's FY 2007 budget proposal: [ ]

POSITIONS

Full-time	2	2	2	2	2	2
Part-time						
Temporary						

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

This bill requires hospitals to collect the name and address of a patient's employer on the hospital intake report (or, if the patient is a dependent, the name and address of the of the employer of the person responsible for the dependent), and to report to the department by July 1 of each year the total number of employees for each business who were uninsured hospital patients.

This bill would also require the department to compile and report to the Legislature (and make public), by January 20 of each year, the names and addresses of employers - taken from hospital intake reports and medical assistance applications - with the total number of employees from each business who were uninsured hospital patients, and also the total number of employees (or employee dependents) from each business who applied for or received medical assistance.

Prepared by: Katherine Farnham, Director — Phone 465-5835
Division: Public Assistance — Date/Time 03/23/2006
Approved by: Karleen Jackson, Commissioner — Date 03/28/2006
Agency: Department of Health and Social Services

STATE OF ALASKA
2006 LEGISLATIVE SESSION

ANALYSIS CONTINUATION

The Division of Public Assistance (DPA) currently collects employment-related information, such as earnings and health insurance coverage information, for persons applying for or receiving Medicaid. DPA does not, however, electronically store employer name and address information in its Eligibility Information System (EIS).

The department estimates two full time eligibility staff will be needed to record employer name and address information in EIS for Medicaid applicants and recipients. This data can then be extracted from EIS, and compiled with the hospital report, to meet the proposed reporting requirement.

Personal Services

Assumptions Made: 20,000 cases per year with employer information
10 minutes per year per case with employer information
200,000 minutes per year or 3,333 hours per year
162 hours worked per position per month = 1,944 hours
3,333 hours per year/1,944 hours per tech position = 1.7 workers

Average salary for an Eligibility Tech II $64,944 salary and benefits

This fiscal note does not include any administrative or data collection costs associated with hospitals meeting this reporting requirement.