ALASKA STATE LEGISLATURE
HOUSE HEALTH, EDUCATION AND SOCIAL SERVICES
STANDING COMMITTEE
April 13, 2004
3:15 p.m.

MEMBERS PRESENT

Representative Peggy Wilson, Chair
Representative Carl Gatto, Vice Chair
Representative John Coghill
Representative Paul Seaton
Representative Kelly Wolf
Representative Sharon Cissna
Representative Mary Kapsner

MEMBERS ABSENT

All members present

COMMITTEE CALENDAR

HOUSE BILL NO. 543
"An Act relating to medical assistance coverage for prescription drugs; and providing for an effective date."

- HEARD AND HELD

HOUSE BILL NO. 434
"An Act relating to the practice of naturopathic medicine; and providing for an effective date."

- HEARD AND HELD

HOUSE BILL NO. 535
"An Act relating to liability for expenses of placement in certain mental health facilities; relating to the mental health treatment assistance program; and providing for an effective date."

- SCHEDULED BUT NOT HEARD

HOUSE BILL NO. 72
"An Act relating to the qualifications and appointment of members of the Board of Regents of the University of Alaska; and providing for an effective date."

- SCHEDULED BUT NOT HEARD

HOUSE BILL NO. 176
"An Act providing that certain obligors can receive credit against their child support obligation for certain types of noncash child support; and providing for an effective date."

- SCHEDULED BUT NOT HEARD

PREVIOUS COMMITTEE ACTION

BILL: HB 543
SHORT TITLE: MEDICAID AND PRESCRIPTION DRUGS
SPONSOR(S): HEALTH, EDUCATION & SOCIAL SERVICES

03/25/04	(H)	READ THE FIRST TIME - REFERRALS
03/25/04	(H)	HES
04/01/04	(H)	HES AT 3:00 PM CAPITOL 106
04/01/04	(H)	Scheduled But Not Heard
04/06/04	(H)	HES AT 3:00 PM CAPITOL 106
04/06/04	(H)	Scheduled But Not Heard
04/13/04	(H)	HES AT 2:00 PM CAPITOL 106

BILL: HB 434
SHORT TITLE: NATUROPATHIC MEDICINE
SPONSOR(S): REPRESENTATIVE(S) HOLM

02/04/04	(H)	READ THE FIRST TIME - REFERRALS
02/04/04	(H)	L&C, JUD
02/04/04	(H)	HES REFERRAL ADDED AFTER L&C
02/18/04	(H)	L&C AT 3:15 PM CAPITOL 17
02/18/04	(H)	Heard & Held <Assigned to Subcmte>
02/18/04	(H)	MINUTE(L&C)
03/03/04	(H)	L&C AT 3:15 PM CAPITOL 17
03/03/04	(H)	<Bill Hearing Postponed>
03/24/04	(H)	L&C AT 3:15 PM CAPITOL 17
03/24/04	(H)	Moved CSHB 434(L&C) Out of Committee
03/24/04	(H)	MINUTE(L&C)
03/29/04	(H)	L&C RPT CS(L&C) 2DP 2NR 3AM
03/29/04	(H)	DP: CRAWFORD, GUTTENBERG; NR: LYNN,
03/29/04	(H)	DAHLSTROM; AM: GATTO, ROKEBERG,
03/29/04	(H)	ANDERSON
04/13/04	(H)	HES AT 2:00 PM CAPITOL 106

WITNESS REGISTER

DWAYNE PEEPLES, Director

Division of Health Care Services
Department of Health and Social Services
Juneau, Alaska
POSITION STATEMENT: Testified on HB 543 and answered questions from the members.

KIM MARTIN, Regional Director
Pharmaceutical Research and Manufacturer of America
[No address given]
POSITION STATEMENT: Testified on HB 543.

BETSY TURNER-BOGREN, Fairbanks District Manager
American Diabetes Association
Fairbanks, Alaska
POSITION STATEMENT: Testified on HB 543 and answered questions of the members.

ELIZABETH LUCAS, State President
AARP
Juneau, Alaska
POSITION STATEMENT: Testified in opposition to HB 543.

MARIE DARLIN, Coordinator
Capital City Task Force
AARP Alaska
Juneau, Alaska
POSITION STATEMENT: Testified in opposition of HB 543 and answered questions from the members.

JEAN MISCHEL, Attorney,
Legislative Legal and Research Services
Legislative Affairs Agency
Alaska State Legislature
Juneau, Alaska
POSITION STATEMENT: As drafter of HB 543 she answered questions from the committee.

ROD BETIT, President
Alaska State Hospital and Nursing Home Association
Juneau, Alaska
POSITION STATEMENT: Testified in support of HB 543.

ALEX MALTER, MD, President
Alaska State Medical Association
Juneau, Alaska
POSITION STATEMENT: Testified in support of HB 543.

VERNER STILLNER, M.D., Psychiatrist
Bartlett Regional Hospital;
Legislative Representative
Alaska Psychiatric Association
Juneau, Alaska
POSITION STATEMENT: Testified on HB 543 and answered questions from the members.

JOE FULLER, Senior Manager
State Government Affairs
AstraZeneca Pharmaceuticals, L.P.
Juneau, Alaska
POSITION STATEMENT: Testified on HB 543 and answered questions from the members.

PAT CARTER, Lobbyist
Glaxo SmithKline
Juneau, Alaska
POSITION STATEMENT: testified on HB 543.

REPRESENTATIVE JIM HOLM
Alaska State Legislature
Juneau, Alaska
POSITION STATEMENT: As sponsor of HB 434, presented the bill and answered questions from the members.

DANIEL YOUNG, ND, LAC
AKANP Legislative Task Force
Juneau, Alaska
POSITION STATEMENT: Testified in support of HB 434, and answered questions from the members.

VERENA NILSSON
Anchorage, Alaska
POSITION STATEMENT: Testified in support of HB 434.

STEVE COMPTON, M.D.
Alaska Heart Institute
Anchorage, Alaska
POSITION STATEMENT: Testified on HB 434 and answered questions from the members.

ACTION NARRATIVE

TAPE 04-30, SIDE A
Number 0001

CHAIR PEGGY WILSON called the House Health, Education and Social Services Standing Committee meeting to order at 3:15 p.m. Representatives Wilson, Gatto, Wolf, Coghill, Seaton, and Cissna were present at the call to order. Representative Kapsner arrived as the meeting was in progress.

HB 543-MEDICAID AND PRESCRIPTION DRUGS

Number 0150

CHAIR WILSON announced that the first order of business would be HOUSE BILL NO. 543, "An Act relating to medical assistance coverage for prescription drugs; and providing for an effective date." She explained that this bill is being sponsored by the House Health, Education and Social Services Standing Committee.

CHAIR WILSON read the following from the sponsor statement:

> The Department of Health and Social Services is currently in the process of implementing a preferred drug list (PDL). This limitation on medical assistance coverage is being done as a cost containment measure. While we believe that cost containment measures are a necessary step in achieving cost savings we believe that we must proceed carefully and judiciously. To that end, the state will need to adopt formal regulations in order to ensure that our efforts to achieve cost saving is not at the expense of Alaskans' health and well-being.
>
> Under this bill the regulations must include: standards, opportunity for public comment, an appeal process, and provision for approved coverage for a drug that is not on the preferred drug list when it is deemed medically necessary.
>
> HB 543 provides that the commissioner must appoint a Prescription Drug Review Advisory Committee prior to the department establishing a PDL or placing any limitation on coverage of a medication.
>
> HB 543 places a temporary moratorium on the implementation of a PDL, or restricted access to medication coverage, for drugs used to treat mental illness. This temporary moratorium expires January 1, 2005. Mental health patients are especially vulnerable to adverse effects from changes to their

medications. HB 543 gives the department ample time to ensure that the necessary protective measures are in place prior to discussion of this drug class.

CHAIR WILSON said she understands that at the next meeting [of the Pharmacy and Therapeutics (P&T) Committee] there will be a discussion on a temporary moratorium on the implementation of a PDL or restricted access to mental health drugs. Chair Wilson noted that an unidentified person is shaking his head that is correct.

Number 0413

DWAYNE PEEPLES, Director, Division of Health Care Services, Department of Health and Social Services, testified on HB 543 and answered questions from the members. The Department of Health and Social Services is undertaking a whole series of cost-containment refinancing efforts to save general funds, he said. One significant cost centers in operating the pharmacy in the Medicaid program. He told the members that the department anticipates that in FY04 the expenditures will be $100 million. The FY05 budget has a reduction of $20 million in the pharmacy expenditure attributed to the full implementation of the preferred drug list (PDL), Mr. Peeples explained. There have been a few delays, but the department is targeted for full implementation during the first half of FY05. He said if the department cannot maintain adequate saving through the use of the PDL it will be necessary to look elsewhere to make up any difference in the $20 million reduction. Mr. Peeples told the members that some of those areas may be reduced services to Medicaid beneficiaries and/or reduced payment rates to health care service providers.

MR. PEEPLES pointed to page 2 of the handout from the Department of Health and Social Services, titled "Forecast Drug Expenditure" and told the members that if the department does not contain costs it is anticipated that the costs will double by the end of the decade. He commented that the PDL process itself is not unique. A lot of states have already implemented them. Alaska is in the last half of the states to do it, he commented. Mr. Peeples stated that it is anticipated that within the next 12 to 18 months all but one or two states will be operating PDLs. There has been a long history of PDL use around the country including in health maintenance organizations and health care plans where it has been successful in containing some costs.

MR. PEEPLES directed the members attention to page 4 of the handout which shows information from the department's PDL website. This information basically explains that the PDL is being implemented to contain costs, provide continuity of drug utilization in the state's programs, and provide assurance for patient care.

Number 0652

MR. PEEPLES told the members that the commissioner of the Department of Health and Social Services has setup a PDL Pharmacy and Therapeutics (P&T) Committee. It is composed of 14 doctors, 2 dentists, 4 pharmacists, and 1 advanced nurse practitioner. He told the members that the list of appointees is in the handout. The P&T Committee procedures are on the website, and a copy of it is also in the members' packet. This page lays out how the committee will operate, which is through public meetings with the agenda advertised before hand.

MR. PEEPLES pointed to the timeline for the public process which started in August of 2003. The first class of drugs which will go on the PDL begins on May 21.

Number 0718

CHAIR WILSON commented that she knows the commissioner went around the state advising the public of the changes that would be taking place. She asked if there were in-depth discussions about the PDL at that time.

MR. PEEPLES replied that the commissioner discussed the department's plans for the PDL with many professional organizations, such as the Alaska State Medical Association and the Alaska State Hospital and Nursing Home Association. He referred to the timeline before the members where it lists presentations that were made.

CHAIR WILSON asked for clarification that the presentations were actually on the PDL.

MR. PEEPLES commented that while he did not attend those meetings because he did not come to work for the department until October, he understands that the commissioner addressed both the changes to the department and the PDL. He commented that he did attend a number of presentations given to the medical community and hospitals that were done by the Health Care Services staff. He added that there is a power point

presentation on the PDL that he can make available to the members if they wish.

MR. PEEPLES explained that the committee listed the classes of drugs that would be reviewed on the website and provided public notice in newspapers. To date almost all of the 14 initial classes of drugs have been reviewed. He directed the members' attention to the agenda in the members packet dated March 19, 2004. These agendas are available on the website, he added. He explained that the committee has a contractor who is the financial intermediary, First Health Services Corporation. First Health Services Corporation is also under contract to do an analysis of the PDL, provide the [P&T] committee members with information, and offer recommendations.

Number 0912

MR. PEEPLES explained that the P & T Committee members received a packet of the drug class analyses about three weeks prior to the meetings. Prior to that the department solicits input from pharmaceutical companies. That information and other comments are compiled and sent in a second packet to the committee members approximately 10 to 12 days before the meeting, he said. The committee members study the material and contact their peers to get input from them. There is a committee meeting where public testimony is taken first, then a presentation from First Health Services Corporation, the committee discusses the therapeutic equivalents of the drugs, take a motion, and votes on it. After a final decision is made the cost of the drugs are considered and it is determined what the supplemental rebate will be. The department publishes and places on its website what has been selected by the committee along with detailed notes, he said. Mr. Peeples told the members that the first implementation begins on May 21. There will be a 60-day educational process where pharmacists and physicians will be advised of the changes.

Number 0994

MR. PEEPLES told the members that currently if a physician wants to write a prescription for a drug that is not on the PDL, he/she will be asked to write "medically necessary" on the prescription as the criteria to override. Some of the criteria the department would like the physicians to consider when using the medically necessary override would be first, allergic reactions, second, contra indications which means an individual cannot take the drug, and three, the drug has not proven

effective in treatment of the diagnosis. The committee also asked if the physician would note if the reason for override is allergic reaction. It is not required, but the committee felt it would be nice to have that information for the pharmacists to have for the patient's safety in the future, he added. During the first 60 days the pharmacists will get an electronic alert or soft edit coming back from First Health Services Corporation saying that the medical override note [Medically Necessary] needs to be on the prescription for those drugs that are not on the PDL. After that period of time there is an educational feedback period on that first class of drugs.

Number 1059

CHAIR WILSON asked Mr. Peeples who notifies the doctor that a particular drug is not on the PDL.

MR. PEEPLES replied it will be the pharmacist. In response to Chair Wilson's further inquiry he explained that this is an alert process, it is informal feedback.

CHAIR WILSON asked if the pharmacists will be paid for the additional work involved.

MR. PEEPLES replied no.

Number 1111

REPRESENTATIVE GATTO asked what the third reason for override of the PDL is.

MR. PEEPLES responded that the third reason is that the doctor believes the drug fails to treat the condition.

REPRESENTATIVE GATTO asked why any physician would write a prescription that had any of those three components.

MR. PEEPLES explained that what is being asked is if a physician is going to write a prescription for a drug that is not on the PDL that the medically necessary note be included on the prescription. These are general criteria that the physician is asked to consider when overriding the PDL.

REPRESENTATIVE GATTO commented that it shouldn't be necessary because physicians would do that anyway.

CHAIR WILSON clarified that the "medically necessary" notation would explain why the physician is using a drug not on the PDL, because for instance the patient is allergic to other drugs.

Number 1209

MR. PEEPLES explained that after the first 60 days First Health Services Corporation system goes to what is called a hard edit. At that point when the pharmacist enters a drug into the system that is not on the PDL the pharmacists will receive feedback that says it is a nonpreferred drug, medically necessary override is not present, it will not be paid, and please contact the physician to get medically necessary override authority, he explained. He offered that the pharmacists could still fill the prescription, but it would not be reimbursed until the medically necessary documentation was provided. Mr. Peeples said it is a fairly flexible approach to prescribing drugs outside of the PDL.

CHAIR WILSON asked if this is commonly done in other states.

MR. PEEPLES said no. He told the members that when setting up the P&T Committee the department reviewed what a lot of other states were doing. While Alaska's P&T Committee is function as many other states, a successful implementation of a PDL in other states has been a fairly strict interpretation. In other states, for example, if a physician wanted to prescribe a drug outside of the PDL one option was requiring preauthorization. What that meant is that the physician would have to call in to get authority to fill that drug, he said. Another option would provide for the physician to call for preauthorization, and would get the preauthorization automatically, but it would require talking to whoever is running the program and provide the reason for using the drug, he added. In this arrangement, the final control rests with the physician.

CHAIR WILSON commented that most states are putting the burden on the doctors, and Alaska is putting the burden on the pharmacists.

MR. PEEPLES responded that the pharmacists is the intermediary. After the first 60 days if the doctor is writing medically necessary on the prescription there is no burden for anyone.

CHAIR WILSON clarified that the doctor does not have to make calls for preauthorization.

MR. PEEPLES said that is correct.

CHAIR WILSON asked what the next step is.

Number 1325

MR. PEEPLES replied that the department is going to monitor this for the first year after full implementation. He added that he does not expect it to be fully implemented until the fall or winter. He suggested that a possible next step might be requiring physicians to write the specific reason for using a drug that is not on the PDL.

Number 1371

CHAIR WILSON asked for clarification that it will be fully implemented in November and no changes will be made until next November.

MR. PEEPLES said that the department will monitor it to see how successful it is. If it is found that prescriptions are way outside of the PDL, the department may look to providing additional outreach and education in an effort to get increased cooperation. He commented that he knows the department will be competing with pharmacy representatives who will be pushing their own products. Mr. Peeples emphasized that it is essential to get the costs under control otherwise the costs will continue to accelerate.

CHAIR WILSON asked Mr. Peeples if he really believes the department can save $20 million and in what timeframe.

MR. PEEPLES acknowledged that the experience in other states using a totally volunteer PDL has not been great. He said that the department estimates that if it uses a totally volunteer approach it may get 50 percent participation.

CHAIR WILSON asked if he hopes to save $10 million in the first year.

MR. PEEPLES replied he hopes to have 70 percent to 80 percent participation the first year. He said that the department will be heavily relying on the medical community to assist in this process.

Number 1482

REPRESENTATIVE SEATON expressed concern for the additional effort pharmacists will be required to make. He asked if pharmacists have to call doctors for clarification of prescriptions normally.

Number 1506

MR. PEEPLES replied yes. He explained that there are 14 classes of prescription drugs and the plan is to stagger the implementation to see how it goes. During the initial 60 to 120 days there will likely be a higher level of exchange [between pharmacists and physicians], but once everyone is more comfortable and familiar with the process that will quiet down, he added.

MR. PEEPLES wanted the members to note that the last class of prescription drugs that will be reviewed are the mental health drugs. It is considered to be the highest level of concern and anxiety. Mr. Peeples explained that an ad hoc advisory committee of psychiatrists to the P&T Committee has been appointed. He added that the ad hoc committee will meet a couple of times before the May 21st meeting when the full committee will take up mental health drugs, he said. Mr. Peeples told the members that there will be meetings this summer going over the mental health drugs and it is not anticipated that this class of drugs will be implemented until all the other classes of drugs have been implemented, probably not until next year. The department wants to see how the other drug classes do first because the mental health drugs will be the most difficult to manage, he explained. Mr. Peeples said that the timeframe has been setback a little longer than the commissioner originally wished which was the beginning of the fiscal year.

Number 1590

REPRESENTATIVE SEATON asked if the mental health drugs are the class of prescription drugs where the most savings can be accomplished. He asked what the percentage of cost reductions are attributed to this class of drugs.

MR. PEEPLES replied that 25 percent of the total savings are represented by the mental health drugs. In HB 543 the department lacks the leverage to work with the drugs on the PDL, he said. The leverage the department would need is to say that if the system is not working it would be necessary to increase the requirements to use nonpreferred drugs. Mr. Peeples told the members that other states have a very strict

preauthorization process, but the P&T Committee has chosen not to go that route. It was done in this way to make it easier on the prescribing physicians. If it does not work, he said, then the department will have to slowly increase the requirements. No work was done on preauthorizations on a drug in the PDL that has to do with narcotics, he said. Although the department has not done the mental health drugs, if it were to put in, for example Oxycodone, a narcotic, on the PDL without allowing any preauthorization to that, it would cause serious concerns, he said. In the past there have been serious problems in Alaska with Medicaid waste and abuse of this drug. Mr. Peeples explained that right now there is an established preauthorization and some other controls on those narcotics. If it was put in the PDL, the department would not be able to manage those drugs for cost, waste, abuse, and other issues. Mr. Peeples said that by not being able to manage that type of activity there could be some other complications with federal requirements for drug utilization review. In summary, Mr. Peeples told the committee that he believes the approach the department is taking in managing the PDL is the best of both worlds. He commented it is a balance of allowing as much flexibility on the PDL as possible and trying to get some cost savings.

Number 1783

KIM MARTIN, Regional Director, Pharmaceutical Research and Manufacturer of America, testified on HB 543. She told the members that she is encouraged that this legislation recognizes the need to allow for a prescriber's ability to opt out of the PDL and prescribe a medicine or treatment that best fits the medical condition being confronted. Ms. Martin emphasized that only when a physician can tailor treatment for their patients will there be assurance that Alaskans are receiving the best medical care. She told the members that she supports friendly amendments that address scientific standards and the appeals process.

Number 1907

BETSY TURNER-BOGREN, Fairbanks District Manager, American Diabetes Association, testified in support of HB 543 and answered questions of the members. She told the members that the association serves over 40,000 Alaskans who are affected by diabetes. While the association supports HB 543 this time there are questions about potential gaps. Ms. Turner-Bogren asked if the term "prescription drug list" includes the medically

prescribed supplies that are necessary to manage diabetes. These supplies are, for example, blood glucose monitors or sugar monitors, test strips, insulin syringes, and (indisc.). Without these supplies the daily challenges of blood sugar and safe management cannot be achieved. She said that the association receives many calls a week and 75 percent of those are focused on access and availability of supplies. Ms. Turner-Bogren pointed out that people without sufficient economic resources often have an impossible time actually managing their disease because it is impossible for them to buy the blood sugar monitor and test strips on top of the insulin. She urged the members to make sure these supplies are covered to protect the 40,000 people in Alaska who are living with diabetes.

Number 1956

CHAIR WILSON commented that this bill does not address the Senior Care program. She asked Ms. Turner-Bogren to clarify her concern with respect to HB 543.

MS. TURNER-BOGREN replied that there are some concerns that the language that refers to "preferred drug list" does not refer to supplies. With the disease of diabetes the supplies are as integral in disease management as the insulin itself, she explained.

MR. PEEPLES stated that the PDL does not address medical supplies.

CHAIR WILSON surmised that this bill would not change the process that is now in place.

MR. PEEPLES replied that is correct.

Number 2008

REPRESENTATIVE GATTO asked if an individual who submits an insurance claim for insulin could also include the medical supplies to that claim.

MS. TURNER-BOGREN responded that three to four years ago that issues was addressed. In Alaska insurance companies cover medication, supplies, and patient education. She said all three of these components are necessary for effective management of diabetes.

REPRESENTATIVE GATTO commented that this bill will not affect those with diabetes if they have insurance coverage.

MS. TURNER-BOGREN agreed with Representative Gatto. She emphasized that the people who are affected by this bill are those who have restricted financial resources who are on Medicaid. She clarified that her concern is that these individuals would not only get insulin, but also the necessary supplies to manage the disease. Ms. Turner-Bogren surmised that this bill will not affect supplies.

CHAIR WILSON confirmed that is correct. This bill will only address prescription drugs for individuals who have no insurance and are on Medicaid. There will be no change in the supplies for Medicaid recipients, she reiterated.

MR. PEEPLES agreed that is correct.

Number 2138

ELIZABETH LUCAS, State President, AARP Alaska, testified in opposition to HB 543. She told the members that in most countries, the U.S. Veterans Administration, the Indian Health Services, more the half of the states, and many private employers utilized some form of a PDL. It does not make sense to pay for a more expensive drug when a less costly medication is just as effective if not more so. A prescription program under Senior Care will use a PDL. She told the members that AARP believes this makes sense for consumers as well as the state. Ms. Lucas stated that AARP was pleased with the benefit package of Senior Care, but particularly pleased to know that the PDL would be used for the program. There is a strong movement in the United States for evidence-based formularies. She said she appreciates that the PDL identifies the most effect, appropriate, and least expensive prescription drugs.

MS. LUCAS commented that it is important to understand how a drug company seeks approval for a new drug from the U. S. Food and Drug Administration (FDA). These companies are only required to show that their new product is more effective than a sugar pill. It is not necessary to prove that the drug is as good as or better than drugs that are already on the market to treat a similar condition, she explained. Drug salesmen tell physicians which drugs are best, but it is important to note that these salesmen work for the company that manufactures them, she pointed out.

MS. LUCAS told the members that the Alaska PDL will serve as the state's consumer report on how effective a prescription is and how it compares in cost to other medications in the same class. By using the PDL other Medicaid beneficiaries and their prescribing physicians will have information that has not been previously available, she said. This makes sense. Everyone will benefit from the comparative information that will be available from the PDL. Ms. Lucas emphasized that the AARP applauds the medical professionals who are developing the PDL.

MS. LUCAS explained that the AARP looks for consumer protections whenever PDLs are developed. The Alaska PDL passes all the AARP checklists and urged the members to support this effort. However, she said that in order to support the PDL under Medicaid AARP believes the members should reject HB 543. The intent of this bill is to slow down the PDL process and if successful, eliminate it as tool for the Medicaid program. She explained that the pharmacy companies will say there needs to be more time in sharing their opinions with the P&T Committee that develops the PDL. Ms. Lucas said that AARP believes the PDL is organized properly. It uses evidence based upon scientific research for decision-making, not the latest marketing pitches. Physicians and the public hear enough from pharmacy companies everyday, she added. She stated that the PDL belongs to the people, not the pharmaceutical companies.

TAPE 04-30, SIDE B

Number 2344

MS. LUCAS urged the members to vote no on HB 543.

REPRESENTATIVE GATTO asked how HB 543 would slow down the PDL process.

Number 2299

MARIE DARLIN, Coordinator, Capital City Task Force, AARP Alaska, testified in opposition of HB 543 and answered questions from the members. She told the members that the transitional provisions in HB 543 will slow down the implementation of the PDL. The department has already indicated that there will be more time spent reviewing psychotropic drugs to ensure that the first part of the PDL is working. Ms. Darlin rephrased an earlier statement made by Ms. Lucas by saying that the bill does not do anything to help implement the PDL. It is for that reason that AARP does not see a need for the bill, she

explained. She pointed out that this bill only addresses Medicaid recipients. Those with health insurance already know that insurance companies already use PDLs. Ms. Darlin said she knows that one of the highest costs of health care is prescription drugs and the use of a PDL is an effort to save money. However, she believes HB 543 is more restrictive than what the PDL was intended. She said that AARP, as a consumer organization, is interested in PDLs so its members can become more aware of what a PDL will tell them. The members will use the list to help them when making decisions.

Number 2136

REPRESENTATIVE SEATON said he believes that what Ms. Darlin is referring to is on page 1, lines [5 and 10], which says:

> (a) If the department undertakes a cost containment measure under this chapter that involves a preferred drug list or limitation of medical assistance coverage for a drug, the department shall adopt regulations to the preferred drug list or the limitation of coverage before the list or limitation maybe implemented.

REPRESENTATIVE SEATON commented that the listed criteria must be met before a PDL could be implemented. He pointed to the third item under that criteria [on page 2, lines 2 through 4] which reads as follows:

> (3) an appeal process for a person who is affected by a decision of the department to place or not to place a drug on the preferred drug list or to limit medical assistance coverage for a drug; and

REPRESENTATIVE SEATON pointed out that this appeals process is not currently in place. He said as he reads the bill, before a PDL could be implemented there would have to be a reauthorization of the PDL with the appeals process in place. Representative Seaton surmised that there would not be time to reauthorize a new list because the Senior Care list does not have the appeals process in place. He told the members that he will offer an amendment to eliminate that section.

Number 2081

CHAIR WILSON explained that all this language does is provide for an appeals process for an individual who has been denied a prescription drug. She commented that all HB 543 does is place

the process in law. Most of this plan has already been done by the department in the last six weeks.

REPRESENTATIVE SEATON responded that he understands the intention, but he said he believes (3) [on page 2, lines 2 through 4] is under [AS 47.07] which is the statute that covers the construction of a PDL.

CHAIR WILSON replied the PDL is already in place.

REPRESENTATIVE SEATON said that this is a new PDL. The only PDL that is currently in place is under the Senior Care bill, he explained.

CHAIR WILSON responded that the PDL is all one in the same.

Number 2042

REPRESENTATIVE SEATON said he believes that if the department is required to have regulations for the construction of a PDL, then it provides that the drug companies have an appeals process if a drug is not on the PDL. In response to Chair Wilson's comment that it is a person who has the right to appeal, not the drug companies, Representative Seaton said this is not a natural person, "a person" can mean a corporation. The language does not refer to a patient, he emphasized. Representative Seaton reiterated that he believes this language would require the reconstruction of a new PDL because the appeals process was not in place while the department was doing the Senior Care PDL. He summarized that he believes that is the root of some of the concerns that are coming forward.

CHAIR WILSON told the members that when the Legislative Legal and Research Services attorney wrote this legislation she was advised that the bill was patterned after other committee processes.

Number 1961

REPRESENTATIVE CISSNA commented that she would like to hear from the department on Representative Gatto's question.

REPRESENTATIVE GATTO asked how the Medicaid claim process works.

MR. PEEPLES explained a Medicaid patient would go to the doctor, get a prescription, go to the pharmacy to get it filled, the pharmacist would contact First Health Services Corporation, and

fair, quick feedback would come back. The feedback would be something like accepted, not accepted, and payment status, et cetera, he said. The patient or Medicaid recipient does not get reimbursed for the prescription. The payment goes from the state to First Health Services Corporation to the pharmacy, he said.

REPRESENTATIVE GATTO asked if there is a PDL in place at the moment.

MR. PEEPLES responded that there is a PDL. The committee has reviewed 14 drug classes and the department will begin implementation on May 21 on the first set of these classes through the 60-day trial education process. After that 60 days, then a harder denial process begins if a prescription comes in for a drug not on the PDL, Mr. Peeples explained. There will need to be a "medically necessary" notation on the prescription, he said.

Number 1842

REPRESENTATIVE GATTO surmised that as of today a physician does not have to look at a PDL before writing a prescription. He asked Mr. Peeples if he believes HB 543 delays phase I of the implementation of the PDL.

MR. PEEPLES responded that he does not believe this bill delays phase I. What it will do is prevent the department from doing any management of a drug on the PDL. There would be no long-term incentive on the part of the prescribing community to participate on the PDL. The physicians would automatically over ride the preferred drug list. He told the members that other states have experienced 50 percent participation. That kind of impact over 18 months would mean that the department would not be realizing the $20 million savings, he said. There would be a projected $10 million loss on that projected savings and there would be a creeping up effect due to inflation and declining participation in writing against the PDL by practicing physicians.

CHAIR WILSON asked how this bill would change when the department plans to put a PDL in place.

Number 1748

MR. PEEPLES replied that the department will have to adopt regulations which will take some time.

CHAIR WILSON commented that she thought the department already had regulations in place.

MR. PEEPLES responded that the department currently has regulations and authorization in statute to move to the preauthorization PDL system. This is what the department is doing now. He told the members that he believes this bill would require the department to codify in regulations everything that has been adopted as operating procedures by the committee. He emphasized that establishing regulations is a long drawn out process.

CHAIR WILSON asked if the department wants to proceed with this through regulations.

MR. PEEPLES replied that regulations bind the committee to respond to different changes. He explained that not being able to manage any drug on the PDL limits the department's ability to pursue cost-containment.

Number 1703

CHAIR WILSON asked how other states have done this.

MR. PEEPLES said other states have established what can be done through statute and regulation, just as the department has obtained authority to proceed. He emphasized that other states have not codified their P&T Committees and regulations.

CHAIR WILSON asked for clarification that most states have a PDL in place and of those the majority have not done it through regulation. It has been accomplished through [standard operating procedures] so the rules can be easily changed.

MR. PEEPLES responded that he has not done a complete review of each state and could not answer that question. However, he said he understands that most states have adopted PDLs through standard operating procedures.

CHAIR WILSON said she is concerned when rules can be easily changed. She asked if the department normally adopt regulations to implement programs.

Number 1642

MR. PEEPLES said yes. The department has a lot of regulations in and around the Medicaid program; however, the operation of the P&T advisory committee has occurred through published operating procedures. He commented that there have been some changes based upon concerns that have been raised. Mr. Peeples told the members if all of this was set up in regulations to change, modify, and improve this process it would be a elaborate, expensive process.

CHAIR WILSON asked if this is the reason other states have taken two years to accomplish what the department has accomplished in six months.

MR. PEEPLES replied no. He explained that the department has taken advantage of what other states have already done and adapted it to suit Alaska. The department has emulated a lot of the processes and used much of the analysis that has been done on PDLs with respect to therapeutic equivalents. Mr. Peeples said the department has been using First Health Services Corporation on much of this, but this week an intergovernmental agreement was signed with the [Oregon Health and Science University] to also provide some analysis to supplement what has been provided by First Health Services Corporation. He told the members that this will likely be tweaked based upon comments and the lessons learned. Mr. Peeples reiterated that to do this process in regulations is expensive and difficult and that is the primary reason the department believes this bill is unnecessary. Everything in the HB 543 is already being done, he stated.

Number 1537

REPRESENTATIVE SEATON read the following portions of the HB 543 [page 1, lines 5 through page 2, lines 4]:

> If the department undertakes a cost containment measure under this chapter that involves a preferred drug list ... the department shall adopt regulations relating to the preferred drug list ... before the list or limitation may be implemented. The regulations must include ... (1) standards ... (2) an opportunity for public comment ...(3) an appeal process ... to place or not place a drug on the preferred drug list ...

REPRESENTATIVE SEATON asked Mr. Peeples if those three standards have been in place during the construction of the current PDL for Senior Care.

MR. PEEPLES addressed (1) by saying that the department has standards for evaluating the therapeutic equivalents of the drugs. There is a list of steps that the contractor undertakes including reviewing the Food and Drug Administration (FDA) status when the drug went on the market, contra-indications, and dosage. He explained that (2) is addressed by advertising all of the meetings, and at the beginning of each meeting there is an allocated time for public comment. The comment time for each testifier is limited to 5 minutes to ensure that there is adequate time to address the agenda. Mr. Peeples said (3) which is the appeals process is handled through the department's Division of Health Care Service. There is an established appeals process all the way up to a fair hearing where the final determination goes to the commissioner. All these elements are already in place he summarized.

Number 1442

CHAIR WILSON asked how much has already occurred.

MR. PEEPLES responded that all of it has occurred. The appeals process is for providers and recipient. The committee has not dealt with that because there is already an established process within the department that is long-standing and established in regulations.

Number 1386

JEAN MISCHEL, Attorney, Legislative Legal and Research Services, Legislative Affairs Agency, Alaska State Legislature, as drafter of HB 543 she answered questions from the committee. She explained that HB 543, Version H, provides for cost-containment measures within the Department of Health and Social Services, that specifies the authorization to adopt a preferred drug list. The bill that passed last session did not specify cost-containment measures, but did give broad authority to the department to adopted cost-containment measures. This bill provides not only specific authority for a preferred drug list, but sets out specific standards that must be met in adopting a PDL, she said. It calls for the department to adopt regulations and standards for placing or not placing a drug on the PDL or otherwise limiting medical assistance for a drug.

CHAIR WILSON asked Ms. Mischel if she looked at the way other states have accomplished this.

MS. MISCHEL replied that she did look at other states and found that the language in the bill is fairly standard language. She explained that Alaska is unique in that it does not have specific statutory requirements for state agencies. She reiterated that many states already have PDLs in place and the language used to implement it is similar to this bill. The language is also somewhat based on federal requirements in terms of establishing a PDL. Ms. Mischel told the members that it was a policy decision to define the PDL broadly as other states have a narrower definition. It was decided that a broad definition of the PDL would give the Department of Health and Social Services some latitude.

Number 1205

MS. MISCHEL explained that the bill specifies what kind of public involvement must take place, an appeals process, and an over ride of the cost-containment measure. She told the members that the over ride provision is part of a federal mandate for matching federal funds. She added that when the department contracts services, as it has done with First Health Services Corporation, it must be done in compliance with the state procurement code.

MS. MISCHEL said the bill also defines and requires that the department set up a prescription review advisory committee, which is also a federal mandate. In Section 2 of the bill under Transition Provisions, if the department decides to make the advisory committee membership smaller it does have that latitude as long as the membership meets the requirements set out in the bill. She told the members that the committee would assist in setting the standards in determining whether a drug was included in the PDL. After reviewing the minutes of the existing committee she said she found it difficult to determine what standards were being applied in reviewing a drug and establishing the PDL. There was some concern about the proprietary cost information being publicized, she added. It appeared that the committee is currently functioning very heavily on the recommendations of the contractor. In summary, she said she could not find any standards available in her review of public documentation. This bill would ensure those standards are reviewed before being adopted.

MS. MISCHEL told the members that this bill provides for a delay in the review of all mental health drugs. The bill says that the department could not place a mental health drug on a cost-containment list or PDL before January 1, 2005. This would provide time for the department to set up regulations with respect to the PDL. There is a delay in the effective date of the bill up to a six months period so the department's work is allowed to continue as it is reviewing and adopting regulations consistent with the bill, she said.

Number 0964

REPRESENTATIVE COGHILL referred to page 3, lines 12 and 13, which refers to 42 U.S.C. 1396r-8(d), and asked if the members could be provided a copy of it.

Number 0905

MS. MISCHEL replied that she would provide copies to the committee. Subsections (A) and (B) [page 3, lines 6 through 11] are modeled after 42 U.S.C. 1396r-8(d), she added.

CHAIR WILSON confirmed that 42 U.S.C. 1396r-8(d) is a federal statute and is required in order to get federal funding.

REPRESENTATIVE CISSNA asked if Ms. Mischel could provide a line-by-line review of language that is required by the federal government in order to obtain funding.

CHAIR WILSON told the members that Ms. Mischel did not have any advance notice that she would be testifying today.

MS. MISCHEL explained that there are statutory, regulatory, and constitutional law which may apply. The public hearing process is part of a due process right.

Number 0779

CHAIR WILSON commented that she believes some states had to start the entire process over again because it was found that the request for proposals (RFP) process was not adhered to. She asked if Ms. Mischel believes Alaska is in jeopardy on this point.

MS. MISCHEL replied that RFPs are part of state law. That is not a federal question, she added. It appears that the state procurement code would apply to this contract and therefore

there was a bidding process, Ms. Mischel said. If someone challenged that the contract was inappropriately awarded it could invalidate the process, she commented.

MS. MISCHEL said that she does not believe there is a [federal] requirement for an appeals process, but pointed out if one is not in place the courts would have to decide on any objection to the placement or procedure. In that regard, the appeals process helps alleviate any due process complaints, she added.

Number 0646

REPRESENTATIVE CISSNA asked for clarification that on page 2, line 2, there needs to be an administrative appeals process in place. She asked if that process is currently in place under existing law.

MS. MISCHEL replied that arguably there is an administrative process in place under the Administrative Procedures Act, but there still needs to be a determination that this is a final administrative decision. The question that remains is if the entire adoption of the PDL would be the final decision or whether each decision to place each drug on the list is the final decision. There are regulations in place that would encompass these decisions, she said.

Number 0559

REPRESENTATIVE SEATON referred to the language on page 2, lines 2 through 4, where it refers to "a person" and commented that it has been read in two different ways. One way is that "a person" is a patient; however, the way he reads it is "a person", when talking about placing a drug on the list, is actually a pharmaceutical corporation.

MS. MISCHEL replied that the language is deliberately drafted with broad language to ensure that a corporation could take advantage of the appeals process.

REPRESENTATIVE SEATON clarified that this language would ensure that a drug company could appeal if its drug were not placed on the PDL.

MS. MISCHEL replied that is correct.

CHAIR WILSON stated that was not her intention when requesting the bill be drafted.

MS. MISCHEL proceeded in discussing federally required language, and referred to subsection (4) on page 2, starting at line 5 [through 10]. She told the members that it is her opinion that this language is required to obtain federal matching funds. She commented that subsection(b), page 2, lines 11 through 13, which refers to a procurement code, is also federally mandated. While the specific language is not required, some kind of procurement code is required to be in place.

MS. MISCHEL referred to subsection (c)(3), page 2, lines 25 through 27, and clarified that the language is broader than federal requirements.

Number 0261

CHAIR WILSON asked for clarification that subsection (c)(3) is federally required.

MS. MISCHEL agreed. Subsection (d), on page 2, lines 28 through 31 [and page 3, line 1] is all state law, she commented. All the definitions on page 3, starting on line 2, is Legislative Legal and Research Services best suggested language on what is federally intended. Ms. Mischel reminded the members that the term "preferred drug list" is more broadly defined than the federal use of the terms.

CHAIR WILSON asked if that definition were narrowed would it be easier for the department to accomplish cost-containment through the PDL. If not, what are the ramification of narrowing the definition.

MS. MISCHEL replied that narrowing the definition would restrict the discretion of the department.

CHAIR WILSON commented that is not the committee's intent. It may be better to leave the definition so it is broadly interpreted.

MS. MISCHEL said under AS 47.07.036 the department currently has broad authority. This bill restricts the department's cost-containment authority with respect to PDL. She commented that if the members restrict the definition of PDL there could be a legislative intent question; however, by leaving the definition broad it gives the department more discretion.

Number 0073

REPRESENTATIVE SEATON read subsection (3)(C), on page 3, line 18 and 19, on preferred drug list as follows:

> (C) for which the department will not require medical justification by the prescribe...

REPRESENTATIVE SEATON suggested that subsection actually goes counter to what the department is trying to accomplish. Doesn't this prevent the physician from writing "medially necessary on the prescription", he asked.

Number 0031

MS. MISCHEL replied no. The medical justification in subsection (4) on page 2, [lines 5 through 10], is an exception to the medical assistance restriction, she said. The subsection that Representative Seaton is referring to says that drugs on the medical drug list do not require that medical justification. The drugs that are prescribed in paragraph (4) are not on the PDL, she pointed out. The drugs prescribed under (3)(C) are on the PDL.

TAPE 04-31, SIDE A

Number 0025

REPRESENTATIVE CISSNA asked what the impact would be if subsection (3) language on page 3 were removed.

MS. MISCHEL asked for clarification that Representative Cissna is asking what the impact would be if the entire definition of "preferred drug list" were removed.

REPRESENTATIVE CISSNA restated her question by saying that if it were her goal to help the department do a good job in putting in a PDL, what portion of subsection (3) could be deleted and still accomplish that goal.

MS. MISCHEL responded that PDL could be defined in a number of different ways. The definition in this bill is intended to be inclusive of any PDL for medical assistance coverage. If the committee restricts that definition or simplifies it, it may create some ambiguity about what authority the department has with respect to restricting coverage for prescription drugs. She suggested that the department address this point.

Number 0227

REPRESENTATIVE CISSNA asked if she misunderstood an earlier comment made by Ms. Mischel that it would be possible to narrow the scope of the department's ability to implement a PDL.

Number 0301

MS. MISCHEL suggested that it may be helpful to look at Section 1 of the bill. The authority for the regulations required in this bill only apply if the department undertakes a cost-containment measure that involves a PDL or the limitation of medical assistance for a drug. She pointed out that that language is broad. Anytime the department undertakes some action to limit medical assistance for a drug the standards and regulations would have to be in place, she explained. The decision to do that would have to go through an advisory committee.

MS. MISCHEL told the members that the definition for a PDL is Legislative Legal and Research Services best guess at what this PDL might look like. The definition is not intended to limit the department; it is meant to give the department the authority needed to design a cost-containment measure that makes sense.

REPRESENTATIVE CISSNA said she would like to hear from the department on this issue. She added that she would like to hear of any other federally mandated language.

Number 0422

REPRESENTATIVE SEATON commented that Ms. Mischel said that the standards would have to be adopted by the Prescription Drug Advisory Committee. If this bill passes by the first of May, he asked what the timeline would be for a PDL to be implemented under this bill.

MS. MISCHEL summarized that the normal process is a 30-day public notice and hearing. The notice is mandatory, but the hearing is not. The department would be free to adopt the regulations as written; however, in this bill the Prescription Drug Advisory Committee is required to participate in reviewing the regulations, so that could create some delay in reviewing and adopting regulations. She estimated that 60 days is probably realistic. Ms. Mischel added that the department does not normally move that quickly, these are technical issues, and the regulations could go out for public comment more than once.

The six-month timeframe in the bill was thought to be a realistic timeframe, she said.

REPRESENTATIVE SEATON said as he understands the bill, after the clarified regulations are in place, a drug list must be constructed. He asked if he understands correctly that this bill would require that the standards that have been adopted would then have to be applied to each of the drugs on the PDL.

Number 0622

MS. MISCHEL replied yes. That is her interpretation of the bill. Public notice must be given, usually 30 days, public testimony is taken, a day or two to review the evidence, and the committee could make a decision, she added. Ms. Mischel pointed out that the appeal process could delay the ultimate finality of the PDL. This is only speculation, which is true of any administrative decision.

CHAIR WILSON asked if the committee could adopt what has already done, or would the process have to start all over again.

MS. MISCHEL agreed that the committee could adopt what has been done. It would be necessary to adopt the standards and procedures in regulations that would be consistent with this bill, she explained. She said it would be necessary to hold additional public hearings, but if the decisions were consistent with regulation there should not be much of a delay.

CHAIR WILSON emphasized that Ms. Mischel agrees the PDL could be implemented within the same timeframe.

Number 0777

REPRESENTATIVE SEATON clarified that would be true assuming that the standards that are adopted within regulation are exactly the same standards that were used to determine the current PDL. He pointed out that any difference in the two standards would require a review of each drug and a public hearing based on the standards that were adopted under regulation.

MS. MISCHEL replied yes. She said even if the standards are identical, there would still need to be a review and an additional public hearing.

CHAIR WILSON commented that this is a policy call. Currently there is nothing in statute, so the department can do whatever it wishes, she explained.

Number 0878

REPRESENTATIVE CISSNA asked for the department to address this point.

Number 0898

MR. PEEPLES noted that there have been quite a few comments as to federal requirements for state eligibility for federally matching funds. All of the federal requirements have already been addressed by the department. The approval process to do this program is submitted through the federal Center for Medicaid Services (CMS). It was necessary for the department to submit a plan amendment before it could proceed in the cost-containment steps being done now. This has been done and approved, he stated. As part of the plan amendment the department had to provide CMS with its contract to do this. He pointed out that has been done. He reiterated that all the criteria required by the federal government has already been approved.

MR. PEEPLES told the members that all procurement procedures have been in accordance with AS 36.30, the State Procurement Act, and have been signed off by the state procurement officer. He summarized that all the basic criteria has been met.

Number 0972

MR. PEEPLES commented on the PDL discussions by saying that there are some problems with this. The definition of a restrictive formulary is a problem because the state cannot offer a restrictive formulary under the federal programs. The department will provide a PDL which offers therapeutic equivalent choices, plus a means for approval outside of the PDL.

Number 1024

ROD BETIT, President, Alaska State Hospital and Nursing Home Association (ASHNHA), testified in support of HB 543. He told the members that ASHNHA supports PDLs in the Medicaid program which is a good tool and is used widely in commercial plans.

The association does not see a problem with the department moving forward with this plan.

MR. BETIT commented that what needs to be determined is how much the committee wants in statute and how much in regulation. There needs to be some assurances through regulation that there is a predictability to the process with respect to the way the PDL is managed and changed. He said he sees the tug-of-war there because of his past experience. There are a lot of reasons why some things are not put in statute and why an agency is given a lot of discretion. Mr. Betit explained that Medicaid has so many areas of complexities and choices for someone to drive a wedge and create conflict. It is for that reason it is probably not a good idea to put something in statute where it is so hard to change it, he commented. So many interpretations can then flow from the statute in terms of what people believe it means, Mr. Betit added. The word "person" is a good example of that.

MR. BETIT told the members that he does not see anything in this bill that is required to run the PDL, as Mr. Peeples pointed out. The legislature created Medicaid and assigned it to a department to manage, and the government then signs a document declaring it the single state governing agency for the state. This is all done through a contract with the federal and state governments, he added. That is where all negotiations occur and that is what the federal government looks for in terms of documentation to make sure everything is in order, he explained. The federal government will not be looking at Alaska's statutes, Mr. Betit told the members.

Number 1134

MR. BETIT said another important issue to look at is the possibility of allowing the department the authority to exclude prior authorization beyond writing "medically necessary" upon the prescription itself. If this bill would preclude that from being possible it could be a problem, he said. There are a lot of reasons why it is important to look at medically necessary when written on a prescription. It is essential to determine that it is appropriate. The department has taken a very slow course in addressing that point, Mr. Betit commented. There may be a time when the department may need to address it if it is found that in certain areas and physicians in the state, when compared to their peers, appear to be out of the "bell curve." It may be necessary to impose additional requirements. Mr.

Betit said he does not believe limiting the department's flexibility is a good thing.

MR. BETIT told the members that while he doubts the department would do anything on mental health drugs before January of 2005, if the committee doesn't want anything to happen there until then the fair trade would be to provide the department with the difference it had hoped to save so that the loss in available funding does not compromise other services the department is trying provide.

Number 1208

MR. BETIT told the members that discerning standards relative to which drugs are in and which drugs are out is difficult. He said this is a PDL not a formulary. A formulary means that is all you have, there is no way off of it, he said. The discerning standards question is a good one, he commented. He told the members that he believes Alaska's move to connect with the [Oregon Health and Science University] is a good move. The program there is being used by more than 16 states and has a lot of research behind it. It is widely accepted across the country now, and that brings a lot of credibility to any choices being made by the Alaska Medicaid Program.

MR. BETIT summarized that he believes it is important to be concerned about a PDL, where it is going, and who would be impacted by it. He told the members that from what he has seen thus far there is a real conscience effort by the department to manage it in a responsible way and move that program forward appropriately. The department has shown that there will be many opportunities to see how this works and to speak to any concerns that may occur, and come back later with any program changes in order to fix something if it is felt that the department is not on the right track, he said.

Number 1279

ALEX MALTER, MD, President, Alaska State Medical Association, testified in support of HB 543. He read the following testimony into the record: [original punctuation provided]

> Representative Wilson, Committee Members: my name is Alex Malter. I am an internist in private practice here in Juneau, Alaska and have the privilege of representing the Alaska State Medical Association as this year's current president.

I am here today to express ASMA's support of HB 543. The Association submitted written testimony to the Committee earlier this month. Hopefully, you all have had a chance to look at it. I would like to take a couple of minutes to elaborate on a few key points of that testimony.

ASMA understands the budgetary stresses involved with the Medicaid program and is supportive of the development of mechanisms to help save money. The Preferred Drug List is one such appropriate mechanism. Through time and education, it should encourage physicians to prescribe less expensive, therapeutically equivalent drugs and this is a worthy goal.

Since the PDL's inception, however, ASMA has been concerned that economics could get in the way of good patient care, and that the process of adopting such a program must be appropriate. We have sent letters to Commissioner Gilbertson, Director Peeples, and the Special House Finance Subcommittee expressing our reservations. The Department has been quite responsive and on March 19, 2004 its ad-hoc P&T committee adopted ASMA's proposal to streamline the “medically necessary” override criteria.

Number 1379

ASMA supports HB 543 because it codifies the solution to some of ASMA's other concerns regarding the development of the PDL: First, the bill requires the PDL to be implemented via the proscribed process for adopting major policy changes—by the formal regulation adoption process called for in the Administrative Procedure Act; and second, the bill puts off implementing the PDL for drugs used to treat mental illnesses until after January 1, 2005.

As noted, we also support a process by which physicians can override the PDL by writing “medically necessary” on a script if a non-preferred drug would be more appropriate for a particular patient. Indeed, ASMA appreciates the approach taken by Medicaid's ad-hoc committee to simplify the override mechanism.

DR. MALTER said he thinks the committee has done a very good job. He told the members that he has had a chance to sit in on the committee meetings and was impressed with their level of professionalism and expertise. Dr. Malter continued reading his statement into the record:

> Mr. Peeples alluded to a valid concern; however, that once doctors realize the "medical necessity" criteria has been memorialized into law, they will be less motivated to change their behaviors. If after two to three years the Division of Health Care Services finds this provision substantially weakens the program, we would support reconsidering this provision of the bill down the line.
>
> In summary, ASMA supports HB 543 and urges the Committee to support the bill as well. Please keep in mind that physicians do not have an income stake in this issue. Rather, we are primarily concerned that Alaskan patients receive high-quality health care, and that as many Alaskans as possible have access to that care. I would be happy to answer any questions. Thank you for your attention.

Number 1448

REPRESENTATIVE SEATON commented that the department told the members that the delay of implementation of a PDL would mean that the $20 million savings that has been built into the budget would have to be absorbed either through reduction of services or reduced payment rates. He asked Dr. Malter if ASMA sees that as a problem or has any other solutions in where to find these funds if it is not saved through the PDL.

DR. MALTER replied that he has not had the opportunity to think that through. Presumably there is a valid concern that a lot of time is being spent looking at the specific language of the potential legislation, he said. As a layperson it was his impression that this could slow down the process. That would be unfortunate if folks had to come off of the Medicaid roles if it prolonged the process. He said he believes that if the legislature enacts legislation it will be done in such as way that it will slow the department down as little as possible.

Number 1568

VERNER STILLNER, M.D., Psychiatrist, Bartlett Regional Hospital; Legislative Representative, Alaska Psychiatric Association, testified on HB 543 and answered questions from the members. He told the members that those in the mental health community are experiencing cuts in community health services, hospitalizations, transportation for the mentally ill, and facilities that treat them. This bill is very important, he stated. Medications for the fragile mentally ill and the Medicaid population are often a life saver, and for that reason this bill appropriately asks for a regulatory process that makes this a more rational and transparent system. Dr. Stillner said his research, through the American Psychiatric Association, found that the states that have implemented PDLs have gone through the regulatory process, not the procedural process as has been suggested. He said he believes the regulatory process provides some safeguards in spite of the disadvantages that may occur.

DR. STILLNER told the members that there are many models throughout the country including those that completely exempt psychotropic drugs from the PDL process because it is thought that it would not save the Medicaid budget any money. The result was that of cost shifting to emergency room visits, hospitalization, nursing homes, and correctional facilities. He suggested the exemptions be provided on anti-psychotics, anti-depressants, anti-anxiety, and mood stabilizers that are used for bipolar disorders or what was once called manic-depressive illness, and attention deficit disorder (ADHD).

Number 1662

DR. STILLNER suggested a minor change on page 2, line 14 through 19, where the makeup of the Prescription Drug Review Advisory Committee is delineated. He suggested the committee have two public members appointed to the committee. He also recommends that the members consider changing the makeup of the committee to more physician members and fewer pharmacists since physicians are the main prescribers in Alaska.

Number 1735

DR. STILLNER explained that he believes the medically necessary component of the bill is important because it allows a physician to grandfather a medication in. For example, one young man who is schizophrenic is currently employed and has been out of the hospital for about nine years. Prior to that time he had been hospitalized five times, both in state and out of state. He

told the members that he would like to continue to keep this patient on the prescription he is currently on. Should those medications not be on the PDL, the override provision would allow him to continue the present treatment. This provision is a very valuable tool for a better clinical judgment than one that can be made in a pharmacy or the Juneau Medicaid office, he stated. There are safety and clinical effectiveness issues that should prevail, when for instance, a clinician with five years of experience with an individual has a better understanding of what is necessary for treatment.

DR. STILLNER summarized that he believes that postponing the inclusion of psychotropic drugs until March 2005 is a good idea. He said he wishes the date were 2006. Dr. Stillner told the members he supports HB 543 in its current form.

Number 1800

REPRESENTATIVE CISSNA commented that it is her understanding that the department is planning on delaying the inclusion of Psychotropic drugs already.

DR. STILLNER replied that was his impression also; however, he said he understands that the May meeting may look at anti-anxiety, anti-depressants, and ADHD drugs. So three of the five psychotropic drugs he mentioned will be reviewed.

REPRESENTATIVE SEATON asked for clarification on Dr. Stillner's comment with respect to the PDL and cost shifting.

Number 1852

DR. STILLNER commented that it is a very appealing notion to save $20 million from a budget. He suggested that taking money away from one area, actually shifts the expense to another area. He told the members that it has been found to be true in Michigan, New Hampshire, and other states. The ultimate cost savings to Medicaid may be non-existent, he said. In some states the PDLs have cut Medicaid expenditures by 15 percent. However, in those states there has been an increased amount of utilization of the emergency room, hospitals, nursing homes, and correctional facilities because people have not been cared for properly. Dr. Stillner claimed that while the PDL was implemented with good intentions, it has the potential of cost shifting to other parts of the Medicaid budget. He emphasized that his comments are only with respect to psychotropic medications.

Number 1895

REPRESENTATIVE SEATON responded that he believes the only way cost shifting could occur is if the team of 20 doctors plus other professionals on the committee were not effective in identifying the most effective drugs for the PDL. He pointed out that the amount of drugs prescribed are not being limited. Representative Seaton asked Dr. Stillner if there is some other element that he is missing.

DR. STILLNER commented that it is an appealing notion to say which drug is the most effective, but most of the drugs on the market have proven to be more effective than the placebo. He said that is how the FDA licenses the drugs. There is not a lot of data out there comparing one drug versus another drug, he added. It is not always an easy call to say which drug is most effective. Dr. Stillner explained that one drug could be very effective for an individual, and another drug that is less expensive could be more effective for another individual. There is a variability there. That is the reason he likes the discretion of a medically necessary over ride, Dr. Stillner stated.

Number 2022

The committee took an at-ease from 5:25 p.m. to 5:31 p.m.

Number 2038

JOE FULLER, Senior Manager, State Government Affairs, AstraZeneca Pharmaceuticals, L.P., testified in support of HB 543 and answered questions from the members. He commented that HB 543 will authorize two primary provisions. The first would be to put regulations in place for the development of the PDL and the second, is to allow a simple hassle-free over ride provision for prescribers. Mr. Fuller commented that the committee is aware of the fact that PDLs are in place in many states around the country. Every state that he is aware of has publicly debated the merits of PDLs and has either passed statutes or adopted regulations regarding its development and implementation. Mr. Fuller told the members that regulations will ensure that there is adequate due process in the development of PDLs, and that it is an open public and transparent process. This is good government that Alaskans including AARP and seniors affected by the PDL should support, he added. He said that his experience with the current process

is that it needs improvement. It is an evolving process because there is no regulation in place or road map to follow, it is always changing, he suggested. Mr. Fuller said the process is getting better, but by adopting regulations the state will have an improved process in place.

Number 2120

MR. FULLER explained that the current public testimony allowed for a manufacturer is five minutes to present any clinical data, regardless of the number of drugs that are being reviewed. He said, for instance, if his company has three or four drugs up for review he is given on 45 seconds per drug to provide input to the committee members.

MR. FULLER said that while the company has the opportunity to submit clinical data, it is not [necessarily provided] to the P&T Committee members, it is to First Health Services Corporation in Arlington, Virginia. First Health Services Corporation synthesizes all the information and passes it out to the committee members to make a decision. Mr. Fuller told the members that he does not have access to the information that is provided to the P&T Committee members. There is no other state in the nation that has a process similar to the one in Alaska, he commented.

Number 2175

MR. FULLER told the members that in Oregon and Washington there is much more time taken in the process in reviewing the classes of drugs. It is taken much more seriously. In Oregon, for instance, there is a cardiac subcommittee that looks at the beta-blocker class and there are two to three meetings before there is consensus on which drug is the preferred drug, he summarized. There is also adequate public testimony, opportunities for manufacturers, and other stakeholders. Mr. Fuller suggested that Alaska look at Oregon's process as a model that should be consider.

Number 2204

MR. FULLER agreed that the over ride provision is good one. It ensures that the final decision in terms of what drug is dispensed is made by the physician. This is the same language that is in the Senior Care bill which was passed unanimously by both houses and signed by the governor.

MR. FULLER commented that it is news to him that the state's plan to CMS has been approved. He questioned whether there was a request for proposals (RFP) put out to open bid when First Health Services Corporation received its contract. Mr. Fuller told the committee that to his knowledge that was never done, and the reason he mentions this is that the committee's legal advisor commented that there may be some risk associated with that. He told the members that both the states of Nevada and Hawaii had to stop its processes for that very reason.

MR. FULLER urged the committee's support of HB 543 because it will add clarity and adequate due process before the implementation of the PDL.

Number 2249

REPRESENTATIVE GATTO asked Mr. Fuller if the state would not use regulations in implementing the PDL.

MR. FULLER replied that the only regulation that was passed was signed by the Lieutenant Governor in January of 2003. It was a one-liner that states that the Department of Health and Social Services has the authority to prior authorize drugs. That is the only regulation in place that allows the department to go forward with the PDL, he explained.

REPRESENTATIVE GATTO questioned that the existing PDL was created without regulations by a committee.

MR. FULLER responded that Mr. Peeples could better speak to that point than he could. He told the members that his discussions with the commissioner last session left him with the impression that regulations would be promulgated, as is the case of any other state he is aware of. The next time he heard that the PDL was going forward there was a memo that provided a very detailed process and the committee was already a few months into that process.

Number 2317

REPRESENTATIVE SEATON referred to [page 2, line 2] which addresses the appeals process, and asked if every company whose drug is not on the PDL will appeal the decision.

MR. FULLER replied that he could tell the members how other states worked. In Oregon, for example, if a drug is not included in the PDL, there is no opportunity to appeal, but

Oregon reviews each class of drugs every six months. That gives the company another opportunity to voice issues with its decision or provide any new clinical data that might be available. He stated that he believed the appeals process in the bill was specific to patients or physicians who wished to appeal the choices the state made.

TAPE 04-31, SIDE B

Number 2326

REPRESENTATIVE SEATON asked Mr. Fuller if he would have any objection to removing the appeals process from the bill which could result in every drug manufacturer appealing a decision.

MR. FULLER said speaking for AstraZeneca Pharmaceuticals, L.P. he would not have a problem with this. If the language were changed to Alaska patients or providers it would clarify the intent of that language, he commented.

Number 2276

PAT CARTER, Lobbyist, Glaxo SmithKline, testified on HB 543. He told the members that he has been to every P&T Committee meeting. Glaxo SmithKline is not opposed to the implementation of a PDL, but would like assurances that there will be an open and fair process. Thus far he believes it has been unsuccessful in that regard. He has talked to department staff and written letters to the department, but the procedures that have been adopted, were adopted very recently. While the procedures may or may not have been in existence from the beginning, Glaxo SmithKline did not have access to anything that the P&T Committee members see, he stated. It is not an open process, Mr. Carter emphasized. For example, the P&T Committee first met in October and the procedure was loose, the meeting was held in a small room, it was teleconferenced to members that were unable to attend via a speakerphone. People in the room could not hear and the people trying to listen in via speakerphone could not hear, there were votes taken, and the votes were not even counted.

CHAIR WILSON asked if that process has been improved.

Number 2193

MR. CARTER agreed that there have been substantive improvements, most notably having professional equipment available. He

commented that all public testimony is taken at the beginning of the meeting. For example, there was one meeting where there were nine different drug classes that were heard, he said. Mr. Carter told the members to imagine having nine bills in front of them, all public testimony on those bills were taken at random at the beginning of that meeting. He asked if the members believe that they could make a reasonable decision based upon the information presented on how to move forward with that piece of legislation. Mr. Carter told the members that he respects the P&T Committee members and believes they are trying to do a good job, but the format that is followed is not one that a reasonable person could come up with a reasonable decision based upon the input from the public testimony. Mr. Carter pointed out that this is not sour grapes from Glaxo SmithKline because every drug that it has tried to get on the PDL thus far has been placed on the PDL. He said he's speaking only about the process because the process is what will ensure that Alaskans are protected.

Number 2137

MR. CARTER told the members that prior to the last meeting letters were submitted in a timely fashion to the department from four of the six pulmonologist in Alaska. He added that he knows one of the letters came in late, but the other three were submitted well under the wire. These physicians were told that those letters would be included in the packet, but when committee members were asked if they saw the letters it was found that the letters were not in the packets. Mr. Carter asked Dave Campana [Pharmacy & Ancillary Services, Division of Health Care Services, Department of Health and Social Services] where the letters from the pulmonologists were since pulmonary drugs were being reviewed. Mr. Carter said he thought the P&T Committee would want to hear from the those that are using and dispensing these drugs; however, Mr. Campana told him the letters were not included in the packets. When asked why, the response was "just didn't." Mr. Carter told the members that he believes that is unacceptable. The idea that procedures have been adopted does not mean very much when the rules change from meeting to meeting. For example, one meeting may allow five minutes per drug company, one meeting it is five minutes per testifier, and the next meeting it is back to five minutes per drug company again. Mr. Carter pointed out that when there are a group of individuals as highly educated as the group on the P&T Committee it seems desirable to give them the information in front of them to make reasoned decisions. He said he believes the goal should be to make sure the right medication gets

through to the right patient, then after reaching that goal look to save money.

MR. CARTER suggested that a better way to conduct the meetings would be to take testimony per drug class and give testifiers a reasonable time to present information. This suggestion was sent to the department via a letter and has thus far been ignored.

MR. CARTER said that after hearing testimony that there were a number of states that have moved forward without regulations, he called his boss, who handles most of the western states. He told the members that his boss does not know of one state that has moved forward with a PDL without regulations in place. Mr. Carter told the members that the process that has been implemented leaves the state open to huge liability possibilities if someone has a problem with a drug being denied because of a lack of regulations and good reasoned due process. If there is a heart attack or stroke or a psychotropic event which causes a death, the state could be open to liability because of that and where are the savings then, he questioned.

MR. CARTER emphasized that he is not trying to stop or slow down the process, he just wants to see a fair and open process. Since it is not happening thus far, he believes this bill is a good step in that direction.

Number 1985

CHAIR WILSON announced that HB 543 will held in committee.

HB 434-NATUROPATHIC MEDICINE

Number 1900

CHAIR WILSON announced that the next order of business would be HOUSE BILL NO. 434, "An Act relating to the practice of naturopathic medicine; and providing for an effective date."

The committee took an at-ease from 5:55 p.m. to 6:01 p.m.

Number 1805

REPRESENTATIVE JIM HOLM, Alaska State Legislature, as sponsor of HB 434, presented the bill and answered questions from the members. He told the members that he offered HB 434 to ensure professional safe naturopathic health care for all Alaskans. It

will bring an outdated 17-year-old Alaskan statute on the practice of naturopathic medicine up to date and in line with about 14 other states that already have these provisions. It provides quality health care to Alaskans through continuing education, requirements, and improved services in the practice of naturopathic medicine. It addresses the shortages of physicians in Alaska while providing alternative care and reducing health care costs to Alaskans. The bill places a continuing education requirement in statute for naturopathic physicians of Alaska. It specifies that naturopathic physicians may perform minor surgery based upon their education, training, and licensure, he said.

Number 1520

DANIEL YOUNG, ND, LAC, AKANP Legislative Task Force, testified in support of HB 434, and answered questions from the members. He provided the following testimony to the committee: [Original text, but some formatting changes were made]

> Chair Wilson and Honorable members of the committee. Thank you for allowing me to testify on behalf of HB 434. Thank you for staying later to hear this.
>
> HB 434 would allow naturopathic physicians to prescribe substances that they are trained to use and to perform minor surgery. You all know the issues before you. You have a packet with all the comparisons and it is pretty comprehensive packet. We have all met with you all on an individual basis and have plead our case.
>
> By now you have heard from naturopathic doctors and patients of naturopathic medicine that are in support of this bill. You have also heard from the medical doctors, doctors of osteopathic medicine, and even the pharmacy board. I don't think that you have heard from patients of allopathic or osteopathic doctors. Unfortunately, I had a nice conversation with Dr. Alex Malter the head of the Alaska State Medical Association in the fall and we had a good discussion. It is too bad he had to leave to care for a patient because I think it would have been helpful to have the two of us here would have been helpful in this issue.
>
> With your permission I would like to direct your attention briefly to facts:

Fact 1: Education

Naturopathic doctors are trained for general family practice. We are not trained to be specialists and do not work in hospital environments, but in out patient in the trenches.

Naturopathic doctors complete 8 years of higher education. Some receive more, but it is a minimum of 8 years.

Requirements to enter a naturopathic medical school are almost identical to that of any other medical school. I almost went to an allopathic medical school and was ready to do that.

The curriculum of a naturopathic medical school compares with allopathic (MD) and osteopathic (DO) schools, in intensity and comprehensiveness.

The clinical studies in naturopathic medical school also compare to allopathic (MD) and osteopathic (DO) schools.

Outpatient based clerkships prepare us for how we practice.

In your packets you can see charts that compare our education with medical schools.

There has also been expert unbiased testimony by Dr. Clyde Jenson in previous committee meetings and with the other body. He has a unique position to comment on the education between these three areas. He has been a president or administrator of allopathic (MD), osteopathic (DO) and (ND) medical schools for long periods of time and is quite versed to attest to the nature of their curriculums. Their first two years are almost identical. That is when you learn your sciences. That is anatomy, physiology, pharmacology, clinical physical diagnosis, and the lab diagnosis, x-ray, radiology, things like that.

The second stage is the clinical sciences that are learned in the third and fourth years. At this time naturopathic physicians go through broad based

training. They work in manipulation, botanical medicine, nutrition, dietetics, homeopathy, and some pharmalogical therapeutics, though not as extensive as a pharmalogical therapeutics in a hospital situation. As you know medical doctors and doctors of naturopathic medicine work extensively on very rigorous internships where all that is studied is pharmalogical therapeutics and they are the experts of that realm of medicine.

Number 1570

We are skilled in the 40 percent of drugs that are coming from a natural substance and there are different generations of that that we are very well versed in the use of that.

Fact 2: Licensure

Graduates of naturopathic medical schools pass rigorous nationally administered board exams. These exams have been examined by federal institutions that determine the level of education that you would need to pass them. That is for bio-medical general practice of medicine.

Fact 3: Federal Regulation

Naturopathic medical institutions are recognized by Federal and State Accrediting Bodies as well as by the Council of Naturopathic Medical education. We wish only to be able to practice how they say we are trained to practice.

Fact 4: Naturopathic Medicine is Safe

No patient complaints in 17 years of practice in Alaska. Naturopathic medicine is safe. I have numbers to show you on a national level in comparison that and we can talk about that.

Fact 5: Scientific Basis

There is research- see your packet “Naturopathic Collaborative Events”

In the packet there is a very nice presentation, Representative Coghill has it. That shows all of the clinical research and all the things that are being done in Naturopathic medicine and complimentary care across the United States.

Number 1497

Fact 6: Naturopathic Physician = Primary Care

The Journal of American Medical Association or J.A.M.A. in 1998 - there is an article in the packet by Dr. Cooper. They are saying that we are trained as primary care and outpatient based, which means we do not work in the hospitals, but we work seeing patients in our clinics. And that is how our training is and it is adequate for that.

Complimentary medicine is the wave of the future; already Alaska's clinics have MD's, DO's and ND's working side by side. It is not as much as in the Lower 48, but it is happening.

We have letters of support from medical doctors who work with us, as well as other types of practitioners.

We have thousands of signatures from patients in your districts that want access to complete Naturopathic scope of practice.

Our current statute is out of date and needs to be updated to reflect the quality of Naturopathic education.

Number 1443

These letters of opposition clearly indicate to me that there is a misunderstanding about the level of our education as naturopathic physicians in this state.

Often times these letters indicate that it is a licensing issue. We have been licensed for 17 years. All it is expanding our scope to include what should be rightfully ours. For 17 years we have been providing service to 30,000 Alaskans. I'm going to cut this short, and ask you to consider this bill. I

appreciate your time and can answer any of your questions at this time.

Number 1413

REPRESENTATIVE GATTO asked why the e-mails he has been receiving have expressed concern that the legislature may take away their right to practice naturopathic medicine. He commented that he does not know how that information got into the community, but for the record, he said, there is nothing in this bill that diminishes anything naturopaths are doing. He asked Dr. Young if he would agree with that.

DR. YOUNG replied that he would agree with respect to the intent of the bill. There is wording in the bill that has been insulting for 17 years and would like to see that corrected, he said. He told the members that his main concern is patients who want their naturopaths to be able to provide the care that they are trained to provide. For example, natural estrogens, natural progesterone, and natural thyroids are prescription drugs that naturopaths are trained to use, Dr. Young stated. He emphasized that it is not their intent to use schedule 2 drugs; naturopathic physicians do not use those drugs. Naturopaths refer their patients to other providers in cases where there is a need for more specialized treatment. When a patient comes into the office for a pap [smear], and it is found that the patient needs a special estrogen prescription that can be made for her, but the naturopath cannot write the prescription, then that is a problem. The insurance company gets billed twice; there is a waiting list; and a patient's health care is at risk. The same thing applies to patients with diabetes and hypertension, he added. Dr. Young commented that naturopaths are not interested in using anti-psychotic drugs because we are not trained for that. Naturopaths would refer appropriately for treatment outside of our area of training, he commented. Dr. Young pointed out that the current bill does not have the [drug] schedules in it.

Number 1301

REPRESENTATIVE GATTO reiterated that everyone who currently sees a naturopath will be able to continue to see his or her naturopaths. If the bill passes there will be additional privileges that will be available to the public. He asked Dr. Young for clarification that schedules were taken out of the bill.

DR. YOUNG replied that he understands the [drug] schedules were taken out of the bill in order to get it out of the House Labor and Commerce Standing Committee. He explained that naturopaths did not want schedules [one and] two because they did not want drugs that have a high incidence of physiological and physiological dependence and are hot topics. Drugs that are listed on schedules three, four, and five are far below naturopaths' level of training, he commented. There are only certain drugs within those levels that a naturopath would use anyway. The bill was originally written with the intent that naturopaths would have access to drugs they would use, he said.

CHAIR WILSON asked if Representative Holm would point out where the language was removed from the bill.

Number 1234

REPRESENTATIVE HOLM referred to CSHB 434(L&C), Section 08.45.120 (4), page 5, line 23, language addressing scheduled drugs was after the following:

> (4) prescribe and implement barrier devices for contraception;

REPRESENTATIVE HOLM commented that in the original version of the bill, the above language was numbered (5) and the language addressing scheduled drugs preceded this language as (4).

CHAIR WILSON asked where in the current bill does it authorize naturopaths to prescribe schedule three, four, and five drugs. She said she believes all of that language was removed.

REPRESENTATIVE HOLM agreed that all the language authorizing use of scheduled prescription drugs was removed.

CHAIR WILSON stated that the only thing that is left in the bill is as follows [page 5, lines 14 through 17]:

> (1) prescribe or administer for preventive and therapeutic purposes the following: food, extracts of food, vitamins, minerals, enzymes, whole gland substances, botanical medicines, and homeopathic preparations;
>
> (2) if authorized under regulations of the department, prescribe or administer legend or prescription drugs,

CHAIR WILSON told the members that legend drugs are anti-biotic, drugs for high blood pressure, diabetes, and most medications in general that can be refilled for one year. She asked if someone from the Department of Health and Social Services is available to speak to this part of the bill.

Number 1103

REPRESENTATIVE SEATON asked if legend or prescription drugs covers schedule three, four, and five drugs.

DR. YOUNG responded that controlled substances represents a relatively small part of what is in a pharmacy. Since 1971 the Controlled Substance Act put prescription drugs into schedules so that there are schedules one, two, three, four, and five. The schedules are based on the physiological and psychological dependence. Five being a relatively minimal dependence compared to one which is only used in research and in governmental research. Examples of schedule one drugs is heroin, LSD, or marijuana. Schedule two drugs are primarily narcotics such as oxycodone. Schedule three, schedule four, and schedule five drugs are other controlled substances as well, but they are of less physiological and psychological dependence. Dr. Young explained that legend drugs is an old term for the legend that use to be on the side of foods which was instituted by the FDA. He clarified that legend drugs are prescription drugs that are not controlled substances.

Number 1029

REPRESENTATIVE SEATON asked for further clarification on the term "legend drugs" and asked if it refers to all five scheduled drugs.

DR. YOUNG replied no. He told the members that his understanding of this terminology is that this language would not allow naturopaths to provide any legend drugs. However, natural thyroid or anti-biotic could be prescribed.

CHAIR WILSON noted that naturopaths would not be allowed to prescribe those drugs unless the department authorizes it.

DR. YOUNG agreed with Chair Wilson's statement.

REPRESENTATIVE SEATON said he is trying to ascertain whether the department's authorization would include schedule three, four,

and five drugs. He asked if legend or prescription drugs are something other than schedules three, four and five drugs.

CHAIR WILSON replied that prescription drugs cover any schedule drug. That is a pretty broad category which could include morphine. She commented that she would like to discuss this point with the department.

Number 0935

REPRESENTATIVE HOLM clarified that without an FDA license naturopaths cannot prescribe a prescription drug.

Number 0905

DR. YOUNG pointed to the original bill and told the members that the language was changed. He read from HB 434, 23-LS1574\D, page 5, lines 16 and 17 as follows:

> (4) after becoming registered with the federal Drug Enforcement Administration, prescribe a controlled substance;

DR. YOUNG commented that this language is no longer in the bill that is before the committee. The original intent was that naturopaths could use prescription drugs, but not controlled substances, he explained. Dr. Young added that there is a misconception that prescription drugs are controlled substances. He summarized that the language was removed from the bill in order to get it out of the House Labor and Commerce Standing Committee.

CHAIR WILSON commented that by removing that language and leaving prescription drugs in the bill it allows a doctor to write a prescription for anything.

DR. YOUNG clarified that doctors can only write prescriptions for controlled substances if he/she has a Drug Enforcement Administration (DEA) number.

Number 0871

CHAIR WILSON stated that a DEA number is required in order to have insurance payment. She questioned how it would be paid.

DR. YOUNG said he has never come across that problem because he has always worked in states where he has had a DEA license.

CHAIR WILSON responded that whenever completing insurance forms it is necessary to provide the doctor's DEA number. Without that number, insurance will not pay for the prescription.

Number 0772

REPRESENTATIVE GATTO pointed to page 5, lines 29 and 30, which reads as follows:

> (7) use the title of "doctor of naturopathy," "naturopath," "naturopathic physician," or their abbreviations.

REPRESENTATIVE GATTO commented that the use of "naturopathic physician" became a contentious point in House Labor and Commerce Standing Committee meeting. The thought there was that the term "physician" means very specific things and it is a guarded term. Representative Gatto said just because someone is a doctor, does not make him/her a physician. He suggested that naturopaths would not want to use the term because it clouds the issue.

Number 0683

REPRESENTATIVE HOLM responded that Representative Gatto makes a good point. However, he offered that the term physician in layman terms means healer. There are different methodologies of healing. There are illness such as psychosomatic illness which have no traditional ways of treatment. Those are addressed through a change in attitude, and can improve an individual's health and truly be considered physicians. Representative Holm commented that nurse practitioners are every bit as much a healer as an allopathic physician. He commented that usually when a person refers to a physician it is a reference to someone who has a doctorate degree versus a nurse practitioner. It is just one level up, he said. Representative Holm suggested the members might wonder if the level has risen to the place where naturopaths should be call physicians or true healers. He stated that he believes it does.

REPRESENTATIVE GATTO replied that if this bill becomes law then any discipline where healing occurs would merit the term physician. He questioned whether the legislature wants to make the term physician so broad that it cannot be used anymore to identify what is now known as a physician. Currently, this term

is reserved for doctors of medicine, Representative Gatto commented.

Number 0547

DR. YOUNG agreed that Representative Gatto made some good points. He explained that the term "physic" is actually a Latin term for nature. He pointed out that chiropractors are also called chiropractic physicians. Naturopathic physicians is a term used in licensed states where naturopaths are differentiated from those who have gone through a medical school and have a doctorate in medicine, so they are able to refer to themselves as physicians. He explained that a naturopath can go into any unlicensed state and hang a shingle which says "naturopath," but could not hang out a sign that says medical doctor or physician. This bill would protect that term for those who are practicing naturopathy as physicians.

Number 0457

REPRESENTATIVE COGHILL referred to AS 08.02.010, under Miscellaneous Provisions, which says:

> Sec. 08.02.010. Professional designation requirements.
>
> (a) An acupuncturist licensed under AS 08.06, an audiologist or speech-language pathologist licensed under AS 08.11, a person licensed in the state as a chiropractor under AS 08.20, a professional counselor licensed under AS 08.29, a dentist under AS 08.36, a dietitian or nutritionist licensed under AS 08.38, a marital and family therapist licensed under AS 08.63, a medical practitioner or osteopath under AS 08.64, a direct-entry midwife certified under AS 08.65, a registered nurse under AS 08.68, an optometrist under AS 08.72, a licensed pharmacist under AS 08.80, a physical therapist or occupational therapist licensed under AS 08.84, a psychologist under AS 08.86, or a clinical social worker licensed under AS 08.95, shall use as professional identification appropriate letters or a title after that person's name that represents the person's specific field of practice. The letters or title shall appear on all signs, stationery, or other advertising in which the person offers or displays personal professional services to the public. In addition, a person engaged in the practice of

> medicine or osteopathy as defined in AS 08.64.380, or a person engaged in any manner in the healing arts who diagnoses, treats, tests, or counsels other persons in relation to human health or disease and uses the letters "M.D." or the title "doctor" or "physician" or another title that tends to show that the person is willing or qualified to diagnose, treat, test, or counsel another person, shall clarify the letters or title by adding the appropriate specialist designation, if any, such as "dermatologist", "radiologist", "audiologist", "naturopath", or the like.

REPRESENTATIVE COGHILL clarified that under Alaska statutes the term is very broad.

Number 0406

REPRESENTATIVE SEATON referred to the Journal of the American Medical Association (JAMA), 1998 article where there is discussion about naturopathic physicians. He said he thinks the distinction that he sees being made through opposing comments is that naturopath are an unlicensed, unregulated group; whereas naturopathic physicians are licensed in state and have the background and training. These are two different groups, he emphasized. For example, currently a naturopath can practice right now with no training, but to be a naturopathic physician an individual must meet the licensing requirements. That is what is really being discussed here, he commented. He suggested that the committee look at the policy call of restricting the word "naturopath" to refer to only naturopathic physicians to prevent the confusion that has occurred in the testimony the members have heard.

REPRESENTATIVE COGHILL told the committee that anyone who is licensed must have the credentials. He added that he has a friend who is called doctor, but he is not a medical doctor. Representative Coghill questioned what the committee wants to define.

Number 0284

REPRESENTATIVE CISSNA asked the committee to look at page 3, lines 26 through 28, which reads as follows:

(B) addiction or severe dependency on alcohol or a drug that impairs the **applicant's or** licensee's ability to practice safely; **or**
(C) physical or mental disability; **or**

REPRESENTATIVE CISSNA pointed out that (C) does not have the same qualifying terms after the condition that (B) does. She pointed out that there are physical or mental disabilities that exist that would not impair an individual's ability to practice safely. She suggested including the same language in (C) that is included in (B).

REPRESENTATIVE CISSNA moved Conceptual Amendment 1 as follows:

On Page 3, Line 28, after "disability"
Insert: "that impairs the applicant's or licensee's ability to practice safely;"

Number 0051

REPRESENTATIVE COGHILL objected for discussion purposes.

REPRESENTATIVE CISSNA told the members that there are many kinds of disabilities, both mental and physical, that would not be an impairment. Many disabilities do not affect an individual's competency in their professional lives.

REPRESENTATIVE GATTO agreed with Representative Cissna. For example, if a person has had an arm amputated, it would not affect that person's ability to practice safely.

TAPE 04-32, SIDE A

DR. YOUNG commented that the Division of Occupational Licensing will regulate naturopaths appropriately. He pointed to the flow chart in the members' packet.

REPRESENTATIVE COGHILL said the Division of Occupational Licensing will have a hearing officer and if there is an appeal it can go straight to the court.

Number 0079

REPRESENTATIVE SEATON pointed to page 3, lines 23 and 24, which reads as follows:

(6) **is** [CONTINUED TO PRACTICE AFTER BECOMING] unfit **to practice naturopathic medicine** due to

REPRESENTATIVE SEATON commented that he is not really opposed to the conceptual amendment; however, he said he believes Representative Cissna's amendment is already covered under (6) where it says "is unfit to practice naturopathic medicine due to." He clarified that this language means that it would have to first be determined that the individual is unfit to practice due to a physical or mental disability.

Number 0131

REPRESENTATIVE CISSNA questioned why the language is included in (B). She withdrew her motion to adopt Conceptual Amendment 1.

Number 0204

VERENA NILSSON testified in support of HB 434. She told the members that she is a patient of Avanti Medical Center in Anchorage and supports the idea of her doctors being able to write prescriptions for medicines. Ms. Nilsson explained that she has had medical problems for the last 12 years and had gone to traditional doctors; however, it was not until she went to a doctor of naturopathy that she discovered what was wrong with her. She is now taking hormones in order to get some of the problems taken care of. It is still a problem for her because she has to go back to the conventional doctor to get a prescription written. Ms. Nilsson told the members that she would like all of her family go to naturopathic doctors.

Number 0346

STEVE COMPTON, M.D., Alaska Heart Institute, testified on HB 434 and answered questions from the members. He detailed his training which consisted of four years of college, four years of medical school, three years of internal medicine residency, three years of cardiology fellowship, and another year of an electrophysiology fellowship. Dr. Compton told the members that he finished training at the age of 33, then taught at the University of Utah for four years. He said he is pretty familiar with the research basis behind allopathic medicine.

DR. COMPTON told the members that he is not sure the members are aware of the profound differences between allopathic medicine and alternative medicine practices. The single most important thing that defines allopathic medicine is that it is evidence

based on scientific methods, he explained. Dr. Compton said what that means is that if patients have a clinical problem and are considering therapy to treat that problem or disease, scientific methods are used to design clinical trials. Randomized placebo controlled trials are used to determine if therapy will actually benefit a patient, he said. Dr. Compton told the members that using this approach helps them in developing new treatment so patients will have longer better lives.

Number 0526

DR. COMPTON said he believes what is not being understood is that most naturopathic practices do not involve the scientific method. It tends to be more of a faith-based practice. He said that the judgment that a treatment is effective should be based on the quality of the scientific evidence. Naturopaths are very good at convincing people that evidence exists when it actually does not or convincing people to accept substandard evidence.

DR. COMPTON explained that some of the practices of naturopathy would not stand up to scientific scrutiny. For example, iridology, which says that it can be determined if something is wrong with an individuals organs by looking at the color of a person's eyes. He said that this is no different than palm reading. Dr. Compton told the members that many of these practices would be determined to be health fraud if perpetrated by medical doctors. He added that the differences between naturopathic medicine and allopathic medicine has not been over come.

Number 0661

DR. COMPTON said when the Massachusetts legislature considered licensing naturopaths three years ago it had a special commission working for fifteen months to study the issue. He read the conclusion of that study into the record as follows:

> For an occupation with little semblance of objective scientific and ethical basis, licensure legitimizes an otherwise illegitimate and dangerous activity. It is the opinion of the Massachusetts Medical Society that it would be irresponsible and unconscionable for the commission to recommend the licensure of naturopathy in the Commonwealth of Massachusetts.

DR. COMPTON said this is an issue because prescription drugs can be dangerous. It takes a lot of training and judgment to use them. He told the members that he knows of no medical physician that learned how to prescribe medications during their medical school years. He added comparing naturopath training to medical school training is not appropriate. Prescription training occurs as an intern, resident, and fellow, Dr. Compton said. His internship was hardcore training of 90 to 100 hours per week.

Number 0769

DR. COMPTON told the committee that two patients were hospitalized in Denver a couple of weeks ago after being treated by a licensed naturopath. One was a 17 year old girl who had cardiac arrest after having UV blood irradiation. This is a procedure where the blood was removed from the girl's body, irradiated with ultra violet light and then infused back in her. Another case in 2002, Lawrence Perry, a naturopath, persuaded an 8 year old diabetic girl's parents to stop her insulin. Type I diabetes requires insulin for survival. There have been several diabetic deaths, Dr. Compton said.

DR. COMPTON shared another example of a naturopath named Reginald Fenn who in February of 2004 was jailed because he persuaded parents of an 18-day old baby with aortic stenosis not to seek surgery. He told the members the only way to treat aortic stenosis is through surgical repair. The child died after treating it with herbs and proclaiming the child was cured. Dr. Compton continued to share other examples of naturopathic malpractice in which patients were harmed. After the death of a young girl following a procedure of a naturopath, Alberta rescinded all licensing of naturopaths.

DR. COMPTON said that naturopaths will say that this is mainstream medicine, but it is not. He told the members that they will be told that naturopaths have these privileges in other states, but that is not true. He told the members that it will not be mentioned that two states have outlawed naturopathy, and only 11 states that even bother with licensure. Whether licensure should be offered is debatable and he said, in his opinion prescriptive authority is unconscionable.

Number 0905

DR. COMPTON suggested that the members look on the web site of the American Association of Naturopathic Physicians. He read a statement from the web site into the record as follows:

> Naturopathic practice excludes major surgery and the use of synthetic drugs.

DR. COMPTON commented if the members are considering giving naturopaths prescriptive authority, what is being discussed is not naturopathy, but medicine. He advised the members to talk to people who prescribe drugs and understand them before passing a bill like this. He told the members that there are dozens of drugs when used aggressively can hurt, maim, or kill people. The few classes in naturopathy schools is unlikely to provide the training to prescribe these drugs.

DR. COMPTON urged the members to educate themselves on this issue and protect Alaskans.

Number 1036

REPRESENTATIVE WOLF commented that Dr. Compton made reference to iridology. He asked if a patient came to him with yellow itchy eyes, what would be his first reaction.

DR. COMPTON responded that he believes Representative Wolf is thinking of liver disease, but that is not the iris. He explained that iridology suggests that by looking at specific color patterns of a person's iris and a specific diagnosis can be made. Dr. Compton agreed with Representative Wolf that a person with liver disease can get yellow discoloration in the white part of the eyes called jaundice.

DR. COMPTON said another questionable practice is homeopathy. Their premise is to take whatever active drug it is believed a patient needs, and repeatedly dilute it down. The idea behind this is that by doing this the essence of the drug is captured and the more diluted it is the more powerful it is. He said this makes absolutely no sense. He pointed out that homeopathy won't hurt anyone, but it is promoted as a way to make people better and there is no basis in physiology or pharmacology for the effectiveness of homeopathy, but this is another main stay of naturopathic medicine. He told the member that naturopath is not based upon science. Dr. Compton told the members that a great way to blow a lot of money on health care is to spend it on therapies that have not been proven to be effective.

Number 1212

REPRESENTATIVE WOLF told Dr. Compton of a family member's experience where after seeing and MD for an itchy condition she was told to put on calamine lotion and soak in Epson salts. He took her to a naturopath who immediately had her get a blood test. It was found that she had a tumor in her bile duct. She was within a couple of months of dying and it was a naturopath that saved her life, he stated. The MD did not address her medical condition.

Number 1263

DR. COMPTON replied that he thinks that there is a lot that naturopaths can offer. A lot can be said for a good diet and exercise. He said well-trained physicians do miss diagnose.

REPRESENTATIVE WOLF clarified that he is not talking about diet and exercise.

DR. COMPTON admitted that there are some naturopaths that are very sharp and well intentioned. There are also those whose training does not include science. In allopathic medicine if a doctor were to provide a patient with a treatment that had no scientific or rational basis and which had not been shown to help people, it would be considered malpractice, he said. Dr. Compton commented that Representative Wolf's mother had an unfortunate experience, but believes that another allopathic doctor would have eventually diagnosed the jaundice she was experiencing.

REPRESENTATIVE WOLF asked if Dr. Compton is familiar with multiple myeloma and asked what he would prescribe for treatment.

DR. COMPTON responded that multiple myeloma is usually treated with chemotherapy. He clarified that he is a cardiologist and has not worked in oncology in over 12 years so he is not an expert in that field.

Number 1408

REPRESENTATIVE WOLF said that several treatment centers in the Lower 48 are now saying that chemotherapy will not touch myeloma. He explained that a dear friend who passed away had myeloma and the doctors wanted to prescribe chemotherapy for him.

DR. COMPTON replied that this is an especially vulnerable group of people. A good oncology practice will be involved in clinical trials. The heart of it is that therapies for cancer are all pretty miserable. He said that if a therapy is offered it is important to know if it works or not. There are nationwide protocols to see if survival rates can be improved. A competent oncologist can tell a patient what the state of the art treatment is for whatever cancer a person has. He said if a cancer patient goes to a naturopath he/she could be assured of getting better with an herb or therapy, but there is no clinical or trial data available for the treatment. All the data comes from testimonial studies or belief systems, he added. In conclusion he said the strength of allopathic medicine is based on scientific methods. All therapies have a potential for harm and it is essential to know that a therapy's benefit outweighs the potential for harm, Dr. Compton stated.

Number 1589

CHAIR WILSON announced that the bill will be held in committee.

ADJOURNMENT

There being no further business before the committee, the House Health, Education and Social Services Standing Committee meeting was adjourned at 7:05 p.m.