ALASKA STATE LEGISLATURE
HOUSE HEALTH AND SOCIAL SERVICES STANDING COMMITTEE
April 12, 2010
8:32 a.m.

MEMBERS PRESENT

Representative Bob Herron, Co-Chair
Representative Wes Keller, Co-Chair
Representative Tammie Wilson, Vice Chair
Representative Bob Lynn
Representative Paul Seaton
Representative Sharon Cissna
Representative Lindsey Holmes

MEMBERS ABSENT

All members present

COMMITTEE CALENDAR

COMMITTEE SUBSTITUTE FOR SENATE BILL NO. 10(HSS)(EFD DEL)
"An Act requiring health care insurers to provide insurance coverage for medical care received by a patient during certain approved clinical trials designed to test and improve prevention, diagnosis, treatment, or palliation of cancer; directing the Department of Health and Social Services to provide Medicaid services to persons who participate in those clinical trials; and relating to experimental procedures under a state plan offered by the Comprehensive Health Insurance Association."

- MOVED CSSB 10(HSS) (EFD DEL) OUT OF COMMITTEE

PREVIOUS COMMITTEE ACTION

BILL: SB 10
SHORT TITLE: MEDICAID/INS FOR CANCER CLINICAL TRIALS
SPONSOR(s): SENATOR(s) DAVIS

01/21/09	(S)	PREFILE RELEASED 1/9/09
01/21/09	(S)	READ THE FIRST TIME - REFERRALS
01/21/09	(S)	HSS, L&C, FIN
02/18/09	(S)	HSS AT 1:30 PM BUTROVICH 205
02/18/09	(S)	Heard & Held
02/18/09	(S)	MINUTE(HSS)

02/20/09	(S)	HSS AT 1:30 PM BUTROVICH 205
02/20/09	(S)	Moved CSSB 10(HSS) Out of Committee
02/20/09	(S)	MINUTE(HSS)
02/23/09	(S)	HSS RPT CS 4DP SAME TITLE
02/23/09	(S)	DP: DAVIS, ELLIS, THOMAS, PASKVAN
03/12/09	(S)	L&C AT 1:30 PM BELTZ 211
03/12/09	(S)	Moved CSSB 10(HSS) Out of Committee
03/12/09	(S)	MINUTE(L&C)
03/13/09	(S)	L&C RPT CS(HSS) 5DP
03/13/09	(S)	DP: PASKVAN, MEYER, THOMAS, BUNDE, DAVIS
04/08/09	(S)	FIN AT 9:00 AM SENATE FINANCE 532
04/08/09	(S)	Heard & Held
04/08/09	(S)	MINUTE(FIN)
04/13/09	(S)	FIN AT 9:00 AM SENATE FINANCE 532
04/13/09	(S)	Scheduled But Not Heard
04/16/09	(S)	FIN RPT CS(HSS) 2DP 4NR
04/16/09	(S)	DP: THOMAS, ELLIS
04/16/09	(S)	NR: HOFFMAN, STEDMAN, HUGGINS, OLSON
04/16/09	(S)	FIN AT 9:00 AM SENATE FINANCE 532
04/16/09	(S)	Moved CSSB 10(HSS) Out of Committee
04/16/09	(S)	MINUTE(FIN)
03/08/10	(S)	TRANSMITTED TO (H)
03/08/10	(S)	VERSION: CSSB 10(HSS)(EFD DEL)
03/10/10	(H)	READ THE FIRST TIME - REFERRALS
03/10/10	(H)	HSS, L&C
04/06/10	(H)	HSS AT 3:00 PM CAPITOL 106
04/06/10	(H)	Scheduled But Not Heard
04/08/10	(H)	HSS AT 3:00 PM CAPITOL 106
04/08/10	(H)	Scheduled But Not Heard
04/10/10	(H)	HSS AT 3:00 PM CAPITOL 106
04/10/10	(H)	-- MEETING CANCELED --
04/12/10	(H)	HSS AT 8:30 AM CAPITOL 106

WITNESS REGISTER

REPRESENTATIVE CARL GATTO
Alaska State Legislature
Juneau, Alaska
POSITION STATEMENT: Testified during discussion of SB 10.

LATHA SUBRAMANIAN, President; Medical Oncologist;
Denali Oncology Group - Alaska (ASHO)
Anchorage, Alaska
POSITION STATEMENT: Testified in support of SB 10.

JEANNE ANDERSON, M.D.; Oncologist

Medical Director of Providence Cancer Center
Anchorage, Alaska
POSITION STATEMENT: Testified and answered questions during the discussion of SB 10.

MARY STEWART, M.D.
Hematologist; Oncologist;
Past President of the Denali Oncology Group
Anchorage, Alaska
POSITION STATEMENT: Testified during the discussion of SB 10.

HANNAH BRICE SMITH, Clinical Research Nurse
Fairbanks, Alaska
POSITION STATEMENT: Testified during the discussion of SB 10.

EMILY NENON, Alaska Government Relations Director
American Cancer Society
Anchorage, Alaska
POSITION STATEMENT: Testified during the discussion of SB 10.

JON SHERWOOD, Medical Special Projects
Medicaid and Health Care Policy
Department of Health and Social Services (DHSS)
Juneau, Alaska
POSITION STATEMENT: Answered questions on the fiscal note.

LINDA HALL, Director
Division of Insurance
Anchorage Office
Department of Community & Economic Development (DCCED)
Anchorage, Alaska
POSITION STATEMENT: Answered questions during the discussion of SB 10.

TOM OBERMEYER, Staff
to Senator Bettye Davis
Alaska State Legislature
Juneau, Alaska
POSITION STATEMENT: Answered questions on Phase 1 cancer clinical trials.

ACTION NARRATIVE

8:32:36 AM

CO-CHAIR BOB HERRON called the House Health and Social Services Standing Committee meeting to order at 8:32 a.m. Representatives Herron, Keller, Cissna, and T. Wilson were present at the call to order. Representatives Holmes, Lynn, and Seaton arrived as the meeting was in progress.

SB 10-MEDICAID/INS FOR CANCER CLINICAL TRIALS

8:33:12 AM

CO-CHAIR HERRON announced that the only order of business would be CS FOR SENATE BILL NO. 10(HSS)(efd del), "An Act requiring health care insurers to provide insurance coverage for medical care received by a patient during certain approved clinical trials designed to test and improve prevention, diagnosis, treatment, or palliation of cancer; directing the Department of Health and Social Services to provide Medicaid services to persons who participate in those clinical trials; and relating to experimental procedures under a state plan offered by the Comprehensive Health Insurance Association."

8:33:46 AM

SENATOR BETTYE DAVIS introduced SB 10, paraphrasing from the sponsor statement in members' packets. The sponsor statement read as follows [original punctuation provided]:

> CS Senate Bill 10: "An Act requiring health care insurers to provide insurance coverage for medical care received by a patient during certain approved clinical trials designed to test and improve prevention, diagnosis, treatment, or palliation of cancer;..."
>
> ... directing the Department of Health and Social Services to provide Medicaid services to persons who participate in clinical trials; relating to experimental procedures under a state plan offered by the Comprehensive Health Insurance Association; and providing for an effective date."
>
> Clinical trials are research studies that test how well new medical approaches work in patients. Each study answers scientific questions and tries to find better ways to prevent, screen for, diagnose, or treat disease. Patients who take part in cancer clinical trials have an opportunity to contribute to the knowledge of, and progress against cancer. They also

receive state-of-the art treatment from experts in the field. The National Cancer Institute, as part of the U.S. National Institutes of Health, reports 6,000 cancer trials in the United States any one time. They include trials in prevention, screening, diagnosis, treatment, quality-of-life, and genetic studies.

CSSB 10 removes important barriers to the participation of patients in cancer clinical trials in Alaska. It requires that applicable health care plans, including Medicaid, cover routine patient care costs for patients enrolled in all phases of clinical trials, including prevention, detection, treatment, and palliation (supportive care) of cancer. Medicare, the VA and military insurance already cover the benefits that SB 10 provides. Currently Alaska health plans may exclude coverage for routine patient-care costs while a patient with cancer is enrolled in a clinical trial. Providers of health care plans often conclude that money is saved by excluding care while patients participate in clinical trials. But these patients, if not enrolled in clinical trials, will continue to receive conventional therapy at roughly the same or slightly increased costs.

Over 2600 Alaskans are diagnosed with cancer each year. In FY 2007 an estimated 4,600 patients received cancer treatments through Alaska's Medicaid program at a cost of $21.5 million. The average payment per beneficiary was about $4,675. The federal government reimburses the state at about 50% of the total costs. Without in-state facilities and support of clinical trials participants in Alaska currently have to travel out of state, increasing the cost of non-emergency transportation which is about 3% of total Medicaid costs.

Studies have shown that only 2% to 3% of adult cancer patients and less than 0.5% Medicare patients enroll in clinical trials of the approximately 20% who are eligible -largely due to fear of denial of insurance. A recent study found only slight increase in treatment costs for adult clinical trial patients compared to nonparticipants, $35,418 versus $33,248 or about 6.5% increase in costs for clinical trial participants compared to nonparticipants. Even if enrollment was increased to the full 20%, it is

unlikely that these numbers will significantly impact overall costs to health plans. See National Conference of State Legislatures, "Clinical Trials: What are States Doing? February, 2009 Update,"

www.ncsl.org/programs/health/clinicaltrials.htm.

Twenty-three or more states have passed legislation or instituted special agreements requiring health plans to pay the cost of routine medical care patients receive while participating in clinical trials. Passage of CSSB 10 will result in more successful outcomes in cancer treatments in Alaska, increase retention of patients in Alaska for their cancer care, and also, after full implementation, result in cost savings in the short and long term.

A description of "The Access to Cancer Clinical Trials Act of 2009" H.R. 716, 111th Congress 2009-2010, (Rep. Sue Myrick) per "The Hill's Congress Blog" January 30, 2009 sums up to a large extent what CSSB 10 is attempting to do:

"Clinical trials are so critical for patients and or medical research, yet many patients find that their health insurance won't cover the rest of their routine cancer treatment if they decide to enroll in clinical trials. We're not asking insurance companies to pay for clinical trials. This bill simply states that insurers must continue to pay for routine treatments — that they would be paying for regardless — if patients enroll in a clinical trial.

No patient should ever have to fear exploring all treatment options at the cost of losing coverage. We should be encouraging participation in clinical trials, not discouraging it by removing coverage for routine care. Were it not for patients who have enrolled in past trials, the medical advancements we've experienced toward finding a cure for cancer would not be possible."

SENATOR DAVIS stated she was anxious to move this bill to the next committee of referral. She expressed concern that adding any amendments at this stage of the legislative process would slow the down the bill and it may not pass. She related her understanding that an amendment "being floated around" would

"gut" the bill by removing the fundamental principles of the bill. She characterized SB 10 as very worthwhile to patients in Alaska. She highlighted the value of having insurance companies cover clinical trials by sharing a personal story about her husband's bout with cancer. She related that five years ago her husband was diagnosed with stage 4 cancer. His oncologist determined the tumor could not be surgically removed but outlined treatment options, which were necessary or he would likely die in six months. His oncologist had trained at University of Texas M.D. Anderson Cancer Center in Houston and recommended it as a treatment center, but also outlined chemotherapy treatment. Her husband chose to stay in Alaska. As the tumor spread to his liver, he then became eligible for clinical trials. He was still healthy so he traveled to Houston to apply for clinical trials. After six weeks her husband found out "did not make the cut" and at that point he returned to Alaska. Later when he was selected to participate in clinical trials his health had deteriorated to a point that he was no longer eligible. She said that as predicted her husband died within six months after diagnosis. She said that she has a vested interest in helping ensure that other people could obtain coverage for treatment in Alaska.

8:40:36 AM

REPRESENTATIVE T. WILSON asked whether the cost of any medical complications from clinical trial are covered by insurance or are absorbed by the clinical trial.

SENATOR DAVIS said she did not know. She deferred to the professionals to answer that question.

8:41:16 AM

REPRESENTATIVE CARL GATTO, Alaska State Legislature, said that patients sign "about a 30-page document" and "if everything goes south" the clinical trials will cover the patient's medical costs. He offered his belief that it is likely less expensive to hold clinical trials and discover a good medicine than for insurance companies to cover medical costs for an extended period, such as for ten years.

REPRESENTATIVE GATTO related an incident, in which researchers tested MDX-010, Ipilimumab, which is a type of monoclonal antibody, to see if it will stimulate a strong immune response to attack the prostate cancer or other cancer cells. Several hundred people participated and after a year, five people

decided they no longer wanted to continue. Prior to the trial, patients were required to have a visible lesion or some measurable evidence of cancer so any progress or deterioration could be measured. During surgery surgeons found that in two of the five instances, the clinical trial patients' cancers had disappeared or were so small, the person would not have initially been qualified to participate in the clinical trial. He suggested the other three patients outcome was not reported, but he surmised they likely were in the placebo group. Clinical trials can produce an effective medicine, he stated. The alternative is to undergo chemotherapy or take drugs, which are generally very expensive and often do not cure the disease, but will delay the patient's death. He offered his view that people who are really sick are the ones selected to participate in the clinical trial.

REPRESENTATIVE GATTO related his personal experience participating in a clinical trial for CTLA4, Cytotoxic T-lymphocyte antigen, which is a protein that plays an important regulatory role in the immune system. The clinical trial was aborted when one patient's blood platelet levels dropped so low that the patient had to be hospitalized. He remarked that the drug was modified and is currently being used again. He offered his view that clinical trials can save money and can offer patients a better life. The one exception is that people who are not "clearly" sick are excluded from the clinical trial, he thought.

8:47:32 AM

REPRESENTATIVE T. WILSON asked for clarification of "routine care" and at what point the care is identified as routine, and whether it includes care given prior to or during the clinical trial.

REPRESENTATIVE GATTO responded that participants frequently must undergo screening tests such as bone scans or CT scans prior to participating in a clinical trial. He explained that drug companies like Bristol-Myers Squibb will provide the drug, administration, and monitoring at no cost, but prefer participants in clinical trials have insurance to cover the remaining costs. He surmised it may cost $1 billion to develop a specific drug. He pointed out routine care for a patient may be an instance in which the patient has a recurring headache and sees his/her physician who subsequently diagnoses the headache as not related to the clinical trial drug. The doctor would treat the headache under routine patient care.

8:49:08 AM

REPRESENTATIVE T. WILSON asked how a primary care physician could differentiate routine care from cancer care.

REPRESENTATIVE GATTO answered the doctor administering the program replaces the patient's normal physician, administers the drug, and performs checkups to monitor blood counts or other tests to determine effectiveness.

8:50:20 AM

CO-CHAIR KELLER asked whether he could report on the medical costs the pharmaceutical company or insurance company covered during the clinical trial.

REPRESENTATIVE GATTO remarked that patients are not declined treatment simply because they do not have insurance.

CO-CHAIR KELLER referred to pages 62 and 63 of the state's insurance plan for further information.

8:51:51 AM

SENATOR DAVIS asked to have members listen to the professionals who will testify today rather than ask questions at this point. She suggested that Representative Gatto should not have to answer all the questions.

CO-CHAIR HERRON agreed that the committee would have opportunities to hear answers from other testifiers.

8:53:31 AM

LATHA SUBRAMANIAN, President; Medical Oncologist; Denali Oncology Group - Alaska (ASHO), offered her support for SB 10 on behalf of the Alaska affiliate of the American Society of Clinical Oncology and her patients. She stated her patients could not participate in cancer clinical trials since their insurance refused to pay for routine patient care costs. She expressed gratitude for the hearing. She stated that cancer is a deadly disease. Our guidelines through National Comprehensive Cancer Network (NCCN), which are based on evidence-based medicine, strongly recommend treatment under clinical trial for patients diagnosed with cancer. She explained that patients decline participation in clinical trials when their insurance

will not cover their costs, yet the same insurers will pay for routine patient care cost when patients are treated outside of clinical trials. She stated that as long as patient has cancer and is under the care of an oncologist, they still need care. It does not matter if the course of action is chemotherapy, clinical trials, or not, the patient still needs care. The patient needs routine care, which is covered by an insurance company if the patient is not on a clinical trial. She said, "That's what this whole bill is about." She understood the main concern has surrounded the cost to the insurers and effect on premiums. However, all the scientifically published data shows the impact on the cost of premiums is less than 1 percent. The Memorial Sloan-Kettering Cancer Center compared clinical trial cost with routine care. The center found the mean total cost for six months for clinical trials was $30,775 as opposed to $37,000 for standard care. The quality of adjusted life years, which was averaged at $50,000 cost effectiveness. She related that spoke to the successes from clinical trials. It turns out the drug, MDX-010, Ipilimumab, is being used for Phase 3 trials for melanoma since the mortality rate decreased and is thought to double the life span for patients with melanoma. She remarked this drug came out of clinical trials. She pointed out that it is because of cancer clinical trials that survival rates in childhood cancer has significantly improved, and death rates have decreased by 62 percent. The survival rate for children with acute lymphocytic leukemia, which is the most common leukemia in children, survival has increased from 4 percent to 80 percent due to advances in treatment made possible through clinical trials. She concluded by emphasizing that the only reason to initiate SB 10 is to ensure that insurers will pay for services of usual and customary care for patients on clinical trials that would be covered it the patient did not participate on clinical trials.

8:57:48 AM

CO-CHAIR KELLER said cost was not a concern if it is "the right thing to do." He asked if she had documentation for denial of routine care.

8:58:25 AM

DR. SUBRAMANIAN answered yes. She referred to two of her patients who would have participated in clinical trials if they had been eligible: one was diagnosed with breast cancer and the other was diagnosed with lymphoma. She stated that their insurance companies opted out of providing routine care. She

reported that both patients currently are undergoing chemotherapy and the insurance companies are paying the costs outside of the clinical trials. In further response to Co-Chair Keller, she clarified that the insurance company would not pay for routine care.

8:59:20 AM

CO-CHAIR KELLER said a section of the bill requires coverage for Medicaid. He referred to the zero fiscal note. He said he is trying to understand the insurance companies' concerns.

DR. SUBRAMANIAN said she asked the same question.

9:00:23 AM

REPRESENTATIVE T. WILSON asked which companies denied the claims.

DR. SUBRAMANIAN did not recall the specific name of the insurance companies for her patients.

REPRESENTATIVE T. WILSON asked who decides which costs are considered routine care and which costs are covered by the clinical trials.

DR. SUBRAMANIAN defined routine care as the care that would normally be given to the patient if they were not on a clinical trial.

REPRESENTATIVE T. WILSON asked for a definition of routine care.

DR. SUBRAMANIAN answered yes. She thought most trials defined routine care and standard care.

9:02:01 AM

CO-CHAIR KELLER related his understanding that clinical trials are experimental and cancer is diagnosed in four phases. He commented that some states have passed the bill excluding Phase 1 cancer patients. He recalled the sponsor's testimony suggested an amendment would gut the bill, which is not the intent. He suggested only providing insurance coverage for cancer clinical trials for Phases 2-4.

9:03:21 AM

DR. SUBRAMANIAN answered that Phase 1 trials relate to the initial step of studying a treatment or a drug on patients with cancer. The drug is designated as promising after lab tests. Since advancement in molecular advancement has occurred, it has become more important since that is how many drugs come into use. She explained that Phase 2 and 3 clinical trials are for drugs known to work in certain cancers that are tested to determine if they work better than the standard of care treatment or if their use can be expanded to treat other cancers, such as Perceptin in breast cancer, which is now used in ovarian cancer or stomach cancer. Phase 4 studies cover a larger group of patients to test for toxicity not detected in preliminary studies. She pointed out that the studies all have their value in cancer care.

9:04:37 AM

CO-CHAIR KELLER asked whether more people participate in Phase 1 clinical trials.

DR. SUBRAMANIAN answered that actually a fewer number of patients participate in Phase 1 clinical trials, usually numbering 10 to 20 patients.

CO-CHAIR KELLER surmised that all Phase 1 clinical trials do not proceed to Phases 2, 3, or 4 so it seems fewer patients would be involved in Phase one clinical trials.

DR. SUBRAMANIAN agreed, but noted that more Phases 2, 3, and 4 trials are currently open.

9:05:44 AM

DR. SUBRAMANIAN, in response to Representative T. Wilson, said patients without insurance can obtain care, but usually the hospitals or physicians write off the cost unless the patient pays something. She emphasized that physicians always try to provide the best care available to their patients.

9:06:33 AM

JEANNE ANDERSON, M.D.; Oncologist, Medical Director of Providence Cancer Center, stated that she has been in private practice in Anchorage for nine years. She stated that she has been involved in clinical trials and cancer treatments for the past twenty years. She worked initially at the University of Washington in Seattle, at the Hutchison Cancer Research Center,

and at the University of Texas Health Science Center, in San Antonio, Texas. She is currently the Medical Director of the Cancer Research Department of the Providence Cancer Center. She reiterated the importance of this bill. She clarified that each patient's plan is examined to determine the Medicare coverage. This analysis uses the National Comprehensive Care Network (NCCN) guidelines to identify routine care. Additionally, she clarified that the bill requires insurance companies to pay for complications. When a patient is enrolled in a study, he/she may obtain a standard chemotherapy drug and a "blind" drug. Thus, when someone has a complication, it is difficult to identify the reason. Cancer patients have so many complications that the medical staff grades and attributes the likelihood that investigation blinded drug "x," the placebo, or other drug caused the complication. It may be due to underlying diabetes, lung cancer, or hypertension.

DR. ANDERSON stated that more studies are in Phase 2 and 3 since many studies are not looking for a development of a new drug. Many studies use standard drugs, such as Adriamycin, which are then combined with other drugs and that the frequency of doses is studied for effectiveness. She offered her view that a myriad of types of clinical trials exist. One reason why an increase in cost for clinical trials is not observed is treatment consists of variations of routine treatments. Last year, Providence Alaska Medical Center (Providence) excluded enrollment of clinical trials to employees. However, Providence will now allow employees to enroll in clinical trials. She currently has two such patients in her care and there has not been additional patient cost to participate in the clinical trials. She surmised that other self insured plans will likely follow suit. Medicare recipients and the Department of Defense recipients have this coverage.

9:12:14 AM

MARY STEWART, M.D., Hematologist; Oncologist; Past President of the Denali Oncology Group, stated she has practiced in Anchorage for 25 years providing care to cancer patients. She explained that clinical trials provide one avenue to find better treatment for cancer patients. She said, "Any barriers to clinical trials should be brought down. Insurance coverage for routine care is one of them. Please pass this bill."

9:13:20 AM

CO-CHAIR KELLER remarked that there were different perspectives in viewing the bill. One is from the patient's perspective. He commented that he is a patient of the Denali Oncology Group. Patients facing death is one perspective. Another perspective considers pharmaceutical and insurance companies. Pharmaceutical companies invest sometimes billions of dollars, assuming risk, in order to develop drugs for profit. Insurance companies make their profits on policies, but are a heavily regulated industry. He expressed concern that the insurance companies may pick up some of the cost and that could affect clinical trials. He said, "We're messing with the market, if we're not real careful." He reiterated that it is difficult to know the effect the bill would have on two huge industries.

DR. STEWART said that the interplay between the entities is complicated, but not the bill. This bill is for insurance covering routine care for patients since those costs would be covered normally. She provides a certain number of blood tests, imaging, x-rays routinely since that is normal patient cancer care. Those tests do not disappear just because a patient is on a clinical trial. This bill does not involve any interplay of pharmaceuticals or insurance entities.

9:17:38 AM

CO-CHAIR KELLER asked whether Dr. Stewart is confident that insurance companies were denying routine care.

DR. STEWART said that insurance denials do happen. She said, "It's very sad. Not only does it deny help to those individuals, but it denies help to people with cancer in general. The more clinical trials we have the more answers we will get, the more people we can help, the more cancers can be cured. This is just routine care."

9:18:29 AM

DR. STEWART, in response to T. Wilson, related that some clinical trials are "blinded" and some "are not" so doctors sometimes know which patients are in each clinical trial group. In further response to Representative T. Wilson, she explained that some clinical trial patients receive placebos, but if those patients were not involved in the clinical trials, they still would have checkups. The NCCN Guidelines previously mentioned identify the standard version of care to determine routine care.

REPRESENTATIVE T. WILSON expressed concern that the patients involved in the placebo group add costs to insurance groups but are not receiving care.

DR. STEWART explained it is rare to have a "placebo only" group so typically the patients receive a standard of care and need regular visits. Placebo trials are only prevention trials, or trials to prevent cancer and some Phase 1 or Phase 2 trials to determine effectiveness in a certain type of cancer.

9:21:29 AM

HANNAH BRICE SMITH, Clinical Research Nurse, referred to previous questions asked by committee members. She clarified that not every drug during the clinical trials process goes through Phases 1-4. The Federal Drug Administration (FDA) conducts clinical trials on Phases 1-4 and subsequently the oncologist and research staff experiment with dosage, combining drugs, and time intervals of administering the drug for effectiveness and work to decrease the side effect. She related that routine care is based on diagnosis and evidence-based practice. Thus, if a person is diagnosed with "cancer A" evidence shows the person requires blood work on day 1, 5, and 10, an x-ray on day 1 and 10. Currently, some insurance companies will agree to pay for these services so long as the person does not participate on any clinical trials. The same insurance companies will deny all coverage for any treatment of patients who participate in clinical trials. Therefore, patients participating in clinical trials are discriminated against by some insurance companies. She explained the national guidelines identify routine care for all types of cancer. This bill would require insurance coverage for routine care. She pointed out that the routine care is based on the diagnosis and not on the cancer phase. She said, "We've gotten so caught up on the phases of the trials that we are forgetting, in some ways, how many different types of clinical trials are out there for cancer." She listed them as prevention trials, symptom management trials, treatment trials, and end-of-life trials. There are trials that look at all aspects of cancer, not just someone who is on the end of the spectrum, she stated. She described an instance in which a patient offered to provide an insurance denial letter, but the patient has since had a recurrence of cancer and feared reprisal from the insurance company. She concluded, "That breaks my heart for my patients." She said she has been an oncology nurse for 23 years and has been in cancer research for the past two years.

9:26:34 AM

EMILY NENON, Alaska Government Relations Director, American Cancer Society, related that initially she did not know much about clinical trials. She learned that clear standards for routine care exist, whether or not the patient is involved in a clinical trial. She advised that placebos are never used solely in a treatment trial. When testing a drug, the efficacy of the drug is tested in conjunction with other drugs. The code of ethics would not allow an oncologist to only administer placebos to their patients during clinical trials. She has examined market segments. The trial sponsors pay for investigational drugs and treatments and any research-related costs such as data collection and analysis but do not pay for routine care. Thus, any uninsured patient involved in a clinical trial and routine care would be absorbed by the doctors. She reported that in Alaska all insurance plans are not regulated, but the group it does cover is usually the last to add coverage. Currently, Medicare, Medicaid, the Veterans Administration, and self-insured plans such as Providence, Banner Health, and many federal employee health benefit plans provide coverage. Thus, a significant portion of the companies all have this as standard coverage. "This is really one of the last pieces we're getting at," she said. Finally, costs are a significant consideration and the costs for routine care are comparable whether or not patients are participating in a study. In some instances the costs are less, she stated.

9:32:01 AM

REPRESENTATIVE T. WILSON asked how this would affect self-insured small businesses.

MS. NENON answered that the bill would not apply to self-insured small plans as they are not technically insurance plans.

9:32:50 AM

REPRESENTATIVE T. WILSON asked how many companies do not cover routine care for cancer treatment.

MS. NENON said she did not know and was not aware of any database.

9:33:59 AM

REPRESENTATIVE CISSNA explained that she is a breast cancer survivor who underwent a mastectomy. Five other women had similar operations at the same time. She learned from support groups that after one year lapsed that only three of the five cancer patients were still alive. She related that she was the first person in her family to have cancer so her daughter inherits the risk of cancer. She offered that clinical trials are reducing the risk for women now and for next generation. She recalled from her work in villages that elders did not remember cancer as a prevalent disease nor was it discussed in oral histories. She surmised that Alaskans face risk and to address the risk requires lifestyle changes and to ensure everything possible is done to eliminate cancer. She offered her belief that clinical trials are the "pathway forward." She said she supported SB 10.

9:39:57 AM

REPRESENTATIVE T. WILSON asked who should be responsible for the costs of clinical trials. She surmised that the pharmaceutical companies will potentially "make a lot of money" from the new drug. She asked if smaller companies would have to pay for the routine care.

REPRESENTATIVE CISSNA replied in Alaska the companies who earn large profits tend to be those involved in chronic health care. She pointed out that there are not any pharmaceutical companies in the state. She offered her view that policy makers should seek to safeguard Alaskans and not discourage profit since that translates to jobs. However, policy makers must also keep in mind whether the policy benefits people. The profit is a separate issue. She is more concerned with keeping people healthy. Hospitals "make a lot of money" but that does not interfere with her desire to provide hospital care to Alaskans.

9:43:17 AM

REPRESENTATIVE T. WILSON surmised that all insurance companies are not required to provide routine care since only 23 percent of the private industry covers this care. The majority of Alaskans are covered under self-insured plans. She asked how that percentage is offset.

JON SHERWOOD, Medical Special Projects, Medicaid and Health Care Policy, Department of Health and Social Services (DHSS), explained that the state's Medicaid program already pays for routine care for clinical trials. He reported that a number of

elderly patients are on Medicare. Thus, a disproportionate number of patients fall into the Medicare group. He stated that the state reviewed its policy and costs and made a determination to add coverage of routine costs.

9:45:42 AM

REPRESENTATIVE T. WILSON referred to the title of bill, which read: "...to provide Medicaid services to persons who participate in those clinical trials; and relating to experimental procedures..." However, Medicaid already covers clinical trials, she said.

MR. SHERWOOD said, "That is correct." This bill would give statutory authority instead of by policy and regulation. The department is not required to do so by statute and SB 10 would put it in statute to disallow policy reversal.

REPRESENTATIVE T. WILSON related this would apply to all insurance companies not just Medicaid. She emphasized that the state cannot mandate groups currently covered under federal law.

9:46:58 AM

LINDA HALL, Director, Division of Insurance, Anchorage Office, Department of Community & Economic Development (DCCED), introduced herself.

REPRESENTATIVE T. WILSON related her understanding that the self-insured companies currently are covered under federal law and would not be affected by SB 10.

MS. HALL agreed that most large companies have self-funded plans but the state's plan does not fall under federal law. The state self-funded plan is not considered to be insurance and governmental plans are exempted from the Employee Retirement Income Security Act (ERISA). The state plan is not regulated by anyone, she advised. She reported that most self-funded plans are regulated by ERISA under the federal Department of Labor.

9:48:22 AM

REPRESENTATIVE T. WILSON asked for the financial impact for those affected by the requirement in SB 10 that insurance plans cover routine care.

MS. HALL responded no. She said she did not think there was any way to know the financial impact ahead of time. Alaska has fewer mandates than most states. It is not tracked to that degree of specificity to obtain a cost for a mandate.

REPRESENTATIVE T. WILSON said what she viewed as happening would result in battles in discerning routine care from clinical trial costs. She asked if doctors could identify routine care costs for patients in clinical trials.

MS. HALL said that she was not sure. She said she just heard testimony that "routine care" was defined. She did not think that a situation existed in which all insurance companies denied coverage for all treatments. She offered to review the individual health policies, if necessary, to examine which companies deny routine care in clinical trials. She was aware that some large companies did provide routine care for certain phases. The exclusion usually falls under policy of not paying for experimental drugs, but does not generally cover routine care. She said she met with her staff on consumer complaints. She reported that about 50 percent were complaints about health insurance. She said she asked whether complaints were made for lack of routine care during clinical trials and was advised that they were not the cause for complaint. Thus, she finds that the division does not currently receive complaints on insurance coverage for clinical trials. She said, "I'm very interested. And I've heard some testimony today that I would be interested in follow-up with people that are seeing that. And it may be a contractual exclusion in the policy." She stated that she was aware of complaints about experimental drugs not being approved. Alaska currently has an internal and external review process that "brings in" outside doctors to review and make determinations. She offered that there are procedures in place that review things like routine care for clinical trials. She anticipated that even if SB 10 became law, that a wide range of matters would not be clarified about experimental exclusion in a policy. She offered that insurance policy is subject to interpretation. She said that the division provides that technical level of expertise, but a lot of questions still remain. She said she did not see this as "cut and dried." She suggested she is available to provide a broader range of information to the legislature as it makes the policy decisions.

9:54:17 AM

CO-CHAIR HERRON recapped her testimony revealed that routine care is not defined in statute, but the federal guidelines define "routine care."

REPRESENTATIVE T. WILSON stated that if the clinical trials are successful, someone will obtain great profits. She saw this bill as one in which "if I can make more profit over here because I can make this group pay for part of this trial, which is exactly what they would have to do if the insurance company didn't do it to make their case go forward." She viewed SB 10 as requiring the company to cover routine costs for clinical trials if the funds are not coming from another source. She asked whether clinical trials would end if this bill did not pass.

MS. HALL said that she could not answer that question. She surmised that drug companies cover a large portion of the cost of clinical trials. She said she did not know if they would end the clinical trials if other funding sources were not available.

9:56:10 AM

REPRESENTATIVE CISSNA asked whether self-insured companies could be required to cover some of the costs even though the DOI does not have oversight.

MS. HALL said the requirement to mandate coverage would have to be in federal law. The state is pre-empted in federal law from having any oversight of the self- insured groups. Sometimes the state passes law that mirrors federal law so the department can regulate.

9:58:02 AM

REPRESENTATIVE CISSNA said, "If I understand it correctly, we can't make the law to do that but we can adopt a federal law to enforce the duties."

MS. HALL agreed. She reiterated that the legislature adopts the federal law by reference so the DOI would enforce the federal law.

CO-CHAIR KELLER asked whether the DOI would take any action if the DOI determined that insurance companies were not covering routine care for patients involved in a clinical trial.

MS. HALL said it would depend on the contract. The DOI would review the contract to see whether the terms were ambiguous, and make a determination whether a specific exclusion in the insurance contract existed. If a specific exclusion did not exist, the DOI would likely debate with the insurer as to whether it should provide coverage. Additionally, if it was not clearly excluded, the DOI would suggest to consumer to go through formal appeals process.

9:59:52 AM

CO-CHAIR HERRON closed public testimony on SB 10.

CO-CHAIR HERRON advised that Rep Keller has withdrawn his written amendment, but will offer a conceptual amendment.

SENATOR DAVIS said she was glad to have a thorough discussion of the issues on SB 10. She said "it boils down" to the debate of covering a portion of the insurance plans, with 23 percent of the plans not covered due to federal law. However, people can choose to have this as part of plan, she stated. She offered her belief that a large percent of patients would be covered under the bill. She offered that currently, the standard routine care is covered regardless of the disease. Thus, it does not matter whether the patient is involved in a clinical trial since the insurance covers the routine care in any case.

10:02:41 AM

REPRESENTATIVE T. WILSON said that routine "follow-up" care depends on treatment. She described a scenario in which a person is diagnosed with cancer and their routine care is based on the number of prescribed chemotherapy sessions. She said the routine care would depend on the treatment. Thus, if the person was involved in a clinical trial, he/she would follow a routine treatment based on the patients receiving the trial drug, even if the patient received a placebo. Therefore, the routine care for the patient receiving the placebo or a portion of the treatment would be different than the patients receiving the full drug regime being tested.

SENATOR DAVIS disagreed. She said routine care is based on the diagnosis and not on the treatment. The insurance companies cover the routine care whether or not the patient is in a clinical trial.

REPRESENTATIVE T. WILSON said, "I'm sorry but that's not true." She illustrated her point with a personal experience when a family member underwent chemotherapy. Her family member's routine care changed when the patient had a stem cell transplant. The standard of care changed once the diagnosis was at the point where nothing more could be done for the patient. She related her understanding that "we're not talking about allowing routine care for everybody who's insured. We're picking out one designated group of private insurance companies and demanding, as a state, that they have to take care of it." She expressed concern with SB 10, since this bill would not apply to every insurance company in the state.

SENATOR DAVIS agreed that "in a perfect world we would want everybody to do it." She explained that this must be handled in phases and anyone can opt out of the routine care coverage, including the state or any independent insurance company. She related that she did not want to debate the matter, but would base her information on the medical professionals' comments. She offered her belief that the costs are comparable for coverage for a patient on clinical trials or not. She did not view SB 10 as placing a burden on the individual or the insurance company for patients to be involved in a clinical trial.

10:07:08 AM

SENATOR DAVIS emphasized that she would prefer not to have any amendments to the bill to improve the chances of passage this legislative session.

10:07:31 AM

CO-CHAIR KELLER offered Conceptual Amendment 1. On page 1, line 12, following "approved" insert "Phases II, III, IV."

CO-CHAIR HERRON restated Conceptual Amendment 1 would also require, after "trial" add "(s)" since it would be plural.

CO-CHAIR KELLER remarked that he did not thing it needed to be plural but since it is a conceptual amendment the bill drafter would decide.

REPRESENTATIVE CISSNA objected.

SENATOR DAVIS asked for the reason for Conceptual Amendment 1.

REPRESENTATIVE SEATON said that he was not cognizant of the intricacies of the phases of the cancer clinical trials. He asked for the definition of the phases, recalling that Phase 1 referred to testing the safety and effectiveness of drug, with Phases 2-4, testing items such as dosages and tolerance and interactions of the drug being tested.

10:09:49 AM

CO-CHAIR KELLER stated that definitions of phases are defined in previously mentioned NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines). He provided a brief synopsis, describing that Phase 1 is the first time a drug has been tried on human beings. He pointed out that clinical trials are by definition "experimental" whose purpose is to determine if the drug should be used for standard of treatment for a disease. He acknowledged the process is not as simplistic as he is suggesting, but he believed he has accurately described the Phase 1 cancer clinical trials.

10:11:35 AM

TOM OBERMEYER, Staff to Senator Bettye Davis, Alaska State Legislature, stated that Representative Keller is largely correct on clinical trials. He referred to members' committee packets and to the two definitions. Definitions are provided on page two of the printout from the National Conference of State Legislatures (NCSL) titled "Clinical Trials: What are State's Doing? February 2009 Update." It defines Phase I clinical trials as research conducted on a small group of people ranging from 20 to 80 people to initially evaluate safety, determine a safe dosage range and identity side effects. He offered his belief that the more persuasive document was a letter dated December 1, 2008, signed by three medical doctors (MD) who are presidents of the American Association for Cancer, the Association of American Cancer Institutes, and the American Society of Clinical Oncology, respectively. This letter was written during discussion of whether Medicare should cover Phase 1 cancer clinical trials. He remarked that Medicare does cover Phase 1 trials. He read: "As the world's leading professional and scientific organizations representing oncology cancer care professionals, we write to affirm our position that Phase 1 cancer clinical trials are the essential gateway for advancement of new cancer treatments - and a vital component of our cancer treatment armamentarium." He referred to page two of the letter, under the heading "Phase 1 Cancer Clinical Trials Have Therapeutic Intent" and read, "The National Cancer Institute's

(NCI) Investigator Handbook" is instructive as to the therapeutic intent of a Phase 1 trial. That handbook includes the following information about Phase 1 cancer clinical trials (emphasis added):

> Phase 1 trials determine a safe dose for Phase 2 trials and define acute effects on normal tissues. In addition, these trials examine the agent's pharmacology and may reveal evidence of antitumor activity. **Therapeutic intent is always present in Phase 1 trials;** indeed, anticancer agents are not tested in patients unless preclinical activity studies have already demonstrated evidence of significant activity in laboratory models.

TOM OBERMEYER referred to page three, which read as follows:

> Additionally, many of the NCI Phase 1 trials involve agents that are already approved for the treatment of one type of cancer and are being studied in a different type of cancer, or in combination with other treatments. As a result, we have some evidence of therapeutic effectiveness that provides solid grounding on which to base therapeutic intent. Indeed, an analysis of 12,000 individuals who participated in 460 NCI-funded Phase 1 trials done in 2005 found that 10.6% of patients experienced an objective response. This number increased to 17.8% of patients when one drug included in the trial regimen was already FDA-approved."
>
> Furthermore, our growing knowledge of the molecular basis of cancer is allowing us to increasingly develop treatments that are targeted to particular molecular pathways and personalized to specific patient populations.

MR. OBERMEYER summarized that these are very important clinical trials and are not random. He explained that the percentages he cited earlier provide enough proof for the FDA approval or are close to FDA approval. He related that the increase from 11 percent to 17.8 percent for FDA approved drugs demonstrates the value of the Phase 1 clinical trials. He pointed out that this letter from the top three organizations regarding cancer and substantiates the importance of cancer clinical trials. Medicare approved Phase I immediately after receiving this letter. He stated that exclusion of one phase will create an

atmosphere of fear for patients who would not be willing to participate in later trials. He referred to statistics cited earlier, that nationally 3 of the 20 percent eligible for clinical trials do not participate in trials. He offered that Alaska falls well below the national norms, with hardly any Phase 1 clinical trials. He offered his belief that adopting Conceptual Amendment 1 would discourage participation in clinical trials and encouraging participation in cancer clinical trials is the intent of the bill and not to target the insurance industry. The insurance companies "will be dragged back into this" under the federal bill in 2014 anyway. This bill is intended to save lives today and help the 2600 new cancer patients each year.

10:16:57 AM

CO-CHAIR HERRON opened public testimony on SB 10.

REPRESENTATIVE SEATON said that Conceptual Amendment 1 would remove Phase 1 trials from SB 10. He asked for the definition of Phase 1 clinical trials.

DR. STEWART explained that Phase 1 clinical trials are primarily to "work out" the dose or schedule for effectiveness, often used for new medications that had been through some clinical trials and animal studies. The Phase 1 clinical trials allow the drug to be checked for specific cancers. As a practical matter, very few patients will choose to participate in Phase 1 clinical trials. The point of studies is therapeutic intent is to help patients and work out the dosage. In response to earlier comments by Representative T. Wilson, she reviewed clinical trials in Anchorage, and very few involve new drugs that potentially would result in large profits to pharmaceutical companies. Most clinical trials in Alaska are not testing new drugs but examine new scheduling. She thought it would be uncommon to involve new drugs.

10:21:08 AM

CO-CHAIR HERRON asked Dr. Stewart supported Conceptual Amendment 1.

DR. STEWART answered absolutely not. She stated that Phase 1 studies should be available to Alaskans. She explained that 8 of the 31 states that have coverage for clinical trials do not include Phase 1 clinical trials. She said, "I don't see any reason why should Alaskans have less availability of studies

than people in other states - Nebraska, Iowa; I think we deserve the best."

CO-CHAIR HERRON closed public testimony on SB 10.

10:22:05 AM

REPRESENTATIVE CISSNA commented on her objection. She related that that number of cancers in Alaska is increasing and Alaska leads the nation in cancer deaths. She raised questions about the causes of cancer and why Alaska has a higher incidence of unusual cancers. She offered her belief that Alaska should be aggressive to acquire tools to protect its citizens and "I think the trials get us there."

10:23:25 AM

REPRESENTATIVE T. WILSON asked for clarification on the reason to remove Phase 1 clinical trials from the bill.

CO-CHAIR KELLER explained that he did not wish to hold up the bill. He said, "The last thing we need is more government regulations, especially when we are talking about government regulations like this that are messing with the market." The pharmaceutical industry has a lot to gain if they have a successful four phase process. Insurance companies pass on the cost on to the customer. In effect, the additional cost helps pay for the experimental process of approving drugs. He stated that the federal government already provides a 50 percent tax credit to pharmaceutical companies for conducting clinical trials. He viewed Phase 1 trials as experimental, whereas clinical trials for Phases 2-4 consider toxicity and dosages. He related some other states exclude Phase 1 clinical trials, although he was not certain which states currently exclude the Phase 1 clinical trials. He cautioned he did not wish to "mess with the market" when the effect is unknown. He offered his belief that this reduces that risk.

10:26:12 AM

REPRESENTATIVE T. WILSON asked whether removing Phase 1 from clinical trials would cause concern that insurance would not cover clinical trials.

CO-CHAIR KELLER said he had not heard convincing evidence that insurance companies refuse routine care. If evidence was produced, he would have a different opinion on the bill. He

said he thought to refuse routine care on the basis of participation in clinical trials would be inappropriate. He said he thought it was telling that no one from the pharmaceutical or insurance industries was present at this hearing.

10:27:30 AM

REPRESENTATIVE SEATON recalled most of the drugs being used in the cancer clinical trials are approved by the Food and Drug Administration (FDA) and are being "cross utilized" by testing the drugs in other cancers. He stated that currently any doctor can prescribe FDA approved drugs approved medicine and the routine care would be covered. However, if the drugs are prescribed in an organized study that can be published, it is called a clinical trial and insurance coverage would not cover the routine care even though it would be covered if an individual doctor prescribed it. He stated based on testimony that he would vote against Conceptual Amendment 1.

10:28:51 AM

REPRESENTATIVE CISSNA maintained her objection on Conceptual Amendment 1.

A roll call vote was taken. Representatives T. Wilson and Keller voted in favor of Conceptual Amendment 1. Representatives Cissna, Holmes, Lynn, Seaton, and Herron voted against it. Therefore, Conceptual Amendment 1 failed the House Health and Social Services Standing Committee by a vote of 2-5.

10:29:29 AM

REPRESENTATIVE T. WILSON referred to the NCCN's definition of routine care, which she did not think was clear. She offered her belief that a better definition of routine care is needed. She stated that people were being caught between drug companies and insurance carriers.

CO-CHAIR HERRON encouraged the research should be performed done for the House Finance Committee.

REPRESENTATIVE T. WILSON said that defining routine care is information that should be examined. She felt it was part of duty of this committee to review the health aspects. She surmised that 50 percent of the people will not be affected by

this bill. She suggested taking a few more hours to explore this issue.

CO-CHAIR HERRON said he appreciated the comments. He expressed concern that placing a definition in statute may not provide the result she seeks. The routine care process or procedure should be determined by professionals for specific diseases for cancers. He did not want to place a "one size fits all" definition in statute.

REPRESENTATIVE T. WILSON expressed concern that the patient would be caught between the insurance and the clinical trial. The bill would "put them in a bad position" and could bring more stress, not less stress. She said she personally has experienced cancer in her family.

CO-CHAIR HERRON offered his opinion that this is important and a finite issue that should be debated by the body.

10:34:28 AM

REPRESENTATIVE SEATON moved to report CSSB10 (HSS)(efd del) out of committee with individual recommendations and the accompanying fiscal notes.

CO-CHAIR KELLER objected. He stated that he would like the bill to move forward but was not sure of the effects of this bill. He said, "The market has a lot to do with health care." He related that it could be covered in 2014, but a really "rocky road" is ahead as the regulations on health care are developed. He offered his belief that the legislature will revisit this matter in the future.

CO-CHAIR KELLER removed his objection.

10:36:19 AM

REPRESENTATIVE T. WILSON objected. She stated that the bill is using small insurance businesses to "make a point", instead of the self-insured big businesses that can afford to make these changes. She said, "That's the wrong way to do things." The committee is taking something that is not a problem and expanding it. She did not want to receive calls from people who have problems as a result of the bill.

A roll call vote was taken. Representatives Holmes, Lynn, Seaton, Cissna, Keller, and Herron voted in favor of CSSB10

(HSS)(efd del). Representative T. Wilson voted against it. Therefore, CSSB10 (HSS)(efd del) was reported out of the House Health and Social Services Standing Committee by a vote of 6-1.

10:37:36 AM

CO-CHAIR HERRON asked to have on the record that his wife and grandson were here for the meeting.

10:39:39 AM

ADJOURNMENT

There being no further business before the committee, the House Health and Social Services Standing Committee meeting was adjourned at 10:39 p.m.