FISCAL NOTE

STATE OF ALASKA
2008 LEGISLATIVE SESSION

Fiscal Note Number:
Bill Version: SB 280
() Publish Date:

ID(File name) SB280-DHSS-MS-03-11-08
Dept. Affected: Health & Social Services
Title MEDICAID/INSURANCE FOR CANCER CLINICAL TRIALS
RDU Health Care Services
Component Medicaid Services

Sponsor DAVIS
Requester SENATE HES
Component No. 2077

Expenditures/Revenues (Thousands of Dollars)

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

	Appropriation Required	Information					
OPERATING EXPENDITURES	**FY 2009**	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012**	**FY 2013**	**FY 2014**
Personal Services							
Travel							
Contractual							
Supplies							
Equipment							
Land & Structures							
Grants & Claims	25.0		50.0	50.0	50.0	50.0	50.0
Miscellaneous							
TOTAL OPERATING	**25.0**	**0.0**	**50.0**	**50.0**	**50.0**	**50.0**	**50.0**
CAPITAL EXPENDITURES							
CHANGE IN REVENUES (0)							

FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts	12.5		25.0	25.0	25.0	25.0	25.0
1003 GF Match	12.5		25.0	25.0	25.0	25.0	25.0
1004 GF							
1037 GF/Mental Health							
Other(Specify Type-do not abbreviate)							
Other(Specify Type-do not abbreviate)							
TOTAL	**25.0**	**0.0**	**50.0**	**50.0**	**50.0**	**50.0**	**50.0**

Estimate of any current year (FY2008) cost:

POSITIONS

Full-time							
Part-time							
Temporary							

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

SB 280 amends the Medicaid statute (AS 47.07.030) to add a new subsection (e) that requires the program to pay for Medicaid covered services for Medicaid recipients even when provided as part of an approved clinical trial related to cancer. Currently, the Medicaid program does not cover clinical trials.

The bill would be effective on January 1, 2009. It is expected to result in a small increase in Medicaid expenditures.

Continued on page 2.

Prepared by: William J. Streur, Deputy Commissioner
Phone 334-2520
Division Health Care Services
Date/Time 03/03/2008
Approved by: Karleen Jackson, Commissioner
Date 03/11/2008
Agency Department of Health and Social Services

ANALYSIS CONTINUATION

ASSUMPTIONS:

Only 2 to 3 percent of eligible adult patients enroll in clinical trials. There is a 6.5% increase in costs for clinical trial participants compared to nonparticipants. (Source: National Conference of State Legislatures, www.ncsl.org/programs/health/clinicaltrials.htm, accessed 2/27/2008.)

Because Alaska does not have any in-state facilities that conduct cancer trials, all participants will have to travel out of state, increasing the cost of non-emergency transportation. Non-emergency transportation is about 3% of total Medicaid costs.

In SFY 2007, approximately 4,600 persons received cancer treatments through Alaska's Medicaid program at a cost of $21.5 million. The average payment per beneficiary was approximately $4,675.

The federal government will reimburse the state 50 percent of the total cost.

ESTIMATE:

Based on a 2.5% participation rate, about 115 persons are expected to participate in clinical trials annually.

A 6.5% increase in treatment costs for 115 persons would add $35.0 per year to Medicaid for cancer treatments.

Non-emergency transportation costs for 115 persons are estimated to add $15.0 per year.

The total additional cost to Medicaid to cover cancer clinical trials for 115 persons is $50.0 per year ($25.0 Federal/$25.0 GF/M).

POSITION PAPER ON HEALTH PLAN COVERAGE FOR PATIENT CARE COSTS IN CANCER CLINICAL TRIALS

Sponsored by the Denali Oncology Group, the Alaska State Affiliate of the American Society of Clinical Oncology

February 24, 2008

BACKGROUND:

1. Clinical trials for cancer patients provide state-of-the-art treatment for patients with life-threatening diseases. Cancer patients and their physicians typically look to clinical trials as an option when the investigational treatment offers as much or more benefit than standard treatment.
2. Currently, in Alaska, health plans can exclude coverage for routine patient care costs while a patient with cancer is enrolled on a clinical trial.
3. Since 2000, Medicare has provided coverage for beneficiaries for routine costs associated with cancer clinical trial enrollment.
4. Twenty-three states in the United States have passed legislation or instituted special agreements requiring health plans to pay the cost of routine medical care a patient receives while participating in a clinical trial.
5. Health plans mistakenly think that money is saved by excluding care while patients participate in clinical trials. However, if not enrolled on a clinical trial, these patients will continue to receive conventional therapy. Studies have shown that there are not differences in cost of care for patients enrolled on clinical trials compared with patients on conventional therapy.
6. Results of clinical trials lead to more rational use of cancer treatment and more successful outcomes, resulting in short-term and long-term cost savings.

PROPOSED LEGISLATION:

We propose that the Senate and House of the State of Alaska pass a bill requiring that all 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.

BENEFITS:

1. Passage of this bill will remove an important barrier to the participation of patients in cancer clinical trials. It will result in physicians more often recommending patient participation and in patients having greater desire to enroll in clinical trials.
2. Greater participation by Alaskans in cancer clinical trials will result in improved care of our patients in the short- and long-term, improved doctor-patient relationship, increased patient satisfaction with treatment, and increased retention of patients in Alaska for their cancer care.
3. Alaska will be in the forefront in making meaningful progress in providing care for cancer and other life threatening conditions.

REFERENCES:

1. States That Require Health Plans to Cover Patient Care Costs in Clinical Trials http://www.cancer.gov/clinicaltrials/learning/laws-about-clinical-trial-costs
2. Clinical Trials and Insurance Coverage - A Resource Guide http://www.cancer.gov/clinicaltrials/learning/insurance-coverage/page1
3. Coverage of Routine Patient Care Costs in Clinical Trials Position Statement http://www.asco.org/asco/downloads/patient_care_costs_3.05.pdf
4. American Society of Clinical Oncology Response to CMS Town Hall Meeting "The Effect of Coverage and Payment on Clinical Research Study Participation and Retention" September 10, 2007
5. Harris Interactive. *Health Care News.* Vol 1, Issue 3. January 22,200 1.
6. Lara PN, et al: Prospective evaluation of cancer clinical trial accrual patterns: identifying potential barriers to enrollment. *Journal of Clinical Oncology.* 19: 1728-1733,200 1.
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8. Goldman DP, et al: Incremental treatment costs in National Cancer Institute-sponsored clinical trials. *JAMA.* 289:2970-2977, 2003.
9. Bennett CL, et al: Evaluating the financial impact of clinical trials in oncology: results from a pilot study from the Association of American Cancer Institutes/Northwestern University Clinical Trials Costs and Charges Project. *Journal of Clinical Oncology.* 18:2805-28 10, 2000.
10. Fireman BH: Cost of care for patients in cancer clinical trials. *Journal of the National Cancer Institute.* 92: 136-142, 2000.
11. Wagner JL, et al: Incremental costs of enrolling cancer patients in clinical trials: a population-based study. *Journal of the National Cancer Institute.* 9 1947-853, 1999.
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13. Bennett C L, et al: Evaluating the financial impact of clinical trials in oncology: Results from a pilot study from the Association of American Cancer Institutes/Northwestern University Clinical Trials Costs and Charges Project. *Journal of Clinical Oncology.* 18:2805-10, 2000 .

CANCER CLINICAL TRIALS FAST FACTS
DENALI ONCOLOGY GROUP, October 28, 2007

Frequently Asked Questions (FAQ)

1. **What is a clinical trial?** A clinical trial is a scientific way of studying a new treatment for a specific disease that may be better and/or safer than existing treatments.
2. **Why are clinical trials necessary?** Without these studies, we can not determine whether a new treatment is safe, effective, and better than existing options.
3. **What types of cancer clinical trials exist?** Trials may be for prevention, early detection, diagnosis, or treatment of cancer. There are also trials for reducing symptoms and improving quality-of-life.
4. **Why would a cancer patient consider participating in a clinical trial?**
    a. Treatment given on the clinical trial offers the potential for better outcome (e.g. longer life or higher cure rate) than the standard treatment.
    b. Results of the trial will help improve treatment for future patients.
5. **Is it risky to be on a clinical trial?** There are risks with any type of cancer treatment. Side effects that occur in patients on a clinical trial are monitored very closely and described in paperwork that patients receive (i.e., consent form).
6. **Are clinical trials available in Alaska?** Yes, more than 50 cancer clinical trials are open in Alaska for patients to receive treatment in-state.
7. **Do doctors or patients gain financially from participating in clinical trials?** We only support the conduct of studies where there is no financial gain for patients or physicians. Support is provided by the sponsor of the study to help pay for costs associated with the trial, such as research personnel and regulatory requirements.

Myths

1. **"I may receive placebo."** Placebo is rarely used in cancer clinical trials because there is usually an acceptable standard treatment. However, if the standard is to offer no treatment, then the new treatment under investigation will be compared to no treatment (i.e., placebo). Patients will always be informed of the potential to receive placebo.
2. **"I will be a guinea pig."** Patients on clinical trials are treated with respect, receive informed consent, and have all questions answered. They have the right to withdraw from the study at any time without compromising their future care.
3. **"I'm not sick enough for a clinical trial."** Many trials are studying ways to prevent cancer in healthy people at risk for cancer. Other trials are studying ways to improve upon the most common types of treatment used when patients are first diagnosed with cancer.

State Laws Addressing Third-Party Reimbursement for Clinical Trials for the Treatment of Cancer
(as of September 30, 2007)

State	Statute	Coverage Requirements			Types of Insurers Covered				Clinical Trial Phases Covered			
		Mandatory Coverage	Mandatory Offer	Prohibits Exclusion of Coverage	Private Insurers	Specified Managed Care	Medicaid/Other Medical Assistance	Public Employee Health Plans	Phase I	Phase II	Phase III	Phase IV
Arizona	ARIZ. REV. STAT. ANN. §§ 20-1342.03, 20-826.01, 20-1057.07, 20-1402.01, 20-1404.01, and 20-2328	X[1]			X	X			X	X	X	X
California	CAL. HEALTH & SAFETY CODE § 1370.6; CAL. INS. CODE § 10145.4; and CAL. WELF. & INST. CODE § 14132.98	X[2]			X	X	X		X	X	X	X
Connecticut	CONN. GEN. STAT. ANN §§ 38a-504a to 38a-504g and 38a-542a to 38a-542g	X[3]			X						X	
Delaware*	DEL. CODE ANN. tit. 18, § 3567	X[4]			X							
Georgia	GA. CODE ANN. § 33-24-59.1	X[5]			X	X		X		X[6]	X[6]	
Louisiana	LA. REV. STAT. ANN. § 22:230.4	X			X	X		X		X	X	X
Maine*	ME. REV. STAT. ANN. tit. 24-A, §§ 4301-A and 4310	X			X	X						
Maryland	MD. CODE ANN., INS. § 15-827	X			X	X			X	X	X	X
Massachusetts	MASS. GEN. LAWS ANN. ch. 175, § 110L	X[4]			X	X			X	X	X	X
Missouri	MO. REV. STAT. § 376.429	X			X	X				X	X	X
Nevada	NEV. REV. STAT. §§ 689A.04033, 689B.0306, 695B.1903, 695C.1693, and 695G.173	X			X	X			X	X	X	X
New Hampshire	N.H. REV. STAT. ANN. § 415:18-l	X[7]			X	X			X	X	X	X
New Mexico	N.M. STAT. ANN. § 59A-22-43	X[4]			X	X	X			X	X	X
North Carolina*	N.C. GEN. STAT. ANN. § 58-3-255	X			X	X				X	X	X
Rhode Island	R.I. GEN. LAWS §§ 27-18-36, 27-18-36.2, 27-19-32 to 27-19-32.3, 27-20-27 to 27-20-27.3, and 27-41-41 to 27-41-41.3	X			X	X				X	X	X
Tennessee	TENN. CODE ANN. § 56-7-2365	X[4]			X	X			X	X	X	X
Vermont	VT. STAT. ANN. tit. 8, § 4088b [8]	X			X	X	X					
Virginia	VA. CODE ANN. §§ 2.2-2818 and 38.2-3418.8	X			X	X		X	X[9]	X	X	X

Source: National Cancer Institute, State Cancer Legislative Database Program, Bethesda, MD: SCLD

State Laws Addressing Third-Party Reimbursement for Clinical Trials for the Treatment of Cancer (as of September 30, 2007)

State	Statute	Coverage Requirements			Types of Insurers Covered				Clinical Trials Covered			
		Mandatory Coverage	Mandatory Offer	Prohibits Exclusion of Coverage	Private Insurers	Specified Managed Care	Medicaid/Other Medical Assistance	Public Employee Health Plans	Phase I	Phase II	Phase III	Phase IV
West Virginia	W. VA. CODE §§ 5-16-7d, 5-16-7e, 5-16B-6a, 5-16B-6b, 9-2-12, 9-2-12a, 33-25F-1, and 33-25F-2	X[4]			X	X	X	X		X	X	X
Wisconsin	WIS. STAT. ANN. §§ 632.87 and 40.51			X[4]	X			X	X	X	X	X

Note: Because arrangements for the reimbursement of clinical trials for several states fall outside the scope of the State Cancer Legislative Database protocols, those states are not included herein. Michigan and New Jersey, for example, instituted special non-legislative agreements whereby insurers voluntarily cover routine medical care that is part of a clinical trial. According to the state employee benefits handbook, Ohio provides coverage for cancer treatment clinical trials to state employees who are enrolled in the state employee health benefit plan. In Georgia, a non-legislative agreement among a number of private health plans and state-based plans provides coverage for adults and children.

* Laws in Delaware, Maine, and North Carolina provide coverage of clinical trials for life threatening medical conditions and not specifically for the treatment of cancer.

[1] Indicated insurers are only obligated to provide coverage for covered patient costs that are directly associated with the clinical trial.

[2] Coverage requirement applies only to routine patient care costs related to cancer clinical trials having a therapeutic purpose, upon recommendation by a treating physician.

[3] In order to be eligible for coverage, clinical trials for the *prevention of cancer* must be a Phase III trial that involves a therapeutic intervention and is conducted at multiple institutions under the auspices of an independent peer-reviewed protocol approved by a specified Federal authority.

[4] Coverage requirement applies only to clinical trials that have a therapeutic intent.

[5] Coverage requirement applies only to routine patient care costs incurred in connection with clinical trials for the treatment of children's cancer.

[6] Applies only to Phase II or III prescription drug clinical trial programs.

[7] Coverage for Phase I and Phase II clinical trials is decided on a case-by-case basis.

[8] Requires the state Department of Banking, Insurance, Securities, and Health Care Administration to issue regulations that specify the requirements for coverage of routine costs for patients who participate in approved cancer clinical trials conducted by specified providers. Coverage requirements are included in Regulation H-2001-04.

[9] Treatment in a Phase I clinical trial may be covered on a case-by-case basis.

Coverage of Routine Patient Care Costs in Clinical Trials
Position Statement

Approved by the ASCO Board of Directors, March 2005

For people with serious or life-threatening illness, like cancer, completely satisfactory or curative treatment often is not available. Those patients are nevertheless able to receive state-of-the-art therapy through high-quality clinical trials, offering not only an important treatment option but an opportunity to advance medical knowledge.

Cancer patients face a number of obstacles to clinical trials enrollment. One of the barriers is the potential denial of third party payment for the routine patient care costs for those enrolled in clinical trials. Historically, payers have denied coverage for care provided in a clinical trial, arguing that such care is "experimental" and therefore not a covered benefit.

Current Clinical Trials Coverage

The American Society of Clinical Oncology (ASCO) and its partners in the patient advocacy community have sought, over the course of more than a decade, to reform clinical trials payment policy in public and private health plans. These efforts have resulted in reforms in Medicare payment policy and in enactment of legislation to ensure clinical trials coverage in more than 20 states.

In 2000, in response to Congressional pressure and cancer community advocacy, the Clinton Administration issued an Executive Memorandum setting a policy for coverage of the routine patient care costs for Medicare beneficiaries enrolled in clinical trials for all diseases.

In addition to action by Medicare, a number of states have enacted legislation that would ensure coverage of routine patient care costs in clinical trials (coverage ranges from cancer clinical trials only to trials for all diseases) by those health plans that are regulated by the state. Some of those states have adopted, either in statute or in implementing regulations, the coverage standards of the Medicare program. In several states without clinical trials coverage mandates, third party payers have entered into voluntary agreements to cover routine costs in clinical trials. States continue to engage in efforts to improve coverage in state plans.

ASCO Position

These federal, state, and private sector initiatives reflect widespread recognition of clinical trials coverage as a critical element of quality cancer care. However, not all of the initiatives meet the standards for coverage endorsed by ASCO, and a significant number of cancer patients remain beyond the reach of these reimbursement reforms. ASCO recommends that every cancer patient should have access to clinical trials under the criteria defined below.

Standards for Clinical Trials Coverage

The following ASCO standards should remain the standard for Medicare coverage and should serve as the model for state legislative initiatives, including provisions governing coverage under state-funded programs like Medicaid, as well as mandates for private insurance and managed care plans.

The cost of medical care provided when a patient with serious or life-threatening disease is entered on a Phase I, II, III, or IV (post-marketing) clinical trial – including hospital, physician, and other health care items and services as well as the cost of approved drugs for labeled or unlabeled uses which might be part of the regimen[1] – should not be denied coverage when all of the following are demonstrated:

- Treatment is provided with a therapeutic intent[2];
- Treatment is being provided pursuant to a clinical trial approved by one of the National Institutes of Health (NIH), an NIH cooperative group or an NIH center; the Food and Drug Administration (FDA) in the form of an investigational new drug (IND) or new device (IDE) exemption; the Department of Defense; the Department of Veterans Affairs; or a qualified non-governmental research entity as identified in National Cancer Institute guidelines or center support grants;
- The trial is conducted according to a written protocol, which includes the following elements: trial design and scientific justification, criteria for inclusion and exclusion, outcome measures, statistical analysis plan, conflicts and other ethical controls, and publication policy;
- The protocol has undergone scientific review by a group of independent and qualified experts;
- The clinical trial has been reviewed and approved by a qualified institutional review board (IRB);
- The facility and personnel providing the treatment are capable of doing so by virtue of their experience or training;
- There is no non-investigational therapy that is clearly superior to the protocol treatment; and
- The available clinical or preclinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as non-investigational therapy.[3]

Originally adopted February 1993
As amended June 1994 and March 2005

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[1] Items and services required by the design of the trial should be covered, except those items or services normally paid for by other funding sources such as the cost of certain investigational drugs, the costs of any non-health services that might be required for a person to receive the treatment, and the costs of managing the research.

[2] Treatment with therapeutic intent may be aimed at improving patient outcome relative to either survival or quality of life.

[3] While these standards refer to clinical trials involving "treatment" or "therapy", the same principles would apply equally to trials of interventions to prevent, rather than treat, diseases.

Reviewed: 05/19/2006

Clinical Trials: Questions and Answers

Key Points

- Clinical trials are research studies that test how well new medical approaches work in people (see Question 1).
- Every clinical trial has a protocol, which describes what will be done in the study, how it will be conducted, and why each part of the study is necessary (see Question 4).
- Informed consent is a process by which people learn the important facts about a clinical trial to help them decide whether to participate (see Question 6).
- Payment of patient care costs in clinical trials varies by health insurance plan and by study (see Question 11).

1. What are clinical trials, and why are they important?

   Clinical trials are research studies that test how well new medical approaches work in people. Each study answers scientific questions and tries to find better ways to prevent, screen for, diagnose, or treat a disease. People who take part in cancer clinical trials have an opportunity to contribute to knowledge of, and progress against, cancer. They also receive up-to-date care from experts.

2. What are the types of clinical trials?

   There are several types of clinical trials:

   - **Prevention trials** test new approaches, such as medications, vitamins, or other supplements, that doctors believe may lower the risk of developing a certain type of cancer. Most prevention trials are conducted with healthy people who have not had cancer. Some trials are conducted with people who have had cancer and want to prevent recurrence (return of cancer), or reduce the chance of developing a new type of cancer.

   - **Screening trials** study ways to detect cancer earlier. They are often conducted to determine whether finding cancer before it causes symptoms decreases the chance of dying from the disease. These trials involve people who do not have any symptoms of cancer.

   - **Diagnostic trials** study tests or procedures that could be used to identify cancer more accurately. Diagnostic trials usually include people who have signs or symptoms of cancer.

   - **Treatment trials** are conducted with people who have cancer. They are designed to answer specific questions about, and evaluate the effectiveness of, a new treatment or a new way of using a standard treatment. These trials test many types of treatments, such as new drugs, vaccines, new approaches to surgery or radiation therapy, or new combinations of treatments.

   - **Quality-of-life (also called supportive care) trials** explore ways to improve the comfort and quality of life of cancer patients and cancer survivors. These trials may study ways to help people who are experiencing nausea, vomiting, sleep disorders, depression, or other effects from cancer or its treatment.

   - **Genetics studies** are sometimes part of another cancer clinical trial. The genetics component of the trial may focus on how genetic makeup can affect detection, diagnosis, or response to cancer treatment.

     Population- and family-based genetic research studies differ from traditional cancer clinical trials. In these studies, researchers look at tissue or blood samples, generally from families or large groups of people, to find genetic changes that are associated with cancer. People who participate in genetics studies may or may not have cancer, depending on the study. The goal

of these studies is to help understand the role of genes in the development of cancer.

3. Who sponsors clinical trials?

Government agencies, such as the National Cancer Institute (NCI) and other parts of the National Institutes of Health (NIH), the Department of Defense, and the Department of Veterans Affairs, sponsor and conduct clinical trials. In addition, organizations or individuals, such as physicians, medical institutions, foundations, volunteer groups, and pharmaceutical companies, also sponsor clinical trials.

NCI sponsors a large number of clinical trials and has a number of programs designed to make clinical trials widely available in the United States. These programs include the following:

- The **Cancer Centers Program** provides support to research-oriented institutions, including those that have been designated as NCI Comprehensive or Clinical Cancer Centers for their scientific excellence. More information is available in the NCI fact sheet *The National Cancer Institute Cancer Centers Program*, which is available at http://www.cancer.gov/cancertopics/factsheet/NCI/cancer-centers on the Internet.

- The **Specialized Programs of Research Excellence (SPOREs)** bring together scientists and researchers to design and implement research programs that can improve prevention, detection, diagnosis, and treatment of specific types of cancer. More information about SPOREs is available at http://spores.nci.nih.gov/index.html on the Internet.

- The **Clinical Trials Cooperative Group Program** brings researchers, cancer centers, and doctors together into cooperative groups. These groups work with the NCI to identify important questions in cancer research, and design and conduct multisite clinical trials to answer these questions. Cooperative groups are located throughout the United States and in Canada and Europe. For more information, refer to the fact sheet *NCI's Clinical Trials Cooperative Group Program* at http://www.cancer.gov/cancertopics/factsheet/NCI/clinical-trials-cooperative-group on the Internet.

- The **Cancer Trials Support Unit (CTSU)** makes NCI-sponsored phase III treatment trials available to doctors and patients in the United States and Canada . Doctors who are not affiliated with an NCI-sponsored Clinical Trials Cooperative Group (see above) must complete an application process, which includes credential verification and site preparedness assessment, to become members of the CTSU's National Network of Investigators. CTSU members can enroll patients in clinical trials through the program's Web site, which is located at http://www.ctsu.org on the Internet. General information about the CTSU is also available on the program's Web site, or by calling 1-888-823-5923.

- The **Community Clinical Oncology Program (CCOP)** makes clinical trials available in a large number of communities across the United States. Local hospitals throughout the country affiliate with a cancer center or a cooperative group. This affiliation allows doctors to offer people participation in clinical trials more easily, so they do not have to travel long distances or leave their usual caregivers. The **Minority-Based Community Clinical Oncology Program** focuses on encouraging minority populations to participate in clinical trials. More information about the CCOP can be found in the NCI fact sheet *Community Clinical Oncology Program: Questions and Answers*, which is available at http://www.cancer.gov/cancertopics/factsheet/NCI/CCOP on the Internet.

- The **National Institutes of Health Clinical Center**, a research hospital located in Bethesda, Maryland, is part of the NIH. Trials at the Clinical Center are conducted by the components of the NIH, including the NCI. The NCI fact sheet *Cancer Clinical Trials at the National Institutes of Health Clinical Center: Questions and Answers* has more information about the Clinical Center. This fact sheet is available at http://www.cancer.gov/cancertopics/factsheet/NCI/clinical-center on the Internet.

4. How are participants protected?

Research with people is conducted according to strict scientific and ethical principles. Every clinical trial has a protocol, or action plan, which acts like a "recipe" for conducting the trial. The plan describes what will be done in the study, how it will be conducted, and why each part of the study is necessary. The same protocol is used by every doctor or research center taking part in the trial.

All clinical trials that are federally funded or that evaluate a new drug or medical device subject to Food and Drug Administration regulation must be reviewed and approved by an Institutional Review Board (IRB). Many institutions require that all clinical trials, regardless of funding, be reviewed and approved by a local IRB. The Board, which includes doctors, researchers, community leaders, and other members of the community, reviews the protocol to make sure the study is conducted fairly and participants are not likely to be harmed. The IRB also decides how often to review the trial once it has begun. Based on this information, the IRB decides whether the clinical trial should continue as initially planned and, if not, what changes should be made. An IRB can stop a clinical trial if the

researcher is not following the protocol or if the trial appears to be causing unexpected harm to the participants. An IRB can also stop a clinical trial if there is clear evidence that the new intervention is effective, in order to make it widely available.

NIH-supported clinical trials require data and safety monitoring. Some clinical trials, especially phase III clinical trials, use a Data and Safety Monitoring Board (DSMB). A DSMB is an independent committee made up of statisticians, physicians, and patient advocates. The DSMB ensures that the risks of participation are as small as possible, makes sure the data are complete, and stops a trial if safety concerns arise or when the trial's objectives have been met.

5. What are eligibility criteria, and why are they important?

Each study's protocol has guidelines for who can or cannot participate in the study. These guidelines, called eligibility criteria, describe characteristics that must be shared by all participants. The criteria differ from study to study. They may include age, gender, medical history, and current health status. Eligibility criteria for treatment studies often require that patients have a particular type and stage of cancer.

Enrolling participants with similar characteristics helps to ensure that the results of the trial will be due to what is under study and not other factors. In this way, eligibility criteria help researchers achieve accurate and meaningful results. These criteria also minimize the risk of a person's condition becoming worse by participating in the study.

6. What is informed consent?

Informed consent is a process by which people learn the important facts about a clinical trial to help them decide whether to participate. This information includes details about what is involved, such as the purpose of the study, the tests and other procedures used in the study, and the possible risks and benefits. In addition to talking with the doctor or nurse, people receive a written consent form explaining the study. People who agree to take part in the study are asked to sign the informed consent form. However, signing the form does not mean people must stay in the study. People can leave the study at any time—either before the study starts or at any time during the study or the follow-up period.

The informed consent process continues throughout the study. If new benefits, risks, or side effects are discovered during the study, the researchers must inform the participants. They may be asked to sign new consent forms if they want to stay in the study.

7. Where do clinical trials take place?

Clinical trials take place in doctors' offices, cancer centers, other medical centers, community hospitals and clinics, and veterans' and military hospitals in cities and towns across the United States and in other countries. Clinical trials may include participants at one or two highly specialized centers, or they may involve hundreds of locations at the same time.

8. How are clinical trials conducted?

Clinical trials are usually conducted in a series of steps, called phases. Treatment clinical trials listed in PDQ®, the NCI's comprehensive cancer information database, are always assigned a phase. However, screening, prevention, diagnostic, and quality-of-life studies do not always have a phase. Genetics clinical trials generally do not have a phase.

- **Phase I** trials are the first step in testing a new approach in people. In these studies, researchers evaluate what dose is safe, how a new agent should be given (by mouth, injected into a vein, or injected into the muscle), and how often. Researchers watch closely for any harmful side effects. Phase I trials usually enroll a small number of patients and take place at only a few locations. The dose of the new therapy or technique is increased a little at a time. The highest dose with an acceptable level of side effects is determined to be appropriate for further testing.

- **Phase II** trials study the safety and effectiveness of an agent or intervention, and evaluate how it affects the human body. Phase II studies usually focus on a particular type of cancer, and include fewer than 100 patients.

- **Phase III** trials compare a new agent or intervention (or new use of a standard one) with the current standard therapy. Participants are randomly assigned to the standard group or the new group, usually by computer. This method, called randomization, helps to avoid bias and ensures that human choices or other factors do not affect the study's results. In most cases, studies move into phase III testing only after they have shown promise in phases I and II. Phase III trials often include large numbers of people across the country.

- **Phase IV** trials are conducted to further evaluate the long-term safety and effectiveness of a

treatment. They usually take place after the treatment has been approved for standard use. Several hundred to several thousand people may take part in a phase IV study. These studies are less common than phase I, II, or III trials.

People who participate in a clinical trial work with a research team. Team members may include doctors, nurses, social workers, dietitians, and other health professionals. The health care team provides care, monitors participants' health, and offers specific instructions about the study. So that the trial results are as reliable as possible, it is important for participants to follow the research team's instructions. The instructions may include keeping logs or answering questionnaires. The research team may continue to contact participants after the trial ends.

9. What are some of the benefits of taking part in a clinical trial?

The benefits of participating in a clinical trial include the following:

- Participants have access to promising new approaches that are often not available outside the clinical trial setting.
- The approach being studied may be more effective than the standard approach.
- Participants receive regular and careful medical attention from a research team that includes doctors and other health professionals.
- Participants may be the first to benefit from the new method under study.
- Results from the study may help others in the future.

10. What are some of the possible risks associated with taking part in a clinical trial?

The possible risks of participating in a clinical trial include the following:

- New drugs or procedures under study are not always better than the standard care to which they are being compared.
- New treatments may have side effects or risks that doctors do not expect or that are worse than those resulting from standard care.
- Participants in randomized trials will not be able to choose the approach they receive.
- Health insurance and managed care providers may not cover all patient care costs in a study.
- Participants may be required to make more visits to the doctor than they would if they were not in the clinical trial.

11. Who pays for the patient care costs associated with a clinical trial?

Health insurance and managed care providers often do not cover the patient care costs associated with a clinical trial. What they cover varies by health plan and by study. Some health plans do not cover clinical trials if they consider the approach being studied "experimental" or "investigational." However, if enough data show that the approach is safe and effective, a health plan may consider the approach "established" and cover some or all of the costs. Participants may have difficulty obtaining coverage for costs associated with prevention and screening clinical trials; health plans are currently less likely to have review processes in place for these studies. It may, therefore, be more difficult to get coverage for the costs associated with them. In many cases, it helps to have someone from the research team talk about coverage with representatives of the health plan.

Health plans may specify other criteria a trial must meet to be covered. The trial might have to be sponsored by a specified organization, be judged "medically necessary" by the health plan, not be significantly more expensive than treatments the health plan considers standard, or focus on types of cancer for which no standard treatments are available. In addition, the facility and medical staff might have to meet the plan's qualifications for conducting certain procedures, such as bone marrow transplants. More information about insurance coverage can be found on the NCI's *Clinical Trials and Insurance Coverage: A Resource Guide* Web page at http://www.cancer.gov/clinicaltrials/learning/insurance-coverage on the Internet.

Many states have passed legislation or developed policies requiring health plans to cover the costs of certain clinical trials. For more information, visit the NCI's Web site at http://www.cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs on the Internet.

Federal programs that help pay the costs of care in a clinical trial include those listed below:

- Medicare reimburses patient care costs for its beneficiaries who participate in clinical trials designed to diagnose or treat cancer. Information about Medicare coverage of clinical trials is available at http://www.medicare.gov on the Internet, or by calling Medicare's toll-free number for beneficiaries at 1–800–633–4227 (1–800–MEDICARE). The toll-free number for the hearing impaired is 1–877–486–2048. Also, the NCI fact sheet *More Choices in Cancer Care: Information for Beneficiaries on Medicare Coverage of Cancer Clinical Trials* is available at http://www.cancer.gov/cancertopics/factsheet/support/medicare on the Internet.

- Beneficiaries of TRICARE, the Department of Defense's health program, can be reimbursed for the medical costs of participation in NCI-sponsored phase II and phase III cancer prevention

(including screening and early detection) and treatment trials. Additional information is available in the NCI fact sheet *TRICARE Beneficiaries Can Enter Clinical Trials for Cancer Prevention and Treatment Through a Department of Defense and National Cancer Institute Agreement*. This fact sheet can be found at http://www.cancer.gov/cancertopics/factsheet/NCI/TRICARE on the Internet.

- The Department of Veterans Affairs (VA) allows eligible veterans to participate in NCI-sponsored prevention, diagnosis, and treatment studies nationwide. All phases and types of NCI-sponsored trials are included. The NCI fact sheet *The NCI/VA Agreement on Clinical Trials: Questions and Answers* has more information. It is available at http://www.cancer.gov/cancertopics/factsheet/NCI/VA-clinical-trials on the Internet.

12. What are some questions people might ask their health care provider before entering a clinical trial?

It is important for people to ask questions before deciding to enter a clinical trial. Questions people might want to ask their doctor or nurse include the following:

The Study

- What is the purpose of the study?
- Why do the researchers think the approach being tested may be effective? Has it been tested before?
- Who is sponsoring the study?
- Who has reviewed and approved the study?
- What are the medical credentials and experience of the researchers and other study personnel?
- How are the study results and safety of participants being monitored?
- How long will the study last?
- How will the results be shared?

Possible Risks and Benefits

- What are the possible short-term benefits?
- What are the possible long-term benefits?
- What are the short-term risks, such as side effects?
- What are the possible long-term risks?
- What other treatment options are available?
- How do the possible risks and benefits of the trial compare with those of other options?

Participation and Care

- What kinds of treatment, medical tests, or procedures will the participants have during the study? How often will they receive the treatments, tests, or procedures?
- Will treatments, tests, or procedures be painful? If so, how can the pain be controlled?
- How do the tests in the study compare with what people might receive outside the study?
- Will participants be able to take their regular medications while in the clinical trial?
- Where will the participants receive their medical care? Will they be in a hospital? If so, for how long?
- Who will be in charge of the participants' care? Will they be able to see their own doctors?
- How long will participants need to stay in the study? Will there be follow-up visits after the study?

Personal Issues

- How could being in the study affect the participants' daily lives?
- What support is available for participants and their families?
- Can potential participants talk with people already enrolled in the study?

Cost Issues

- Will participants have to pay for any treatment, tests, or other charges? If so, what will the approximate charges be?
- What is health insurance likely to cover?
- Who can help answer questions from the insurance company or health plan?

13. What happens when a clinical trial is over?

After a clinical trial is completed, the researchers look carefully at the data collected during the trial before making decisions about the meaning of the findings and further testing. After a phase I or II trial, the researchers decide whether to move on to the next phase, or stop testing the agent or intervention because it was not safe or effective. When a phase III trial is completed, the researchers look at the data and decide whether the results have medical importance.

The results of clinical trials are often published in peer-reviewed, scientific journals. Peer review is a process by which experts review the report before it is published to make sure the analysis and conclusions are sound. If the results are particularly important, they may be featured by the media and discussed at scientific meetings and by patient advocacy groups before they are published. Once a new approach has been proven safe and effective in a clinical trial, it may become standard practice. (Standard practice is a currently accepted and widely used approach.)

The National Library of Medicine's Web site offers links to resources for finding the results of clinical trials. It includes information about published and unpublished results. This resource can be found at http://www.nlm.nih.gov/services/ctresults.html on the Internet.

14. Where can people find more information about clinical trials?

In addition to the resources described in Question 3, people interested in taking part in a clinical trial should talk with their health care provider. Information about cancer clinical trials is also available from the NCI's Cancer Information Service (CIS). Information specialists at the CIS use PDQ to identify and provide detailed information about specific ongoing clinical trials. PDQ includes all NCI-funded clinical trials and some studies conducted by independent investigators at hospitals and medical centers in the United States and Europe.

People also have the option of searching for clinical trials on their own. The clinical trials page of the NCI's Web site, located at http://www.cancer.gov/clinicaltrials/ on the Internet, provides information about clinical trials and links to PDQ. Another resource is the NIH's ClinicalTrials.gov Web site. ClinicalTrials.gov lists clinical trials sponsored by the NIH, other Federal agencies, and the pharmaceutical industry for a wide range of diseases, including cancer and other conditions. This site can be found at http://clinicaltrials.gov on the Internet.

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Related Resources

Publications (available at http://www.cancer.gov/publications)

- National Cancer Institute Fact Sheet 1.2. *The National Cancer Institute Cancer Centers Program*
- National Cancer Institute Fact Sheet 1.3. *Community Clinical Oncology Program: Questions and Answers*
- National Cancer Institute Fact Sheet 1.4. *NCI's Clinical Trials Cooperative Group Program*
- National Cancer Institute Fact Sheet 1.13. *TRICARE Beneficiaries Can Enter Clinical Trials for Cancer Prevention and Treatment Through a Department of Defense and National Cancer Institute Agreement*
- National Cancer Institute Fact Sheet 1.17. *The NCI/VA Agreement on Clinical Trials: Questions and Answers*
- National Cancer Institute Fact Sheet 1.22. *Cancer Clinical Trials at the National Institutes of Health Clinical Center: Questions and Answers*
- National Cancer Institute Fact Sheet 8.14. *More Choices in Cancer Care: Information for Beneficiaries on Medicare Coverage of Cancer Clinical Trials*
- *Taking Part in Clinical Trials: What Cancer Patients Need To Know*
- *Taking Part in Clinical Trials: Cancer Prevention Studies*

National Cancer Institute (NCI) Resources

Cancer Information Service (toll-free)
Telephone: 1-800-4-CANCER (1-800-422-6237)
TTY: 1-800-332-8615

Online
NCI's Web site: http://www.cancer.gov
LiveHelp, NCI's live online assistance.
https://cissecure.nci.nih.gov/livehelp/welcome.asp

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H.R.2676

Access to Cancer Clinical Trials Act of 2007 (Introduced in House)

SEC. 2. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.

(a) Group Health Plans-

(1) PUBLIC HEALTH SERVICE ACT AMENDMENTS- Subpart 2 of part A of title XXVII of the Public Health Service Act is amended by adding at the end the following new section:

`SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.

`(a) Coverage-

`(1) IN GENERAL- If a group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer--

`(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

`(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

`(C) may not discriminate against the individual on the basis of the individual's participation in such trial.

`(2) EXCLUSION OF CERTAIN COSTS-

`(A) IN GENERAL- For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services

provided in the clinical trial that are otherwise generally available to the qualified individual, except--

`(i) in the cases of drugs and devices, the investigational item or service, itself; or

`(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient.

`(B) INCLUSIONS- Such routine patient costs include costs for the following:

`(i) CONVENTIONAL CARE- Items or services that are typically provided absent a clinical trial.

`(ii) ADMINISTRATIVE ITEMS- Items or services required solely for the provision of the investigational item or service (such as the administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.

`(iii) REASONABLE AND NECESSARY CARE- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, including the diagnosis or treatment of complications.

`(3) USE OF IN-NETWORK PROVIDERS- If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

`(b) Qualified Individual Defined- For purposes of subsection (a), the term `qualified individual' means an individual who is a participant or beneficiary in a group health plan and who meets the following conditions:

`(1)(A) The individual has been diagnosed with cancer.

`(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

`(2) Either--

`(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

`(B) the participant or beneficiary provides medical and scientific

information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

`(c) Payment-

`(1) IN GENERAL- Under this section a group health plan (or health insurance issuer offering health insurance coverage in connection with the plan) shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are customarily provided by the research sponsors free of charge for individuals participating in the trial.

`(2) PAYMENT RATE- In the case of covered items and services provided by--

`(A) a participating provider, the payment rate shall be at the agreed upon rate, or

`(B) a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable items and services under subparagraph (A).

`(d) Approved Clinical Trial Defined-

`(1) IN GENERAL- In this section, the term `approved clinical trial' means a clinical research study or clinical investigation that relates to the treatment of cancer (including related symptoms) and is described in any of the following subparagraphs:

`(A) FEDERALLY FUNDED TRIALS- The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

`(i) NIH- The National Institutes of Health.

`(ii) CDC- The Centers for Disease Control and Prevention.

`(iii) AHRQ- The Agency for Health Care Research and Quality.

`(iv) CMS- The Centers for Medicare & Medicaid Services.

`(v) COOPERATIVE CENTER- A cooperative group or center of any of the entities described in clauses (i) through (iv) or the Departments of Defense or Veterans Affairs.

`(vi) CENTER SUPPORT GRANTEES- A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

`(vii) DOD; VA; DOE- Any of the following if the conditions

described in paragraph (2) are met:

`(I) The Department of Veterans Affairs.

`(II) The Department of Defense.

`(III) The Department of Energy.

`(B) FDA DRUG TRIAL UNDER IND- The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

`(C) EXEMPT DRUG TRIAL- The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

`(2) CONDITIONS FOR DEPARTMENTS- The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines--

`(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

`(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

`(e) Construction- Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.'.

(2) ERISA AMENDMENTS- (A) Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new section:

`SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.

`(a) Coverage-

`(1) IN GENERAL- If a group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer--

`(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

`(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

`(C) may not discriminate against the individual on the basis of the

individual's participation in such trial.

`(2) EXCLUSION OF CERTAIN COSTS-

`(A) IN GENERAL- For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services provided in the clinical trial that are otherwise generally available to the qualified individual, except--

`(i) in the cases of drugs and devices, the investigational item or service, itself; or

`(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient.

`(B) EXCLUSION- Such routine patient costs do include costs for the following:

`(i) CONVENTIONAL CARE- Items or services that are typically provided absent a clinical trial.

`(ii) ADMINISTRATIVE ITEMS- Items or services required solely for the provision of the investigational item or service (such as the administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.

`(iii) REASONABLE AND NECESSARY CARE- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, including the diagnosis or treatment of complications.

`(3) USE OF IN-NETWORK PROVIDERS- If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

`(b) Qualified Individual Defined- For purposes of subsection (a), the term `qualified individual' means an individual who is a participant or beneficiary in a group health plan and who meets the following conditions:

`(1)(A) The individual has been diagnosed with cancer.

`(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

`(2) Either--

`(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

`(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

`(c) Payment-

`(1) IN GENERAL- Under this section a group health plan (or health insurance issuer offering health insurance coverage in connection with the plan) shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are customarily provided by the research sponsors free of charge for individuals participating in the trial.

`(2) PAYMENT RATE- In the case of covered items and services provided by--

`(A) a participating provider, the payment rate shall be at the agreed upon rate, or

`(B) a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable items and services under subparagraph (A).

`(d) Approved Clinical Trial Defined-

`(1) IN GENERAL- In this section, the term `approved clinical trial' means a clinical research study or clinical investigation that relates to the treatment of cancer (including related symptoms) and is described in any of the following subparagraphs:

`(A) FEDERALLY FUNDED TRIALS- The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

`(i) NIH- The National Institutes of Health.

`(ii) CDC- The Centers for Disease Control and Prevention.

`(iii) AHRQ- The Agency for Health Care Research and Quality.

`(iv) CMS- The Centers for Medicare & Medicaid Services.

`(v) COOPERATIVE CENTER- A cooperative group or center of any of the entities described in clauses (i) through (iv) or the Departments of Defense or Veterans Affairs.

`(vi) CENTER SUPPORT GRANTEES- A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

`(vii) DOD; VA; DOE- Any of the following if the conditions described in paragraph (2) are met:

`(I) The Department of Veterans Affairs.

`(II) The Department of Defense.

`(III) The Department of Energy.

`(B) FDA DRUG TRIAL UNDER IND- The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

`(C) EXEMPT DRUG TRIAL- The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

`(2) CONDITIONS FOR DEPARTMENTS- The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines--

`(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

`(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

`(e) Construction- Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.'.

(B) Section 732(a) of such Act (29 U.S.C. 1191a(a)) is amended by striking `section 711' and inserting `sections 711 and 714'.

(C) The table of contents in section 1 of such Act is amended by inserting after the item relating to section 713 the following new item:

`Sec. 714. Coverage for individuals participating in approved cancer clinical trials.'.

(3) INTERNAL REVENUE CODE AMENDMENTS-

(A) IN GENERAL- Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended--

(i) in the table of sections, by inserting after the item relating to section 9812 the following new item:

`Sec. 9813. Coverage for individuals participating in approved cancer clinical trials.';

and

(ii) by inserting after section 9812 the following:

`SEC. 9813. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.

`(a) Coverage-

`(1) IN GENERAL- If a group health plan provides coverage to a qualified individual (as defined in subsection (b)), the plan--

`(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

`(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

`(C) may not discriminate against the individual on the basis of the individual's participation in such trial.

`(2) EXCLUSION OF CERTAIN COSTS-

`(A) IN GENERAL- For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services provided in the clinical trial that are otherwise generally available to the qualified individual, except--

`(i) in the cases of drugs and devices, the investigational item or service, itself; or

`(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient.

`(B) EXCLUSION- Such routine patient costs do include costs for the following:

`(i) CONVENTIONAL CARE- Items or services that are typically provided absent a clinical trial.

`(ii) ADMINISTRATIVE ITEMS- Items or services required solely for the provision of the investigational item or service (such as the administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.

`(iii) REASONABLE AND NECESSARY CARE- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, including the diagnosis or treatment of complications.

`(3) USE OF IN-NETWORK PROVIDERS- If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

`(b) Qualified Individual Defined- For purposes of subsection (a), the term `qualified individual' means an individual who is a participant or beneficiary in a group health plan and who meets the following conditions:

`(1)(A) The individual has been diagnosed with cancer.

`(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

`(2) Either--

`(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

`(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

`(c) Payment-

`(1) IN GENERAL- Under this section a group health plan shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are customarily provided by the research sponsors free of charge for individuals participating in the trial.

`(2) PAYMENT RATE- In the case of covered items and services provided by--

`(A) a participating provider, the payment rate shall be at the agreed upon rate, or

`(B) a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable items and services under subparagraph (A).

`(d) Approved Clinical Trial Defined-

`(1) IN GENERAL- In this section, the term `approved clinical trial' means a clinical research study or clinical investigation that relates to the treatment of cancer (including related symptoms) and is described in any of the following subparagraphs:

`(A) FEDERALLY FUNDED TRIALS- The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

`(i) NIH- The National Institutes of Health.

`(ii) CDC- The Centers for Disease Control and Prevention.

`(iii) AHRQ- The Agency for Health Care Research and Quality.

`(iv) CMS- The Centers for Medicare & Medicaid Services.

`(v) COOPERATIVE CENTER- A cooperative group or center of any of the entities described in clauses (i) through (iv) or the Departments of Defense or Veterans Affairs.

`(vi) CENTER SUPPORT GRANTEES- A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

`(vii) DOD; VA; DOE- Any of the following if the conditions described in paragraph (2) are met:

`(I) The Department of Veterans Affairs.

`(II) The Department of Defense.

`(III) The Department of Energy.

`(B) FDA DRUG TRIAL UNDER IND- The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

`(C) EXEMPT DRUG TRIAL- The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

`(2) CONDITIONS FOR DEPARTMENTS- The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines--

`(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

`(B) assures unbiased review of the highest scientific standards by

qualified individuals who have no interest in the outcome of the review.

`(e) Construction- Nothing in this section shall be construed to limit a plan's coverage with respect to clinical trials.'.

(B) CONFORMING AMENDMENT- Section 4980D(d)(1) of such Code is amended by striking `section 9811' and inserting `sections 9811 and 9813'.

(b) Individual Health Insurance- Part B of title XXVII of the Public Health Service Act is amended--

(1) by redesignating the first subpart 3 (relating to other requirements) as subpart 2; and

(2) by adding at the end of subpart 2 the following new section:

`SEC.

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Next Hit	Forward	New Bills Search
Prev Hit	Back	HomePage
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NFIB
The Voice of Small Business®

Alaska

March 29, 2008

The Honorable Bettye Davis
Alaska State Senate
State Capitol Building
Juneau, Alaska 99801-1182

RE: Senate Bill 280

Dear Senator Davis,

On behalf of the National Federation of Independent Business/Alaska, I wish to express our opposition to Senate Bill 280. The National Federation of Independent Business is the largest small-business advocacy group in Alaska.

This is a mandate that applies only to Alaska based businesses, mostly small businesses. It does not cover our competitors who are multi-state or large enough to provide ERISA plans, such as the "big box stores" and the petroleum industry. It would not provide a benefit to individuals covered by most union welfare benefit plans. Additionally we would point out that this benefit would not be mandated on state employee programs for whom you are the employer!

While we understand the concern with coverage for clinical trials related to cancer, we must oppose mandatory benefits, especially when directed to a specific disease. Small businesses in Alaska budget a portion of their revenues to employee compensation. The distribution of those funds should be left to discussions between employees and employers, without the interference of the state. Mandating this benefit limits the options of employee compensation.

Unfortunately, mandates such as those in SB 280 force employers to consider whether they can afford to continue coverage or may be forced by increased prices to eliminate health insurance for their employees. Mandates prevent small employers from providing affordable insurance programs tailored to its specific work force.

National Federation of Independent Business — ALASKA
P.O. Box 34761 • Juneau, AK 99803 • 907-723-6667 • denny.dewitt@nfib.org

We are further concerned with the precedent this type of legislation would establish. Employee benefits should not be determined by the legislature for private employers. Such action is nothing less than an unfunded state mandate on small Alaskan employers.

Sincerely,

Dennis L. DeWitt
Alaska State Director
National Federation of Independent Business

cc: Senate Labor & Commerce Committee

Alaska State Medical Association

4107 Laurel Street • Anchorage, Alaska 99508 • (907) 562-0304 • (907) 561-2063 (fax)

March 14, 2008

Honorable Bettye Davis
Chair, Senate Health, Education and Social Services Committee
State Senate
State Capitol, Room 30
Juneau, AK 99801-1182

RE: SB 280 - Insurance Coverage for Cancer Care Received During Approved Clinical Trials

Dear Senator Davis:

The Alaska State Medical Association (ASMA) represents physicians statewide and is primarily concerned with the health of all Alaskans.

Denali Oncology Group, who is the Alaska State Affiliate of the American Society of Clinical Oncology, sought the introduction of SB280, an effort which ASMA has supported. The Oncologists and Hematologists, the "Cancer Doctors", have sought this legislation to better serve those patients who face these life threatening cancers.

ASMA supports SB280.

ASMA will not provide any testimony other than this written testimony of support, as I understand the specialists, the "Cancer Doctors", will provide oral testimony and will be providing you with significant information and will bring the expertise to answer your questions at the hearing.

Sincerely,

J. Ross Tanner, DO, President

March 13, 2008

Honorary Members of the Alaska State Senate,

I am writing on behalf of Alaska Breast Cancer Advocacy Partners (ABCAP) in support of SB280. As a Breast Cancer lobby group, most of our lobby efforts have focused on key State and National legislation that directly impacts those affected by breast cancer. We very rarely deviate from our goal of supporting meaningful breast cancer legislation as we have very stringent guidelines and expectations of the legislation we support. Our organization has earned a reputation of being extremely mindful and cautious of the legislation we support. That being said, we feel that SB280 is very significant to breast cancer and all cancers, in that clinical trials are vitally important to increase survivorship, improve quality of life and decrease mortality for so many Alaskans that are impacted by a cancer diagnosis. If clinical trials are not supported by Medicaid, it significantly decreases the "pool" of potential clinical trial participants, and therefore reduces the overall effectiveness and impact of these trials. Alaskans deserve to have the capability of participating in these trials in order to have access to the latest advances in medical treatments. The passage of this bill would have a drastic impact on medical advancements in Alaska and the rest of the country. Please pass this very important legislation and give all Alaskans the right to participate in clinical trials. They are our best hope in eradicating cancer and improving overall quality of life. Thank you for your consideration.

Sincerely,

Alaska Breast Cancer Advocacy Partners – ABCAP
Carla Williams – President
Carla Wyrick – Vice President
Virginia Cress – Treasurer
Elisha "Bear" Baker - Secretary
Sasha Prewitt – Electronics Communication Coordinator

P.O. Box 101744 Anchorage, Alaska 99510-1744 **www.abcap.alaska.com**

Don Burrell

From: Tammy [Tammy@hotsheet.com]

Sent: Friday, March 14, 2008 9:29 AM

To: Don Burrell

Subject: Denali Oncology Group, SB 280

Attachments: Telephone%20hearing%20attendee%20list%203-14-08(1)(1).xls; Testimony-Alaska_Senate_Committee_LTRHD[1]NSABP-Dr. Wickerham.doc

Good morning Mr. Burrell,

Thank you for taking time to talk with me this morning regarding the details of us calling in for the hearing on SB 280.
I'm attaching our schedule as it stands now of our speakers and attendees. I'm also attaching the written testimony
of Dr. Larry Wickerham from the NSABP.

If you need any additoinal information, I'm happy to help. Have a great day!!

Tammy Thiel
Executive Director
Denali Oncology Group
(907) 257-9803

NSABP
National Surgical Adjuvant Breast and Bowel Project
PARTNERS IN CANCER RESEARCH

Norman Wolmark, MD
Chairman

Operations Center

Medical Affairs
412/330-4600 412/330-4660 Fax
412/330-4661 Fax

Administrative and Fiscal Affairs
412/330-4600 412/330-4662 Fax

Clinical Coordinating Division
1-800/477-7227

TESTIMONY OF D. LAWRENCE WICKERHAM, MD, ASSOCIATE CHAIRMAN OF THE NSABP, CONCERNING SB280

I am Dr. Lawrence Wickerham, the Associate Chairman of the National Surgical Adjuvant Breast and Bowel Project (NSABP), which is one of the National Cancer Institute's Cooperative Trials Groups.

The NSABP conducts large phase III studies that compare standard treatments with newer innovative therapies in patients with early stage breast or colorectal cancer. The group's mission is to improve the survival and quality of life of these patients. 2008 is the 50th anniversary of the NSABP and over those years we have entered over 130,000 individuals into our trials. Today we have 200 participating centers and 300 satellite centers located throughout the U.S., Canada, Puerto Rico, and Ireland, and we do have centers in Alaska.

Results of previous NSABP studies have had a major impact in improving the care of both breast and bowel cancer The results of our breast cancer studies have eliminated the use of true radical mastectomies, demonstrated that lumpectomy is an effective alternative, and we have shown that adjuvant treatment (treatment after surgery) can improve survival. Adjuvant therapy for breast cancer includes chemotherapy, hormonal therapy, and newer targeted treatments.

Figures from the American Cancer Society demonstrate that the mortality rate from breast cancer in the U.S. has declined for over a decade. This improvement is thought to be the result of screening mammograms to detect the disease and improvements in treatment. These improvements in care come primarily from clinical

trials like those conducted by the NSABP. The more patients that enter these studies, the more quickly we get results and the faster we can improve care. Unfortunately, for a variety of reasons, less than 5% of cancer patients choose to enter clinical trials. Cost is a major barrier.

Requiring health care insurers to cover the standard of care costs for individuals participating in cancer clinical trials would remove one significant barrier to increasing participation. Any research trial includes two general categories of costs: 1) research costs – expenses that the patient would not routinely incur if he or she was not a part of the trial (extra lab tests, x-rays, etc.), and 2) standard of care costs – expenses that would occur whether or not the patient entered the trial.

NSABP studies routinely identify the non-standard of care components. We provide the drug(s) being studied and typically provide additional non-federal funding to help defray the costs of trial participation, including the cost of non-standard of care items. The goal is to minimize any additional costs to the patient, improve trial participation and improve cancer care in general.

I and the NSABP strongly urge you to enact this bill so that cancer patients in Alaska can have improved access to state-of-the-art research studies like those available to patients in other states.

Thank you for listening to my testimony and I would be pleased to try to answer your questions.

TELEPHONE HEARING ON SB 280, MARCH 14, 2008 AT 1:40PM (Alaska standard time)
Call in number...1-888-295-4546 NOTE: SB 280 is 2nd on the hearing schedule today.

Speakers

Name	Title	Time
Dr. Jeanne Anderson	Medical Oncologist, Private Practice, Katmai Oncology Group, Treasurer, Denali Oncology Group, & Medical Director, Providence Cancer Center Clinical Trials Program, Anchorage, AK	1-3 mins
Dr. Mary Stewart	Medical Oncologist, Private Practice, Alaska Oncology and Hematology & President, Denali Oncology Group, Anchorage, AK	1-3 mins
Dr. Allen Lichter	Chief Executive Officer, American Society of Clinical Oncologists (ASCO)	1-3 mins
Dr. Larry Wickerman	National Surgical Breast and Bowel Project (NSABP), Pittsburgh, PA	1-3 mins
Dr. Thomas Brown	Chief Operating Officer, Arizona Cancer Center	1-3 mins
Krista Rangitsch, RN	Cancer Research RN, Providence Alaska Medical Center, Anchorage, AK	1-3 mins
Nina Brady	Breast Cancer Patient and Teacher, Wasilla, AK	1-3 mins
	Questions and Answers	5 mins

Conference Call Attendees - available for questions

Dr. Doug Debenham	Radiation Oncologist, Private Practice, Valley Radiation & Therapy Center, & President-Elect, Denali Oncology Group, Palmer, AK
Dr. John Halligan	Radiation Oncologist, Providence Alaska Medical Center, Anchorage, AK
Dr. Michael Carroll	Medical Oncologist, Private Practice, Fairbanks, AK
Dr. Verneeda Spencer	Medical Oncologist, Private Practice, Alaska Oncology and Hematology, Anchorage, AK
Dr. Steven Liu	Medical Oncologist, Private Practice, Alaska Oncology and Hematology, Anchorage, AK
Dr. Steven Compton	Cardiologist, Private Practice, Alaska Heart Institute, Anchorage, AK
Dr. George Ryneer	Cardiologist, Private Practice, Alaska Heart Institute, Anchorage, AK
Emily Neon	American Cancer Society, Anchorage, AK
Jerry Nicholson, MBA	Administrator, Katmai Oncology Group, Anchorage, AK
Tammy Thiel	Administrator, Alaska Oncology & Executive Director, Denali Oncology Group, Anchorage, AK
Sally duBois	Wife of a late cancer patient, Alaska
Deb Apperson	Cancer Patient, Alaska
Beverly Wooley	Breast Cancer Survivor, Alaska
Claire Waddout	Breast Cancer Survivor, Alaska

Alaska State Medical Association

4107 Laurel Street • Anchorage, Alaska 99508 • (907) 562-0304 • (907) 561-2063 (fax)

March 14, 2008

Honorable Bettye Davis
Chair, Senate Health, Education and Social Services Committee
State Senate
State Capitol, Room 30
Juneau, AK 99801-1182

RE: SB 280 - Insurance Coverage for Cancer Care Received During Approved Clinical Trials

Dear Senator Davis:

The Alaska State Medical Association (ASMA) represents physicians statewide and is primarily concerned with the health of all Alaskans.

Denali Oncology Group, who is the Alaska State Affiliate of the American Society of Clinical Oncology, sought the introduction of SB280, an effort which ASMA has supported. The Oncologists and Hematologists, the "Cancer Doctors", have sought this legislation to better serve those patients who face these life threatening cancers.

ASMA supports SB280.

ASMA will not provide any testimony other than this written testimony of support, as I understand the specialists, the "Cancer Doctors", will provide oral testimony and will be providing you with significant information and will bring the expertise to answer your questions at the hearing.

Sincerely,

J. Ross Tanner, DO, President

To

Office of Senator Bettye Davis
Thomas Obermeyer, Leg. Admin. Assist.

Subject: SB 280

Committee Packets

From: Nina Brady
(907)376-2751

--------1 page follows--------

TO: Senate HESS Committee
FROM: Nina Brady NB
3000 Rattan Dr.
Wasilla, AK 99654
(907)376-2751
RE: SB 280
DATE: March 11, 2008

Two years ago I was asked by my treating oncologist if I would be interested in being part of a clinical research study in the use of gemcitabine as part of my chemotherapy treatment. Research had thus far supported a positive outcome in the use of this component. But more clinical trials had to be undertaken before it could become available to the public as an accepted treatment.

However, due to certain disclosures pertaining to a possible health insurance conflict, I addressed my intent to my health provider, EBMS of the NEA Alaska plan. I was informed unequivocally that should any individual so much as begin one day of participation in any clinical research treatment, all coverage for the condition would be denied henceforth. Needless to say, I withdrew my application to become part of the clinical research study.

Being faced with the "big C" word is traumatic for any of us. The additional courage to become part of research in hopes of helping those who will follow us does not come lightly. However, finding insurance companies not wanting to have anything to do with possible better treatment options leaves one with a sense of "somebody needs to do something about this." How are we going to advance more effective treatment methods if creditable clinical research is not allowed to go forward?

I ask that you support SB 280 in the interest of cancer research in conjunction with guaranteed health care for those who are willing to become participants in clinical trials. Tomorrow belongs to our children. We shouldn't have to face becoming destitute in our choice to improve treatments for those who are yet to come.

SB

288

ALASKA STATE LEGISLATURE

Co-chair, Joint Armed Services Committee
•
Resources Committee
•
Judiciary Committee
•
Transportation Committee

State Capitol, Rm. 115
Juneau, AK 99801
(907) 465-2435
Fax: (907) 465-6615

716 W. 4th Ave, Ste. 440
Anchorage, AK 99501
(907) 269-0102
Fax: (907) 269-6122

SENATOR BILL WIELECHOWSKI

March 2, 2008

Senator Bettye Davis, Chair
Senate State Affairs Committee
Room 30, State Capitol
Juneau, Alaska 99801

I respectfully request a hearing on SB 288 and SJR 18, which seek to limit Alaska children's exposure to toxic chemicals.

Children, teachers, and other staff members spend a significant part of their lives in school buildings and are exposed to chemicals from a plethora of sources. SB 288 seeks to prevent unnecessary exposure of children and staff to chemical pesticides, provide notification to parents and guardians when pesticides are used, and to provide a healthy learning environment through promoting non-chemical pest prevention and control. The Anchorage School District already follows a similar plan, so we'd like to extend the protection to children all over Alaska.

SJR 18 requests the federal government in to test the materials used in toys and other children's products for toxicity. Currently the regulatory agency only conducts tests to determine if a toy presents a choking, aspiration or ingestion hazard but relies on toy and child product manufacturers to self-regulate the materials used in their products.

These changes will help ensure our children's safety and health. Thank you for your speedy consideration of this request.

Sincerely,

Senator Bill Wielechowski

ALASKA STATE LEGISLATURE

Co-chair, Joint Armed Services Committee
•
Senate Resources Committee
•
Senate Judiciary Committee
•
Senate Transportation Committee

Session:
State Capitol, Rm. 115
Juneau, AK 99801
(907) 465-2435
Fax: (907) 465-6615

Interim:
716 W. 4th Ave, Rm. 540
Anchorage, AK 99501
(907) 269-0120
Fax: (907) 269-0120

SENATOR BILL WIELECHOWSKI

Senate Bill 288: Pesticides in Schools
Sponsor Statement

SB 288 seeks to prevent unnecessary exposure of children and staff at schools to chemical pesticides, provide notification to parents and guardians when pesticides are used, and provide the healthiest learning environment, playgrounds and playfields as possible through promoting nonchemical pest prevention and control.

Children, teachers, and other staff members spend a significant part of their lives in school buildings and are often exposed to toxic pesticides. Pesticide exposure at school can occur whether applications are made before children enter the building or while they are present. Chemicals fill the air and settle on desks, counters, shades, and walls. Children and staff breathe in contaminated air or touch contaminated surfaces, unknowingly exposing themselves to residues that can remain for days. In addition, children's normal behaviors, such as crawling on the ground and putting their hands in their mouths, can result in exposures not faced by adults. The United State Environmental Protection Agency estimates that human exposure to air pollutants indoors can be two to five times, occasionally up to 100 times higher than outdoor levels. The National Academy of Science estimates that 25 percent of learning and behavioral disabilities in children are due to exposure to neurotoxic pesticides.

The National Education Association and numerous other public interest organizations have announced support for the reduction of pesticide use at schools. The National Parent Teacher Association passed a resolution in 1992 calling for the reduction of pesticide use at schools and calling on policy makers to consider all possible alternatives before using pesticides. The Anchorage School District already follows a plan for non-chemical pest prevention and control, with pesticides used only as a last resort.

Please join us in passing this critical legislation for all Alaskans—protecting our children, teachers, and staff from unnecessary exposure to chemicals.

Sectional Analysis SB 288

Section 1.

Legislative findings on the danger and use of pesticides, the connection between pesticide use and asthma, the health care costs of asthma, and the increased exposure of children and staff in schools to pesticides used there. The intent of the Legislature to minimize this exposure.

Section 2. Article 5. Pesticide Use at Schools

Sec 14.33.300 Pest Management in Schools

a) The use, handling, storing, and disposal of pesticides on school grounds as provided in this bill.

b) Other available safe alternative nonchemical methods of pest prevention have to be tried and fail before pesticides can be used.

c) Governing body of a school district will adopt a policy for approval of pesticide use while reducing exposure to students, prohibiting the use of the most toxic pesticides as defined by the Environmental Protection Agency, and requires pest management strategies that will minimize the need for pesticides

14.33.310 Notification of Pesticide Use

Requires the notification and posting of planned pesticide use between 2-5 days prior to application. (Currently, notification is only one day prior.) In emergency cases, a waiver can be obtained from DEC for this notification.

14.33.320 Record Keeping

Requires the maintenance of a written or electronic record of pesticide use on the grounds for at least 5 years and available at public request.

14.33.350 Definitions.

ALASKA CENTER *for the* ENVIRONMENT
807 G Street, Suite 100 * Anchorage, Alaska 99501
907-274-3621 phone * 907-274-8733 fax * ace@akcenter.org * www.akcenter.org

March 3, 2008

The Honorable Bill Wielechowski
Alaska State Senate
Alaska State Capitol
Juneau, Alaska 99801-1182

Dear Senator Wielechowski,

I am writing to offer our support for SB 288, "An Act relating to the procurement, use, storage, and handling of pesticides and broadcast chemicals; and relating to notice and record keeping requirements pertaining to pesticides."

As you know, ACE is a non-profit environmental education and advocacy organization. Founded by a group of concerned Alaskans in 1971, ACE is the largest grassroots conservation organization in Alaska with over 6,000 members a vast majority of which are Alaskan residents. Thousands of Alaskans find expression for their conservation values through membership in ACE's values of balance, common sense, and long-range stewardship in managing our natural resources.

SB 288 is important to our organization because it would prevent the unnecessary exposure of children and staff to highly toxic pesticides in schools. This legislation promotes alternatives, requiring that the 'least amount of the least toxic' as the only exception. SB 288 is important because pesticides are a risk factor for several types of cancer in children - non-Hodgkin lymphoma, leukemia, and Wilm's tumor. These consequences can easily be avoided by understanding the risks involved with the use of pesticides and the alternatives available.

On behalf of our staff, board, and members thank you for introducing this important piece of legislation to protect Alaska's communities.

Sincerely,

Randy Virgin
Executive Director

FISCAL NOTE

STATE OF ALASKA
2008 LEGISLATIVE SESSION

Fiscal Note Number:
Bill Version: SB 288
() Publish Date:

Identifier (file name): SB288-DEC-SW-3-10-08
Title: Pesticides/Broadcast Chemicals in Schools
Sponsor: Senator Wielechowski
Requester: Senate HESS

Dept. Affected: Dept. of Environmental Conservation
RDU: Environmental Health
Component: Solid Waste
Component Number: 2344

Expenditures/Revenues (Thousands of Dollars)

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

	Appropriation Required	Information					
OPERATING EXPENDITURES	**FY 2009**	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012**	**FY 2013**	**FY 2014**
Personal Services							
Travel							
Contractual							
Supplies							
Equipment							
Land & Structures							
Grants & Claims							
Miscellaneous							
TOTAL OPERATING	*** INDETERMINATE ***						
CAPITAL EXPENDITURES							
CHANGE IN REVENUES ( )							

FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts							
1003 GF Match							
1004 GF							
1005 GF/Program Receipts							
1037 GF/Mental Health							
Other Interagency Receipts							
TOTAL	*** INDETERMINATE ***						

Estimate of any current year (FY2008) cost: Indeterminate

POSITIONS

Full-time							
Part-time							
Temporary							

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

The fiscal impacts of SB 288 to the Department of Environmental Conservation (DEC) cannot be determined without further information.

The following items would need to be clarified in order to prepare a statement of costs:

1. How much involvement will DEC have in providing technical assistance to school administrators under 14.33.300(b) and (c)? This will impact the number of additional technical assistance staff required? This would include technical assistance for the following items:

(Continued on Page 2)

Prepared by: Kristin Ryan, Director — Phone 269-7645
Division: Environmental Health — Date/Time 3/10/08 12:00 PM
Approved by: Dan Easton — Date 3/11/2008
Department of Environmental Conservation

ANALYSIS CONTINUATION

a. Evaluating "safe nonchemical alternatives";
b. Defining "property damage";
c. Evaluating "avoidance of health effects related to an identified pest";
d. Defining "potentially harmful pesticides"; and
e. Defining an "emergency".

2. What type of enforcement is expected to ensure compliance with 14.33.300(b), 14.33.300(c), 14.33.310(a), and 14.33.320? This will impact the number of additional inspectors required. This would include enforcement/inspections for the following items:
a. Has the school administrator unsuccessfully tried "safe alternative nonchemical methods" and documented the results?
b. Has the school administrator properly documented any pesticide use only for the prevention of property damage or to avoid health effects related to an identified pest? What documentation is required?
c. Has the school administrator prohibited the use of Category I and II pesticides, unless approved by DEC?
d. Has the school administrator completed appropriate documentation and notification? What documentation is required?
e. Has the school administrator kept appropriate records of all pesticide use?

3. What role is expected from DEC under 14.33.310(b), "The Department of Environmental Conservation may waive the 48-hour notification requirement under (a) of this section in an emergency, as defined by the department?" The interpretation of "emergency" will impact the number of hours required to ensure compliance with this section.

4. Incremental staff time will be required to revamp the current regulations under 18 AAC 90, sections 90.300(a)(9), 90.420, 90.615, and 90.625.

5. Depending on the role of DEC as defined in the questions above, incremental staff time will also be required to conduct extensive outreach to schools throughout the state to educate school administrators regarding the new requirements.

Alaska Conservation Alliance

Uniting for Alaska's Future

March 10, 2008

The Honorable Senator Wielechowski
State Capitol
Juneau, Alaska 99801

Re: SB 288 – Pesticides/Broadcast Chemical in Schools

Dear Senator Wielechowski,

On behalf of the Alaska Conservation Alliance (ACA), a consortium of 40 Alaska-based conservation groups, I would like to express our enthusiastic support for SB 288, an act limiting the amount of toxic pesticides children are exposed to in schools in Alaska. In fact, ACA member groups chose the issue of pesticides in Alaskan schools as a top priority at the Annual General Meeting last November.

The use of pesticides in schools is a concern for ACA because of the health risks to children and the environment. As you know, exposure to pesticides has been linked with cancer, birth defects, asthma, endocrine disruption, acute poisoning, impaired neurological development in fetuses and infants, lymphoma, leukemia, and other human health effects. The National Academy of Sciences estimated that 25% of learning and behavioral disabilities in children are the result of exposure to neurotoxic pesticides. Pesticides are particularly dangerous to children because they take in more pesticides pound-for-pound than adults and their brains and other organs are still developing. For example, a child's lungs do not fully develop until between six and eight years, making their respiratory system particularly vulnerable to pesticides.

Pesticides have been shown to both cause asthma and trigger asthma attacks in individuals already suffering from the disease. Dr. Ruth Etzel, MD, PhD, from the George Washington University School of Public Health and Health Services wrote that "epidemiologic studies suggest that children with asthma may breathe easier if they are exposed to fewer pesticides at home and at school." Of the 48 pesticides commonly used in schools, studies have shown the 39 may contribute to asthma. When you consider that children spend an average of 30 hours a week at school it becomes even more imperative that we reduce the use of pesticides in and around schools.

While it is difficult to quantify the cost of pesticide related illnesses in children, asthma can be used as a proxy. As explained above, pesticides can cause asthma in children and can cause asthma attacks in children already suffering from the illness. In the 2006 report from the Alaska Department of Health and Social Services, "Asthma in Alaska", the Department reported that approximately 11,000 children in Alaska have asthma. Asthma is the most common chronic illness in children and the most common reason for school absence. As mentioned above, asthma can be triggered by pesticide exposure. On average, every time an Alaskan child is admitted to

the hospital for an asthma attack the cost of that hospital stay in $7,333. The total cost of asthma related hospital visits for children under the age of 15 between 2001 and 2004 was $4,487,664. This is a significant burden on parents and health care providers in Alaska that has the potential to be lessened by exposing children to fewer pesticides in schools.

Critics of this bill will argue that eliminating the use of EPA Class I & II pesticides will cost schools money and limit the tools available to school administrators. On the issue of cost, preliminary data suggests that the long-term costs of using fewer pesticides and putting more energy into prevention may be less than conventional pest management practices. However, there are short-term expenses including training, purchasing new equipment, and making repairs to school buildings. Making these initial investments will hopefully result in the need for fewer pesticides, exposing fewer school children to these toxics.

While schools will have to alter their pest management strategies to place more emphasis on prevention, fears that schools will be adversely limited in pest management techniques are also unfounded. The Anchorage School District (ASD) has already actualized success in limiting pesticide use. In 2000 the Anchorage School Board approved ASD Memorandum #199 from February 14, 2000, mandating that the ASD Superintendent "establish a pest management plan" that uses "non-chemical pest prevention and control first...with pesticides used only as a last resort." All students in Alaska's schools deserve this same level of protection from exposure to pesticides and this bill would do just that.

This bill would raise the policy bar in Alaska and provide our kids equal protection from unnecessary pesticide applications. Alaska Conservation Alliance would like to join the National Parent Teacher Association, the National Education Association, 33 other states and over 400 school districts, including the Anchorage School District, in urging the reduction of pesticide use in schools. ACA believes that the tool to accomplish this is SB 288. SB 288 would prevent the unnecessary exposure of children and staff at schools to pesticides at an acceptable cost and we encourage the swift passage of this bill. Thank you for bringing this issue to our attention and taking proactive measures to ensure the health and safety for children in Alaska's schools.

Sincerely,

Kate Troll

Kate Troll
Executive Director

CC: Senator Davis
Senator Thomas
Senator Cowdery
Senator Elton
Senator Dyson

PO Box 1006600, Anchorage, Alaska 99501 • Ph. 907.258.6171 • Fax 907.258.6177 • www.akvoice.org
419 6th Street, Ste. 321, Juneau, Alaska 99801 • Ph. 907.463.3366 • Fax 907.463.2554

SB

300

Alaska State Legislature

Interim: (May - Dec.)
716 W. 4th Ave
Anchorage, AK 99501
Phone: (907) 269-0144
Fax: (907) 269-0148

Session: (Jan. - May)
State Capitol, Suite 30
Juneau, AK 99801-1182
Phone: (907) 465-3822
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Toll free: (800) 770-3822

Senator_Bettye_Davis@legis.state.ak.us
http://www.akdemocrats.org

Senator Bettye Davis

Senate Bill 300: Health Care: Plan/Commission/Facilities

"An Act establishing the Alaska Health Care Commission and the Alaska health care information office; relating to health care planning and information; and providing for an effective date."

Sponsor Statement

The Alaska Healthcare Strategies Council, established by Governor Sarah Palin, met during the 2007 Legislative Interim to set long term goals for the Healthcare of Alaskans. During the Legislative Interim, these legislatures, Healthcare professionals, and committed citizens of Alaska provided seven clearly delineated goals for "***Making Alaskans the healthiest people in the nation.***"

Among the Council's top recommendations, Senate Bill 300, sponsored by the Senate Health, Education, & Social Services committee, would establish the Alaska Health Care Commission to develop policy recommendations and oversee the newly formed Healthcare Information Office. The Alaska Health Care Commission would also oversee the database and website implementation and regarding healthcare and healthy living in Alaska.

The commission would be comprised of 15 members including Alaska Health Care Providers, a small business owner, state officials and public members. Chaired by the Medical Director of the Department of Health & Social Services, the Alaska Health Commission would meet regularly establishing specific goals designed to promote the health and well being of the citizens of the State of Alaska.

SB 300 will also establish the Alaska Health Care Information Office and related database Internet sites to provide transparency to Alaska Healthcare industry for Healthcare consumers. The Information provided by the Alaska Healthcare Information Office would be consistently updated as specified in the bill.

These two functions of the bill will provide the citizens of Alaska a great avenue for choosing Healthcare for themselves and their families. It is with Alaska's citizens in mind that your consideration and passage of this bill to the next committee of referral is requested.

FISCAL NOTE

STATE OF ALASKA
2008 LEGISLATIVE SESSION

Fiscal Note Number:
Bill Version: SB 300
() Publish Date:

ID(File name) SB300-DHSS-AHCIO-03-10-08
Dept. Affected: Health & Social Services
Title HEALTH CARE: PLAN/COMISSION/FACILITIES
RDU Commissioner's Office
Component AK Health Care Information Office
Sponsor SENATE HES
Requester SENATE HES
Component No. 2899

Expenditures/Revenues (Thousands of Dollars)

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

	Appropriation Required	Information					
OPERATING EXPENDITURES	**FY 2009**	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012**	**FY 2013**	**FY 2014**
Personal Services	494.9		494.9	494.9	494.9	494.9	494.9
Travel	18.0		18.0	18.0	18.0	18.0	18.0
Contractual	250.0		235.0	235.0	235.0	235.0	235.0
Supplies	22.2		10.0	10.0	10.0	10.0	10.0
Equipment	15.0		10.0	10.0	10.0	10.0	10.0
Land & Structures							
Grants & Claims							
Miscellaneous							
TOTAL OPERATING	**800.1**	**0.0**	**767.9**	**767.9**	**767.9**	**767.9**	**767.9**
CAPITAL EXPENDITURES							
CHANGE IN REVENUES (0)							

FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts							
1003 GF Match							
1004 GF	800.1		767.9	767.9	767.9	767.9	767.9
1037 GF/Mental Health							
Other(Specify Type-do not abbreviate)							
Other(Specify Type-do not abbreviate)							
TOTAL	**800.1**	**0.0**	**767.9**	**767.9**	**767.9**	**767.9**	**767.9**

Estimate of any current year (FY2008) cost:

POSITIONS

Full-time	4		4	4	4	4	4
Part-time							
Temporary							

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

The bill creates the Alaska Health Care Information Office and related database Internet sites to provide consumers consistently updated information about health care facilities, prevention, and healthy living options in Alaska.

71000 Personal Services Two information technology positions are being requested to design, develop, implement, and support the dissemination of information on the internet for all health care facilities in the state to provide objective, unbiased, and factually based information on those facilities. In addition, an interactive website will be created to assist the public in obtaining timely and accurate information about personal responsibility in preventing chronic health conditions and promoting healthy living. Two planner positions will be needed to assist in research and data collection for the Commission.

Prepared by: Jay C. Butler, MD
Phone 269-8045
Division Chief Medical Officer
Date/Time 03/07/2008
Approved by: Karleen Jackson, Commissioner
Date 03/10/2008
Agency Department of Health and Social Services

ANALYSIS CONTINUATION

Funding is needed to support two existing positions—Public Information Officer and Publications Technician. These positions will coordinate internal and external communications for the Alaska Health Care Information Office.

72000 Travel
Travel and per diem for professional staff.

73000 Contractual
Professional services contracts will be needed to facilitate and supplement formative research methods to develop messages to promote healthy behaviors. Core Service RSAs will be required to provide lease space, telecommunications, mainframe connectivity, postage, etc.

74000 Supplies
In addition to day-to-day office supplies, FY09 includes one-time-only start-up costs such as computers, office furniture, reconfiguring leased space, wiring needs for connectivity, printers, fax, and photocopier.

75000 Equipment
FY09 includes a one-time-only purchase of a server; subsequent fiscal years provide for technology upgrades and maintenance.

FISCAL NOTE

STATE OF ALASKA
2008 LEGISLATIVE SESSION

Fiscal Note Number:
Bill Version: SB 300
() Publish Date:

ID(File name) SB300-DHSS-AHCC-03-10-08
Dept. Affected: Health & Social Services
Title HEALTH CARE: PLAN/COMISSION/FACILITIES
RDU Boards & Commissions
Component AK Health Care Commission
Sponsor SENATE HES
Requester SENATE HES
Component No. 2900

Expenditures/Revenues (Thousands of Dollars)

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

	Appropriation Required	Information					
OPERATING EXPENDITURES	**FY 2009**	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012**	**FY 2013**	**FY 2014**
Personal Services	173.1		173.1	173.1	173.1	173.1	
Travel	218.3		218.3	218.3	218.3	218.3	
Contractual	250.0		250.0	250.0	250.0	250.0	
Supplies	72.0		10.0	10.0	10.0	10.0	
Equipment	15.0		10.0	10.0	10.0	10.0	
Land & Structures							
Grants & Claims							
Miscellaneous							
TOTAL OPERATING	**728.4**	**0.0**	**661.4**	**661.4**	**661.4**	**661.4**	**0.0**
CAPITAL EXPENDITURES							
CHANGE IN REVENUES (0)							

FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts							
1003 GF Match	728.4		661.4	661.4	661.4	661.4	
1004 GF							
1037 GF/Mental Health							
Other(Specify Type-do not abbreviate)							
Other(Specify Type-do not abbreviate)							
TOTAL	**728.4**	**0.0**	**661.4**	**661.4**	**661.4**	**661.4**	**0.0**

Estimate of any current year (FY2008) cost:

POSITIONS

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

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

This bill establishes the Alaska Health Care Commission in DHSS to develop policy recommendations and oversee websites and databases regarding health care issues and healthy living in Alaska. The Commission would be composed of 15 members and chaired by the DHSS Medical Director. The Commission would meet regularly in person and via teleconference. The Commission would sunset July 1, 2013, so no costs are projected for FY2014.

71000 Personal Services: Two new positions are needed to support the Commission. The bill states that an Executive Director would staff the Commisison; one administrative support position would also be needed.

72000 Travel: Travel and per diem for Commission staff and for 11 Commission members to conduct public meetings around Alaska. The four other members are legislators and would have per diem and travel covered. (Continued on Page 2)

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Division Chief Medical Officer
Date/Time 03/07/2008
Approved by: Karleen Jackson, Commissioner
Date 03/10/2008
Agency Department of Health and Social Services

ANALYSIS CONTINUATION

73000 Contractual

Professional services contracts will be needed to supplement staff research, and core service RSAs will be required to provide lease space, telecommunications, mainframe connectivity, postage, etc.

74000 Supplies

In addition to day-to-day office supplies, FY09 includes one-time-only start-up costs such as computers, office furniture, reconfiguring leased space, wiring needs for connectivity, printers, fax, and photocopier.

75000 Equipment

FY09 includes a one-time-only purchase of a server; subsequent fiscal years provide for technology upgrades and maintenance.