

ALASKA LEGISLATURE COMMITTEE FILES 2007-2008 SL&C 12631

**(12) Class IIIC: limited to the design, installation, maintenance, and testing of special hazard systems;**

**(13) Class IIIC-DO: limited to the design of special hazard systems;**

**(14) Class IV: limited to the installation, maintenance, and testing of pre-engineered dry and wet chemical fire suppression systems for restaurant and commercial hoods, ducts and associated cooking appliances.**

**(h) To qualify for a permit under this section, an applicant**

**(1) shall submit an application to the state fire marshal on a form provided by the marshal;**

**(2) must be 18 years of age or older; and**

**(3) at the time of application, must meet the following minimum requirements for the class of permit for which the applicant has applied:**

**(A) Class IA: have**

**(i) not less than two years cumulative experience in the fire alarm signaling system business; and**

**(ii) passed the examination for NICET II certification elements in fire alarm systems or the equivalent;**

**(B) Class IB:**

**(i) have not less than two years cumulative experience in the fire alarm signaling systems business;**

**(ii) be employed in a position of supervisory responsibility for the installation, maintenance, and testing of fire alarm signaling systems; and**

**(iii) have passed the examination for NICET II certification elements in fire alarm systems or the equivalent;**

**(C) Class IB-Special:**

**(i) have completed an approved electrical apprentice program;**

**(ii) be a current Alaska journeyman electrician; and**

**(iii) not hold a position of supervisory responsibility;**

**(D) Class IC:**

- (i) have not less than five years cumulative experience in the fire alarm signaling systems business;**
- (ii) be employed in a position of supervisory responsibility for the preparation of technical documents and the installation, maintenance, and testing of fire alarm signaling systems; and**
- (iii) have passed the examination for NICET III certification elements in fire alarm systems or the equivalent;**

**(E) Class IC-DO:**

- (i) have not less than five years cumulative experience in the design of fire alarm signaling systems business;**
- (ii) be employed in a position of supervisory responsibility for the design of fire signaling systems; and**
- (iii) have passed the examination for NICET III certification elements in fire alarm systems or the equivalent;**

**(F) Class IIA: have**

- (i) not less than two years cumulative experience in the water-based fire suppression system business; and**
- (ii) passed the examination for NICET II certification elements in automatic sprinkler systems or the equivalent;**

**(G) Class IIB:**

- (i) have not less than two years cumulative experience in the water-based fire suppression system business;**
- (ii) be employed in a position of supervisory responsibility for the installation, maintenance, and testing of water-based fire suppression systems; and**
- (iii) have passed the examination for NICET II certification elements in automatic sprinkler systems layout or the equivalent;**

**(H) Class IIC:**

- (i) have not less than five years cumulative experience in the water-based fire suppression system business;**

**(ii) be employed in a position of supervisory responsibility for the preparation of technical documents and the maintenance and testing of water-based fire suppression systems; and**

**(iii) have passed the examination for NICET III certification elements in automatic sprinkler systems or the equivalent;**

**(I) Class IIC-DO:**

**(i) have not less than five years cumulative experience in the design of water-based fire suppression system business;**

**(ii) be employed in a position of supervisory responsibility for the design of sprinkler systems; and**

**(iii) have passed the examination for NICET III certification elements in automatic sprinkler systems layout or the equivalent;**

**(J) Class IIIA: have**

**(i) not less than two years cumulative experience in the special hazard systems business; and**

**(ii) have passed the examination for NICET II certification elements in special hazard systems or the equivalent;**

**(K) Class IIIB:**

**(i) have not less than two years cumulative experience in the special hazard systems business;**

**(ii) be employed in a position of supervisory responsibility for the installation, maintenance, and testing of special hazard systems; and**

**(iii) have passed the examination for NICET II certification elements in special hazard systems or the equivalent;**

**(L) Class IIIC:**

**(i) have not less than five years cumulative experience in the special hazard systems business;**

**(ii) be employed in a position of supervisory responsibility for the preparation of technical documents and the maintenance and testing of special hazard systems; and**

(iii) have passed the examination for NICET III certification elements in special hazard systems or the equivalent;

(M) Class IIIC-DO:

(i) have not less than five years cumulative experience in the design of special hazard system business;

(ii) be employed in a position of supervisory responsibility for the design of special hazard systems; and

(iii) have passed the examination for NICET III certification elements in special hazard systems layout or the equivalent;

(N) Class IV:

(i) have not less than two years cumulative experience in the kitchen fire suppression system maintenance business;

(ii) have passed the examination for NICET special hazard elements 52001, 52002, 53002, 53004, 53005, and 54013 or the equivalent;

(iii) possess at least one manufacturers training certificate; and

(iv) possess the specific system manuals for the systems to be serviced.

(i) Repealed 9/13/2007.

(j) If a company or individual is involved in the installation, maintenance, or design of a fire suppression system or fire alarm signaling system and does not possess a required permit, the state fire marshal will, in the marshal's discretion, order work stopped by service of an order in writing in accordance with 13 AAC 50.070.

(k) The state fire marshal will provide written notice to a permit holder at least 10 days before an action to revoke or suspend a permit. The fire marshal will, in the marshal's discretion, revoke or suspend a pennit

(1) if a permit holder has materially misrepresented that individual's qualifications in obtaining or renewing the permit or is subject to revocation under 13 AAC 55.100(c) ;

(2) if a permit holder is found, after an administrative investigation, to be negligent, incompetent, or to have committed substantial misconduct in the preparation of technical drawings, or the installation or maintenance of a system;

(3) based upon documented repetitious violations of 13 AAC 50 - 13 AAC 55 by a permit holder;

(4) for other good cause found by the state fire marshal.

(l) An order of suspension must state the length of the suspension. The period of suspension may not be less than 30 days and may not exceed one year from the date of the order.

(m) An order of revocation must state the length of the revocation. The period of revocation may not be less than one year and may not exceed two years.

(n) Unless the context indicates otherwise, in this section,

(1) "company" means any individual, partnership, firm, group, organization, corporation, or any other entity that performs or represents itself as qualified to perform any of the following functions related to a fire alarm signaling system or fire suppression system, or any portion of a system:

(A) preparation of technical design documents;

(B) installation, either in whole or in part;

(C) maintenance; or

(D) inspection;

(2) "design" means the preparation of detailed drawings of a fire alarm signaling system or fire suppression system and the calculations and specifications for those systems completed in accordance with the requirements of 13 AAC 50 - 13 AAC 55;

(3) "direct oversight and supervision" means that a company must have sufficient personnel with appropriate permits to inspect and certify that work being performed on systems is in substantial compliance with applicable laws, product listings, and manufacturer's installation instructions;

(4) "equivalent" means 20 years of relevant experience in the design, installation, or maintenance of systems or such other combination or documented training, experience, or certification, that the fire marshal determines is substantially equivalent to the requirements of (h) of this section;

(5) "fire alarm signaling system" means any signaling system that is either automatically or manually activated to notify persons on or off the property of a fire condition;

(6) "fire suppression system" means a system that is either automatic or manual and designed to protect a process, building, or structure from fire; "fire suppression system" includes piping, fire mains, standpipes, and thermal systems connected to the system;

(7) "installation" means the initial placement of equipment or the extension, modification, or alteration of a system after the initial placement;

(8) "maintenance" means to repair, service, or replace a system or a system component when, for any reason, it becomes undependable or inoperative; "maintenance" includes periodically recurrent inspections and tests required to keep a system and its component parts in an operative condition at all times;

(9) "NICET" means the National Institute for Certification in Engineering Technologies;

(10) "owner maintenance" means basic maintenance performed by an owner or the owner's representative who is capable of performing maintenance in accordance with the law and nationally recognized standards of good practice; owner maintenance includes the following nontechnical repairs:

(A) replacing sprinkler heads;

(B) resetting valves;

(C) replacing damaged or missing pipe hangers;

(D) replacing batteries;

(E) replacing indicator lamps;

(F) tightening electrical connections; or

(G) replacing damaged or inoperative detection or audible devices;

(11) "permit" means the document issued under this section by the state fire marshal to an individual as verification of that individual's qualifications to design, install, and maintain fire protection systems in accordance with this section;

(12) "permit holder" means an individual who has been issued a permit under this section by the state fire marshal;

(13) "special hazard system" means a system that uses gases, chemicals, or foam as the fire suppression agent and includes Halon systems, CO<sub>2</sub> systems, wet chemical systems, dry chemical systems, AFFF systems, and protein foam systems;

(14) "system" means a fire alarm signaling system or fire suppression system;

(15) "water-based fire suppression system" means a system that uses water as the suppression agent; "water-based fire suppression system" includes automatic fire sprinkler systems and standpipe systems.

**History: Eff. 6/10/93, Register 126; am 8/31/96, Register 139; am 9/13/2007, Register 183**

**Authority: AS 18.70.010**

**AS 18.70.080**

**AS 18.70.090**

**Editor's note: Copies of NICET publications are available from the National Institute for Certification in Engineering Technologies, 1420 King Street, Alexandria, Virginia 22314.**

**SB**

**280**

# SENATE COMMITTEE REPORT

DATE: 3/27/08

FURTHER: Finance

DATE TURNED  
IN TO OFFICE: 4/6/08

Labor and Commerce Committee considered SENATE BILL NO. 280

## SB 280 MEDICAID/ INS FOR CANCER CLINICAL TRIALS

"An Act requiring health care insurers to provide insurance coverage for medical care received by a patient during certain approved clinical trials designed to test and improve prevention, diagnosis, treatment, or palliation of cancer; directing the Department of Health and Social Services to provide Medicaid services to persons who participate in clinical trials; relating to experimental treatments; and providing for an effective date."

and recommends:

- be replaced with  SCS or  CS \_\_\_\_\_ (\_\_\_\_\_)
- adopt previous  SCS or  CS SB 280 (HES)
- attached amendment(s)
- adopt \_\_\_\_\_ Letter of Intent
- further referral to \_\_\_\_\_ Committee

<b>SENATE BILL:</b>	
<input type="checkbox"/>	Same Title
<input checked="" type="checkbox"/>	New Title
<hr/>	
<b>HOUSE BILL:</b>	
<input type="checkbox"/>	Same Title
<input type="checkbox"/>	Technical Title Change
<input type="checkbox"/>	New Title w/ SCR # _____

**NEW FISCAL NOTE(S):**

Department	Date	Fiscal	Indel.	Zero	FN#

**PREVIOUS FISCAL NOTE(S):**

Department	Date	Fiscal	Indel.	Zero	FN#
HSS	3/06/08	✓			

APPROPRIATION - no fiscal note

SIGNATURES AND RECOMMENDATIONS	NAME	YES	NO	NOT PART	NO RES.	PAGE
<i>Betty Davis</i>	DAVIS	✓				
<i>[Signature]</i>	STEVENS			✗		
CHAIR: <i>[Signature]</i>	ELLIS	✓				

# Alaska State Legislature

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Senator Bettye Davis@legis.state.ak.us  
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## Senator Bettye Davis

### CS for Senate Bill 280(HES), 25-LS1464\M (3/27/08)

**“An Act requiring health care insurers to provide insurance coverage for medical care received by a patient during certain approved clinical trials designed to test and improve prevention, diagnosis, treatment, or palliation of cancer; directing the Department of Health and Social Services to provide Medicaid services to persons who participate in clinical trials; relating to experimental procedures; and providing for an effective date.”**

### SPONSOR STATEMENT

Clinical trials are research studies that test how well new medical approaches work in patients. Each study answers scientific questions and tries to find better ways to prevent, screen for, diagnose, or treat disease. Patients who take part in cancer clinical trials have an opportunity to contribute to the knowledge of, and progress against cancer. They also receive state-of-the-art treatment from experts in the field. The National Cancer Institute, as part of the U.S. National Institutes of Health, reports 6,000 cancer trials in the United States any one time. They include trials in prevention, screening, diagnosis, treatment, quality-of-life, and genetic studies.

SB 280 removes important barriers to the participation of patients in cancer clinical trials in Alaska. It requires 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. Currently Alaska health plans can exclude coverage for routine patient-care costs while a patient with cancer is enrolled in a clinical trial. Providers of health care plans often conclude that money is saved by excluding care while patients participate in clinical trials. But these patients, if not enrolled in clinical trials, will continue to receive conventional therapy at roughly the same or slightly increased costs in the short-run.

Studies have shown that only 2-3 percent of eligible adult patients enroll in clinical trials with a 6.5% increase in costs for clinical trial participants compared to nonparticipants. (National Conference of State Legislatures, [www.ncsl.org/programs/health/clinicaltrials.htm](http://www.ncsl.org/programs/health/clinicaltrials.htm), accessed 2/27/08) Without in-state facilities and support of clinical trials participants in Alaska currently have to travel out of state, increasing the cost of non-emergency transportation which is about 3% of total Medicaid costs.

In FY 2007 an estimated 4,600 patients received cancer treatments through Alaska's Medicaid program at a cost of \$21.5 million. The average payment per beneficiary was about \$4,675. The federal government reimburses the state at about 50% of the total costs. Based on an estimated 2.5% participation rate per above, about 115 patients are expected to participate in clinical trials each year. A 6.5% increase for 115 persons would add \$35.00 per year to Medicaid for cancer treatments. Non-emergency transportation costs for the same group are estimated to add another \$15.00 per year. The fiscal note adds an estimated \$50,000 per year with the federal government paying half of this.

Twenty-three states have passed legislation or instituted special agreements requiring health plans to pay the cost of routine medical care patients receive while participating in clinical trials. Passage of SB 280 will result in more successful outcomes in cancer treatments in Alaska, increase retention of patients in Alaska for their cancer care, and also, after full implementation, result in cost savings in the short and long term.

# LEGAL SERVICES

DIVISION OF LEGAL AND RESEARCH SERVICES  
LEGISLATIVE AFFAIRS AGENCY  
STATE OF ALASKA

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## MEMORANDUM

March 27, 2008

**SUBJECT:** Mandatory insurance for clinical trials for cancer; sectional summary (CSSB 280(HES); Work Order No. 25-LS1464(M))

**TO:** Senator Bettye Davis  
Chair of Senate Health, Education & Social Services Committee  
Attn: Tom Obermeyer

**FROM:** Dennis C. Bailey *dc*  
Legislative Counsel

You have requested a sectional summary of the above-described bill.

As a preliminary matter, note that a sectional summary of a bill should not be considered an authoritative interpretation of the bill and the bill itself is the best statement of its contents.

**Section 1.** Requires health care insurers to cover approved clinical trials for cancer if there is no clearly superior noninvestigational treatment alternative, and available clinical or preclinical data provide a reasonable expectation that the treatment in the clinical trial will be at least as efficacious as any noninvestigational alternative; makes coverage for clinical trials subject to standard policy provisions that are applicable to other benefits; and defines covered clinical trials and patient costs.

**Section 2.** Requires the state health insurance plan provided by the Comprehensive Health Care Insurance Association to include clinical trials related to cancer in its minimum standard benefits.

**Section 3.** Requires the state Medicaid program to cover clinical trials related to cancer.

**Section 4.** Gives the Act a January 1, 2009, effective date.

DCB:med  
06-228.med

## **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](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, 2001.
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, 2001.
7. Lara PN, et al: Evaluation of factors affecting awareness of and willingness to participate in cancer clinical trials. *Journal of Clinical Oncology*. 23:9282-9289, 2005.
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*. 18:2805-2810, 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*. 91:847-853, 1999.
12. Quirk J, et al: Clinical trial costs are similar to and may be less than standard care and inpatient (InPT) charges at an academic medical center (AMC) are similar to major, minor, and non-teaching hospitals. *Proc American Society Clinical Oncology*. 19:433a, (abstr. 1696), 2000.
13. 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*. 18:2805-10, 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)**

		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 <sup>1</sup>			X	X			X	X	X	X
California	CAL. HEALTH & SAFETY CODE § 1370.6; CAL. INS. CODE § 10145.4; and CAL. V/ELF. & INST. CODE § 14132.98	X <sup>2</sup>			X	X	X		X	X	X	X
Connecticut	CONN. GEN. STAT. ANN §§ 38a-504a to 38a-504g and 38a-542a to 38a-542g	X <sup>3</sup>			X						X	
Delaware*	DEL. CODE ANN. tit. 18, § 3567	X <sup>4</sup>			X							
Georgia	GA. CODE ANN. § 33-24-59.1	X <sup>5</sup>			X	X		X		X <sup>6</sup>	X <sup>6</sup>	
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 <sup>4</sup>			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-I	X <sup>7</sup>			X	X			X	X	X	X
New Mexico	N.M. STAT. ANN. § 59A-22-43	X <sup>4</sup>			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 <sup>4</sup>			X	X			X	X	X	X
Vermont	VT. STAT. ANN. tit. 8, § 4088b <sup>8</sup>	X			X	X	X					
Virginia	VA. CODE ANN. §§ 2.2-2818 and 38.2-3418.8	X			X	X		X	X <sup>9</sup>	X	X	X

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

		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 <sup>4</sup>			X	X	X	X		X	X	X
Wisconsin	WIS. STAT. ANN. §§ 632.87 and 40.51			X <sup>4</sup>	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.

<sup>1</sup> Indicated insurers are only obligated to provide coverage for covered patient costs that are directly associated with the clinical trial.

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

<sup>3</sup> 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.

<sup>4</sup> Coverage requirement applies only to clinical trials that have a therapeutic intent.

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

<sup>6</sup> Applies only to Phase II or III prescription drug clinical trial programs.

<sup>7</sup> Coverage for Phase I and Phase II clinical trials is decided on a case-by-case basis.

<sup>8</sup> 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.

<sup>9</sup> 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<sup>1</sup> – should not be denied coverage when all of the following are demonstrated:

- Treatment is provided with a therapeutic intent<sup>2</sup>;
- 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.<sup>3</sup>

Originally adopted February 1993  
As amended June 1994 and March 2005


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<sup>1</sup> 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.

<sup>2</sup> Treatment with therapeutic intent may be aimed at improving patient outcome relative to either survival or quality of life.

<sup>3</sup> 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.

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## 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<sup>®</sup>, 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.htm> 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://ciasecure.nci.nih.gov/livehelp/welcome.a?2](https://ciasecure.nci.nih.gov/livehelp/welcome.a?)

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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 GRANTEEES-** 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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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 50<sup>th</sup> 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

D. Lawrence Wickerham, MD

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.

**SB 280 Testimony 4/3/08**

**Jeanne E. Anderson, MD  
Katmai Oncology Group, LLC  
3851 Piper Street, Suite U340  
Anchorage, AK 99508-4627**

I am Jeanne Anderson, a Medical Oncologist in practice in Anchorage. On behalf of Alaska cancer physicians and patients, I thank the members of the Labor and Commerce Committee members for considering this bill. It is predicted that 2,650 Alaskans will be diagnosed with cancer in 2008. In the 1970's, only 50% of cancer patients lived 5 years after diagnosis. In 2008, 66% are predicted to survive 5 years. We all know that many Alaskans die of cancer every day and that improvements are desperately needed. The cancer physicians in Alaska are committed to providing the best care possible to our patients, to relieve suffering and reduce death from cancer. In caring for our patients, we often turn to clinical trial as providing the best treatment for our patients. A clinical trial is a formal, scientific way to test whether a new treatment is safe, effective, and superior to existing treatments. The physicians and hospitals in Alaska support clinical trials and there are over 50 trials open in this state for our cancer patients. However, only a small number of our patients enroll on these clinical trials, approximately 40 per year. There are many reasons why enrollment is low. These reasons include lack of knowledge or interest on the part of the patient or physician, lack of availability of an appropriate trial for the patient, and (relevant to this bill) lack of insurance coverage or fear by the patient they will lose coverage if enrolled on a study. Passage of this bill will clearly remove an important barrier to access of a clinical trial. It will result in Alaska physicians providing improved care for our patients, reducing the burden of cancer in our population, and facilitating patients to stay in Alaska for state-of-the-art care.



April 2, 2008

The Honorable Johnny Ellis, Chair  
Senate Labor and Commerce Committee  
Alaska State Capitol, Room 9  
Juneau, AK 99801-1182

RE: SB 280 (Davis)—Support

Dear Chair Ellis,

On behalf of the members of AARP in Alaska, we encourage you and your colleagues on the Senate Labor and Commerce Committee to support SB 280, sponsored by your Committee colleague, Senator Bettye Davis.

SB 280 would require insurance programs, including Medicaid, to provide coverage for cancer victims undergoing clinical trials.

Most of our significant advances in cancer treatment that have become standard procedures began as clinical trials.

It makes no sense not to offer health insurance coverage for procedures that may be still considered experimental but offer some hope for the cancer victim. We purchase insurance (or the State provides it through Medicaid) so that we can have help with the costs that accompany a threatening disease. SB 280 is one of those bills that AARP believes makes sense, especially to a cancer victim and his/her family.

AARP recommends an "AYE" vote on SB 280.

Should you have any questions about our position, please feel free to contact me (586-3637) or Patrick Luby, AARP Advocacy Director (907-762-3314).

Thank you for your consideration.

Sincerely,

Marie Darlin, Coordinator  
AARP Capital City Task Force  
415 Willoughby Avenue Apt. 506  
Juneau, AK 99801  
586-3637 (voice)  
463-3580 (fax)

DO

CC: Senator Gary Stevens  
Senator Bettye Davis

Senator Lyman Hoffinan  
Senator Con Bunde



**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!**

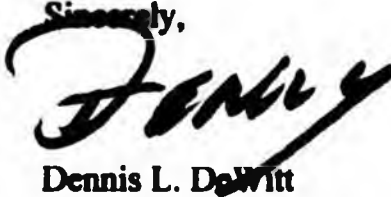
**While we understand the concern with coverage for clinical trials related to cancer, we must oppose mandatory benefits, especially when directed to a specific disease. Small businesses in Alaska budget a portion of their revenues to employee compensation. The distribution of those funds should be left 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.**

**Senator Bettye Davis**  
**March 29, 2008**  
**Page 2**

**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,*

A handwritten signature in black ink, appearing to read "Dennis L. DeWitt". The signature is written in a cursive, flowing style with a long, sweeping underline.

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

**cc: Senate Labor & Commerce Committee**

## **Bob Boerner**

---

**From:** "Dick Cauchi" <dick.cauchi@ncsl.org>  
**To:** "Bob Boerner" <bob.boerner@ncsl.org>  
**Sent:** Thursday, April 03, 2008 2:58 PM  
**Subject:** Clinical Trials What are States Doing 2008

Although it is not possible to provide this live by phone today, the NCSI report provided below is our best information on this topic. Next week Karmen Hanson, our author and expert, may be able to provide additional information or insights.

The online version is located at: <http://www.ncsl.org/programs/health/clinicaltrials.htm>

NCSL Health Program



### **Clinical Trials: What are States Doing? April 2008 Update**



#### **What is a Clinical Trial?**

A clinical trial is a research study on human patients to test the safety and effectiveness of new treatments. These trials offer patients access to new and potentially life saving drugs and cures.

The dramatic progress made in treating childhood cancers in recent years, is attributable, in part, to clinical trials, because 60 percent of all children with cancer are enrolled in some kind of trial. A ten percent drop in breast cancer mortality for women under the age of 50 is said to be the result of clinical trials research conducted in the 1970's.

#### **Who Enrolls in Clinical Trials?**

Only two to three percent of eligible adult patients enroll in clinical trials. For cancer patients, clinical trials are often the last resort after exhausting all other approved means of treatment.

#### **Insurance Coverage for Clinical Trials**

Typically, when a patient enrolls in a clinical trial, the cost of tests, procedures, drugs and any research activity directly associated with the investigation, are covered by the group sponsoring the trial, such as a pharmaceutical company or the National Cancer Institute. However, because some health plans define clinical trials as "experimental" or "investigational," health insurance coverage may or may not include some or all of the costs of "routine patient care," such as the doctor visits, hospital stays, tests and x-rays, that a patient would normally receive whether or not they were enrolled in trial.

Nevertheless, a growing number of states have passed legislation or instituted special agreements requiring health plans to pay the cost of the routine medical care a patient receives as a participant in a clinical trial.

#### **Advantages:**

For cancer patients, properly designed and conducted clinical trials represent an important therapeutic option, as well as a critical means of advancing medical knowledge. Lack of insurance coverage is a barrier to patients who might otherwise participate. Sixty percent of patients in one survey cited fear of insurance denial as a major reason for not participating in clinical trials. And finally, a recent study found only a slight increase in treatment costs for adult clinical trial patients compared to nonparticipants--\$35,418 versus \$33,248.

**Disadvantages:**

Even though the same recent study found only a slight increase in treatment costs, the 6.5 percent increase between participants and nonparticipants in clinical trials translated into an additional \$16 million in 1999 spent on treatment costs for the 19,000 adult patients enrolled in National Cancer Institute-sponsored clinical trials. These additional insurance costs, like other mandated benefits and services, may result in higher insurance premium rates, which are often cost-shifted onto workers in the form of higher deductibles and copayments.

**Definitions of Phases:**

A clinical trial study is conducted in four phases.

**Phase I:** Research is conducted on a small group of volunteers (20 to 80 people) for the first time to evaluate its safety, determine a safe dosage range and identify side effects.

**Phase II:** The experimental drug or treatment is given to or a procedure is performed on a larger group of people (100 to 300 individuals) to further measure its effectiveness and safety.

**Phase III:** Further research is conducted to confirm the effectiveness of the drug, treatment or procedure, monitor the side effects, compare commonly used treatments and collect information on safe use. Phase III trials are typically conducted on 1,000 to 3,000 individuals.

**Phase IV:** After the drug, treatment or medical procedure is marketed, investigators continue testing to determine the effects on various populations and whether there are side effects associated with long-term use.

**Summary of State Laws**

Table One provides a summary of the 20 states that have enacted laws regarding mandated coverage of clinical trials.

<p align="center"><b>Table One Clinical Trials Laws April 2006</b></p>			
<p align="center"><b>State Year of Enactment Bill Number and/or Citation</b></p>	<p align="center"><b>Who is Required to Pay?</b></p>	<p align="center"><b>What Services or Benefits are Covered?</b></p>	<p align="center"><b>Other Key Criteria:</b></p>
<p>Arizona (2000) Senate Bill 1213 20-232B</p>	<p>Hospital or medical service corporations, benefit insurers, health care service organizations, disability insurers, group disability insurers and accountable health plans</p>	<p>Patient costs associated with participation in Phase I through IV cancer clinical trials.</p>	<p>Trial must be reviewed by an Institutions Review Board in AZ. Health professional must agree to accept reimbursement from insurer as payment in full. Only covers trial when no clearly superior noninvestigational treatment exists. Trial must be in AZ.</p>
<p>California (2000) Senate Bill 37</p>	<p>All California insurers, including Medicaid and other medical assistance programs</p>	<p>Routine patient care costs associated with Phase I through IV cancer clinical trials.</p>	<p>May restrict coverage to services in CA.</p>
<p>Connecticut (2001) Senate Bill 325</p>	<p>Private insurers, individual and group health plans</p>	<p>Routine patient care costs associated with cancer clinical trials.</p>	<p>Prevention trials are covered only in Phase III and only if involve therapeutic intervention.</p>

Public Act 01-121			Insurer may require documentation of the likelihood of therapeutic benefit, informed consent, protocol information and/or summary of costs.
Delaware (2001) Senate Bill 181	Every group of blanket policy, including policies or contracts issued by health service corporations	Routine patient care costs for covered persons engaging in clinical trials for the treatment of life threatening diseases under specified conditions.	Trial must have therapeutic intent and enroll individuals diagnosed with the disease. Trial must not be designed exclusively to test toxicity or disease pathophysiology.
Georgia* (1998) 33-24-59.1	Insurers and the state health plan	Routine patient costs incurred in Phase II and III of prescription drug clinical trial programs for the treatment of children's cancer.	For the treatment of cancer that generally first manifests itself in children under the age of 19.
Illinois (1999) House Bill 1622 (amended 2004) Senate Bill 2339 Public Act No. 03-1000 20 ILCS 1405/56.3**	HMOs and individual/group insurance policies to offer coverage to the applicant or policyholder (2004 amendment: Plans may not be canceled or non-renewed based on an individual's participation in a qualified clinical trial)	Routine patient care if the individual participates in an approved Phase II through IV cancer research trial.	Coverage benefit can have annual limit of \$10,000. Trial must be conducted at multiple sites in state. Primary care MD must be involved in coordination of care. Researchers must submit results of trial for publication in nationally recognized scientific literature.
Louisiana (1999) RS 22:230.4	HMOs, PPOs, State Employee Benefits Program and other specified insurers	Patient costs incurred in Phase II through IV cancer clinical trials.	Only covers costs when no clearly superior, noninvestigational approach exists. Available data must support reasonable expectation that the treatment will be as effective as the noninvestigational alternative. Patient must sign an Institutional Review Board-approved consent form.
Maine (2000) 24-A-431D	Managed care organizations and private insurers	Routine patient care costs associated with clinical trial.	Participation must offer meaningful potential for significant clinical benefit. Referring physician must conclude that trial participation is appropriate.
Maryland*** (1998) Chap 146-15-827	Private insurers and other specified managed care organizations.	Patient costs for Phase I through IV cancer treatment, supportive care, early detection, and prevention trials. Phase II through IV for other life-threatening conditions, with Phase I considered on a case-by-case basis.	There is no clearly superior, noninvestigational alternative. The data provide a reasonable expectation that the treatment will be as least as effective as the alternative.
Massachusetts (2002)	All health plans issued or renewed after Jan. 1,	Patient care services associated with all phases of qualified cancer clinical	Insurers must provide payment for services that are consistent with the

<p>Chap. 176A, Sec IX</p>	<p>2003</p>	<p>trials.</p>	<p>usual and customary standard of care provided under the trial's protocol and that would be covered if the patient did not participate in the trial.</p>
<p>Missouri (2002) SB 376.029  (2006)- Phase II SB 567.0792</p>	<p>All health benefit plans operating in the state</p>	<p>Routine patient care costs as the result of Phase II, III or IV clinical trials for the prevention, early detection, or treatment of cancer.</p>	<p>There must be identical or superior noninvestigational treatment alternatives available before providing clinical trial treatment, and there must be a reasonable expectation that the trial will be superior to the alternatives. Requires coverage of FDA-approved drugs and devices even if they have not been approved for use in treatment of patient's particular condition.</p>
<p>New Hampshire (2000) SA 415:18</p>	<p>Private insurers and specified managed care plans</p>	<p>Medically necessary routine patient care costs incurred as a result of a treatment for Phase I through IV cancer clinical trial or trial for a life-threatening disease.</p>	<p>Coverage for Phases I or II decided on case-by-case basis. Coverage is required for services needed to administer drug or device under evaluation. Coverage is required for routine patient care associated with drugs or devices which are not subject of trial, as long as they have been approved by FDA.</p>
<p>Nevada (2003) (amended 2005) SB 29 NRS 695G.173</p>	<p>All health insurance insurers, medical service corporations, HMOs and managed care organizations</p>	<p>Patient costs associated with Phase I through IV cancer or chronic fatigue clinical trial</p>	<p>Healthcare facility and personnel must have experience and training to provide the treatment in a capable manner. There must be no medical treatment available which is considered a more appropriate alternative medical treatment than the medical treatment provided in the clinical trial. There must be a reasonable expectation based on clinical data that the medical treatment provided in the clinical trial or study will be at least as effective as any other medical treatment. Amendment revises type of medical treatment covered.</p>
<p>New Mexico (2002) (amended 2004 to delay repeal until July 1, 2009) 59A-22-43</p>	<p>A health insurer; a nonprofit health service provider; a HMO; a managed care organization; a provider service organization; or the state's medical</p>	<p>Routine patient care costs incurred as a result of the patient's participation in a phase II, III or IV cancer clinical trial.</p>	<p>Must be undertaken for the purposes of the prevention of recurrence of cancer, early detection or treatment of cancer for which no equally or more effective standard cancer treatment exists. Must not be designed exclusively to</p>

	assistance program.		<p>most toxicity or disease pathophysiology and it has a therapeutic intent.</p> <p>Must be provided as part of a scientific study of a new therapy or intervention and is for the prevention of reoccurrence, early detection, treatment or palliation of cancer in humans and in which includes specific provisions of scientific study.</p>
New Mexico (2001) 59A-22-43	Private insurers, specified managed care plans, and Medicaid and other state medical assistance programs	Routine patient care costs incurred as result of Phase I through IV cancer clinical trial.	<p>Effective through July 1, 2004.</p> <p>Trial must have therapeutic intent.</p> <p>Reasonable expectation that investigational treatment will be at least as effective as standard treatment.</p>
North Carolina (2001) 258-3-255	All health insurance plans and teachers' and state employees' comprehensive major medical plan.	Medically necessary costs of health care services associated with Phase II through IV of covered clinical trials.	Patients suffering from a life-threatening disease or chronic condition may designate a specialist who is capable of coordinating their health care needs.
Rhode Island (1994, 1997) 34-S 2623B 37-S 1A am	Private insurers and specified managed care plans	Coverage for new cancer therapies if treatment is provided under Phase II through IV cancer clinical trial.	
Tennessee (2005) HB 837	All health benefit plans	Routine patient care costs related to Phase I through IV cancer clinical trial.	Treatment must involve drug that is exempt under federal regulations from a new drug application, or approved by: NIH, FDA in form of new drug application, DOD, or VA.
Vermont (2001) (amended 2005 to remove March 1, 2005 sunset provision) Chap 107 24088b 1B 6	All health insurance policies and health benefit plans, including Medicaid	Routine patient care costs incurred during the participation in a cancer clinical trial.	<p>Providers and insurers required to participate in a cost analysis to determine impact of the program on health insurance premiums.</p> <p>Amended law allows for participation in trial outside of Vermont if patient notifies health benefit plan prior to participation, and no clinical trial is available at Vermont or New Hampshire cancer care providers.</p>
Virginia (1999) 238.2-3418.8	Private insurers, specified managed care plans, and public employee health plans	<p>Patient costs incurred during the participation in Phase II through IV cancer clinical trials.</p> <p>Coverage provided on a case-by-case basis for Phase I.</p>	<p>There must be no clearly superior, noninvestigational alternative.</p> <p>Data must provide a reasonable expectation that the treatment will be at least as effective as the alternative.</p>
West Virginia (2003) 29-2-12	Individual and group insurers, health service corporations, health care corporations,	Patient costs associated with the participation in Phase II through IV clinical trial for treatment of life-threatening condition or the	Facility and personnel providing the treatment are capable of doing so by virtue of their experience, training and volume of patients

	Medicaid, public employees insurance agency, Medicaid and the Children's health insurance program	prevention, early detection and treatment of cancer.	<p>designed to maintain expertise. There must be no clearly superior, noninvestigational treatment alternative.</p> <p>Data provide a reasonable expectation that the treatment will be more effective than the noninvestigational treatment alternative.</p>
Wisconsin AB 617 (2006) Act 194	Any health insurance plan offered by the state, any self-insured plans	<p>Routine patient care costs incurred during the participation in all phases of a cancer clinical trial.</p> <p>No policy, plan, or contract may exclude coverage for the cost of any routine patient care that is administered to an insured in a cancer clinical trial satisfying the criteria under par. (c) and that would be covered under the policy, plan, or contract if the insured were not enrolled in a cancer clinical trial.</p>	<p>Trial must meet all criteria:</p> <ol style="list-style-type: none"> <li>1. The purpose is to test whether the intervention potentially improves the trial participant's health outcomes.</li> <li>2. The treatment provided as part of the trial is given with the intention of improving the trial participant's health outcomes.</li> <li>3. The trial has therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology.</li> <li>4. The trial does one of the following: <ol style="list-style-type: none"> <li>a. Tests how to administer a health care service, item, or drug for the treatment of cancer.</li> <li>b. Tests responses to a health care service, item, or drug for the treatment of cancer.</li> <li>c. Compares the effectiveness of health care services, items, or drugs for the treatment of cancer with that of other health care services, items, or drugs for the treatment of cancer.</li> <li>d. Studies new uses of health care services, items, or drugs for the treatment of cancer.</li> </ol> </li> <li>5. The trial is approved by one of the following: <ol style="list-style-type: none"> <li>a. A National Institute of Health, or one of its cooperative groups or centers, under the federal department of health and human services; federal food and drug administration; federal department of defense; federal department of veterans affairs.</li> </ol> </li> </ol>
Wyoming SF 024 (2008 budget)	All health insurance policies, contracts, and certificates providing	Routine patient care for a person enrolled in a Phases II-IV clinical trial. Includes a medical service or	Trial must also be approved by NIH, FDA, Dept. of Defense, or Dept. of Veterans Affairs. The medical

ession)	coverage to any resident of this state.	treatment that is a benefit under a health plan that would be covered if the patient were receiving standard cancer treatment; or a drug provided to a patient during a cancer clinical trial, other than the drug that is the subject of the clinical trial, if the drug has been approved by the federal food and drug administration for use in treating the patient's particular condition.	treatment must be provided by a licensed health care provider operating within the scope of his/her license in a facility whose personnel has the experience and training necessary to provide the treatment in a competent manner. The clinical trial participant must have signed an informed consent document prior to starting the trial.
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\*In 2002, all major insurers in Georgia agreed to cover routine patient care costs associated with Phase I, II, III, or IV cancer clinical trials. Trials include those that involve a drug that is currently exempt under federal regulations from a new drug application or those that are approved by specified federal agencies or a local institutional review board. The agreement also provides for the coverage of cancer screens and examinations in accordance with the most recently published guidelines and recommendations established by any nationally recognized health care organization (see below).

\*\*Illinois Executive Branch Administrative Code (20 ILCS 1405/1405-20) required the Department of Insurance to conduct an analysis and study of costs and benefits derived from the implementation of the coverage requirements for investigational cancer treatments. The study covered the years 2000 through 2002 and included an analysis of the effect of the coverage requirements on the cost of insurance and health care, the results of the treatments to patients, the mortality rate among cancer patients, any improvements in care of patients, and any improvements in the quality of life of patients.

\*\*\*A 2003 Maryland law (S 128) repealed a reporting requirement for insurers, nonprofit health service plans, and HMOs to submit a report that described the trials covered during the previous year.

Sources: National Cancer Institute, Health Policy Tracking Service.

### Summary of Other Actions

Table Two summarizes the special agreements some states have arranged with insurance companies to voluntarily provide coverage for clinical trials.

State (Year Agreement Became Effective) Web Address of Agreement	Who is Required to Pay?	What Services or Benefits are Covered?	Other Key Criteria:
Georgia (2002) <u>Georgia Cancer Coalition</u>	All major insurers	Routine patient care costs associated with Phase I through IV cancer clinical trials.	Trials include those that involve a drug that is currently exempt under federal regulations from a new drug application or those that are approved by specified federal agencies or a local institutional review board.  Provides for the coverage of cancer screens and examinations in accordance with the most recently published guidelines and recommendations established

			by any nationally recognized health care organization.
Michigan (2002) Michigan Consensus Agreement	Private insurance plans, HMOs and Medicaid	Routine patient care costs associated with Phase II and III cancer clinical trials.	Coverage for Phase I trials is under consideration.
New Jersey (1999) New Jersey Consensus Agreement	All insurers	Routine patient care costs associated with all phases of cancer clinical trials.	
Ohio (1999) Ohio Med Plan	State employees on Ohio Med Plan	Routine patient care costs associated with Phase II and III cancer treatment clinical trials.	Preauthorization is required for clinical trial participation.

### Federal Activity

In 2000, Medicare began covering beneficiaries patient care costs in clinical trials. While many state Medicaid programs have no legal requirement to cover clinical trials costs, many do cover all or some of the costs.

To legislators and legislative staff: For more information please contact Kaitlyn Hanson at [health-info@ncsl.org](mailto:health-info@ncsl.org)

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**SB**

**289**

**SENATE COMMITTEE REPORT  
First Committee of Referral**

DATE: 2/19/08

FURTHER: Finance

Date of 5-Day Notice: \_\_\_\_\_  
(in accordance with Uniform Rule 23)

DATE TURNED  
IN TO OFFICE: 3/11/08

Labor and Commerce Committee considered SENATE BILL NO. 289

**SB 289 HOME ENERGY CONSERVATION**

"An Act relating to home energy conservation and weatherization for purposes of certain programs of the Alaska Housing and Finance Corporation."

and recommends:

- be replaced with  SCS or  CS \_\_\_\_\_ ( )
- adopt previous  SCS or  CS \_\_\_\_\_ ( )
- attached amendment(s)
- adopt \_\_\_\_\_ Letter of Intent
- further referral to \_\_\_\_\_ Committee

<b>SENATE BILL:</b>	
<input type="checkbox"/>	Same Title
<input type="checkbox"/>	New Title
<hr/>	
<b>HOUSE BILL:</b>	
<input type="checkbox"/>	Same Title
<input type="checkbox"/>	Technical Title Change
<input type="checkbox"/>	New Title w/ SCR # _____

**NEW FISCAL NOTE(S):**

Bill Number	Date	Item	Zero	
REV	3/9/08			✓

**PREVIOUS FISCAL NOTE(S):**

Bill Number	Date	Item	Zero	

APPROPRIATION - no fiscal note

<i>Boyer Evans</i>	DAVIS	1			
<i>[Signature]</i>	Hoffman	✓			
<i>[Signature]</i>	STEVEN	X			
CHAIR: <i>Jo Ellis</i>	ELLIS	X			