

# Alaska State Legislature

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## Senator Bettye Davis

### SB 10 - 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 procedures under a state plan offered by the Comprehensive Health Insurance Association; 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.

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

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

**Studies have shown that only 2% to 3% of adult cancer patients and less than 0.5% Medicare patients enroll in clinical trials of the approximately 20% who are eligible -largely due to fear of denial of insurance.** A recent study found only slight increase in treatment costs for adult clinical trial patients compared to nonparticipants, \$35,418 versus \$33,248 or about 6.5% increase in costs for clinical trial participants compared to nonparticipants. Even if enrollment was increased to the full 20%, it is unlikely that these numbers will significantly impact overall costs to health plans. See National Conference of State Legislatures, “Clinical Trials: What are States Doing? February, 2009 Update,” [www.ncsl.org/programs/health/clinicaltrials.htm](http://www.ncsl.org/programs/health/clinicaltrials.htm).

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

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

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

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

**CS FOR SENATE BILL NO. 10(HSS)**

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-SIXTH LEGISLATURE - FIRST SESSION

BY THE SENATE HEALTH AND SOCIAL SERVICES COMMITTEE

Offered: 2/23/09

Referred: Labor and Commerce, Finance

Sponsor(s): SENATORS DAVIS, Paskvan

**A BILL**

**FOR AN ACT ENTITLED**

1 "An Act requiring health care insurers to provide insurance coverage for medical care  
2 received by a patient during certain approved clinical trials designed to test and  
3 improve prevention, diagnosis, treatment, or palliation of cancer; directing the  
4 Department of Health and Social Services to provide Medicaid services to persons who  
5 participate in those clinical trials; relating to experimental procedures under a state  
6 plan offered by the Comprehensive Health Insurance Association; and providing for an  
7 effective date."

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

9 \* **Section 1.** AS 21.42 is amended by adding a new section to read:

10 **Sec. 21.42.410. Coverage for clinical trials related to cancer.** (a) A health  
11 care insurer that offers, issues for delivery, delivers, or renews a health care insurance  
12 plan in the state shall cover routine patient care costs incurred by a patient enrolled in  
13 an approved clinical trial related to cancer, including leukemia, lymphoma, and bone

1 marrow stem cell disorders.

2 (b) The health care insurer is required to provide coverage under this section  
3 only if the patient's treating physician determines that

4 (1) there is no clearly superior noninvestigational treatment alternative;  
5 and

6 (2) available clinical or preclinical data provide a reasonable  
7 expectation that the treatment provided in the clinical trial will be at least as  
8 efficacious as any noninvestigational alternative.

9 (c) The coverage to be provided under (a) of this section must include  
10 payment for the costs of

11 (1) prevention, diagnosis, treatment, and palliative care of cancer;

12 (2) medical care for an approved clinical trial related to cancer that  
13 would otherwise be covered under a health care insurance plan if the medical care  
14 were not in connection with an approved clinical trial related to cancer;

15 (3) items or services necessary to provide an investigational item or  
16 service;

17 (4) the diagnosis or treatment of complications;

18 (5) a drug or device approved by the United States Food and Drug  
19 Administration without regard to whether the United States Food and Drug  
20 Administration approved the drug or device for use in treating a patient's particular  
21 condition, but only to the extent that the drug or device is not paid for by the  
22 manufacturer, distributor, or provider of the drug or device;

23 (6) services necessary to administer a drug or device under evaluation  
24 in the clinical trial; and

25 (7) transportation for the patient that is primarily for and essential to  
26 the medical care.

27 (d) The coverage to be provided under (a) of this section may not include the  
28 cost of

29 (1) a drug or device that is associated with the clinical trial that has not  
30 been approved by the United States Food and Drug Administration;

31 (2) housing, companion expenses, or other nonclinical expenses

1 associated with the clinical trial;

2 (3) an item or service provided solely to satisfy data collection and  
3 analysis and not used in the clinical management of the patient;

4 (4) an item or service excluded from coverage under the patient's  
5 health care insurance plan; and

6 (5) an item or service paid for or customarily paid for through grants or  
7 other funding.

8 (e) The coverage required by this section is subject to the standard policy  
9 provisions applicable to other benefits, including deductible, coinsurance, or  
10 copayment provisions.

11 (f) This section does not apply to a fraternal benefit society.

12 (g) In this section, "approved clinical trial" means a scientific study using  
13 human subjects designed to test and improve prevention, diagnosis, treatment, or  
14 palliative care of cancer, or the safety and effectiveness of a drug, device, or procedure  
15 used in the prevention, diagnosis, treatment, or palliative care of a subject, if the study  
16 is approved by

17 (1) an institutional review board that complies with 45 CFR Part 46;

18 and

19 (2) one or more of the following:

20 (A) the United States Department of Health and Human  
21 Services, National Institutes of Health, or its institutes or centers;

22 (B) the United States Department of Health and Human  
23 Services, United States Food and Drug Administration;

24 (C) the United States Department of Defense;

25 (D) the United States Department of Veterans' Affairs; or

26 (E) a nongovernmental research entity abiding by current  
27 National Institute of Health guidelines.

28 \* **Sec. 2.** AS 21.55.140(a) is amended to read:

29 (a) A state plan may not provide benefits for charges for the following:

30 (1) care for an injury or disease either

31 (A) arising out of and in the course of an employment subject

1 to a workers' compensation or similar law or where the benefit is available to  
 2 be provided under a workers' compensation policy or equivalent self-insurance  
 3 to a sole proprietor, business partner, or corporation officer; or

4 (B) to the extent benefits are payable without regard to fault  
 5 under a coverage statutorily required to be contained in a motor vehicle or  
 6 other liability insurance policy or equivalent self-insurance;

7 (2) treatment for cosmetic purposes other than surgery for the prompt  
 8 repair of an accidental injury sustained while covered or for replacement of an  
 9 anatomic structure removed during treatment of tumors;

10 (3) travel, other than transportation covered under AS 21.55.110(17);

11 (4) private room accommodations to the extent it is in excess of the  
 12 institution's most common charge for a semiprivate room;

13 (5) services or articles to the extent that the charge exceeds the  
 14 reasonable charge in the locality for the service;

15 (6) services or articles that are determined not to be medically  
 16 necessary, except for the fabrication or placement of the prosthesis as specified in  
 17 AS 21.55.110(12) and (2) of this subsection;

18 (7) services or articles that are not within the scope of the license or  
 19 certificate of the institution or individual rendering the services or articles;

20 (8) services or articles furnished, paid for, or reimbursed directly by or  
 21 under any law of a government, except as otherwise provided in this chapter;

22 (9) services or articles for custodial care or designed primarily to assist  
 23 an individual in the activities of daily living;

24 (10) service charges that would not have been made if no insurance  
 25 existed or that the covered individual is not legally obligated to pay;

26 (11) eyeglasses, contact lenses, or hearing aids or the fitting of them;

27 (12) dental care not specifically covered by this chapter;

28 (13) services of a registered nurse who ordinarily resides in the  
 29 covered individual's home, or who is a member of the covered individual's family or  
 30 the family of the covered individual's spouse;

31 (14) experimental procedures, except during an approved clinical

1            **trial; in this paragraph, "approved clinical trial" has the meaning given in**  
2            **AS 21.42.410**; and

3                            (15) services and supplies for which the patient was not charged.

4            \* **Sec. 3.** AS 47.07.030 is amended by adding a new subsection to read:

5                            (e) The department shall provide the services set out in (a) and (b) of this  
6            section to an eligible person, notwithstanding the person's participation in an approved  
7            clinical trial. In this subsection, "approved clinical trial" has the meaning given in  
8            AS 21.42.410.

9            \* **Sec. 4.** This Act takes effect January 1, 2010.

# LEGAL SERVICES

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

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Mail Stop 3101

State Capitol  
Juneau, Alaska 99801-1182  
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## MEMORANDUM

April 17, 2009

**SUBJECT:** Mandatory health care insurance coverage for clinical trials for cancer (CSSB 10(HSS), Work Order No. 26-LS0073\S)

**TO:** Senator Bettye Davis  
Attn: Thomas Obermeyer

**FROM:** Dennis C. Bailey *DCB*  
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; identifies the items that must be included in and excluded from the required coverage; makes coverage for clinical trials subject to standard policy provisions that are applicable to other benefits; and defines the meaning of an approved clinical trial.

**Section 2.** Allows 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, 2010, effective date.

DCB:ljw  
09-262.ljw

# FISCAL NOTE

**STATE OF ALASKA**  
**2009 LEGISLATIVE SESSION**

Fiscal Note Number: 1  
 Bill Version: CSSB 10(HSS)  
 (S) Publish Date: 2/23/09

Identifier (file name): SB010-DHSS-MS-02-11-09 Dept. Affected: Health & Social Services  
 Title Medicaid/Insurance For Cancer Clinical Trials RDU Health Care Services  
 Component Medicaid Services  
 Sponsor Davis  
 Requester Senate HSS Component Number 2077

**Expenditures/Revenues** (Thousands of Dollars)

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

	Appropriation Required	Information						
		FY 2010	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
<b>OPERATING EXPENDITURES</b>								
Personal Services								
Travel								
Contractual								
Supplies								
Equipment								
Land & Structures								
Grants & Claims								
Miscellaneous								
<b>TOTAL OPERATING</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>

<b>CAPITAL EXPENDITURES</b>								
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<b>CHANGE IN REVENUES (</b>								
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**FUND SOURCE** (Thousands of Dollars)

1002 Federal Receipts								
1003 GF Match								
1004 GF								
1005 GF/Program Receipts								
1037 GF/Mental Health								
Other Interagency Receipts								
<b>TOTAL</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>

Estimate of any current year (FY2009) cost: 0.0

**POSITIONS**

Full-time								
Part-time								
Temporary								

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

SB 010 amends the Medicaid statute (AS 47.07.030) to add a new subsection (e) that requires the program to pay for Medicaid covered services for Medicaid recipients even when provided as part of an approved clinical trial related to cancer.

The bill would be effective on January 1, 2010. It is not expected to result in an increase in Medicaid expenditures as Medicaid already covers these services.

Prepared by: William J. Streur, Deputy Commissioner Phone 907-269-7827  
 Division Health Care Services Date/Time 2/10/09 12:00 AM  
 Approved by: Alison Elgee, Assistant Commissioner Date 2/11/2009  
DHSS Finance Management Services

# FISCAL NOTE

**STATE OF ALASKA**  
**2009 LEGISLATIVE SESSION**

Fiscal Note Number: 2  
 Bill Version: CSSB 10(HSS)  
 (S) Publish Date: 2/23/09

Identifier (file name): SB10-CED-INS-2-4-09  
 Title: Medicaid/Insurance for cancer clinical trials  
 Sponsor: Senator Davis  
 Requester: Senate Health and Social Services  
 Dept. Affected: DCCED  
 RDU: Insurance (116)  
 Component: Insurance  
 Component Number: 354

**Expenditures/Revenues** (Thousands of Dollars)

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

	Appropriation Required	Information						
		FY 2010	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
<b>OPERATING EXPENDITURES</b>								
Personal Services								
Travel								
Contractual								
Supplies								
Equipment								
Land & Structures								
Grants & Claims								
Miscellaneous								
<b>TOTAL OPERATING</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>

<b>CAPITAL EXPENDITURES</b>								
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<b>CHANGE IN REVENUES ( )</b>								
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**FUND SOURCE** (Thousands of Dollars)

1002 Federal Receipts								
1003 GF Match								
1004 GF								
1005 GF/Program Receipts								
1037 GF/Mental Health								
Other Interagency Receipts								
<b>TOTAL</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>

Estimate of any current year (FY2009) cost: \_\_\_\_\_

**POSITIONS**

Full-time								
Part-time								
Temporary								

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

This bill requires companies that offer health care insurance in Alaska cover routine patient care costs incurred by a patient enrolled in an approved clinical trial related to cancer. The coverage provided must include the costs of prevention, diagnosis, treatment, and palliative care of cancer. The health care insurer is required to provide coverage under this section only if the patient's treating physician determines that there is no clearly superior non-investigational treatment alternative; and available clinical or preclinical data provide a reasonable expectation that the treatment provided in the clinical trial will be at least as efficacious as any non-investigational alternative.

Prepared by: Linda S. Hall, Director  
 Division: Insurance  
 Approved by: Emil R. Notti, Commissioner  
Commerce, Community, and Economic Development

Phone 907-269-7900  
 Date/Time 2/4/09 10:48 AM  
 Date 2/4/2009

# Clinical Trials: What are States Doing?

## August 2009 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 lifesaving 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. Only a small percentage (approximately 20%) of cancer patients are eligible to participate in a clinical trial and very few (approximately 3% of cancer patients and less than 0.5% of Medicare patients) currently enroll. Even if enrollment was increased to the full 20 percent, it is unlikely that these numbers will significantly impact overall costs to health plans;<sup>1</sup>

### 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 a trial.

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.<sup>2</sup>

Some large HMOs have computed costs associated with patients in clinical trials. Kaiser Permanente discovered the cost of medical care for enrollees in clinical trials that haven't had bone marrow transplant were no higher than for patients who were not enrolled in a trial. The Kaiser Report further states, "Kaiser has been participating in cancer clinical trials without substantial increases in the direct costs of medical care."<sup>3</sup>

Researchers at the Mayo Clinic found that patient care costs for those enrolled in clinical trials is only slightly more than for patients who received standard therapy protocols.<sup>4</sup>

The Institutes of Medicine has also found the following:

- The reimbursement costs are limited to the cost of "standard care" which would be covered if the patient were not enrolled in the trial;<sup>1</sup>
- Only a small percentage (approximately 20%) of cancer patients are eligible to participate in a clinical trial and very few (approximately 3% of cancer patients and less than 0.5% of Medicare patients) currently enroll. Even if enrollment was increased to the full 20 percent, it is unlikely that these numbers will significantly impact overall costs to health plans;<sup>1</sup>
- Through clinical trials, we will be able to identify ineffective treatments, which could save health plans money and will benefit the nation as a whole.<sup>1</sup>

## **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.<sup>2</sup> 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.

For states without insurance mandates, it is possible that some physicians may enroll patients in clinical trials but not inform the patients' insurance companies, bypassing the reimbursement issue for the patient and potentially the physician.<sup>5</sup>

It may also be possible to encourage participation in clinical trials by working within networks of health care providers and industry, research facilities, patient groups, as well as major media outlets, without enacting a state wide insurance mandate.

#### Sources:

1. Aaron HJ, Gelband H, editors. Extending Medicare reimbursement in clinical trials. Washington, DC: National Academy Press; 2000. p 13.
2. Goldman DP, Berry SH, McCabe M, et al. Incremental Treatment Costs in National Cancer Institute–Sponsored Clinical Trials. *JAMA*. 2003;289(22):2970-2977 (doi:10.1001/jama.289.22.2970) <http://jama.ama-assn.org/cgi/reprint/289/22/2970.pdf>
3. Fireman BH, Fehrenbacher L, Gruskin EP, Ray GT. Cost of care for patients in cancer clinical trials. *J Natl Cancer Inst* 2000;92:136-42.
4. Wagner JL, Alberts SR, Sloan JA, et al. Incremental costs of enrolling cancer patients in clinical trials: a population-based study. *J Natl Cancer Inst* 1999;91:847-53.
5. McBride G, More States Mandate Coverage of Clinical Trial Costs, But Does It Make a Difference?, *JNCI Journal of the National Cancer Institute* 2003 95(17):1268-1269; doi:10.1093/jnci/95.17.1268

#### 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 as of August 2009

Table One provides a summary of the **23 states and District of Columbia** that have enacted laws regarding mandated coverage of clinical trials.

<b>Table One</b>			
<b>Clinical Trials Laws</b>			
<b>State</b>	<b>Who is Required to Pay?</b>	<b>What Services or Benefits are Covered?</b>	<b>Other Key Criteria:</b>
<b>Year of Enactment</b>			
<b>Bill Number and/or Citation</b>			
Arizona (2000) Senate Bill 1213 20-2328	Hospital or medical service corporations, benefit insurers, health care service organizations, disability insurers, group disability insurers and accountable health plans	Patient costs associated with participation in Phase I through IV cancer clinical trials.	Trail 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 non-investigational treatment exists. Trail must be in AZ.
California (2000) Senate Bill 37	All California insurers, including Medicaid and other medical assistance programs	Routine patient care costs associated with Phase I through IV cancer clinical trials.	May restrict coverage to services in CA.
Connecticut (2001) Senate Bill 325 Public Act 01-171	Private insurers, individual and group health plans	Routine patient care costs associated with cancer clinical trials.	Prevention trials are covered only in Phase III and only if involve therapeutic intervention. 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.

<p>District of Columbia (2008) Bill 17-469 (D.C. Law 17-166)</p>	<p>All insurers in the District</p>	<p>Routine patient care costs for people in clinical trials undertaken for prevention, early detection, treatment, or monitoring of cancer and approved or funded in full or in part by one of the following: National Institutes of Health or one of its cooperative groups or centers, Centers for Disease Control and Prevention, Agency for Health Care Research and Quality, Centers for Medicare and Medicaid Services, U.S. Food and Drug Administration (FDA), U.S. Department of Defense, U.S. Department of Veterans Affairs, U.S. Department of Energy, nongovernmental research entity that has been awarded a National Cancer Institute support grant.</p>	<p>Routine patient care costs shall not include tests or measurements conducted primarily for the purpose of the clinical trial involved. Services or products provided solely for data collection and analysis purposes. Services or products customarily provided free of charge to trial participants by the research sponsors.</p>
<p>Georgia* (1998) 33-24-59.1</p>	<p>Insurers and the state health plan</p>	<p>Routine patient costs incurred in Phase II and III of prescription drug clinical trial programs for the treatment of children's cancer.</p>	<p>For the treatment of cancer that generally first manifests itself in children under the age of 19.</p>
<p>Illinois (1999) House Bill 1622 (amended 2004) Senate Bill 2339 Public Act No. 93-1000 20 ILCS 1405/56.3**</p>	<p>HMOs and individual/group insurance policies to <u>offer</u> 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)</p>	<p>Routine patient care if the individual participates in an approved Phase II through IV cancer research trial.</p>	<p>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.</p>

Indiana (2009) House Bill 1382 Public Law 109	State employee health plan, the state Medicaid program, a policy of accident and sickness insurance, and a HMO contract	Requires coverage for routine patient care related to Phase I through IV clinical trials approved by NIH, FDA, VA or DoD.	(1) Require an insurer that issues a policy of accident and sickness insurance to provide coverage for clinical trial services rendered by a contracted provider. (2) Prohibit an insurer that issues a policy of accident and sickness insurance from providing coverage for clinical trial services rendered by a contracted provider. (3) Require reimbursement under a policy of accident and sickness insurance for services that are rendered in a clinical trial by a non-contracted provider at the same rate of reimbursement that would apply to the same services rendered by a contracted provider.
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, non-investigational approach exists. Available data must support reasonable expectation that the treatment will be as effective as the non-investigational alternative. Patient must sign an Institutional Review Board-approved consent form.
Maine (2000) 24-A-4310	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, non-investigational alternative. The data provide a reasonable expectation that the treatment will be at least as effective as the alternative.
Massachusetts (2002) Chap 176A Sec 8X	All health plans issued or renewed after Jan. 1, 2003	Patient care services associated with all phases of qualified cancer clinical trials.	Insurers must provide payment for services that are consistent with the 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>Missouri (2002) 376.429 (2006)- Phase II SB 567 &amp; 792</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 non-investigational 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 be approved for use in treatment of patient's particular condition.</p>
<p>New Hampshire (2000) 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 assistance program.</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 reoccurrence 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 test toxicity or disease pathophysiology and it has a therapeutic intent. 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.	Effective through July 1, 2004. Trial must have therapeutic intent. Reasonable expectation that investigational treatment will be at least as effective as standard treatment.
New Mexico (2009) SB 42 Chap 2009-212	Group health coverage, including any form of self-insurance, offered, issued or renewed under the Health Care Purchasing Act shall provide coverage pursuant to Section 59A-22-43 NMSA 1978	Routine patient care costs as a result of the patient's participation in a clinical trial. 1) a medical service or treatment that is a benefit under a health plan that would be covered if the patient were receiving standard cancer treatment; or 2) a drug provided to a patient during a cancer clinical trial if the drug has been approved by the federal food and drug administration, whether or not that organization has approved the drug for use in treating the patient's particular condition, but only to the extent that the drug is not paid for by the manufacturer, distributor or provider of the drug.	Does not include: 1) the cost of an investigational drug, device or procedure; 2) the cost of a non-health care service that the patient is required to receive as a result of participation in the cancer clinical trial; 3) costs associated with managing the research that is associated with the cancer clinical trial; 4) costs that would not be covered by the patient's health plan if non-investigational treatments were provided; 5) costs of those extra tests that would not be performed except for participation in the cancer clinical trial; and 6) costs paid or not charged for by the cancer clinical trial providers.
North Carolina (2001) 58-3-255	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.
Ohio (2008) ORC Ann. 1751.01 (2008)	All health benefit plans including those for public employees.	Medically necessary costs of health care services associated with any stage of clinical trial.	Trial must be approved by NIH or another group under HHS, FDA, DOD or VA. May exclude coverage for service or product that is part of the investigative trial, item or procedure used only for data collection for the trial, item not approved by FDA, and transportation, lodging and food related to travel for participation in the trial.

<p>Oregon (2009) SB 316 Chap 274</p>	<p>Requires health benefit plan to provide coverage of routine costs of care in qualifying clinical trials subject to copayment and other cost sharing requirements.</p>	<p>Covers 'routine costs':</p> <p>(a) Means medically necessary conventional care, items or services covered by the health benefit plan if typically provided absent a clinical trial.</p> <p>Trial must be funded by the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, the United States Department of Defense or the United States Department of Veterans Affairs;</p> <p>or (b) supported by a center or cooperative group that is funded by one of the above agencies.</p> <p>(c) Conducted as an investigational new drug application, an investigational device exemption or a biologics license application subject to approval by the United States Food and Drug Administration; or</p> <p>(d) Exempt by federal law from the requirement to submit an investigational new drug application to the United States Food and Drug Administration.</p>	<p>Does not include:</p> <p>(A) The drug, device or service being tested in the clinical trial unless the drug, device or service would be covered for that indication by the health benefit plan if provided outside of a clinical trial;</p> <p>(B) Items or services required solely for the provision of the drug device or service being tested in the clinical trial;</p> <p>(C) Items or services required solely for the clinically appropriate monitoring of the drug, device or service being tested in the clinical trial;</p> <p>(D) Items or services required solely for the prevention, diagnosis or treatment of complications arising from the provision of the drug, device or service being tested in the clinical trial;</p> <p>(E) Items or 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;</p> <p>(F) Items or services customarily provided by a clinical trial sponsor free of charge to any participant in the clinical trial;</p> <p>(G) Items or services that are not covered by the health plan if provided outside of the clinical trial.</p>
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Rhode Island (1994, 1997) 94-S 2623B 97-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 Sec. 4088b HB 6	All health insurance policies and health benefit plans, including Medicaid	Routine patient care costs incurred during the participation in a cancer clinical trial.	Providers and insurers required to participate in a cost analysis to determine impact of the program on health insurance premiums. 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.
Virginia (1999) ? 38.2-3418.8	Private insurers, specified managed care plans, and public employee health plans	Patient costs incurred during the participation in Phase II through IV cancer clinical trials. Coverage provided on a case-by-case basis for Phase I.	There must be no clearly superior, non-investigational alternative. Data must provide a reasonable expectation that the treatment will be at least as effective as the alternative.
West Virginia (2003) Section 9-2-12	Individual and group insurers, health service corporations, health care corporations, HMOs, public employees insurance agency, Medicaid and the children's health insurance program	Patient costs associated with the participation in Phase II through IV clinical trial for treatment of life-threatening condition or the prevention, early detection and treatment of cancer.	Facility and personnel providing the treatment are capable of doing so by virtue of their experience, training and volume of patients treated to maintain expertise. There must be no clearly superior, non-investigational treatment alternative. Data provide a reasonable expectation that the treatment will be more effective than the non-investigational treatment alternative.

<p>Wisconsin AB 617 (2006) Act 194</p>	<p>Any health insurance plan offered by the state, any self-insured plans</p>	<p>Routine patient care costs incurred during the participation in all phases of a cancer clinical trial. 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>
<p>Wyoming SF 024 (2008 budget session)</p>	<p>All health insurance policies, contracts, and certificates providing coverage to any resident of this state.</p>	<p>Routine patient care for a person enrolled in a Phases II- IV clinical trial. Includes a medical service or 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.</p>	<p>Trial must also be approved by NIH, FDA, Dept. of Defense, or Dept. of Veterans Affairs. The medical 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.</p>

\*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.

Table Two Special Agreements			
State (Year Agreement Became Effective)	Who is Required to Pay?	What Services or Benefits are Covered?	Other Key Criteria:
Georgia (2002) Georgia Cancer Coalition	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 requirements to cover clinical trials costs, many do cover all or some of the costs.

## Additional Resources

American Cancer Society, National Government Relations memo on Clinical Trials. [http://www.indianacancer.org/documents/factsheet\\_ACS\\_clinical%20trials.pdf](http://www.indianacancer.org/documents/factsheet_ACS_clinical%20trials.pdf)

National Cancer Institute, States That Require Health Plans to Cover Patient Care Costs in Clinical Trials. Information and Overview: <http://www.cancer.gov/clinicaltrials/ctlaws-home>

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

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