CS FOR SENATE BILL NO. 10(HSS)(efd del)

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-SIXTH LEGISLATURE - SECOND SESSION

BY THE SENATE HEALTH AND SOCIAL SERVICES COMMITTEE

Amended: 3/8/10
Offered: 2/23/09

Sponsor(s): SENATORS DAVIS, Paskvan

A BILL

FOR AN ACT ENTITLED

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

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

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

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

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

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

(2) 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 noninvestigational alternative.

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

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

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

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

(4) the diagnosis or treatment of complications;

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

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

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

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

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

(2) housing, companion expenses, or other nonclinical expenses associated with the clinical trial;

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

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

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

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

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

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

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

(2) one or more of the following:

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

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

(C) the United States Department of Defense;

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

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

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

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

(1) care for an injury or disease either

(A) arising out of and in the course of an employment subject to a workers' compensation or similar law or where the benefit is available to

be provided under a workers' compensation policy or equivalent self-insurance to a sole proprietor, business partner, or corporation officer; or

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

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

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

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

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

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

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

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

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

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

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

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

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

(14) experimental procedures**, except during an approved clinical trial; in this paragraph, "approved clinical trial" has the meaning given in**

AS 21.42.410; and

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

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

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