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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

REPRESENTATIVES Lynn, Gatto, Muñoz, Petersen, Millett, Gara, Buch, Tuck, Holmes, Kawasaki, Kerttula, Gardner, Cissna, Guttenberg

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; and relating to experimental procedures under a state**
6 **plan offered by the Comprehensive Health Insurance Association."**

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

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

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

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

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

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

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

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

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

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

16 (4) the diagnosis or treatment of complications;

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

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

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

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

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

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

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

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

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

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

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

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

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

18 (2) one or more of the following:

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

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

23 (C) the United States Department of Defense;

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

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

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

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

29 (1) care for an injury or disease either

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 AS 21.42.410; and

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

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

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