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**HOUSE BILL 2751**

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**State of Washington****56th Legislature****2000 Regular Session**

**By** Representatives Schual-Berke, Scott, Cody, Hatfield, Morris, Edwards and Edmonds

Read first time 01/19/2000. Referred to Committee on Health Care.

1       AN ACT Relating to coverage of patient costs for participation in  
2 clinical trials; adding new sections to chapter 48.43 RCW; and creating  
3 a new section.

4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

5       NEW SECTION. **Sec. 1.** A new section is added to chapter 48.43 RCW  
6 to read as follows:

7           (1) The definitions in this subsection apply throughout this  
8 section unless the context clearly requires otherwise.

9           (a) "Cooperative group" means a formal network of facilities that  
10 collaborate on research projects and have an established national  
11 institutes of health-approved peer review program operating within the  
12 group. "Cooperative group" includes:

13           (i) The national cancer institute clinical cooperative group;

14           (ii) The national cancer institute community clinical oncology  
15 program;

16           (iii) The AIDS clinical trials group; and

17           (iv) The community programs for clinical research in AIDS.

18           (b) "Multiple project assurance contract" means a contract between  
19 an institution and the federal department of health and human services

1 that defines the relationship of the institution to the federal  
2 department of health and human services and sets out the  
3 responsibilities of the institution and the procedures that will be  
4 used by the institution to protect human subjects.

5 (c) "Patient cost" means the cost of a medically necessary health  
6 care service that is incurred as a result of the treatment being  
7 provided to the enrollee for purposes of the clinical trial. "Patient  
8 cost" does not include:

9 (i) The cost of an investigational drug or device;

10 (ii) The cost of nonhealth care services that a patient may be  
11 required to receive as a result of the treatment being provided for  
12 purposes of the clinical trial;

13 (iii) Costs associated with managing the research associated with  
14 the clinical trial; or

15 (iv) Costs that would not be covered under the patient's health  
16 plan for noninvestigational treatments.

17 (2) A carrier shall provide coverage for patient costs to an  
18 enrollee in a clinical trial, as a result of treatment provided for a  
19 life-threatening condition, or prevention, early detection, and  
20 treatment studies on cancer.

21 (3) The coverage under subsection (2) of this section shall be  
22 required if:

23 (a) The treatment is being provided or the studies are being  
24 conducted in a phase I, phase II, phase III, or phase IV clinical trial  
25 for cancer; or the treatment is being provided in a phase II, phase  
26 III, or phase IV clinical trial for any other life-threatening  
27 condition;

28 (b) The treatment is being provided in a clinical trial approved  
29 by:

30 (i) One of the national institutes of health;

31 (ii) A national institutes of health cooperative group or a  
32 national institutes of health center;

33 (iii) The federal food and drug administration in the form of an  
34 investigational new drug application;

35 (iv) The federal department of veterans affairs; or

36 (v) An institutional review board of an institution in the state  
37 which has a multiple project assurance contract approved by the  
38 national institutes of health;

1       (c) The facility and personnel providing the treatment are capable  
2 of doing so by virtue of their experience, training, and volume of  
3 patients treated to maintain expertise;

4       (d) There is no clearly superior, noninvestigational treatment  
5 alternative; and

6       (e) The available clinical or preclinical data provide a reasonable  
7 expectation that the treatment will be at least as effective as the  
8 noninvestigational alternative.

9       (4) The coverage under subsection (3) of this section may be  
10 provided on a case-by-case basis if the treatment is being provided in  
11 a phase I clinical trial for any life-threatening condition other than  
12 cancer.

13      (5) In conjunction with the provisions of subsection (3) of this  
14 section, a health plan shall provide coverage for patient cost incurred  
15 for drugs and devices that have been approved for sale by the federal  
16 food and drug administration whether or not it has approved the drug or  
17 device for use in treating the enrollee's particular condition, to the  
18 extent that the drugs or devices are not paid for by the manufacturer,  
19 distributor, or provider of that drug or device.

20      (6)(a) An entity seeking coverage for treatment in a clinical trial  
21 approved by an institutional review board under subsection (3)(b)(v) of  
22 this section shall post electronically and keep up-to-date a list of  
23 the clinical trials meeting the requirements of subsections (2) and (3)  
24 of this section.

25      (b) The list shall include, for each clinical trial:

26       (i) The phase for which the trial is approved;

27       (ii) The entity approving the trial;

28       (iii) Whether the trial is for treatment of cancer or another life-  
29 threatening disease and, if not cancer, the particular disease; and

30       (iv) The estimated number of participants in the trial.

31      NEW SECTION. **Sec. 2.** A new section is added to chapter 48.43 RCW  
32 to read as follows:

33      (1) The insurance commissioner shall create a workgroup on health  
34 plan coverage for patient care cost in clinical trials.

35      (2) The purpose of the workgroup is to assess the costs and  
36 benefits of insurance coverage for patient care cost incurred in  
37 clinical trials.

38      (3) At a minimum, the workgroup shall:

1       (a) Develop a methodology for assessing the economic and clinical  
2 impact of the coverage required by section 1 of this act for patient  
3 care cost in clinical trials;

4       (b) Request and collect from health care providers and payers  
5 pertinent aggregate clinical and financial data on patient treatment to  
6 assess differences in patient care costs and clinical outcomes between  
7 patients treated in clinical trials and patients treated outside of  
8 clinical trials; and

9       (c) Review any other issues the workgroup considers appropriate to  
10 make recommendations pertaining to coverage for patient care cost in  
11 clinical trials.

12     (4) The workgroup shall be comprised of eleven members, appointed  
13 by the commissioner. The members of the workgroup shall include  
14 representatives of universities in the state engaged in health  
15 research, the Washington state medical association, carriers, the  
16 general public, and the commissioner. The workgroup shall select a  
17 chairman from among its members. Staffing for the workgroup shall be  
18 provided by the office of the insurance commissioner and the department  
19 of health.

20     (5) The workgroup shall present a preliminary report on the results  
21 of its study, including findings and recommendations, to the  
22 appropriate policy committees of the senate and the house of  
23 representatives on or before October 1, 2001.

24     NEW SECTION. **Sec. 3.** Section 1 of this act applies to new health  
25 plan contracts issued on or after July 1, 2001, and to contracts  
26 renewing after June 30, 2001.

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