S-4139.1

SENATE BILL 6734

State of Washington 56th Legislature 2000 Regular Session

By Senator Costa

Read first time . Referred to Committee on .

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

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

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

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

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

(i) The national cancer institute clinical cooperative group;

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

(iii) The AIDS clinical trials group; and

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

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

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

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

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

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

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

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

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

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

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

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

(i) One of the national institutes of health;

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

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

(iv) The federal department of veterans affairs; or

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

(c) The 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;

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

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

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

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

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

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

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

(ii) The entity approving the trial;

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

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

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

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

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

(3) At a minimum, the workgroup shall:

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

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

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

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

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

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

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