

# SENATE BILL REPORT

## SB 6734

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As of February 11, 2000

**Title:** An act relating to coverage of patient costs for participation in clinical trials.

**Brief Description:** Requiring coverage for patient costs for participation in certain clinical trials.

**Sponsors:** Senator Costa.

**Brief History:**

**Committee Activity:** Health & Long-Term Care: 2/16/2000.

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### SENATE COMMITTEE ON HEALTH & LONG-TERM CARE

**Staff:** Jinnah Rose-McFadden (786-7444)

**Background:** A clinical trial is an organized study conducted to answer specific questions about the treatment of cancer and other life threatening conditions. The goal is to increase medical knowledge and find better ways to help patients.

Most clinical trials are carried out in steps called phases. Each new phase of a clinical trial depends on and builds on information from an earlier phase, and is designed to elicit different information. Patients participating in clinical trials provide researchers with information on the effectiveness and risks of new treatments.

Phase I studies are generally used to find the best way to administer a new treatment and set proper dosage levels. Phase II studies look at whether the treatment identified in phase I is effective by administering the treatment to a small group of patients and studying the results. Phase III studies compare standard treatments with treatments tested in phase II. Phase IV allows the new research treatment to become part of standard treatment in patient care.

Some health plans define clinical trials as "experimental" or "investigational," and deny coverage of costs incurred through trial participation. This lack of coverage can keep patients from participating in clinical trials.

**Summary of Bill:** Insurance coverage is mandated to include enrolled patients who are receiving medical treatment as clinical trial participants. Coverage extends to patient costs for medically necessary health care services provided through trial participation.

Mandated coverage applies to phase I, II, III, and IV cancer trials and phase II, III, and IV trials for any life threatening condition. Phase I clinical trials for life threatening conditions may be covered on a case-by-case basis.

Mandated coverage applies only where: a clinical trial has been approved by a professional group or institute listed in the bill; no clearly superior noninvestigational treatment

alternative is available to the enrolled patient; and preclinical data, when available, provides a reasonable expectation that treatment will be at least as effective as a noninvestigational alternative.

The Insurance Commissioner is required to create a workgroup to assess the costs and benefits associated with this bill. A preliminary report of the workgroup's findings must be presented by October 1, 2001.

This bill applies to health plan contracts issued on or before July 7, 2001, and health plan contracts renewed after June 30, 2001.

**Appropriation:** None.

**Fiscal Note:** Not requested.

**Effective Date:** Ninety days after adjournment of session in which bill is passed.