

REVENUE: No revenue impact
FISCAL: Fiscal statement issued

Action: Do Pass
Vote: 9 - 0 - 1
Yeas: Bruun, Cannon, Dembrow, Garrett, Harker, Kennemer, Kotek, Thompson, Greenlick
Nays: 0
Exc.: Maurer
Prepared By: Roxie Cuellar, Administrator
Meeting Dates: 5/13, 5/15

WHAT THE MEASURE DOES: Modifies routine costs to exclude items and services; (1) required solely for provision of investigational drug, device or services; (2) required solely for clinically appropriate monitoring of the investigational drug, device or service; and (3) required solely for prevention, diagnosis or treatment of complications arising from provision of investigational drug, device or service. Removes requirement that health plan must reimburse health care providers who do not participate in plan at same rate as plan pays participating providers for same service not delivered in a clinical trial, taking into account copayments, coinsurance or deductibles.

ISSUES DISCUSSED:

- Definition of routine costs
- Uncovered costs as a deterrent to participation in clinical trials
- Public benefit of clinical trials
- Clarity for insurers

EFFECT OF COMMITTEE AMENDMENT: No amendment.

BACKGROUND: Clinical trials are considered to be biomedical or health-related research studies in human beings that follow a pre-defined protocol. Participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research. All clinical trials have guidelines about who can participate, based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions, all of which are important in determining if a person is qualified for the study. A qualifying clinical trial is defined as a clinical trial funded by the National Institutes of Health, the Centers for Disease Control and Prevention, the Centers of Medicare and Medicaid Services, the Department of Veterans' Affairs, the United States Department of Defense, or United States Food and Drug Administration.

Senate Bill 316 requires health benefit plans to provide coverage for routine costs of care of patients enrolled in and participating in qualifying clinical trials. Currently, insurers are contractually obligated to pay for routine costs of care; however, some health plans do not cover these costs once a patient joins a clinical trial. The measure also defines routine costs of care and clinical trials, and requires health plans to cover these routine costs of care for patients. An insurer that provides coverage is not liable for any adverse effects of the clinical trial.