Ian Best *Legislative Service Commission*

Bill Analysis

S.B. 186

127th General Assembly
(As Introduced)

Sens. Stivers, D. Miller, R. Miller, Gardner

BILL SUMMARY

- Requires health insurers to cover routine patient care administered during any stage of an eligible cancer clinical trial.

CONTENT AND OPERATION

Current law

Under current law, insurers, public employee benefit plans, and multiple employer welfare arrangements may exclude coverage for routine patient care administered as part of a cancer clinical trial. A cancer clinical trial is a research study on human patients to test the safety and effectiveness of new treatments. Because clinical trials may be defined as "experimental," health insurers do not always cover all the costs of routine patient care that would normally be covered if the patient was not enrolled in a clinical trial.

Prohibition of insurers from excluding coverage

The bill prohibits insurers, public employee benefit plans, and multiple employer welfare arrangements from excluding coverage for routine patient care administered as part of an eligible cancer clinical trial. The bill requires insurers to cover the routine medical costs of patients who are part of a clinical trial that would be covered under an insurance policy if the individual was not enrolled in a clinical trial. (Sec. 3923.80(A).) The bill covers routine patient care, which is defined as all health care services, items, and drugs consistent with the usual and customary standard of care for the treatment of cancer, including the type and frequency of any diagnostic modality, that a health care provider typically provides to a cancer patient who is not enrolled in a cancer clinical trial. (Sec. 3923.80(C)(4).)

Application to plans of health coverage

The bill applies to all plans of health coverage in which the contract, policy, or plan provides payment or reimbursement for the costs of health care services other than for specific diseases or accidents only, and which are any of the following: (1) an individual or group policy of sickness and accident insurance, (2) an individual or group contract of a health insuring corporation, (3) a public employee benefit plan, and (4) a multiple employer welfare arrangement. (Sec. 3923.80(C)(3).)

Eligible cancer clinical trials

The bill does not require all cancer clinical trials to be covered. To be eligible under the bill, a cancer clinical trial must meet the following criteria:

(1) A purpose of the trial is to test whether the intervention potentially improves the trial participant's health outcomes.

(2) The treatment provided as part of the trial is given with the intention of improving the trial participant's health outcomes.

(3) The trial has a therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology (i.e. the functional changes associated with the disease).

(4) The trial does one of the following: (a) tests how to administer a health care service, item, or drug for the treatment of cancer, (b) tests responses to a health care service, item, or drug for the treatment of cancer, (c) compares the effectiveness of a health care service, item, or drug for the treatment of cancer with that of other health care services, items, or drugs for the treatment of cancer, or (d) studies new uses of a health care service, item, or drug for the treatment of cancer.

(5) The trial is approved by one of the following entities: (a) the National Institutes of Health or one of its cooperative groups or centers under the United States Department of Health and Human Services, (b) the United States Food and Drug Administration, (c) the United States Department of Defense, or (d) the United States Department of Veterans' Affairs. (Sec. 3923.80(C)(1).)

Exclusions from coverage

The bill allows a plan of health coverage to exclude coverage for the following: (1) a health care service, item, or drug that is the subject of the cancer clinical trial, (2) a health care service, item, or drug provided solely to satisfy data collection and analysis needs for the cancer clinical trial that is not used in the

direct clinical management of the patient, (3) an investigational drug or device that has not been approved for market by the United States Food and Drug Administration, (4) transportation, lodging, food, or other expenses for the patient, or a family member or companion of the patient, that are associated with the travel to or from a facility providing the cancer clinical trial, (5) an item or drug provided by the cancer clinical trial sponsors free of charge for any patient, and (6) a service, item, or drug that is eligible for reimbursement by a person other than the insurer, including the sponsor of the cancer clinical trial. (Sec. 3923.80(C)(5).)

HISTORY

ACTION	DATE
Introduced	06-13-07

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