CORRECTED VERSION*

***Bill Analysis***

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# Am. S.B. 186

127th General Assembly
(As Passed by the Senate)

**Sens. Stivers, D. Miller, R. Miller, Gardner, Cafaro, Carey, Cates, Fedor, Goodman, Harris, Kearney, Mason, Morano, Mumper, Niehaus, Padgett, Roberts, Sawyer, Schuring, Seitz, Smith, Spada, Wagoner, Wilson**

## BILL SUMMARY

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

## CONTENT AND OPERATION

***Coverage of routine patient care***

Current law does not require health insurers to provide coverage for experimental procedures or drugs (secs. 1753.01, 1751.66, and 3923.60). Cancer clinical trials are by definition experimental and, therefore, current law does not require health insurers to provide coverage for them. However, some cancer clinical trials include routine patient care that generally would be covered by a person's health insurance plan.

The bill prohibits insurers, public employee benefit plans, and multiple employer welfare arrangements from denying coverage for routine patient care administered as part of an *eligible cancer clinical trial* if that care would be covered under an insurance policy for an individual who was not enrolled in a clinical trial. (Sec. 3923.80(A).) The bill defines "routine patient care," as all health care services consistent with the coverage provided in the plan of health coverage or agreement for the treatment of cancer, including the type and frequency of any diagnostic modality, that is typically covered for a cancer patient who is not enrolled in a cancer clinical trial, and that was not necessitated solely because of the trial. (Sec. 3923.80(C)(4).)

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The previously prepared version of this analysis incorrectly stated that the bill included provisions to exempt its requirements from possible review under H.B. 478 of the 119th General Assembly (R.C. 3901.71).

The bill specifies that nothing in it should be construed as doing either of the following:

(1) Requiring reimbursement to a provider or facility providing the routine care that does not have a health care contract with the entity issuing the plan of health care coverage;

(2) Prohibiting a plan of health care coverage from negotiating a single case or other agreement for coverage with a provider or facility providing the care with which the plan of health coverage does not have a contract. (Sec. 3923.80.)

***Eligible cancer clinical trials***

Under the bill, an "eligible cancer clinical trial" is one that meets all of 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 or experimental 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).)

***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).)

***H.B. 478 requirements***

The benefits provided for in this bill may be considered a coverage mandate (see **COMMENT**). Am. Sub. H.B. 478 of the 119th General Assembly provides that no mandated health benefits legislation enacted on or after January 14, 1993, can apply to any health benefits arrangement until the Superintendent of Insurance holds a public hearing and determines that the provision can be applied fully and equally in all respects to (1) employee benefit plans subject to the Employee Retirement Income Security Act of 1974 (ERISA) and (2) employee benefit plans established or modified by the state or its political subdivisions.[1] (Section 3901.71, not in the bill.)

[1] ERISA is a comprehensive federal statute governing the administration of employee benefit plans. ERISA generally precludes state regulation of benefits offered by private employers that self-insure their benefit programs. Larger employers frequently choose to establish their own health insurance plans for their employees in lieu of purchasing coverage from an insurer or health insuring corporation.

## COMMENT

***Actuarial review***

The benefits required by the bill may be considered "mandated benefits."[2] Pursuant to Sub. H.B. 405 of the 124th General Assembly, the chairperson of a standing committee of either house may, at any time, request that the Director of the Legislative Service Commission review any bill assigned to the chairperson's committee to determine whether the bill includes a mandated benefit. If the Director determines that the bill includes a mandated benefit, the presiding officer of the house that is considering the bill may request the Director to arrange for the performance of an independent healthcare actuarial review of the benefit. Not later than 60 days after the presiding officer's request for a review, the Director must submit the findings of the actuarial review to the chairperson of the committee to which the bill is assigned and to the ranking minority member of that committee. (Secs. 103.144 to 103.146, not in the bill.)

## HISTORY

| ACTION | DATE |
|---|---|
| Introduced | 06-13-07 |
| Reported, S. Insurance, Commerce & Labor | 11-06-07 |
| Passed Senate (33-0) | 01-15-08 |

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[2] "Mandated benefit" means the following, considered in the context of a sickness and accident insurance policy or a health insuring corporation policy, contract, or agreement: (1) any required coverage for a specific medical or health-related service, treatment, medication, or practice, (2) any required coverage for the services of specific health care providers, (3) any requirement that an insurer or health insuring corporation offer coverage to specific individuals or groups, (4) any requirement that an insurer or health insuring corporation offer specific medical or health-related services, treatments, medications, or practices to existing insureds or enrollees, (5) any required expansion of, or addition to, existing coverage, and (6) any mandated reimbursement amount to specific health care providers (sec. 103.144, not in the bill).