CORRECTED VERSION*

Final Analysis

Katie Bentley *Legislative Service Commission*

Sub. S.B. 186

127th General Assembly
(As Passed by the General Assembly)

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**

Reps. **Adams, Barrett, DeBose, Batchelder, Aslanides, Beatty, Blessing, Bolon, Book, Boyd, Brady, Brown, Budish, Carmichael, Celeste, Chandler, Combs, Daniels, DeGeeter, Dodd, Dolan, Domenick, Dyer, Evans, Fende, Fessler, Flowers, Foley, Gardner, Garrison, Gerberry, Gibbs, Goodwin, Goyal, J. Hagan, R. Hagan, Harwood, Heard, Hite, Hottinger, Hughes, Jones, Letson, Luckie, Lundy, Mallory, J. McGregor, R. McGregor, Mecklenborg, Newcomb, Oelslager, Okey, J. Otterman, Patton, Peterson, Reinhard, Sayre, Schindel, Schlichter, Schneider, Setzer, Skindell, Slesnick, D. Stewart, J. Stewart, Strahorn, Sykes, Szollosi, Uecker, Ujvagi, White, Widener, B. Williams, S. Williams, Yates, Yuko, Zehringer**

Effective date: August 5, 2008; certain provisions effective October 4, 2008

ACT 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

The act 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 individual's insurance policy if that individual was not enrolled in a clinical trial. (Sec. 3923.80(A).) The act defines "routine patient care," as all

---

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

health care services consistent with the coverage provided in the health benefit plan or public employee benefit plan 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).)

The act specifies that nothing in the bill's provisions 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 health benefit plan or public employee benefit plan;

(2) Prohibiting the entity issuing a health benefit plan or public employee benefit plan 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 act, 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 act allows a health benefit plan or public employee benefit plan 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 of coverage requirement

The act's coverage requirement applies to public employee benefit plans and health benefit plans. Under the act, the term health benefit plan includes any hospital or medical expense policy or certificate or any health plan provided by a sickness and accident insurance company or health insuring corporation authorized to issue health benefit plans in this state or a multiple employer welfare arrangement (MEWA). However, "health benefit plan" does not include policies covering only accident, credit, dental, disability income, long-term care, hospital indemnity, Medicare supplement, specified disease, or vision care; coverage under a one-time-limited-duration policy of no longer than six months; coverage issued as a supplement to liability insurance; insurance arising out of a workers' compensation or similar law; automobile medical-payment insurance; or insurance under which benefits are payable with or without regard to fault and which is statutorily required to be contained in any liability insurance policy or equivalent self-insurance. (Sec. 3924.01, not in the act.)

Effective date

The act delays for 60 days the new coverage requirements of the act. (Section 3.)

H.B. 478 requirements

The benefits provided for in this act may be considered a mandated benefit.[1] 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. (Section 3901.71, not in the act.)

HISTORY

ACTION	DATE
Introduced	06-13-07
Reported, S. Insurance, Commerce & Labor	11-06-07
Passed Senate (33-0)	01-15-08
Reported, H. Insurance	04-09-08
Passed House (94-0)	04-29-08
Senate concurred in House amendments (32-0)	04-30-08

08-sb186-corrected-127.doc/kl

[1] "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 act).