(127th General Assembly)
(Substitute Senate Bill Number 186)

AN ACT

To amend sections 1739.05 and 1751.01 and to enact section 3923.80 of the Revised Code to prohibit insurers, public employee benefit plans, and multiple employer welfare arrangements from excluding coverage for routine patient care administered as part of a cancer clinical trial.

Be it enacted by the General Assembly of the State of Ohio:

SECTION 1. That sections 1739.05 and 1751.01 be amended and section 3923.80 of the Revised Code be enacted to read as follows:

Sec. 1739.05. (A) A multiple employer welfare arrangement that is created pursuant to sections 1739.01 to 1739.22 of the Revised Code and that operates a group self-insurance program may be established only if any of the following applies:

(1) The arrangement has and maintains a minimum enrollment of three hundred employees of two or more employers.

(2) The arrangement has and maintains a minimum enrollment of three hundred self-employed individuals.

(3) The arrangement has and maintains a minimum enrollment of three hundred employees or self-employed individuals in any combination of divisions (A)(1) and (2) of this section.

(B) A multiple employer welfare arrangement that is created pursuant to sections 1739.01 to 1739.22 of the Revised Code and that operates a group self-insurance program shall comply with all laws applicable to self-funded programs in this state, including sections 3901.04, 3901.041, 3901.19 to 3901.26, 3901.38, 3901.381 to 3901.3814, 3901.40, 3901.45, 3901.46, 3902.01 to 3902.14, 3923.282, 3923.30, 3923.301, 3923.38, 3923.581, 3923.63, 3923.80, 3924.031, 3924.032, and 3924.27 of the Revised Code.

(C) A multiple employer welfare arrangement created pursuant to sections 1739.01 to 1739.22 of the Revised Code shall solicit enrollments only through agents or solicitors licensed pursuant to Chapter 3905. of the Revised Code to sell or solicit sickness and accident insurance.

(D) A multiple employer welfare arrangement created pursuant to sections 1739.01 to 1739.22 of the Revised Code shall provide benefits only

to individuals who are members, employees of members, or the dependents of members or employees, or are eligible for continuation of coverage under section 1751.53 or 3923.38 of the Revised Code or under Title X of the "Consolidated Omnibus Budget Reconciliation Act of 1985," 100 Stat. 227, 29 U.S.C.A. 1161, as amended.

Sec. 1751.01. As used in this chapter:

(A)(1) "Basic health care services" means the following services when medically necessary:

(a) Physician's services, except when such services are supplemental under division (B) of this section;

(b) Inpatient hospital services;

(c) Outpatient medical services;

(d) Emergency health services;

(e) Urgent care services;

(f) Diagnostic laboratory services and diagnostic and therapeutic radiologic services;

(g) Diagnostic and treatment services, other than prescription drug services, for biologically based mental illnesses;

(h) Preventive health care services, including, but not limited to, voluntary family planning services, infertility services, periodic physical examinations, prenatal obstetrical care, and well-child care;

(i) Routine patient care for patients enrolled in an eligible cancer clinical trial pursuant to section 3923.80 of the Revised Code.

"Basic health care services" does not include experimental procedures.

Except as provided by divisions (A)(2) and (3) of this section in connection with the offering of coverage for diagnostic and treatment services for biologically based mental illnesses, a health insuring corporation shall not offer coverage for a health care service, defined as a basic health care service by this division, unless it offers coverage for all listed basic health care services. However, this requirement does not apply to the coverage of beneficiaries enrolled in Title XVIII of the "Social Security Act," 49 Stat. 620 (1935), 42 U.S.C.A. 301, as amended, pursuant to a medicare contract, or to the coverage of beneficiaries enrolled in the federal employee health benefits program pursuant to 5 U.S.C.A. 8905, or to the coverage of beneficiaries enrolled in Title XIX of the "Social Security Act," 49 Stat. 620 (1935), 42 U.S.C.A. 301, as amended, known as the medical assistance program or medicaid, provided by the department of job and family services under Chapter 5111. of the Revised Code, or to the coverage of beneficiaries under any federal health care program regulated by a federal regulatory body, or to the coverage of beneficiaries under any

contract covering officers or employees of the state that has been entered into by the department of administrative services.

(2) A health insuring corporation may offer coverage for diagnostic and treatment services for biologically based mental illnesses without offering coverage for all other basic health care services. A health insuring corporation may offer coverage for diagnostic and treatment services for biologically based mental illnesses alone or in combination with one or more supplemental health care services. However, a health insuring corporation that offers coverage for any other basic health care service shall offer coverage for diagnostic and treatment services for biologically based mental illnesses in combination with the offer of coverage for all other listed basic health care services.

(3) A health insuring corporation that offers coverage for basic health care services is not required to offer coverage for diagnostic and treatment services for biologically based mental illnesses in combination with the offer of coverage for all other listed basic health care services if all of the following apply:

(a) The health insuring corporation submits documentation certified by an independent member of the American academy of actuaries to the superintendent of insurance showing that incurred claims for diagnostic and treatment services for biologically based mental illnesses for a period of at least six months independently caused the health insuring corporation's costs for claims and administrative expenses for the coverage of basic health care services to increase by more than one per cent per year.

(b) The health insuring corporation submits a signed letter from an independent member of the American academy of actuaries to the superintendent of insurance opining that the increase in costs described in division (A)(3)(a) of this section could reasonably justify an increase of more than one per cent in the annual premiums or rates charged by the health insuring corporation for the coverage of basic health care services.

(c) The superintendent of insurance makes the following determinations from the documentation and opinion submitted pursuant to divisions (A)(3)(a) and (b) of this section:

(i) Incurred claims for diagnostic and treatment services for biologically based mental illnesses for a period of at least six months independently caused the health insuring corporation's costs for claims and administrative expenses for the coverage of basic health care services to increase by more than one per cent per year.

(ii) The increase in costs reasonably justifies an increase of more than one per cent in the annual premiums or rates charged by the health insuring

corporation for the coverage of basic health care services.

Any determination made by the superintendent under this division is subject to Chapter 119. of the Revised Code.

(B)(1) "Supplemental health care services" means any health care services other than basic health care services that a health insuring corporation may offer, alone or in combination with either basic health care services or other supplemental health care services, and includes:

(a) Services of facilities for intermediate or long-term care, or both;

(b) Dental care services;

(c) Vision care and optometric services including lenses and frames;

(d) Podiatric care or foot care services;

(e) Mental health services, excluding diagnostic and treatment services for biologically based mental illnesses;

(f) Short-term outpatient evaluative and crisis-intervention mental health services;

(g) Medical or psychological treatment and referral services for alcohol and drug abuse or addiction;

(h) Home health services;

(i) Prescription drug services;

(j) Nursing services;

(k) Services of a dietitian licensed under Chapter 4759. of the Revised Code;

(l) Physical therapy services;

(m) Chiropractic services;

(n) Any other category of services approved by the superintendent of insurance.

(2) If a health insuring corporation offers prescription drug services under this division, the coverage shall include prescription drug services for the treatment of biologically based mental illnesses on the same terms and conditions as other physical diseases and disorders.

(C) "Specialty health care services" means one of the supplemental health care services listed in division (B) of this section, when provided by a health insuring corporation on an outpatient-only basis and not in combination with other supplemental health care services.

(D) "Biologically based mental illnesses" means schizophrenia, schizoaffective disorder, major depressive disorder, bipolar disorder, paranoia and other psychotic disorders, obsessive-compulsive disorder, and panic disorder, as these terms are defined in the most recent edition of the diagnostic and statistical manual of mental disorders published by the American psychiatric association.

(E) "Closed panel plan" means a health care plan that requires enrollees to use participating providers.

(F) "Compensation" means remuneration for the provision of health care services, determined on other than a fee-for-service or discounted-fee-for-service basis.

(G) "Contractual periodic prepayment" means the formula for determining the premium rate for all subscribers of a health insuring corporation.

(H) "Corporation" means a corporation formed under Chapter 1701. or 1702. of the Revised Code or the similar laws of another state.

(I) "Emergency health services" means those health care services that must be available on a seven-days-per-week, twenty-four-hours-per-day basis in order to prevent jeopardy to an enrollee's health status that would occur if such services were not received as soon as possible, and includes, where appropriate, provisions for transportation and indemnity payments or service agreements for out-of-area coverage.

(J) "Enrollee" means any natural person who is entitled to receive health care benefits provided by a health insuring corporation.

(K) "Evidence of coverage" means any certificate, agreement, policy, or contract issued to a subscriber that sets out the coverage and other rights to which such person is entitled under a health care plan.

(L) "Health care facility" means any facility, except a health care practitioner's office, that provides preventive, diagnostic, therapeutic, acute convalescent, rehabilitation, mental health, mental retardation, intermediate care, or skilled nursing services.

(M) "Health care services" means basic, supplemental, and specialty health care services.

(N) "Health delivery network" means any group of providers or health care facilities, or both, or any representative thereof, that have entered into an agreement to offer health care services in a panel rather than on an individual basis.

(O) "Health insuring corporation" means a corporation, as defined in division (H) of this section, that, pursuant to a policy, contract, certificate, or agreement, pays for, reimburses, or provides, delivers, arranges for, or otherwise makes available, basic health care services, supplemental health care services, or specialty health care services, or a combination of basic health care services and either supplemental health care services or specialty health care services, through either an open panel plan or a closed panel plan.

"Health insuring corporation" does not include a limited liability

company formed pursuant to Chapter 1705. of the Revised Code, an insurer licensed under Title XXXIX of the Revised Code if that insurer offers only open panel plans under which all providers and health care facilities participating receive their compensation directly from the insurer, a corporation formed by or on behalf of a political subdivision or a department, office, or institution of the state, or a public entity formed by or on behalf of a board of county commissioners, a county board of mental retardation and developmental disabilities, an alcohol and drug addiction services board, a board of alcohol, drug addiction, and mental health services, or a community mental health board, as those terms are used in Chapters 340. and 5126. of the Revised Code. Except as provided by division (D) of section 1751.02 of the Revised Code, or as otherwise provided by law, no board, commission, agency, or other entity under the control of a political subdivision may accept insurance risk in providing for health care services. However, nothing in this division shall be construed as prohibiting such entities from purchasing the services of a health insuring corporation or a third-party administrator licensed under Chapter 3959. of the Revised Code.

(P) "Intermediary organization" means a health delivery network or other entity that contracts with licensed health insuring corporations or self-insured employers, or both, to provide health care services, and that enters into contractual arrangements with other entities for the provision of health care services for the purpose of fulfilling the terms of its contracts with the health insuring corporations and self-insured employers.

(Q) "Intermediate care" means residential care above the level of room and board for patients who require personal assistance and health-related services, but who do not require skilled nursing care.

(R) "Medical record" means the personal information that relates to an individual's physical or mental condition, medical history, or medical treatment.

(S)(1) "Open panel plan" means a health care plan that provides incentives for enrollees to use participating providers and that also allows enrollees to use providers that are not participating providers.

(2) No health insuring corporation may offer an open panel plan, unless the health insuring corporation is also licensed as an insurer under Title XXXIX of the Revised Code, the health insuring corporation, on June 4, 1997, holds a certificate of authority or license to operate under Chapter 1736. or 1740. of the Revised Code, or an insurer licensed under Title XXXIX of the Revised Code is responsible for the out-of-network risk as evidenced by both an evidence of coverage filing under section 1751.11 of

the Revised Code and a policy and certificate filing under section 3923.02 of the Revised Code.

(T) "Panel" means a group of providers or health care facilities that have joined together to deliver health care services through a contractual arrangement with a health insuring corporation, employer group, or other payor.

(U) "Person" has the same meaning as in section 1.59 of the Revised Code, and, unless the context otherwise requires, includes any insurance company holding a certificate of authority under Title XXXIX of the Revised Code, any subsidiary and affiliate of an insurance company, and any government agency.

(V) "Premium rate" means any set fee regularly paid by a subscriber to a health insuring corporation. A "premium rate" does not include a one-time membership fee, an annual administrative fee, or a nominal access fee, paid to a managed health care system under which the recipient of health care services remains solely responsible for any charges accessed for those services by the provider or health care facility.

(W) "Primary care provider" means a provider that is designated by a health insuring corporation to supervise, coordinate, or provide initial care or continuing care to an enrollee, and that may be required by the health insuring corporation to initiate a referral for specialty care and to maintain supervision of the health care services rendered to the enrollee.

(X) "Provider" means any natural person or partnership of natural persons who are licensed, certified, accredited, or otherwise authorized in this state to furnish health care services, or any professional association organized under Chapter 1785. of the Revised Code, provided that nothing in this chapter or other provisions of law shall be construed to preclude a health insuring corporation, health care practitioner, or organized health care group associated with a health insuring corporation from employing certified nurse practitioners, certified nurse anesthetists, clinical nurse specialists, certified nurse midwives, dietitians, physician assistants, dental assistants, dental hygienists, optometric technicians, or other allied health personnel who are licensed, certified, accredited, or otherwise authorized in this state to furnish health care services.

(Y) "Provider sponsored organization" means a corporation, as defined in division (H) of this section, that is at least eighty per cent owned or controlled by one or more hospitals, as defined in section 3727.01 of the Revised Code, or one or more physicians licensed to practice medicine or surgery or osteopathic medicine and surgery under Chapter 4731. of the Revised Code, or any combination of such physicians and hospitals. Such

control is presumed to exist if at least eighty per cent of the voting rights or governance rights of a provider sponsored organization are directly or indirectly owned, controlled, or otherwise held by any combination of the physicians and hospitals described in this division.

(Z) "Solicitation document" means the written materials provided to prospective subscribers or enrollees, or both, and used for advertising and marketing to induce enrollment in the health care plans of a health insuring corporation.

(AA) "Subscriber" means a person who is responsible for making payments to a health insuring corporation for participation in a health care plan, or an enrollee whose employment or other status is the basis of eligibility for enrollment in a health insuring corporation.

(BB) "Urgent care services" means those health care services that are appropriately provided for an unforeseen condition of a kind that usually requires medical attention without delay but that does not pose a threat to the life, limb, or permanent health of the injured or ill person, and may include such health care services provided out of the health insuring corporation's approved service area pursuant to indemnity payments or service agreements.

Sec. 3923.80. (A) No health benefit plan or public employee benefit plan shall deny coverage for the costs of any routine patient care administered to an insured participating in any stage of an eligible cancer clinical trial, if that care would be covered under the plan if the insured was not participating in a clinical trial.

(B) The coverage that may not be excluded under division (A) of this section is subject to all terms, conditions, restrictions, exclusions, and limitations that apply to any other coverage under the plan, policy, or arrangement for services performed by participating and nonparticipating providers. Nothing in this section shall be construed as 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, or as prohibiting the entity issuing a health benefit plan or public employee benefit plan that does not have a health care contract with the provider or facility providing the routine care from negotiating a single case or other agreement for coverage.

(C) As used in this section:

(1) "Eligible cancer clinical trial" means a cancer clinical trial that meets all of the following criteria:

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

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

(c) The trial has a therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology.

(d) The trial does one of the following:

(i) Tests how to administer a health care service, item, or drug for the treatment of cancer;

(ii) Tests responses to a health care service, item, or drug for the treatment of cancer;

(iii) 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;

(iv) Studies new uses of a health care service, item, or drug for the treatment of cancer.

(e) The trial is approved by one of the following entities:

(i) The national institutes of health or one of its cooperative groups or centers under the United States department of health and human services;

(ii) The United States food and drug administration;

(iii) The United States department of defense;

(iv) The United States department of veterans' affairs.

(2) "Subject of a cancer clinical trial" means the health care service, item, or drug that is being evaluated in the clinical trial and that is not routine patient care.

(3) "Health benefit plan" has the same meaning as in section 3924.01 of the Revised Code.

(4) "Routine patient care" means all 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.

(5) For purposes of this section, a health benefit plan or public employee benefit plan may exclude coverage for any of the following:

(a) A health care service, item, or drug that is the subject of the cancer clinical trial;

(b) 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;

(c) An investigational or experimental drug or device that has not been approved for market by the United States food and drug administration;

(d) 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;

(e) An item or drug provided by the cancer clinical trial sponsors free of charge for any patient;

(f) 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.

SECTION 2. That existing sections 1739.05 and 1751.01 of the Revised Code are hereby repealed.

SECTION 3. Section 3923.80 of the Revised Code, as enacted by this act, shall take effect sixty days after the effective date of this act and shall apply only to plans of health coverage that are delivered, issued for delivery, or renewed in this state on or after that delayed effective date.

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Speaker _____ of the House of Representatives.

_____

President _____ of the Senate.

Passed _____, 20____

Approved _____, 20____

_____

Governor.

The section numbering of law of a general and permanent nature is complete and in conformity with the Revised Code.

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Director, Legislative Service Commission.

Filed in the office of the Secretary of State at Columbus, Ohio, on the ____ day of _____, A. D. 20____.

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Secretary of State.

File No. _____ Effective Date _____