SENATE BILL NO. 428

INTRODUCED BY C. KAUFMANN

A BILL FOR AN ACT ENTITLED: "AN ACT REQUIRING INSURANCE COVERAGE OF ROUTINE PATIENT CARE COSTS FOR PATIENTS PARTICIPATING IN A CANCER CLINICAL TRIAL; AMENDING SECTIONS 33-22-101, 33-31-111, 33-35-306, 53-4-1005, AND 53-6-101, MCA; AND PROVIDING A DELAYED EFFECTIVE DATE AND A TERMINATION DATE."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. **Section 1. Coverage of clinical trials -- definitions.** (1) As used in this section, the following definitions apply:

(a) "Cooperative group" means a formal network of facilities that collaborate on research projects and have, operating within the group, an established peer review program approved by the national institutes of health. The term includes but is not limited to the clinical trials cooperative group program and the community clinical oncology program of the national cancer institute.

(b) "Investigational drug or device" means a drug or device that has not been approved by the U.S. food and drug administration.

(c) "Multiple project assurance contract" means a contract between an institution and the U.S. department of health and human services that defines the relationship of the institution to the federal department and sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

(d) (i) "Routine patient care cost" means the cost of a medical item or service that is otherwise covered under the person's group or individual disability policy, certificate of insurance, or membership contract, including the administration of the drug or item under evaluation in the clinical trial.

(ii) The term does not include the cost of:

(A) the investigational drug or device or other investigational service;

(B) an item or service that is provided solely to satisfy data collection and analysis needs for the clinical trial and that is not used in the direct clinical management of the person's condition;

(C) a service that is defined in the clinical trial protocol and that is outside of conventional care; or

(D) an item or service that is customarily provided by the research sponsors free of charge for an enrollee

in the clinical trial.

(2) Each group or individual disability policy, certificate of insurance, or membership contract that is delivered, issued for delivery, renewed, extended, or modified in this state must provide coverage for routine patient care costs incurred as the result of a phase I, phase II, phase III, or phase IV clinical trial if:

(a) the clinical trial is undertaken for the purposes of prevention, early detection, or treatment of cancer;

(b) the clinical trial is being conducted with the approval of one of the entities provided for in subsection (3); and

(c) the facility and personnel providing treatment under the clinical trial:

(i) have the expertise and training to provide the treatment; and

(ii) treat a sufficient volume of patients to maintain expertise.

(3) This section applies to clinical trials that are approved or funded by one of the following entities:

(a) one of the national institutes of health;

(b) a cooperative group or center of one of the national institutes of health;

(c) the U.S. food and drug administration if an investigational drug or device is involved;

(d) the U.S. department of veterans affairs;

(e) the U.S. department of defense;

(f) an institutional review board of an institution that has a multiple project assurance contract approved by the national institutes of health; or

(g) a qualified research entity that meets the eligibility criteria for national institutes of health cancer center support grants;

(4) A health plan may not provide benefits that supplant a portion of a cancer clinical trial that is customarily paid for by a government agency or by biotechnical, pharmaceutical, or medical device industry sources.

(5) This section applies to the state employee group insurance program, the university system employee group insurance program, any employee group insurance program of a city, town, school district, or other political subdivision of this state, and any self-funded multiple employer welfare arrangement that is not regulated by the Employee Retirement Income Security Act of 1974, 29 U.S.C. 1001, et seq.

(6) This section does not apply to disability income, hospital indemnity, medicare supplement, accident-only, vision, dental, specific disease, or long-term care policies.

Section 2. Section 33-22-101, MCA, is amended to read:

"33-22-101. Exceptions to scope. (1) Subject to subsection (2), parts 1 through 4 of this chapter, except 33-22-107, 33-22-110, 33-22-111, 33-22-114, 33-22-125, 33-22-129, 33-22-130 through 33-22-136, 33-22-140, 33-22-141, 33-22-142, [section 1], 33-22-243, and 33-22-304, and part 19 of this chapter do not apply to or affect:

(a) any policy of liability or workers' compensation insurance with or without supplementary expense coverage;

(b) any group or blanket policy;

(c) life insurance, endowment, or annuity contracts or supplemental contracts that contain only those provisions relating to disability insurance that:

(i) provide additional benefits in case of death or dismemberment or loss of sight by accident or accidental means; or

(ii) operate to safeguard contracts against lapse or to give a special surrender value or special benefit or an annuity if the insured or annuitant becomes totally and permanently disabled as defined by the contract or supplemental contract;

(d) reinsurance.

(2) Sections 33-22-150, 33-22-151, [section 1], and 33-22-301 apply to group or blanket policies."

Section 3. Section 33-31-111, MCA, is amended to read:

"33-31-111. (Temporary) Statutory construction and relationship to other laws. (1) Except as otherwise provided in this chapter, the insurance or health service corporation laws do not apply to a health maintenance organization authorized to transact business under this chapter. This provision does not apply to an insurer or health service corporation licensed and regulated pursuant to the insurance or health service corporation laws of this state except with respect to its health maintenance organization activities authorized and regulated pursuant to this chapter.

(2) Solicitation of enrollees by a health maintenance organization granted a certificate of authority or its representatives is not a violation of any law relating to solicitation or advertising by health professionals.

(3) A health maintenance organization authorized under this chapter is not practicing medicine and is exempt from Title 37, chapter 3, relating to the practice of medicine.

(4) This chapter does not exempt a health maintenance organization from the applicable certificate of need requirements under Title 50, chapter 5, parts 1 and 3.

(5) This section does not exempt a health maintenance organization from the prohibition of pecuniary

interest under 33-3-308 or the material transaction disclosure requirements under 33-3-701 through 33-3-704. A health maintenance organization must be considered an insurer for the purposes of 33-3-308 and 33-3-701 through 33-3-704.

(6) This section does not exempt a health maintenance organization from:

(a) prohibitions against interference with certain communications as provided under chapter 1, part 8;

(b) the provisions of Title 33, chapter 22, part 19;

(c) the requirements of 33-22-134 and 33-22-135;

(d) network adequacy and quality assurance requirements provided under chapter 36, except as provided in 33-22-262; or

(e) the requirements of Title 33, chapter 18, part 9.

(7) Except as provided in 33-22-262, Title 33, chapter 1, parts 12 and 13, Title 33, chapter 2, part 19, 33-2-1114, 33-2-1211, 33-2-1212, 33-3-422, 33-3-431, 33-15-308, Title 33, chapter 19, 33-22-107, 33-22-129, 33-22-131, 33-22-136, 33-22-141, 33-22-142, [section 1], 33-22-244, 33-22-246, 33-22-247, 33-22-514, 33-22-521, 33-22-523, 33-22-524, 33-22-526, and 33-22-706 apply to health maintenance organizations. (Terminates June 30, 2009--sec. 14, Ch. 325, L. 2003.)

33-31-111. (Effective July 1, 2009) Statutory construction and relationship to other laws. (1) Except as otherwise provided in this chapter, the insurance or health service corporation laws do not apply to a health maintenance organization authorized to transact business under this chapter. This provision does not apply to an insurer or health service corporation licensed and regulated pursuant to the insurance or health service corporation laws of this state except with respect to its health maintenance organization activities authorized and regulated pursuant to this chapter.

(2) Solicitation of enrollees by a health maintenance organization granted a certificate of authority or its representatives is not a violation of any law relating to solicitation or advertising by health professionals.

(3) A health maintenance organization authorized under this chapter is not practicing medicine and is exempt from Title 37, chapter 3, relating to the practice of medicine.

(4) This chapter does not exempt a health maintenance organization from the applicable certificate of need requirements under Title 50, chapter 5, parts 1 and 3.

(5) This section does not exempt a health maintenance organization from the prohibition of pecuniary interest under 33-3-308 or the material transaction disclosure requirements under 33-3-701 through 33-3-704. A health maintenance organization must be considered an insurer for the purposes of 33-3-308 and 33-3-701 through 33-3-704.

(6) This section does not exempt a health maintenance organization from:

(a) prohibitions against interference with certain communications as provided under chapter 1, part 8;

(b) the provisions of Title 33, chapter 22, part 19;

(c) the requirements of 33-22-134 and 33-22-135;

(d) network adequacy and quality assurance requirements provided under chapter 36; or

(e) the requirements of Title 33, chapter 18, part 9.

(7) Title 33, chapter 1, parts 12 and 13, Title 33, chapter 2, part 19, 33-2-1114, 33-2-1211, 33-2-1212, 33-3-422, 33-3-431, 33-15-308, Title 33, chapter 19, 33-22-107, 33-22-129, 33-22-131, 33-22-136, 33-22-141, 33-22-142, [section 1], 33-22-244, 33-22-246, 33-22-247, 33-22-514, 33-22-521, 33-22-523, 33-22-524, 33-22-526, and 33-22-706 apply to health maintenance organizations."

Section 4. Section 33-35-306, MCA, is amended to read:

"33-35-306. Application of insurance code to arrangements. (1) In addition to this chapter, self-funded multiple employer welfare arrangements are subject to the following provisions:

(a) Title 33, chapter 1, part 4, but the examination of a self-funded multiple employer welfare arrangement is limited to those matters to which the arrangement is subject to regulation under this chapter;

(b) Title 33, chapter 1, part 7;

(c) 33-3-308;

(d) Title 33, chapter 18, except 33-18-242;

(e) Title 33, chapter 19;

(f) 33-22-107, 33-22-131, 33-22-134, ~~and~~ 33-22-135, and [section 1]; and

(g) 33-22-525 and 33-22-526.

(2) Except as provided in this chapter, other provisions of Title 33 do not apply to a self-funded multiple employer welfare arrangement that has been issued a certificate of authority that has not been revoked."

Section 5. Section 53-4-1005, MCA, is amended to read:

"53-4-1005. (Temporary) Benefits provided. (1) Benefits provided to participants in the program may include but are not limited to:

(a) inpatient and outpatient hospital services;

(b) physician and advanced practice registered nurse services;

(c) laboratory and x-ray services;

(d) well-child and well-baby services;

(e) immunizations;

(f) clinic services;

(g) dental services;

(h) prescription drugs;

(i) mental health and substance abuse treatment services;

(j) hearing and vision exams; ~~and~~

(k) eyeglasses; and

(l) routine patient care costs of clinical trials pursuant to [section 1].

(2) The department is specifically prohibited from providing payment for birth control contraceptives under this program. (Terminates on occurrence of contingency--sec. 15, Ch. 571, L. 1999.)"

Section 6. Section 53-6-101, MCA, is amended to read:

"53-6-101. Montana medicaid program -- authorization of services. (1) There is a Montana medicaid program established for the purpose of providing necessary medical services to eligible persons who have need for medical assistance. The Montana medicaid program is a joint federal-state program administered under this chapter and in accordance with Title XIX of the Social Security Act, 42 U.S.C. 1396, et seq. The department shall administer the Montana medicaid program.

(2) The department and the legislature shall consider the following funding principles when considering changes in medicaid policy that either increase or reduce services:

(a) protecting those persons who are most vulnerable and most in need, as defined by a combination of economic, social, and medical circumstances;

(b) giving preference to the elimination or restoration of an entire medicaid program or service, rather than sacrifice or augment the quality of care for several programs or services through dilution of funding; and

(c) giving priority to services that employ the science of prevention to reduce disability and illness, services that treat life-threatening conditions, and services that support independent or assisted living, including pain management, to reduce the need for acute inpatient or residential care.

(3) Medical assistance provided by the Montana medicaid program includes the following services:

(a) inpatient hospital services;

(b) outpatient hospital services;

(c) other laboratory and x-ray services, including minimum mammography examination as defined in

33-22-132;

(d) skilled nursing services in long-term care facilities;

(e) physicians' services;

(f) nurse specialist services;

(g) early and periodic screening, diagnosis, and treatment services for persons under 21 years of age;

(h) ambulatory prenatal care for pregnant women during a presumptive eligibility period, as provided in 42 U.S.C. 1396a(a)(47) and 42 U.S.C. 1396r-1;

(i) targeted case management services, as authorized in 42 U.S.C. 1396n(g), for high-risk pregnant women;

(j) services that are provided by physician assistants within the scope of their practice and that are otherwise directly reimbursed as allowed under department rule to an existing provider;

(k) health services provided under a physician's orders by a public health department; ~~and~~

(l) federally qualified health center services, as defined in 42 U.S.C. 1396d(l)(2); and

(m) routine patient care costs of clinical trials pursuant to [section 1].

(4) Medical assistance provided by the Montana medicaid program may, as provided by department rule, also include the following services:

(a) medical care or any other type of remedial care recognized under state law, furnished by licensed practitioners within the scope of their practice as defined by state law;

(b) home health care services;

(c) private-duty nursing services;

(d) dental services;

(e) physical therapy services;

(f) mental health center services administered and funded under a state mental health program authorized under Title 53, chapter 21, part 10;

(g) clinical social worker services;

(h) prescribed drugs, dentures, and prosthetic devices;

(i) prescribed eyeglasses;

(j) other diagnostic, screening, preventive, rehabilitative, chiropractic, and osteopathic services;

(k) inpatient psychiatric hospital services for persons under 21 years of age;

(l) services of professional counselors licensed under Title 37, chapter 23;

(m) hospice care, as defined in 42 U.S.C. 1396d(o);

(n) case management services, as provided in 42 U.S.C. 1396d(a) and 1396n(g), including targeted case management services for the mentally ill;

(o) services of psychologists licensed under Title 37, chapter 17;

(p) inpatient psychiatric services for persons under 21 years of age, as provided in 42 U.S.C. 1396d(h), in a residential treatment facility, as defined in 50-5-101, that is licensed in accordance with 50-5-201; and

(q) any additional medical service or aid allowable under or provided by the federal Social Security Act.

(5) Services for persons qualifying for medicaid under the medically needy category of assistance, as described in 53-6-131, may be more limited in amount, scope, and duration than services provided to others qualifying for assistance under the Montana medicaid program. The department is not required to provide all of the services listed in subsections (3) and (4) to persons qualifying for medicaid under the medically needy category of assistance.

(6) In accordance with federal law or waivers of federal law that are granted by the secretary of the U.S. department of health and human services, the department may implement limited medicaid benefits, to be known as basic medicaid, for adult recipients who are eligible because they are receiving financial assistance, as defined in 53-4-201, as the specified caretaker relative of a dependent child under the FAIM project and for all adult recipients of medical assistance only who are covered under a group related to a program providing financial assistance, as defined in 53-4-201. Basic medicaid benefits consist of all mandatory services listed in subsections (3)(a) through (3)(l) but may include those optional services listed in subsections (4)(a) through (4)(q) that the department in its discretion specifies by rule. The department, in exercising its discretion, may consider the amount of funds appropriated by the legislature, whether approval has been received, as provided in 53-1-612, and whether the provision of a particular service is commonly covered by private health insurance plans. However, a recipient who is pregnant, meets the criteria for disability provided in Title II of the Social Security Act, 42 U.S.C. 416, et seq., or is less than 21 years of age is entitled to full medicaid coverage.

(7) The department may implement, as provided for in Title XIX of the Social Security Act, 42 U.S.C. 1396, et seq., as may be amended, a program under medicaid for payment of medicare premiums, deductibles, and coinsurance for persons not otherwise eligible for medicaid.

(8) The department may set rates for medical and other services provided to recipients of medicaid and may enter into contracts for delivery of services to individual recipients or groups of recipients.

(9) The services provided under this part may be only those that are medically necessary and that are the most efficient and cost-effective.

(10) The amount, scope, and duration of services provided under this part must be determined by the

department in accordance with Title XIX of the Social Security Act, 42 U.S.C. 1396, et seq., as may be amended.

(11) Services, procedures, and items of an experimental or cosmetic nature may not be provided.

(12) If available funds are not sufficient to provide medical assistance for all eligible persons, the department may set priorities to limit, reduce, or otherwise curtail the amount, scope, or duration of the medical services made available under the Montana medicaid program after taking into consideration the funding principles set forth in subsection (2)."

NEW SECTION. **Section 7. Codification instruction.** [Section 1] is intended to be codified as an integral part of Title 33, chapter 22, part 1, and the provisions of Title 33, chapter 22, apply to [section 1].

NEW SECTION. **Section 8. Effective date.** [This act] is effective January 1, 2008.

NEW SECTION. **Section 9. Termination.** (1) [Section 5] terminates on the date that the director of the department of public health and human services certifies to the governor that the federal government has terminated the program or that federal funding for the program has been discontinued.

(2) The governor shall transmit a copy of the certification to the code commissioner.

(3) Any excess funds remaining upon the termination of the program must be transferred to the general fund.

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