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LEGISLATIVE COUNSEL'S DIGEST

Bill No.
as introduced, Jackson.
General Subject: Clinical trials.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care, and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan or health insurer to provide coverage for routine patient care costs related to a clinical trial for cancer, including, among other things, health care services required for the clinically appropriate monitoring of the investigational item or service. Existing law requires the clinical trial to either be exempt from a federal new drug application or be approved by a specified federal agency.

This bill would expand required coverage for clinical trials under a plan contract or insurance policy to include a clinical trial relating to the prevention, detection, or treatment of a life-threatening disease or condition, as defined, and include a trial funded by, among others, a qualified nongovernmental research entity. The bill would prohibit a plan contract or insurance policy from, among other things, discriminating against an enrollee or insured for participating in an approved clinical trial. The bill would authorize a plan or insurer to require a qualified enrollee or insured to participate in a clinical trial, as specified, and to restrict coverage to an approved clinical trial in this state, unless the clinical trial is not offered or available through a provider in this state. Because a willful violation of the bill's requirements relative to health care service plans would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

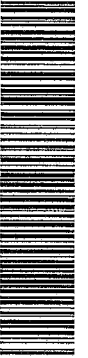


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An act to repeal and add Section 1370.6 of the Health and Safety Code, and to repeal and add Section 10145.4 of the Insurance Code, relating to clinical trials.



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THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1370.6 of the Health and Safety Code is repealed.

~~1370.6. (a) For an enrollee diagnosed with cancer and accepted into a phase I, phase II, phase III, or phase IV clinical trial for cancer, every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed in this state, shall provide coverage for all routine patient care costs related to the clinical trial if the enrollee's treating physician, who is providing covered health care services to the enrollee under the enrollee's health benefit plan contract, recommends participation in the clinical trial after determining that participation in the clinical trial has a meaningful potential to benefit the enrollee. For purposes of this section, a clinical trial's endpoints shall not be defined exclusively to test toxicity, but shall have a therapeutic intent.~~

~~(b) (1) "Routine patient care costs" means the costs associated with the provision of health care services, including drugs, items, devices, and services that would otherwise be covered under the plan or contract if those drugs, items, devices, and services were not provided in connection with an approved clinical trial program, including:~~

~~(A) Health care services typically provided absent a clinical trial.~~

~~(B) Health care services required solely for the provision of the investigational drug, item, device, or service.~~

~~(C) Health care services required for the clinically appropriate monitoring of the investigational item or service.~~

~~(D) Health care services provided for the prevention of complications arising from the provision of the investigational drug, item, device, or service.~~

~~(E) Health care services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including the diagnosis or treatment of the complications.~~

~~(2) For purposes of this section, "routine patient care costs" does not include the costs associated with the provision of any of the following:~~

~~(A) Drugs or devices that have not been approved by the federal Food and Drug Administration and that are associated with the clinical trial.~~

~~(B) Services other than health care services, such as travel, housing, companion expenses, and other nonclinical expenses, that an enrollee may require as a result of the treatment being provided for purposes of the clinical trial.~~

~~(C) Any item or service that is provided solely to satisfy data collection and analysis needs and that is not used in the clinical management of the patient.~~

~~(D) Health care services that, except for the fact that they are being provided in a clinical trial, are otherwise specifically excluded from coverage under the enrollee's health plan.~~

~~(E) Health care services customarily provided by the research sponsors free of charge for any enrollee in the trial.~~

~~(3) Nothing in this section shall require a health care service plan contracting with the State Department of Health Services for the purpose of providing Medi-Cal benefits to enrolled beneficiaries or contracting with the Managed Risk Medical Insurance Board for the purposes of providing benefits under the Healthy Families Program, the Access for Infants and Mothers Program, or the California Major Risk~~



Medical Insurance Program, to be responsible for reimbursement of services excluded from their contract because another entity is responsible by statute or otherwise for reimbursement of the service provider.

~~(c) The treatment shall be provided in a clinical trial that either:~~

~~(1) Involves a drug that is exempt under federal regulations from a new drug application:~~

~~(2) Is approved by one of the following:~~

~~(A) One of the National Institutes of Health;~~

~~(B) The federal Food and Drug Administration, in the form of an investigational new drug application;~~

~~(C) The United States Department of Defense;~~

~~(D) The United States Veterans' Administration;~~

~~(d) In the case of health care services provided by a participating provider, the payment rate shall be at the agreed-upon rate. In the case of a nonparticipating provider, the payment shall be at the negotiated rate the plan would otherwise pay to a participating provider for the same services, less any applicable copayments and deductibles.~~

~~(e) Nothing in this section shall be construed to prohibit a health care service plan from restricting coverage for clinical trials to participating hospitals and physicians in California unless the protocol for the clinical trial is not provided for at a California hospital or by a California physician.~~

~~(f) The provision of services when required by this section shall not, in itself, give rise to liability on the part of the health care service plan.~~

~~(g) Nothing in this section shall be construed to limit, prohibit, or modify an enrollee's rights to the independent review process available under Section 1370.4 or to the Independent Medical Review System available under Article 5.55 (commencing with Section 1374.30).~~

~~(h) Nothing in this section shall be construed to otherwise limit or modify any existing requirements under the provisions of this chapter or to prevent application of copayment or deductible provisions in a plan.~~

~~(i) Copayments and deductibles applied to services delivered in a clinical trial shall be the same as those applied to the same services if not delivered in a clinical trial.~~

SEC. 2. Section 1370.6 is added to the Health and Safety Code, to read:

1370.6. (a) An individual or group health care service plan contract that is issued, amended, or renewed on or after January 1, 2020, shall not:

(1) Deny a qualified enrollee's participation in an approved clinical trial.

(2) Deny, limit, or impose additional conditions on the coverage of routine patient care costs for items and services furnished in connection with a qualified enrollee's participation in an approved clinical trial.

(3) Discriminate against an enrollee based on the qualified enrollee's participation in an approved clinical trial.

(b) (1) Subdivision (a) applies to:

(A) A qualified enrollee participating in an approved clinical trial conducted by a participating provider.



(B) A qualified enrollee participating in an approved clinical trial conducted by a nonparticipating provider, including a nonparticipating provider located outside this state, if the clinical trial is not offered or available through a participating provider.

(2) If one or more participating providers is conducting an approved clinical trial, a health care service plan may require a qualified enrollee to participate in the clinical trial through a participating provider if the participating provider accepts the enrollee as a clinical trial participant.

(3) A health care service plan may restrict coverage to an approved clinical trial in this state, unless the clinical trial is not offered or available through a provider in this state.

(c) (1) The payment rate for routine patient care costs provided by a participating provider under a contract that is issued, amended, or renewed on or after January 1, 2020, shall be the negotiated rate the health care service plan would otherwise pay a participating provider for the same services, less applicable cost sharing.

(2) Cost sharing for routine patient care costs shall be the same as that applied to the same services not delivered in a clinical trial, except that the in-network cost sharing and out-of-pocket maximum shall apply if the clinical trial is not offered or available through a participating provider.

(3) This section does not limit or modify any existing requirements under this chapter or prevent application of cost-sharing provisions in a contract, except as provided in paragraph (2).

(d) For purposes of this section:

(1) "Approved clinical trial" means a phase I, phase II, phase III, or phase IV clinical trial conducted in relation to the prevention, detection, or treatment of cancer or another life-threatening disease or condition that meets at least one of the following:

(A) The study or investigation is approved or funded, which may include funding through in-kind donations, by one or more of the following:

(i) The National Institutes of Health.

(ii) The federal Centers for Disease Control and Prevention.

(iii) The Agency for Healthcare Research and Quality.

(iv) The Centers for Medicare and Medicaid Services.

(v) A cooperative group or center of any of the entities described in clauses (i) to (iv), inclusive, the Department of Defense, or the United States Department of Veterans Affairs.

(vi) A qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

(vii) One of the following departments, if the study or investigation has been reviewed and approved through a system of peer review that the Secretary of the United States Department of Health and Human Services determines is comparable to the system of peer review used by the National Institutes of Health and assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review:

(I) The United States Department of Veterans Affairs.

(II) The United States Department of Defense.

(III) The United States Department of Energy.

(B) The study or investigation is conducted under an investigational new drug application reviewed by the United States Food and Drug Administration.



(C) The study or investigation is a drug trial that is exempt from an investigational new drug application reviewed by the United States Food and Drug Administration.

(2) "Life-threatening disease or condition" means a disease or condition from which the likelihood of death is probable, unless the course of the disease or condition is interrupted.

(3) "Qualified enrollee" means an enrollee who meets both of the following conditions:

(A) The enrollee is eligible to participate in an approved clinical trial, according to the clinical trial protocol, for the treatment of cancer or another life-threatening disease or condition.

(B) Either of the following applies:

(i) The referring health care professional is a participating provider and has concluded that the enrollee's participation in the clinical trial would be appropriate because the enrollee meets the conditions of subparagraph (A).

(ii) The enrollee provides medical and scientific information establishing that the enrollee's participation in the trial would be appropriate because the enrollee meets the conditions of subparagraph (A).

(4) "Routine patient care costs" include drugs, items, devices, and services provided consistent with coverage under the contract for an enrollee who is not enrolled in an approved clinical trial, including the following:

(A) Drugs, items, devices, and services typically covered absent a clinical trial.

(B) Drugs, items, devices, and services required solely for the provision of an investigational drug, item, device, or service.

(C) Drugs, items, devices, and services required for the clinically appropriate monitoring of the investigational drug, item, device, or service.

(D) Drugs, items, devices, and services provided for the prevention of complications arising from the provision of the investigational drug, item, device, or service.

(E) Drugs, items, devices, and services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including diagnosis and treatment of complications.

(5) "Routine patient care costs" does not include the following:

(A) The investigational drug, item, device, or service itself.

(B) Drugs, items, devices, and services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the enrollee.

(C) Drugs, items, devices, and services specifically excluded from coverage in the contract, except for drugs, items, devices, and services required to be covered pursuant to this section or other applicable law.

(D) Drugs, items, devices, and services customarily provided free of charge to a clinical trial participant by the research sponsor.

(e) This section shall not be construed to limit coverage provided by a health care service plan with respect to clinical trials.

(f) The provision of services required by this section shall not, in itself, give rise to liability on the part of the health care service plan.

(g) This section does not apply to vision-only, dental-only, accident-only, specified disease, hospital indemnity, Medicare supplement, CHAMPUS supplement, long-term care, or disability income plan contracts, except that for specified disease



and hospital indemnity plan contracts, coverage for benefits under this section shall apply, but only to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the contract. This section shall not be construed as imposing a new benefit mandate on specified disease or hospital indemnity plans.

(h) This section does not limit, prohibit, or modify an enrollee's rights to the independent review process available under Section 1370.4 or to the Independent Medical Review System available under Article 5.55 (commencing with Section 1374.30).

SEC. 3. Section 10145.4 of the Insurance Code is repealed.

~~10145.4. (a) For an insured diagnosed with cancer and accepted into a phase I, phase II, phase III, or phase IV clinical trial for cancer, every policy of disability insurance that provides hospital, medical, or surgical coverage in this state shall provide coverage for all routine patient care costs related to the clinical trial if the insured's treating physician, who is providing covered health care services to the insured under the insured's health benefit plan contract, recommends participation in the clinical trial after determining that participation in the clinical trial has a meaningful potential to benefit the insured. For purposes of this section, a clinical trial's endpoints shall not be defined exclusively to test toxicity, but shall have a therapeutic intent.~~

~~(b) (1) "Routine patient care costs" means the costs associated with the provision of health care services, including drugs, items, devices, and services that would otherwise be covered under the plan or contract if those drugs, items, devices, and services were not provided in connection with an approved clinical trial program, including the following:~~

~~(A) Health care services typically provided absent a clinical trial.~~

~~(B) Health care services required solely for the provision of the investigational drug, item, device, or service.~~

~~(C) Health care services required for the clinically appropriate monitoring of the investigational item or service.~~

~~(D) Health care services provided for the prevention of complications arising from the provision of the investigational drug, item, device, or service.~~

~~(E) Health care services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including the diagnosis or treatment of the complications.~~

~~(2) For purposes of this section, "routine patient care costs" does not include the costs associated with the provision of any of the following:~~

~~(A) Drugs or devices that have not been approved by the federal Food and Drug Administration and that are associated with the clinical trial.~~

~~(B) Services other than health care services, such as travel, housing, companion expenses, and other nonclinical expenses, that an insured may require as a result of the treatment being provided for purposes of the clinical trial.~~

~~(C) Any item or service that is provided solely to satisfy data collection and analysis needs and that is not used in the clinical management of the patient.~~

~~(D) Health care services which, except for the fact that they are not being provided in a clinical trial, are otherwise specifically excluded from coverage under the insured's health plan.~~



~~(E) Health care services customarily provided by the research sponsors free of charge for any enrollee in the trial.~~

~~(e) The treatment shall be provided in a clinical trial that either (1) involves a drug that is exempt under federal regulations from a new drug application or (2) that is approved by one of the following:~~

~~(A) One of the National Institutes of Health.~~

~~(B) The federal Food and Drug Administration, in the form of an investigational new drug application.~~

~~(C) The United States Department of Defense.~~

~~(D) The United States Veterans' Administration.~~

~~(d) In the case of health care services provided by a contracting provider, the payment rate shall be at the agreed-upon rate. In the case of a noncontracting provider, the payment shall be at the negotiated rate the insurer would otherwise pay to a contracting provider for the same services, less applicable copayments and deductibles. Nothing in this section shall be construed to prohibit a disability insurer from restricting coverage for clinical trials to hospitals and physicians in California unless the protocol for the clinical trial is not provided for at a California hospital or by a California physician.~~

~~(e) The provision of services when required by this section shall not, in itself, give rise to liability on the part of the insurer.~~

~~(f) This section shall not apply to vision-only, dental-only, accident-only, specified disease, hospital indemnity, Medicare supplement, CHAMPUS supplement, long-term care, or disability income insurance, except that for specified disease and hospital indemnity insurance, coverage for benefits under this section shall apply, but only to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy. Nothing in this section shall be construed as imposing a new benefit mandate on specified disease or hospital indemnity insurance.~~

~~(g) Nothing in this section shall be construed to prohibit, limit, or modify an insured's rights to the independent review process available under Section 10145.3 or to the Independent Medical Review System available under Article 3.5 (commencing with Section 10169).~~

~~(h) Nothing in this section shall be construed to otherwise limit or modify any existing requirements under the provisions of this chapter or to prevent application of deductible or copayment provisions contained in the policy.~~

~~(i) Copayments and deductibles applied to services delivered in a clinical trial shall be the same as those applied to the same services if not delivered in a clinical trial.~~

SEC. 4. Section 10145.4 is added to the Insurance Code, to read:

10145.4. (a) An individual or group health insurance policy that is issued, amended, or renewed on or after January 1, 2020, shall not:

(1) Deny a qualified insured's participation in an approved clinical trial.

(2) Deny, limit, or impose additional conditions on the coverage of routine patient care costs for items and services furnished in connection with a qualified insured's participation in an approved clinical trial.

(3) Discriminate against an insured based on the qualified insured's participation in an approved clinical trial.



(b) (1) Subdivision (a) applies to:

(A) A qualified insured participating in an approved clinical trial conducted by a participating provider.

(B) A qualified insured participating in an approved clinical trial conducted by a nonparticipating provider, including a nonparticipating provider located outside this state, if the clinical trial is not offered or available through a participating provider.

(2) If one or more participating providers is conducting an approved clinical trial, a health insurer may require a qualified insured to participate in the clinical trial through a participating provider if the participating provider accepts the insured as a clinical trial participant.

(3) A health insurer may restrict coverage to an approved clinical trial in this state, unless the clinical trial is not offered or available through a provider in this state.

(c) (1) The payment rate for routine patient care costs provided by a participating provider under a contract that is issued, amended, or renewed on or after January 1, 2020, shall be the negotiated rate the health insurer would otherwise pay a participating provider for the same services, less applicable cost sharing.

(2) Cost sharing for routine patient care costs shall be the same as that applied to the same services not delivered in a clinical trial, except that the in-network cost sharing and out-of-pocket maximum shall apply if the clinical trial is not offered or available through a participating provider.

(3) This section does not limit or modify any existing requirements under this chapter or prevent application of cost-sharing provisions in a contract, except as provided in paragraph (2).

(d) For purposes of this section:

(1) "Approved clinical trial" means a phase I, phase II, phase III, or phase IV clinical trial conducted in relation to the prevention, detection, or treatment of cancer or another life-threatening disease or condition that meets at least one of the following:

(A) The study or investigation is approved or funded, which may include funding through in-kind donations, by one or more of the following:

(i) The National Institutes of Health.

(ii) The federal Centers for Disease Control and Prevention.

(iii) The Agency for Healthcare Research and Quality.

(iv) The Centers for Medicare and Medicaid Services.

(v) A cooperative group or center of any of the entities described in clauses (i) to (iv), inclusive, the Department of Defense, or the United States Department of Veterans Affairs.

(vi) A qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

(vii) One of the following departments, if the study or investigation has been reviewed and approved through a system of peer review that the Secretary of the United States Department of Health and Human Services determines is comparable to the system of peer review used by the National Institutes of Health and assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review:

(I) The United States Department of Veterans Affairs.

(II) The United States Department of Defense.

(III) The United States Department of Energy.



(B) The study or investigation is conducted under an investigational new drug application reviewed by the United States Food and Drug Administration.

(C) The study or investigation is a drug trial that is exempt from an investigational new drug application reviewed by the United States Food and Drug Administration.

(2) "Life-threatening disease or condition" means a disease or condition from which the likelihood of death is probable, unless the course of the disease or condition is interrupted.

(3) "Qualified insured" means an insured who meets both of the following conditions:

(A) The insured is eligible to participate in an approved clinical trial, according to the clinical trial protocol, for the treatment of cancer or another life-threatening disease or condition.

(B) Either of the following applies:

(i) The referring health care professional is a participating provider and has concluded that the insured's participation in the clinical trial would be appropriate because the insured meets the conditions of subparagraph (A).

(ii) The insured provides medical and scientific information establishing that the insured's participation in the trial would be appropriate because the insured meets the conditions of subparagraph (A).

(4) "Routine patient care costs" include drugs, items, devices, and services provided consistent with coverage under the contract for an insured who is not enrolled in an approved clinical trial, including the following:

(A) Drugs, items, devices, and services typically covered absent a clinical trial.

(B) Drugs, items, devices, and services required solely for the provision of an investigational drug, item, device, or service.

(C) Drugs, items, devices, and services required for the clinically appropriate monitoring of the investigational drug, item, device, or service.

(D) Drugs, items, devices, and services provided for the prevention of complications arising from the provision of the investigational drug, item, device, or service.

(E) Drugs, items, devices, and services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including diagnosis and treatment of complications.

(5) "Routine patient care costs" does not include the following:

(A) The investigational drug, item, device, or service itself.

(B) Drugs, items, devices, and services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the insured.

(C) Drugs, items, devices, and services specifically excluded from coverage in the contract, except for drugs, items, devices, and services required to be covered pursuant to this section or other applicable law.

(D) Drugs, items, devices, and services customarily provided free of charge to a clinical trial participant by the research sponsor.

(e) This section shall not be construed to limit coverage provided by a health insurer with respect to clinical trials.

(f) The provision of services required by this section shall not, in itself, give rise to liability on the part of the health insurer.



(g) This section does not apply to vision-only, dental-only, accident-only, specified disease, hospital indemnity, Medicare supplement, CHAMPUS supplement, long-term care, or disability income insurance policies, except that for specified disease and hospital indemnity insurance, coverage for benefits under this section shall apply, but only to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy. This section shall not be construed as imposing a new benefit mandate on specified disease or hospital indemnity insurance.

(h) This section does not limit, prohibit, or modify an insured's rights to the independent review process available under Section 10145.3 or to the Independent Medical Review System available under Article 3.5 (commencing with Section 10169).

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

