§ 1370.6. Coverage for approved clinical trials

(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 participating provider in this state.

(c)(1) The payment rate for routine patient care costs provided by a nonparticipating 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 federal 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 ensures 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 clinical 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 contract 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 a specialized health care service plan contract.

(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).

HISTORY:

Added Stats 2019 ch 482 § 2 (SB 583), effective January 1, 2020.