SENATE
STATE OF MINNESOTA
NINETY-FIRST SESSION

S.F. No. 3125

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DATE	D-PG	OFFICIAL STATUS
02/13/2020		Introduction and first reading
		Referred to Health and Human Services Finance and Policy

A bill for an act

relating to medical assistance; providing coverage for routine patient costs that are incurred in the course of a clinical trial if the medical assistance program would provide coverage for the same routine patient costs not incurred in a clinical trial; amending Minnesota Statutes 2018, section 256B.0625, by adding a subdivision.

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

Section 1. Minnesota Statutes 2018, section 256B.0625, is amended by adding a subdivision to read:

Subd. 67. **Qualified clinical trials.** (a) For purposes of this subdivision, the terms defined in this paragraph have the meanings given:

(1) "approved clinical trial" means a phase I, II, III, or IV research study involving the prevention, detection, or treatment of cancer or any other life-threatening disease or condition or severely debilitating disease or condition if one or more of the following conditions apply:

(i) the study or investigation is conducted under an investigational new drug application or an investigational device exemption reviewed by the federal Food and Drug Administration;

(ii) the study or investigation is a drug trial that is exempt from having an investigational new drug application or an investigational device exemption from the federal Food and Drug Administration; or

(iii) the study or investigation is funded, including funding through in-kind contributions, or approved by:

(A) the National Institutes of Health;

(B) the Centers for Disease Control and Prevention;

(C) the Agency for Healthcare Research and Quality;

(D) the Patient-Centered Outcomes Research Institute;

(E) the federal Centers for Medicare and Medicaid Services;

(F) a cooperative group or center of any of the entities described in subitems (A) to (E);

(G) a cooperative group or center of the United States Department of Defense;

(H) a cooperative group or center of the United States Department of Veterans Affairs;

(I) a qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants; or

(J) the United States Department of Veterans Affairs, the United States Department of Defense, or the United States Department of Energy, provided that review and approval of the study or investigation occurs through a system of peer review that is comparable to the peer review of studies performed by the National Institutes of Health, including an unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review;

(2) "care method" means the use of a particular drug or device in a particular manner;

(3) "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;

(4) "severely debilitating disease or condition" means a disease or condition that causes major irreversible morbidity;

(5) "routine patient costs" means the costs of medically necessary services related to the care method that is under evaluation in a clinical trial. Routine care costs include the costs of items and services related to the prevention, detection, and treatment of any adverse effects and complications arising from the patient's medical care, including any complications related to participation in the clinical trial. The term does not include the following:

(i) the drug or device that is under evaluation in a clinical trial; or

(ii) items or services that are:

(A) provided solely for data collection and analysis and not in the direct clinical management of an individual enrolled in a clinical trial;

(B) customarily provided at no cost by a research sponsor to an individual enrolled in a clinical trial; or

(C) provided solely to determine eligibility of an individual for participation in a clinical trial.

(b)(1) The medical assistance program must provide coverage for routine patient costs that are incurred in the course of an approved clinical trial if the medical assistance program would provide coverage for the same routine care costs not incurred in a clinical trial.

(2) The coverage that must be provided under this subdivision is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the medical assistance program, including terms, conditions, restrictions, exclusions, or limitations that apply to health care services rendered by participating and nonparticipating providers.

EFFECTIVE DATE. This section is effective August 1, 2020, and applies to medical assistance coverage as defined in section 256B.02.