HB2438

LRB10328969KTG55355b

103RD GENERAL ASSEMBLY

State of Illinois

2023 and 2024

HB2438

Introduced 2/15/2023, by Rep. Camille Y. Lilly

SYNOPSIS AS INTRODUCED:

305 ILCS 5/5-5.28 new

Amends the Medical Assistance Article of the Illinois Public Aid Code. Provides that the medical assistance program shall provide coverage for routine care 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. Defines "approved clinical trial" to mean a phase I, II, III, or IV clinical trial involving the prevention, detection, or treatment of cancer or any other life-threatening disease or condition. Defines "routine care cost" to mean the cost of medically necessary services related to the care method that is under evaluation in a clinical trial, including the cost of services related to the detection and treatment of any complications arising from the patient's medical care and any complications related to participation in the clinical trial. Defines other terms.

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A BILL FOR

AN ACT concerning public aid.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 5. The Illinois Public Aid Code is amended by changing Section 5-5.28 as follows:

(305 ILCS 5/5-5.28 new)

Sec. 5-5.28. Coverage for clinical trials.

(a) The medical assistance program shall provide coverage for routine care 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.

(b) The coverage that must be provided under this Section 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 providers and nonparticipating providers.

(c) As used in this Section:

"Approved clinical trial" means a phase I, II, III, or IV clinical trial involving the prevention, detection, or treatment of cancer or any other life-threatening disease or

condition if one or more of the following conditions apply:

(1) the Department makes a determination that the study or investigation is an approved clinical trial;

(2) 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;

(3) 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

(4) the study or investigation is approved or funded (which may include funding through in-kind contributions) 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 subparagraphs (A) through (E) or the United States Department of Defense or the United

States Department of Veterans Affairs;

(G) a qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants; or

(H) 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.

"Care method" means the use of a particular drug or device in a particular manner.

"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.

"Routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. Routine care costs include the cost of services related to the detection and treatment of any 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:

(1) The drug or device that is under evaluation in a clinical trial.

(2) 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.