



101ST GENERAL ASSEMBLY

State of Illinois

2019 and 2020

SB2499

Introduced 1/28/2020, by Sen. Andy Manar and Jennifer Bertino-Tarrant

SYNOPSIS AS INTRODUCED:

305 ILCS 5/5-5.27 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.

LRB101 17423 KTG 66832 b

FISCAL NOTE ACT
MAY APPLY

A BILL FOR

1 AN ACT concerning public aid.

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

4 Section 5. The Illinois Public Aid Code is amended by
5 changing Section 5-5.27 as follows:

6 (305 ILCS 5/5-5.27 new)

7 Sec. 5-5.27. Coverage for clinical trials.

8 (a) The medical assistance program shall provide coverage
9 for routine care costs that are incurred in the course of an
10 approved clinical trial if the medical assistance program would
11 provide coverage for the same routine care costs not incurred
12 in a clinical trial.

13 (b) The coverage that must be provided under this Section
14 is subject to the terms, conditions, restrictions, exclusions,
15 and limitations that apply generally under the medical
16 assistance program, including terms, conditions, restrictions,
17 exclusions, or limitations that apply to health care services
18 rendered by participating providers and nonparticipating
19 providers.

20 (c) As used in this Section:

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

1 condition if one or more of the following conditions apply:

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

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

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

12 (4) the study or investigation is approved or funded
13 (which may include funding through in-kind contributions)
14 by:

15 (A) the National Institutes of Health;

16 (B) the Centers for Disease Control and
17 Prevention;

18 (C) the Agency for Healthcare Research and
19 Quality;

20 (D) the Patient-Centered Outcomes Research
21 Institute;

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

24 (F) a cooperative group or center of any of the
25 entities described in subparagraphs (A) through (E) or
26 the United States Department of Defense or the United

1 States Department of Veterans Affairs;

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

5 (H) the United States Department of Veterans
6 Affairs, the United States Department of Defense, or
7 the United States Department of Energy, provided that
8 review and approval of the study or investigation
9 occurs through a system of peer review that is
10 comparable to the peer review of studies performed by
11 the National Institutes of Health, including an
12 unbiased review of the highest scientific standards by
13 qualified individuals who have no interest in the
14 outcome of the review.

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

17 "Life-threatening disease or condition" means a disease or
18 condition from which the likelihood of death is probable unless
19 the course of the disease or condition is interrupted.

20 "Routine care cost" means the cost of medically necessary
21 services related to the care method that is under evaluation in
22 a clinical trial. Routine care costs include the cost of
23 services related to the detection and treatment of any
24 complications arising from the patient's medical care,
25 including any complications related to participation in the
26 clinical trial. The term does not include the following:

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

3 (2) Items or services that are:

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

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

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