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State/Territory Name: Illinois

State Plan Amendment (SPA) #: 22-0005

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form
- 3) Approved SPA Page

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
601 E. 12th St., Room 355
Kansas City, Missouri 64106



Medicaid and CHIP Operations Group

May 2, 2022

Theresa Eagleson
Director
Illinois Department of Healthcare and Family Services
201 South Grand Avenue East
3rd Floor
Springfield, IL 62763-0001

Re: Illinois State Plan Amendment (SPA) 22-0005

Dear Ms. Eagleson:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0005. This amendment proposes to implement Sections 1905(a)(30) and 1905(gg) of the Social Security Act, which require coverage of routine patient costs associated with participation in qualifying clinical trials.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations. This letter is to inform you that Illinois Medicaid SPA 22-0005 was approved on May 2, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Courtenay Savage at 708-567-2048 or via email at Courtenay.Savage@cms.hhs.gov.

Sincerely,

A black rectangular redaction box covers the signature of James G. Scott.

James G. Scott, Deputy Director
Division of Program Operations

Enclosures

cc: Kelly Cunningham
Mary Doran
Jane Eckert


TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER <u>2 2 - 0 0 0 5</u>	2. STATE <u>IL</u>
	3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT <input checked="" type="radio"/> XIX <input type="radio"/> XXI	
TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE January 1, 2022	
5. FEDERAL STATUTE/REGULATION CITATION Section 1905(gg) of the Social Security Act	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a. FFY <u>2022</u> \$ <u>0</u> b. FFY <u>2023</u> \$ <u>0</u>	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Attachment 3.1-A, Page 10B	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (if Applicable)	

9. SUBJECT OF AMENDMENT
Clinical trials and routine care.

10. GOVERNOR'S REVIEW (Check One)

GOVERNOR'S OFFICE REPORTED NO COMMENT
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

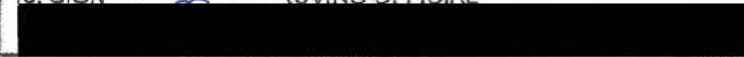
OTHER, AS SPECIFIED:

11. SIGNATURE OF STATE AGENCY OFFICIAL 	15. RETURN TO Department of Healthcare and Family Services Bureau of Program and Policy Coordination Attn: Mary Doran 201 South Grand Avenue East Springfield, IL 62763-0001
12. TYPED NAME Theresa Eagleson	
13. TITLE Director of Healthcare and Family Services	
14. DATE SUBMITTED 3/27/2022	

FOR CMS USE ONLY

16. DATE RECEIVED March 28, 2022	17. DATE APPROVED May 2, 2022
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PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL January 1, 2022	19. SIGNATURE OF APPROVING OFFICIAL 
20. TYPED NAME OF APPROVING OFFICIAL James G. Scott	21. TITLE OF APPROVING OFFICIAL Director, Division of Program Operations

22. REMARKS

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State: **Illinois**

**AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE
AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY**

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

Provided:

General Assurances:

Routine Patient Cost – Section 1905(gg)(1)

Coverage of routine patient cost for items and services as defined in section 1905(gg)(1) that are furnished in connection with participation in a qualified clinical trial.

Qualifying Clinical Trial – Section 1905(gg)(2)

A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).

Coverage Determination – Section 1905(gg)(3)

A determination with respect to coverage for an individual participating in a qualified clinical trial will be made in accordance with section 1905(gg)(3).

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing Section 210 of the Consolidated Appropriations Act of 2021 amending section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30). Section 210 mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials effective January 1, 2022. Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage (also referred to as alternative benefit plans, or ABPs). Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-1148 (CMS-10398 #74). Public burden for all of the collection of information requirements under this control number is estimated to take about 56 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 Security Boulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.