

Table of Contents

State/Territory Name: Florida

State Plan Amendment (SPA) #: 22-0003

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS-179
- 3) Approved SPA Pages

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

April 29, 2022

Mr. Thomas Wallace
Deputy Secretary for Medicaid
Agency for Health Care
Administration
2727 Mahan Drive, MS #8
Tallahassee, Florida 32308

Re: Florida State Plan Amendment (SPA) Transmittal #22-0003

Dear Mr. Wallace:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) #22-0003. This amendment is submitted to come into compliance with the Consolidated Appropriations Act, 2021 requiring mandatory coverage of routine patient costs for services furnished in connect with participation in qualifying clinical trials on or after January 1, 2022.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and the Consolidated Appropriations Act, 2021. This letter is to inform you that Florida Medicaid SPA #22-0003 was approved on April 28, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Tandra Hodges at 404-562-7409 or via email at Tandra.Hodges@cms.hhs.gov.

Sincerely,



Ruth A. Hughes, Acting Director
Division of Program Operations

cc: Cole Giering

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER <u>2 2 — 0 0 0 3</u>	2. STATE <u>FL</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 <p style="text-align: center; color: blue;">January 1, 2022</p>	
5. FEDERAL STATUTE/REGULATION CITATION <p style="color: blue;">Section 1905(gg) of the SSA</p>	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a. FFY <u>21-22</u> \$ <u>0</u> b. FFY <u>22-23</u> \$ <u>0</u>	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT <p style="color: blue;">Attachment 3.1-A pg 62 Attachment 3.1-B pg 54 Attachment 4.19-B pg 50</p>	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)	

9. SUBJECT OF AMENDMENT

Clinical Trial Coverage

10. GOVERNOR'S REVIEW (Check One)

GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED:
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

11. SIGNATURE OF STATE AGENCY OFFICIAL 	15. RETURN TO Mr. Tom Wallace Deputy Secretary for Medicaid Agency for Health Care Administration 2727 Mahan Drive, Mail Stop #8 Tallahassee, FL 32308 Attn: Cole Giering
12. TYPED NAME Tom Wallace	
13. TITLE Deputy Secretary for Medicaid	
14. DATE SUBMITTED March 4, 2022	

FOR CMS USE ONLY

16. DATE RECEIVED March 4, 2022	17. DATE APPROVED April 28, 2022
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PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL January 1, 2022	
20. TYPED NAME OF APPROVING OFFICIAL Ruth A. Hughes	21. TITLE OF APPROVING OFFICIAL Acting Director, Division of Program Operations

22. REMARKS

Clinical Trial Coverage Reimbursement Pursuant to section 1905(a)(30) and 1905(gg)(1) of the Social Security Act

The State attests to reimbursement for routine patient costs for a beneficiary participating in a qualifying clinical trial including any item or service provided to the individual under the qualifying clinical trial to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial.

Services otherwise covered outside the course of participation in the qualifying clinical trial are paid based on state developed fee schedule rates which are the same for both governmental and private providers. All rates, including current and prior rates, are published and maintained on the agency's website. Specifically, the fee schedule is published at http://ahca.myflorida.com/medicaid/review/fee_schedules.shtml

TN-Number 22-0001
Supersede NEW

Effective Date 1/1/2022
Approval Date 4/28/2022

State/Territory: Florida**AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED****CATEGORICALLY NEEDY GROUP(S)**

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

Provided: X

I. General Assurances:

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

X 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)

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

Coverage Determination – Section 1905(gg)(3)

X 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.

TN: 21-0003
Supersedes TN: New

Approval Date: 04/28/22
Effective Date: 01/01/2022

State/Territory: Florida**AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED****MEDICALLY NEEDY GROUP(S)****30. Coverage of Routine Patient Cost in Qualifying Clinical Trials**

*The state needs to check each assurance below.

Provided: X

I. General Assurances:**Routine Patient Cost – Section 1905(gg)(1)**

X 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)

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

Coverage Determination – Section 1905(gg)(3)

X 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.

TN: 22-0003
Supersedes TN: NEW

Approval Date: 04/28/2022
Effective Date: 01/01/2022