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State/Territory Name: Louisiana

State Plan Amendment (SPA) #: 22-0012

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form
- 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

June 9, 2022

Mr. Patrick Gillies
Medicaid Executive Director
State of Louisiana
Department of Health
628 N 4th Street
P.O. Box 91030
Baton Rouge, LA 70821-9030

Re: Louisiana State Plan Amendment (SPA) TN 22-0012

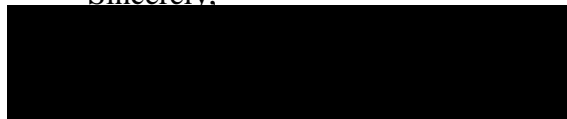
Dear Mr. Gillies:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0012. This amendment proposes to implement 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 1905(a)(30) of the Social Security Act. This letter is to inform you that Louisiana Medicaid SPA TN 22-0012 was approved on June 9, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Tobias Griffin at 214-767-7725 or via email at tobias.griffin@cms.hhs.gov.

Sincerely,



James G. Scott, Director
Division of Program Operations

Enclosures

cc: Karen Barnes, LA Department of Health
Billy Bob Farrell, Branch Manager

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER 22-0012	2. STATE LA
3. PROGRAM IDENTIFICATION: TITLE <u>XIX</u> OF THE SOCIAL SECURITY ACT	
4. PROPOSED EFFECTIVE DATE January 1, 2022	
5. 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 13 Attachment 3.1-A, Page 14 - New Page Attachment 3.1-B, Page 12 - New Page Attachment 3.1-B, Page 132 - New Page Attachment 4.19-B, Item 30, Page 1 - New Page	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Same (TN 15-0038)

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

5. FEDERAL STATUTE/REGULATION CITATION
1905(a)(30) of the Social Security Act
~~42 CFR Section 1396d(l)(3)B~~

9. SUBJECT OF AMENDMENT
The purpose of this SPA is to implement coverage of routine patient costs associated with participation in qualifying clinical trials; ~~revise Attachment 3.1-A, Freestanding Birth Centers, to correct duplicate item numbers; and to add Attachment 3.1-B, Freestanding Birth Centers, to provide appropriate flow of State Plan pages.~~

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:
The Governor does not review State Plan material.

11. TITLE AGENCY OFFICIAL
[Redacted]

12. TYPED NAME
Ruth Johnson, designee for Dr. Courtney N. Phillips

13. TITLE
Secretary

14. DATE SUBMITTED
March 31, 2022

15. RETURN TO
**Patrick Gillies, Medicaid Executive Director
Louisiana Department of Health
628 North 4th Street
P.O. Box 91030
Baton Rouge, LA 70821-9030**

FOR CMS USE ONLY

16. DATE RECEIVED
March 31, 2022

17. DATE APPROVED
June 9, 2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
January 1, 2022

[Redacted]

20. TYPED NAME OF APPROVING OFFICIAL
James G. Scott

21. TITLE OF APPROVING OFFICIAL
Director, Division of Program Operations

22. REMARKS
The State requests a pen and ink change to boxes 5, 7, 8 and 9.

State/Territory: Louisiana

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 SecurityBoulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

State/Territory: Louisiana

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

II. 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.

STATE OF LOUISIANA

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICES

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - OTHER TYPES OF CARE OR SERVICE LISTED IN SECTION 1902(a) OF THE ACT THAT ARE INCLUDED IN THE PROGRAM UNDER THE PLAN ARE DESCRIBED AS FOLLOWS:

1905(a)(30) Qualifying Clinical Trials

Reimbursement Methodology

Medicaid will reimburse routine patient costs associated with beneficiaries participating in qualifying clinical trials on or after January 1, 2022.

Except as otherwise noted in the plan, state-developed fee schedule rates are the same for both governmental and private providers of services to beneficiaries participating in qualified clinical trials. The agency's fee schedule rate was set as of January 1, 2022 and is effective for services provided on or after that date. All rates are published on the Louisiana Medicaid website at www.lamedicaid.com.