John Bel Edwards
GOVERNOR

Dr. Courtney N. Phillips
SECRETARY

State of Louisiana

Louisiana Department of Health
Office of the Secretary

March 31, 2022

James G. Scott, Director
Division of Program Operations
Medicaid & CHIP Operations Group
601 East 12th Street, Room 0300
Kansas City, Missouri 64106-2898

RE: Louisiana Title XIX State Plan
Transmittal No. 22-0012

Dear Mr. Scott:

I have reviewed and approved the enclosed Louisiana Title XIX State Plan material.

I recommend this material for adoption and inclusion in the body of the State Plan. Should you have any questions or concerns regarding this matter, please contact Karen Barnes at (225) 342-3881 or via email at Karen.Barnes@la.gov.

Sincerely,

_____, for
Dr. Courtney N. Phillips
Secretary

Attachments (2)

CNP:PG:LT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB No. 0938-0193

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 XIX OF THE SOCIAL SECURITY ACT

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
1905(a)(30) of the Social Security Act
42 CFR Section 1396d(l)(3)B

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY **2022** **$ 0**
b. FFY **2023** **$ 0**

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 13 – 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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*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)

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. SIGNATURE OF STATE AGENCY OFFICIAL

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

17. DATE APPROVED

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL

19. SIGNATURE OF APPROVING OFFICIAL

20. TYPED NAME OF APPROVING OFFICIAL

21. TITLE OF APPROVING OFFICIAL

22. REMARKS

Instructions on Back

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: With limitations

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).

Limitations:

Routine patient costs in qualified clinical trials do not include the following:

1. Any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the State Plan; and

2. Any item or service that is provided to the beneficiary solely to satisfy data collection and analysis needs for the qualifying clinical trial and not used in the direct clinical management of the beneficiary and that is not otherwise covered under the State Plan.

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 notconduct 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: With limitations

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).

Limitations:

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2. Any item or service that is provided to the beneficiary solely to satisfy data collection and analysis needs for the qualifying clinical trial and not used in the direct clinical management of the beneficiary and that is not otherwise covered under the State Plan.

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.

The following are excluded from reimbursement:

1. Any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the State Plan; and

2. Any item or service that is provided to the beneficiary solely to satisfy data collection and analysis needs for the qualifying clinical trial and not used in the direct clinical management of the beneficiary and that is not otherwise covered under the State Plan.

Attachment 3.1A: Freestanding Birth Center Services

29. (i) Licensed or Otherwise State-Approved Freestanding Birth Centers

Provided: ☐ No limitations ☒ With limitations ☐None licensed or approved

Please describe any limitations:

Stays for delivery at the free-standing birthing centers (FSBC) are typically less than 24 hours and the services rendered for labor and delivery are very limited in comparison to delivery services rendered during inpatient hospital stays. Services shall be provided by the attending practitioner from the time of the pregnant woman's admission through the birth and the immediate postpartum period.

The FSBC shall be located within a ground travel time distance from a general acute care hospital with which the FSBC shall maintain a contractual relationship, including a transfer agreement, that allows for an emergency caesarian delivery to begin within 30 minutes of the decision a caesarian delivery is necessary.

29. (ii) Licensed or Otherwise State-Recognized covered professionals providing services in the Freestanding Birth Center

Provided: ☐ No limitations ☒ with limitations (please describe below)

☐ Not Applicable (there are no licensed or State approved Freestanding Birth Centers)

Please describe any limitations:

Free-standing birthing center staff shall not administer general or epidural anesthesia services.

Please check all that apply:

☒ (a) Practitioners furnishing mandatory services described in another benefit category and otherwise covered under the State plan (i.e., physicians and certified nurse midwives).

☒ (b) Other licensed practitioners furnishing prenatal, labor and delivery, or postpartum care in a freestanding birth center within the scope of practice under State law whose services are otherwise covered under 42 CFR 440.60 (e.g., lay midwives, certified professional midwives (CPMs), and any other type of licensed midwife). *

☐ (c) Other health care professionals licensed or otherwise recognized by the State to provide these birth attendant services (e.g., doulas, lactation consultant, etc.).*

*For (b) and (c) above, please list and identify below each type of professional who will be providing birth center services:

Licensed midwives

OMB Approved 0938-1024

Attachment 3.1B: Freestanding Birth Center Services

29. (i) Licensed or Otherwise State-Approved Freestanding Birth Centers

Provided: ☐ No limitations ☒ With limitations ☐None licensed or approved

Please describe any limitations:

Stays for delivery at the free-standing birthing centers (FSBC) are typically less than 24 hours and the services rendered for labor and delivery are very limited in comparison to delivery services rendered during inpatient hospital stays. Services shall be provided by the attending practitioner from the time of the pregnant woman's admission through the birth and the immediate postpartum period.

The FSBC shall be located within a ground travel time distance from a general acute care hospital with which the FSBC shall maintain a contractual relationship, including a transfer agreement, that allows for an emergency caesarian delivery to begin within 30 minutes of the decision a caesarian delivery is necessary.

29. (ii) Licensed or Otherwise State-Recognized covered professionals providing services in the Freestanding Birth Center

Provided: ☐ No limitations ☒ with limitations (please describe below)

☐ Not Applicable (there are no licensed or State approved Freestanding Birth Centers)

Please describe any limitations:

Free-standing birthing center staff shall not administer general or epidural anesthesia services.

Please check all that apply:

☒ (a) Practitioners furnishing mandatory services described in another benefit category and otherwise covered under the State plan (i.e., physicians and certified nurse midwives).

☒ (b) Other licensed practitioners furnishing prenatal, labor and delivery, or postpartum care in a freestanding birth center within the scope of practice under State law whose services are otherwise covered under 42 CFR 440.60 (e.g., lay midwives, certified professional midwives (CPMs), and any other type of licensed midwife). *

☐ (c) Other health care professionals licensed or otherwise recognized by the State to provide these birth attendant services (e.g., doulas, lactation consultant, etc.).*

*For (b) and (c) above, please list and identify below each type of professional who will be providing birth center services:

Licensed midwives