



State of Louisiana

Louisiana Department of Health
Office of the Secretary

February 8, 2023

Via Statutorily Prescribed Email

To: The Honorable Fred H. Mills, Jr., Chairman, Senate Health & Welfare Committee
The Honorable Larry Bagley, Chairman, House Health & Welfare Committee

From: Dr. Courtney N. Phillips
Secretary

A handwritten signature in blue ink, appearing to read "C. Phillips", written over the printed name of the Secretary.

Re: Second Report LAC 48:I.Chapter 67 – Free-Standing Birth Centers – Licensing Standards

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Bureau of Health Services Financing, submits its second report regarding the proposed Rule for Free-Standing Birth Centers – Licensing Standards, LAC 48:I.Chapter 67.

A Notice of Intent on the proposed amendments was published in the August 20, 2021 issue of the *Louisiana Register* (LR 48:3024). Written comments were received; however, no requests for a public hearing were received during the notice period. Because there were no requests for a public hearing, one was not held for these proposed amendments. After thoroughly reviewing and giving due consideration to the comments received, no substantive changes were made to the proposed amendments since the report provided for in R.S. 49:966B-C was submitted.

Unless otherwise directed, the Department anticipates adopting the December 20, 2022, Notice of Intent when it is published as a final rule in the March 20, 2023, issue of the *Louisiana Register*.

Please contact Cynthia York, Cynthia.York@la.gov, if you have any questions or require additional information about this matter.

Cc: Tara LeBlanc, Medicaid Director, LDH
Shannon Bibbins, Medicaid Deputy Director, LDH
Tasheka Dukes, HSS Assistant Secretary, LDH
Veronica Dent, Medicaid Program Manager, LDH
Bethany Blackson, Legislative Liaison, LDH
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

NOTICE OF INTENT
Department of Health
Bureau of Health Services Financing

Free-Standing Birth Centers—Licensing Standards
(LAC 48:I.Chapter 67)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 48:I.Chapter 67 as authorized by R.S. 36:254. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

The Department of Health proposes to amend the provisions governing the licensing of free-standing birth centers (FSBCs) in order to: 1) add and update definitions; 2) clarify licensing requirements and responsibilities of the governing board; 3) modify education and training requirements of personnel; and, 4) update FSBC service delivery requirements.

Title 48
PUBLIC HEALTH-GENERAL
Part I. General Administration
Subpart 3. Licensing and Certification
Chapter 67. Free-Standing Birth Centers
Subchapter A. General Provisions
§6703. Definitions

* * *

Certified Nurse Midwife (CNM)—an advanced practice registered nurse as defined by R.S. 37:913, or current law.

* * *

Emergent—a medical condition that, if not stabilized, could reasonably be expected to result in the loss of the person's life, serious permanent disfigurement, or loss or impairment of the function of a bodily member or organ.

* * *

Line of Credit—a credit arrangement with a federally insured, licensed lending institution which is established to assure that the provider has available funds as needed to

continue the operations of the agency and the provision of services to clients. The line of credit shall be issued to the licensed entity and shall be specific to the geographic location shown on the license. For purposes of FSBC licensure, the line of credit shall not be a loan, credit card or a bank balance.

* * *

Transfer Agreement—a written agreement made with at least one receiving hospital in the community for the timely transport of emergency clients to a licensed hospital that will provide obstetric/newborn acute care should an emergency arise which would necessitate hospital care and services.

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254, R.S. 40:2180.21-2180.28, R.S. 37:1270 and R.S. 37:3241-3259.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2107 (August 2022), amended LR 49:

§6705. General Requirements

A. - J. ...

K. Each FSBC shall have requirements and protocols for assessing, transferring, and transporting clients to a licensed hospital, and arrangements with a local ambulance service for the transport of emergency clients to a licensed hospital. Arrangements may include an annual, written notification to a local ambulance company advising of the FSBC's operational status. The written notification shall, at a minimum, include the FSBC's name, address, and telephone number.

L. - N. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2108 (August 2022), amended LR 49:

§6709. Initial Licensure Application Process

A. ...

B. The initial licensing application packet shall include:

1. - 4. ...

5. proof of each insurance coverage as follows:

a. - b. ...

c. professional liability insurance of at least \$100,000 per occurrence/\$300,000 per annual aggregate, or proof of self-insurance of at least \$100,000, along with proof of enrollment as a qualified healthcare provider with the Louisiana Patient's Compensation Fund (PCF). If the FSBC is not enrolled in the PCF, professional liability limits shall be \$1,000,000 per occurrence/\$3,000,000 per annual aggregate; and

i. Repealed.

d. ...

6. proof of financial viability which entails:

a. a line of credit issued from a federally insured, licensed lending institution in the amount of at least \$25,000; or

b. verification of sufficient assets equal to \$25,000 or the cost of three months of operation, whichever is less;

B.7. - H. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2109 (August 2022), amended LR 49:

§6715. Changes in Licensee Information or Personnel

A. - H. ...

1. An on-site physical environment survey by the HSS, and an on-site inspection by the OPH and the OSFM shall be required prior to the issuance of the new license.

2. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2111 (August 2022), amended LR 49:

§6717. Renewal of License

A. The FSBC shall submit a completed license renewal application packet to the department at least 30 days prior to the expiration of the current license. The license renewal application packet shall include the:

1. ...

2. non-refundable license renewal/delinquent fee;

3. - 5. ...

6. proof of each insurance coverage as follows:

a. - b. ...

c. professional liability insurance of at least \$100,000 per occurrence/\$300,000 per annual aggregate, or proof of self-insurance of at least \$100,000, along with proof of enrollment as a qualified healthcare provider with the PCF. If the FSBC is not enrolled in the PCF, professional liability limits shall be \$1,000,000 per occurrence/\$3,000,000 per annual aggregate; and

i. Repealed.

d. ...

7. proof of financial viability that entails:

a. a line of credit issued from a federally insured, licensed lending institution in the amount of at least \$25,000; or

b. verification of sufficient assets equal to \$25,000 or the cost of three months of operation, whichever is less; and

A.8. - E. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2111 (August 2022), amended LR 49:

Subchapter B. Administration and Organization

§6735. Governing Body

A. - C. ...

D. The governing body of an FSBC shall:

1. ...

2. review and approve the FSBC's annual budget;

a. - b. Repealed.

3. designate a person to act as the administrator and delegate enough authority to this person to manage the day-to-day operations of the FSBC;

4. annually evaluate the administrator's performance;

5. have the authority to dismiss the administrator;

6. formulate and annually review, in consultation with the administrator, written policies and procedures concerning the FSBC's philosophy, goals, current services, personnel practices, job descriptions, fiscal management, and contracts:

a. the FSBC's written policies and procedures shall be maintained within the FSBC and made available to all staff during hours of operation;

7. determine, in accordance with state law, which licensed healthcare practitioners are eligible candidates for appointment to the FSBC staff;

a. Repealed.

8. ensure and maintain quality of care, inclusive of a quality assurance/performance improvement process that measures client, process, and structural (e.g. system) outcome indicators to enhance client care;

9. ensure that birthing procedures shall not be performed in areas other than the birthing rooms;

10. ensure that birthing procedures are initiated in accordance with acceptable standards of practice;

11. meet with designated representatives of the department whenever required to do so;

12. inform the department, or its designee, prior to initiating any substantial changes in the services provided by the FSBC; and

13. ensure that pursuant to R.S. 40:1191.2, prior to the final disposition of a miscarried child, but not more than 24 hours after a miscarriage occurs in an FSBC, the FSBC shall notify the client, or if the client is incapacitated, the spouse of the client, both orally and in writing, of both of the following:

a. the parent's right to arrange for the final disposition of the miscarried child using the notice of parental rights form as provided for in R.S. 40:1191.3; and

b. the availability of a chaplain or other counseling services concerning the death of the miscarried child, if such services are provided by the FSBC.

14. - 14.b. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2116 (August 2022), amended LR 49:

Subchapter C. Admissions, Transfers and Discharges

§6743. Prohibitions to Admission or Continued Care in an FSBC

A. The FSBC shall not knowingly accept or thereafter maintain responsibility for the prenatal or intrapartum care of a woman who:

1. - 16. ...

17. has a parity greater than five, with poor obstetrical history;

A.18. - B. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2117 (August 2022), amended LR 49:

§6745. Admissions and Assessments

A. ...

B. An FSBC shall ensure that each client has the appropriate pre-natal and postpartum assessments completed, inclusive of the FSBC's ability to provide services needed in the postpartum period in accordance with the prescribed plan of care, and discharge plans to home or another licensed facility setting. The FSBC shall ensure that any length of client care does not exceed 23 hours post-delivery.

C. - F. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2117 (August 2022), amended LR 49:

§6747. Required Newborn Care

A. Each delivery shall be attended by two qualified personnel currently trained in:

1. the use of emergency equipment;
2. adult cardiopulmonary resuscitation equivalent to American Heart Association Class C Basic Life Support; and
3. Neonatal Resuscitation Program endorsed by the American Academy of Pediatrics/American Heart Association.

B. - G. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2118 (August 2022), amended LR 49:

§6751. Required Physician Consultation, Postpartum Period

A. The licensed healthcare practitioner shall obtain medical consultation or refer for emergent medical care any woman who, during the postpartum period:

1. - 7. ...

B. The licensed healthcare practitioner shall obtain medical consultation or refer for emergent medical care any infant who:

B.1. - C. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2118 (August 2022), amended LR 49:

Subchapter D. Service Delivery

§6757. Perinatal Services

A. - C. ...

D. Except for the requirements of §6747.A. specific to deliveries, at least one licensed healthcare practitioner shall be immediately available in the FSBC until all clients are assessed as stable, and shall have been trained in:

1. ...

2. adult cardiopulmonary resuscitation equivalent to American Heart Association Class C Basic Life Support; and

3. Neonatal Resuscitation Program endorsed by American Academy of Pediatrics/American Heart Association.

4. Repealed.

E. - G.5. ...

H. There shall be enough staff assigned to the postpartum care area to meet the needs of the clients.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2119 (August 2022), amended LR 49:

§6759. Transfer Agreements and Client Transfers

A. ...

B. If the FSBC is not able to secure a written transfer agreement, the licensed healthcare practitioner shall be responsible for the safe and immediate transfer of the patients from the FSBC to a hospital when a higher level of care is indicated. Transportation to a local hospital shall be mediated by ambulance when emergency consultation is needed.

C. - C.3. ...

D. The FSBC shall be located within 20 minutes' transport time to a general acute care hospital providing obstetric services 24 hours per day and seven days a week, with which the FSBC has a written transfer agreement. The FSBC shall maintain a contractual relationship with the general acute care hospital, including a written transfer agreement, which allows for an emergency cesarean delivery to begin within 30 minutes of the decision made by a licensed obstetrician at the receiving hospital that a cesarean delivery is necessary.

E. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2119 (August 2022), amended LR 49:

Subchapter E. Facility Responsibilities

§6767. General Provisions

A. - A.5. ...

B. An FSBC shall have qualified staff sufficient in number to meet the needs of clients and to ensure provision of services.

C. The FSBC shall develop and maintain documentation of an orientation program for all employees, either contract or staff that is sufficient in scope and duration to inform the individual about his/her responsibilities, how to fulfill them, review of policies and procedures, job descriptions, competency evaluations, and performance expectations. An orientation program and documented competency evaluation and/or job expectations of assigned or reassigned duties shall be conducted prior to any assignments or reassignments.

D. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2120 (August 2022), amended LR 49:

§6769. Staffing Requirements

A. Administrative Staff. The following administrative staff is required for all FSBCs:

1. a qualified administrator at each licensed geographic location who shall meet the qualifications as established in these provisions; and

2. other administrative staff as necessary to operate the FSBC and to properly safeguard the health, safety, and welfare of the clients receiving services.

3. Repealed.

B. - B.2. ...

3. The administrator shall meet the following qualifications:

a. possess a college degree from an accredited university; or

b. have three years of relevant work experience involving administrative duties in a healthcare facility.

B.4. - D.9. ...

E. Licensed Healthcare Practitioner Staff

1. The FSBC shall have an organized licensed healthcare practitioner staff, inclusive of one or more of the following, who shall attend each woman in labor from the time of admission through birth, and the immediate postpartum period:

E.1.a. - F.1. ...

2. The FSBC shall ensure that the delivery services are directed under the leadership of licensed healthcare practitioner(s) sufficient in number, to plan, assign, supervise, and evaluate delivery services, as well as to give clients the high-quality care that requires the judgment and specialized skills of licensed healthcare practitioners.

2.a. - 3....

4. A formalized program on in-service training shall be developed and implemented for all categories of the FSBC. Training shall be required on a quarterly basis related to required job skills.

a. Documentation of such in-service training shall be maintained on-site in the FSBC's files. Documentation shall include the:

- i. training content;
- ii. date and time of the training;
- iii. names and signatures of personnel in attendance; and
- iv. name of the presenter(s).

5. General staffing provisions for the delivery rooms shall be the following:

a. each delivery procedure shall be performed by a licensed healthcare practitioner; and

i. - iv. Repealed.

b. appropriately trained qualified personnel may perform assistive functions during each delivery procedure.

6. - 6.b.Repealed.

G. - G.4.g. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2120 (August 2022), amended LR 49:

§6773. Clinical Records

A. - F. ...

G. The following data shall be documented and included as part of each client's basic clinical record:

1. - 16.d. ...

17. name(s) of the treating licensed healthcare practitioner(s);

G.18. - K.2. ...

L. All pertinent observations, treatments, and medications given to a client shall be entered in the staff notes as part of the clinical record. All other notes relative to specific instructions from the licensed healthcare practitioner shall be recorded.

M. - P. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2122 (August 2022), amended LR 49:

Subchapter F. Safety, Sanitization and Emergency Preparedness

§6781. Infection Control

A. - G. ...

1. Employees with symptoms of illness that have the potential of being potentially contagious or infectious (i.e. diarrhea, skin lesions, respiratory symptoms, infections, etc.) shall be either evaluated by a physician or another qualified licensed healthcare practitioner and/or restricted from working with clients during the infectious stage.

H. - L. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2124 (August 2022), amended LR 49:

Subchapter G. Physical Environment

§6793. General Requirements

A. - E. ...

F. Waivers

1. The secretary of the department or their designee may, within their sole discretion, grant waivers to building and construction guidelines. The facility shall submit a waiver request in writing to the HSS. The facility shall demonstrate how patient safety and the quality of care offered is not compromised by the waiver. The facility shall demonstrate their ability to completely fulfill all other requirements of the service. The department will make a written determination of the request. Waivers are not transferable in an ownership change, and are subject to review or revocation upon any change in circumstances related to the waiver. The facility does not have the right to an administrative appeal in regards to the denial or revocation of any waiver.

2. - 3. Repealed.

G. Facility within a Facility

1. If more than one healthcare provider occupies the same building, premises, or physical location, all treatment facilities and administrative offices for each healthcare facility shall be clearly separated from the other by a clearly defined and recognizable boundary.

2. There shall be clearly identifiable and distinguishable signs posted inside the building as well as signs posted on the outside of the building for public identification of the FSBC. Compliance with the provisions of R.S. 40:2007 shall be required.

3. An FSBC that is located within a building that is also occupied by one or more other businesses and/or other healthcare facilities shall have all licensed spaces and rooms of the FSBC contiguous to each other and defined by cognizable boundaries.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2127 (August 2022), amended LR 49:

§6795. General Appearance and Space Requirements

A. - F. ...

G. The FSBC shall meet the following requirements including, but not limited to:

1. - 5. ...

6. each FSBC shall provide for a well-marked, illuminated entrance for drop off and/or pick up of clients before and after delivery services are complete.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2128 (August 2022), amended LR 49:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have no impact on family

functioning, stability and autonomy as described in R.S. 49:972.

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973.

Small Business Analysis

In compliance with the Small Business Protection Act, the economic impact of this proposed Rule on small businesses has been considered. It is anticipated that this proposed Rule may have a positive impact on small businesses by ensuring that the administrative Rule governing free-standing birth centers aligns with current requirements for licensure.

Provider Impact Statement

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, and will have no impact on the provider's ability to provide the same level of service as described in HCR 170.

Public Comments

Interested persons may submit written comments to Tasheka Dukes, RN, Health Standards Section, P.O. Box 3767, Baton Rouge, LA 70821. Ms. Dukes is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on January 30, 2023.

Public Hearing

Interested persons may submit a written request to conduct a public hearing by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on January 9, 2023. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on January 26, 2023 in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after January 9, 2023. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage, which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Dr. Courtney N. Phillips
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Free-Standing Birth Centers Licensing Standards

- I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)
It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 22-23. It is anticipated that \$2,376 will be expended in FY 22-23 for the state's administrative expense for promulgation of this proposed rule and the final rule.
- II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)
It is anticipated that the implementation of this proposed rule will have no effect on revenue collections since the fees from currently licensed providers will continue to be collected in the same amounts.
- III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS (Summary)
This proposed rule amends the provisions governing the licensing of free-standing birth centers (FSBCs) in order to: 1) add and update definitions; 2) clarify licensing requirements and responsibilities of the governing board; 3) modify education and training requirements of personnel; and, 4) update FSBC service delivery requirements. Implementation of this proposed rule is not anticipated to result in costs to FSBCs for FY 22-23, FY 23-24, and FY 24-25, but will be beneficial for these providers by ensuring that the provisions in the Louisiana Administrative Code align with current requirements for licensure.
- IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)
This rule has no known effect on competition and employment.

Tasheka Dukes, RN
Deputy Assistant Secretary
2212#047

Alan M. Boxberger
Interim Legislative Fiscal Officer
Legislative Fiscal Office

Veronica Dent

From: Cynthia York
Sent: Monday, February 6, 2023 2:16 PM
To: Scott Kirkpatrick
Cc: Tasheka Dukes; Veronica Dent; Jennifer Haines (LDH); William Whatley; Christina Robertson; Cynthia York; Kimberly Humbles; Kimberly Sullivan; Allen Enger (LDH)
Subject: LAC: 48.I.Chapter 67 - Free-Standing Birth Center Licensing Standards Notice of Intent - published December 20, 2022
Attachments: FSBC public comment response letter 1.31.23.pdf

Mr. Kirkpatrick:

On behalf of Ms. Tasheka Dukes, Health Standards Section Deputy Assistant Secretary, please find attached a response to the comments that you submitted regarding the Free-Standing Birth Center Licensing Standards Notice of Intent.

Please let me know if you have any questions,

Best regards,

Cynthia York

Cynthia York, DNP, RN, MCPM, FRE
Health Standards Section, Rulemaking Liaison
Fellow, NCSBN Institute of Regulatory Excellence
Louisiana Department of Health
628 North 4th Street
Baton Rouge, LA 70802
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From: Scott Kirkpatrick <scott@pelicanstate.com>
Sent: Monday, January 30, 2023 5:16 PM
To: takesha.dukes@la.gov

Cc: Cynthia York <Cynthia.York@LA.GOV>

Subject: Free-Standing Birth Center Rule

EXTERNAL EMAIL: Please do not click on links or attachments unless you know the content is safe.

Please see the comments below regarding the Free Standing Birth Center Rule sent on behalf of birth centers across the state:

In Section 6709 regarding the initial licensure application process, B(5)(c) and Section 6717A(6)(c) - the professional liability requirements are overly burdensome. The level of coverage required for the FSBCs is unnecessarily high and appears to be above what is required of similarly situated facilities. The Patient Compensation Fund coverage quotes for FSBCs are robust, particularly for smaller FSBCs, some of which have less than \$200,000 in gross annual revenues. At the same time, not all FSBCs are able to receive quotes for the alternative \$1,000,000 per occurrence/\$3,000,000 annual aggregate. A lower professional liability requirement would be appropriate, while still ensuring adequate professional liability coverage.

Also, in both 6709 and 6717, the general liability requirement of at least \$300,000 per occurrence is overly burdensome. Available insurance quotes are \$100,000 per occurrence or \$500,000 per occurrence. Therefore, the current rule requirement effectively requires \$500,000 per occurrence with an accompanying large annual premium. A lower general liability requirement would be more appropriate.

Finally, regarding Standard 6743: Prohibitions to Admission or Continued Care in an FSBC - particularly regarding women who have had prior cesarean sections, we continue to object to the VBAC prohibitions. Of note, certified nurse midwives are advanced practice nurses who are capable of providing prenatal care to women who have had prior cesarean sections. Some midwives have privileges in local hospitals and are credentialed to perform VBACs on women in hospitals. Even if current guidelines preclude them from delivering VBAC patients in a birth center/out of hospital setting, the guidelines should not preclude them from performing services within their scope of practice. In effect, the proposed FSBC guidelines concerning VBACs overstep its authority in taking away the ability of the certified nurse midwife to provide VBAC care in a hospital setting, just because their clinic is in a birth center.

Thank you for your attention to these comments.

Sincerely,

Scott Kirkpatrick

John Bel Edwards
GOVERNOR



Dr. Courtney N. Phillips
SECRETARY

State of Louisiana
Louisiana Department of Health
Bureau of Health Services Financing

February 1, 2023

Mr. Scott Kirkpatrick
Pelican State Partners
504 Lakeland Drive
Baton Rouge, LA 70802

**RE: Notice of Intent for Free-Standing Birth Center Licensing Standards
(LAC 48:I.Chapter 67)**

Dear Mr. Kirkpatrick:

This letter is in response to your correspondence regarding the Notice of Intent (NOI) for Free-Standing Birth Center (FSBC) licensing standards, which was published in the December 20, 2022 edition of the *Louisiana Register*.

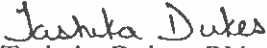
The NOI proposed revisions to the minimum licensing standards for FSBCs to update/add definitions; to clarify licensing requirements and the responsibilities of the governing board; to modify education and training requirements of personnel; and to update FSBC service delivery requirements. After thoroughly reviewing and giving due consideration to your concerns, the decision has been made to continue with the provisions of the December 20, 2022 NOI as published in the *Louisiana Register*.

We appreciate your willingness to provide comments regarding the amendments to the licensing provisions for FSBCs, and hope that you will continue to work with us as we strive to improve healthcare outcomes for Louisiana citizens.

Mr. Scott Kirkpatrick
Pelican State Partners
February 1, 2023
Page 2

Should you have any questions or comments regarding Medicaid administrative rulemaking activity or rulemaking activity relative to healthcare licensing standards, you may contact Ms. Veronica Dent, Medicaid Program Manager, at 225-342-3238 or by email to Veronica.Dent@la.gov.

Sincerely,


Tasheka Dukes, RN
Deputy Assistant Secretary
LDH Health Standards Section

TD/KHB/VYD

cc: Kelly Zimmerman
Kimberly Humbles



State of Louisiana
Louisiana Department of Health
Office of the Secretary

February 8, 2023

Via Statutorily Prescribed Email

To: The Honorable Fred H. Mills, Jr., Chairman, Senate Health & Welfare Committee
The Honorable Larry Bagley, Chairman, House Health & Welfare Committee

From: Dr. Courtney N. Phillips
Secretary

A handwritten signature in blue ink, appearing to read "C. Phillips", written over the printed name of the Secretary.

Re: Second Report to LAC 50:XXI.2301 – Home and Community-Based Services
Waivers – Adult Day Health Care Waiver – Assistive Technology Services

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Bureau of Health Services Financing, submits its second report regarding the Home and Community-Based Services Waivers – Adult Day Health Care Waiver Assistive Technology Services, LAC 50:XXI.2301.

A Notice of Intent on the proposed amendments was published in the December 20, 2022 issue of the *Louisiana Register* (LR 48:3028). No written comments were received and there was no request for a public hearing were received during the notice period. Because there were no requests for a public hearing, one was not held for these proposed amendments. Additionally, no substantive changes were made to the proposed amendments since the report provide for in R.S. 49:966B-C was submitted.

Unless otherwise directed, the Department anticipates adopting the December 20, 2022, Notice of Intent when it is published as a final rule in the March 20, 2023, issue of the *Louisiana Register*.

Please contact Layne Janet, Layne.Janet@la.gov, if you have any questions or require additional information about this matter.

Cc: Tara LeBlanc, Medicaid Director, LDH
Melinda Richard, OAAS Assistant Secretary, LDH
Kirsten Clebert, OAAS Policy Division Director, LDH
Veronica Dent, Medicaid Program Manager, LDH
Bethany Blackson, Legislative Liaison, LDH
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

NOTICE OF INTENT
Department of Health
Bureau of Health Services Financing
and
Office of Aging and Adult Services

Home and Community-Based Services Waivers
Adult Day Health Care Waiver
Assistive Technology Services
(LAC 50:XX1.2301)

The Department of Health, Bureau of Health Services Financing and the Office of Aging and Adult Services propose to amend LAC 50:XX1.2301 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

The U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) authorized funding under section 9817 of the American Rescue Plan Act of 2021 (ARPA) to expand and enhance services provided to home and community-based services waiver participants in the Medicaid program.

The Department of Health, Bureau of Health Services Financing and the Office of Aging and Adult Services promulgated an Emergency Rule which amended the provisions governing the Adult Day Health Care (ADHC) Waiver in order to add assistive technology as a covered service, as authorized under section 9817 of ARPA (*Louisiana Register*, Volume 48, Number 12). This proposed Rule continues the provisions of the November 18, 2022 Emergency Rule.

Title 50

PUBLIC HEALTH-MEDICAL ASSISTANCE Part XXI. Home and Community-Based Services Waivers

Subpart 3. Adult Day Health Care Waiver

Chapter 23. Services

§2301. Covered Services

A. - A.3.b. ...

c. Support coordinators may assist participants to transition for up to six months while the participants still reside in the facility.

4. ...

a. Allowable expenses are those necessary to enable the individual to establish a basic household (excluding expenses for room and board) including, but not limited to:

i. ...

ii. specific set up fees or deposits;

a.iii. - e. ...

f. Funds are available for specific items up to the lifetime maximum amount identified in the federally-approved waiver document.

5. Assistive Technology. These services include the following:

a. an item, piece of equipment, or product system, acquired commercially, that is used to increase, maintain, or improve functional capabilities of participants; and

b. the assistance provided to the participant in the acquisition, set up, and use of an assistive technology device:

i. evaluating to determine if an assistive technology device is appropriate for the participant;

ii. purchasing the most appropriate assistive technology device for the participant; and

iii. costs associated with the delivery, set up, and training.

B. - E. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Family Security. LR 11:623 (June 1985), amended LR 13:181 (March 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing. LR 23:1149 (September 1997), amended LR 25:1100 (June 1999), repromulgated LR 30:2036 (September 2004), amended by the Department of Health and Hospitals, Office of Aging and Adult Services. LR 34:2162 (October 2008), repromulgated LR 34:2566 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult

Services. LR 37:2625 (September 2011), LR 39:2495 (September 2013), LR 40:791 (April 2014), amended by the Department of Health, Bureau of Health Services Financing and the Office of Aging and Adult Services. LR 44:2163 (December 2018), LR 49:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have a positive impact on family functioning, stability and autonomy as described in R.S. 49:972 by providing assistive technology to improve the quality of life for ADHC waiver participants by allowing them to participate in their healthcare decisions and socialize with others virtually.

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have a positive impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973 by providing assistive technology to participants who would otherwise not have access to these services.

Small Business Analysis

In compliance with the Small Business Protection Act, the economic impact of this proposed Rule on small businesses has been considered. It is anticipated that this proposed Rule will have a positive impact on small businesses by providing reimbursement for a service that was previously not covered.

Provider Impact Statement

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, but may reduce the total direct and indirect cost to the provider to provide the same level of service, and may enhance the provider's ability to provide the same level of service as described in HCR 170 since this proposed Rule provides reimbursement for a service that was previously not covered.

Public Comments

Interested persons may submit written comments to Tara A. LeBlanc, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. Ms. LeBlanc is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on January 30, 2023.

Public Hearing

Interested persons may submit a written request to conduct a public hearing by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on January 9, 2023. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on January 26, 2023 in Room 118 of the Bienville Building,

which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after January 9, 2023. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage, which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Dr. Courtney N. Phillips
Secretary

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**
**RULE TITLE: Home and Community-Based Services
Waivers—Adult Day Health Care Waiver
Assistive Technology Services**

**I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO
STATE OR LOCAL GOVERNMENT UNITS (Summary)**

It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 22-23. It is anticipated that \$648 (\$324 SGF and \$324 FED) will be expended in FY 22-23 for the state's administrative expense for promulgation of this proposed rule and the final rule.

**II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE
OR LOCAL GOVERNMENTAL UNITS (Summary)**

It is anticipated that implementation of this proposed rule will increase federal revenue collections by approximately \$41,294 for FY 22-23, \$40,970 for FY 23-24, and \$0 for FY 24-25. The funding for these services is authorized under section 9817 of the American Rescue Plan Act of 2021 (ARPA) through March 31, 2025 or until it is exhausted. It is anticipated that \$324 will be collected for the federal share in FY 22-23 of the expense for promulgation of the proposed and final rule.

**III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO
DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR
NONGOVERNMENTAL GROUPS (Summary)**

This proposed rule continues the provisions of the November 18, 2022 Emergency Rule, which amended the provisions governing the Adult Day Health Care (ADHC) Waiver in order to add assistive technology as a covered service, as authorized under section 9817 of the American Rescue Plan Act of 2021 (ARPA). This proposed rule will benefit ADHC waiver participants who would otherwise not have access to virtual technology by providing iPads/Tablets and Kindles to allow them to participate in their healthcare decisions and socialize with others virtually to improve their quality of life. Providers of ADHC waiver services will benefit from this proposed rule since it provides reimbursement for a service that was previously not covered. It is anticipated that this proposed rule will increase payments to ADHC providers by approximately \$40,970 for FY 22-23, \$40,970 for FY 23-24, and \$0 for FY 24-25.

**IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT
(Summary)**

This rule has no known effect on competition and employment.

Tara A. LeBlanc
Medicaid Executive Director
2212#048

Alan M. Boxberger
Interim Legislative Fiscal Officer
Legislative Fiscal Office



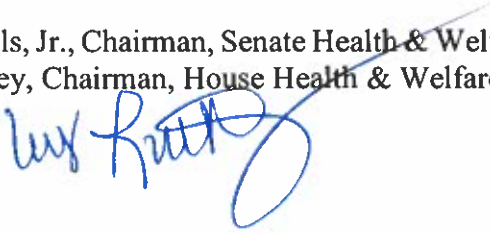
State of Louisiana

Louisiana Department of Health
Office of the Secretary

February 8, 2023

Via Statutorily Prescribed Email

To: The Honorable Fred H. Mills, Jr., Chairman, Senate Health & Welfare Committee
The Honorable Larry Bagley, Chairman, House Health & Welfare Committee

From: Dr. Courtney N. Phillips
Secretary 

Re: Second Report to LAC 50:XXI.Chapter 83 and 9501 – Home and Community-Based Services Waivers – Community Choices Waiver – Home Delivered Meals and Assistive Technology

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Bureau of Health Services Financing, submits its second report regarding the Home and Community-Based Services Waivers – Community Choices Waiver – Home Delivered Meals and Assistive Technology, LAC 50: Chapter 83 and 9501.

A Notice of Intent on the proposed amendments was published in the December 20, 2022 issue of the *Louisiana Register* (LR 48:3030). No written comments were received and there was no request for a public hearing were received during the notice period. Because there were no requests for a public hearing, one was not held for these proposed amendments. Additionally, no substantive changes were made to the proposed amendments since the report provide for in R.S. 49:966B-C was submitted.

Unless otherwise directed, the Department anticipates adopting the December 20, 2022, Notice of Intent when it is published as a final rule in the March 20, 2023, issue of the *Louisiana Register*.

Please contact Layne Janet, Layne.Janet@la.gov, if you have any questions or require additional information about this matter.

Cc: Tara LeBlanc, Medicaid Director, LDH
Melinda Richard, OAAS Assistant Secretary, LDH
Kirsten Clebert, OAAS Policy Division Director, LDH
Veronica Dent, Medicaid Program Manager, LDH
Bethany Blackson, Legislative Liaison, LDH
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

NOTICE OF INTENT

**Department of Health
Bureau of Health Services Financing
and
Office of Aging and Adult Services**

Home and Community-Based Services Waivers
Community Choices Waiver
Home Delivered Meals and Assistive Technology Services
(LAC 50:XXI.Chapter 83 and 9501)

The Department of Health, Bureau of Health Services Financing and the Office of Aging and Adult Services propose to amend LAC 50:XXI.Chapter 83 and §9501 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

The U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) authorized funding under section 9817 of the American Rescue Plan Act of 2021 (ARPA) to expand and enhance services provided to home and community-based services waiver participants in the Medicaid program.

The Department of Health, Bureau of Health Services Financing and the Office of Aging and Adult Services promulgated an Emergency Rule, which amended the provisions governing the Community Choices Waiver (CCW) in order to add medically tailored meals and assistive technology as covered services, as authorized under section 9817 of ARPA (*Louisiana Register*, Volume 48, Number 12). This proposed Rule continues the provisions of the November 18, 2022 Emergency Rule.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE

**Part XXI. Home and Community-Based Services
Waivers**

Subpart 7. Community Choices Waiver

Chapter 83. Covered Services

§8307. Personal Assistance Services

A. - C. ...

D. PAS may be provided through the “a.m.” and “p.m.” delivery option defined as follows:

1. ...

2. a minimum of one hour and a maximum of two hours of PAS provided to assist the participant at the end of

his/her day, referred to as the "p.m." portion of this PAS delivery method; and

3. - 4. ...

5. "a.m. and p.m." PAS cannot be "shared";

D.6. - K. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:3519 (December 2011), amended LR 39:320 (February 2013), LR 39:1778 (July 2013), LR 40:791 (April 2014), amended by the Department of Health, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 44:1898 (October 2018), LR 47:885 (July 2021), LR 49:

§8317. Home Delivered Meals

A. - C. ...

D. Medically tailored meals (MTMs) may be delivered to participants with chronic conditions when discharging from the hospital and/or nursing facility. In addition, participants will receive nutritional guidance to support healthy food choices for their third meal and snacks.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:3522 (December 2011), amended by the Department of Health, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 49:

§8331. Assistive Technology

A. Assistive technology services include the following:

1. an item, piece of equipment or product system, acquired commercially, that is used to increase, maintain or improve functional capabilities of participants; and

2. the assistance provided to the participant in the acquisition, set up and use of an assistive technology device:

a. evaluating to determine if an assistive technology device is appropriate for the participant;

b. purchasing the most appropriate assistive technology device for the participant; and

c. costs associated with the delivery, set up, and training.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 49:

Chapter 95. Reimbursement

§9501. Reimbursement and Rate Requirements

A. - A.6. ...

B. The following services shall be reimbursed at the authorized rate or approved amount of the assessment, inspection, installation/fitting, maintenance, repairs, adaptation, device, equipment, or supply item and when the service has been prior authorized by the plan of care:

1. - 5. ...

6. monitored in-home caregiving (MIHC) assessment;

7. certain nursing, and skilled maintenance therapy procedures; and

8. assistive technology.

C. - H. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:3525 (December 2011), amended LR 39:322 (February 2013), LR 39:508, 508 (March 2013), repromulgated LR 39:1048 (April 2013), amended LR 39:1779 (July 2013), LR 40:793 (April 2014), LR 42:897 (June 2016), amended by the Department of Health, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 44:1902 (October 2018), LR 47:886 (July 2021), LR 49:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have a positive impact on family functioning, stability and autonomy as described in R.S. 49:972 by providing medically tailored meals to CCW participants to improve their health and decrease hospitalizations, and assistive technology to improve their quality of life by allowing them to participate in their healthcare decisions and socialize with others virtually.

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have a positive impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973, by providing low-cost, specialized meals to CCW participants to improve their health and decrease hospitalizations, and assistive technology to those who would otherwise not have access to these services.

Small Business Analysis

In compliance with the Small Business Protection Act, the economic impact of this proposed Rule on small businesses has been considered. It is anticipated that this proposed Rule will have a positive impact on small businesses by providing reimbursement for services that were previously not covered.

Provider Impact Statement

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, but may reduce the total direct and indirect cost to the provider to provide the same level of service, and may enhance the provider's ability to provide the same level of service as described in HCR 170 since this proposed Rule provides reimbursement for services that were previously not covered.

Public Comments

Interested persons may submit written comments to Tara A. LeBlanc, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. Ms. LeBlanc is responsible for responding to inquiries regarding this

proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on January 30, 2023.

Public Hearing

Interested persons may submit a written request to conduct a public hearing by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on January 9, 2023. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on January 26, 2023 in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after January 9, 2023. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage, which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Dr. Courtney N. Phillips
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

**RULE TITLE: Home and Community-Based Services
Waivers—Community Choices Waiver
Home Delivered Meals and Assistive Technology
Services**

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 22-23. It is anticipated that \$864 (\$432 SGF and \$432 FED) will be expended in FY 22-23 for the state's administrative expense for promulgation of this proposed and final rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that implementation of this proposed rule will increase federal revenue collections by approximately \$1,013,062 for FY 22-23, \$899,230 for FY 23-24, and \$0 for FY 24-25. The funding for these services is authorized under section 9817 of the American Rescue Plan Act of 2021 (ARPA) through March 31, 2025 or until it is exhausted. It is anticipated that \$432 will be collected for the federal share of the expense for promulgation of the proposed and final rule.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS (Summary)

This proposed rule continues the provisions of the November 18, 2022 Emergency Rule, which amended the provisions governing the Community Choices Waiver (CCW) in order to add medically tailored meals and assistive technology as covered services, as authorized under section 9817 of the American Rescue Plan Act of 2021 (ARPA). This proposed rule will benefit CCW participants by providing low-cost, specialized meals to improve their health and decrease hospitalizations. The proposed rule also provides iPads/Tablets

and Kindles to participants who otherwise would not have access to virtual technology, which will allow them to participate in their healthcare decisions and socialize with others virtually to improve their quality of life. Providers of CCW services will benefit from this proposed rule since it provides reimbursement for services that were previously not covered. It is anticipated that implementation of this proposed rule will increase payments to CCW providers by approximately \$1,012,630 for FY 22-23, \$899,230 for FY 23-24, and \$0 for FY 24-25.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Tara A. LeBlanc
Medicaid Executive Director
2212#049

Alan M. Boxberger
Interim Legislative Fiscal Officer
Legislative Fiscal Office



State of Louisiana
Louisiana Department of Health
Office of the Secretary

February 8, 2023

Via Statutorily Prescribed Email

To: The Honorable Fred H. Mills, Jr., Chairman, Senate Health & Welfare Committee
The Honorable Larry Bagley, Chairman, House Health & Welfare Committee
The Honorable Chairman Mack "Bodi" White, Senate Finance Committee
The Honorable Chairman Jerome Zeringue, House Appropriations Committee

From: Dr. Courtney N. Phillips
Secretary

A handwritten signature in blue ink, appearing to read "C. Phillips", is written over the "From:" field.

Re: Second Report to LAC 50:V.119 – Inpatient Hospital Services – Coverage of Genetic Testing of Critically Ill Infants

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Bureau of Health Services Financing, submits its second report regarding the Inpatient Hospital Services – Coverage of Genetic Testing of Critically Ill Infants, LAC 50:V.119.

A Notice of Intent on the proposed amendments was published in the December 20, 2022 issue of the *Louisiana Register* (LR 48:3032). No written comments were received and there was no request for a public hearing were received during the notice period. Because there were no requests for a public hearing, one was not held for these proposed amendments. Additionally, no substantive changes were made to the proposed amendments since the report provide for in R.S. 49:966B-C was submitted.

Unless otherwise directed, the Department anticipates adopting the December 20, 2022, Notice of Intent when it is published as a final rule in the March 20, 2023, issue of the *Louisiana Register*.

Please contact Amanda Dumas, Amanda.Dumas@la.gov, if you have any questions or require additional information about this matter.

Cc: Tara LeBlanc, Medicaid Director, LDH
Daniel Cocran, Medicaid Deputy Director, LDH
Tizi Robinson, Medicaid Program Manager, LDH
Debbie Gough, Medicaid Program Manager, LDH
Veronica Dent, Medicaid Program Manager, LDH
Bethany Blackson, Legislative Liaison, LDH
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

NOTICE OF INTENT

**Department of Health
Bureau of Health Services Financing**

**Inpatient Hospital Services
Coverage of Genetic Testing of Critically Ill Infants
(LAC 50:V.119)**

The Department of Health, Bureau of Health Services Financing proposes to adopt LAC 50:V.119 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Act 501 of the 2022 Regular Session of the Louisiana Legislature requires the Department of Health to provide coverage for genetic testing of critically ill infants participating in the Medical Assistance Program. In compliance with Act 501, the Department of Health, Bureau of Health Services Financing proposes to adopt provisions governing coverage of genetic testing of critically ill infants and to provide Medicaid reimbursement outside of the inpatient hospital per diem.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE

Part V. Hospital Services

Subpart 1. Inpatient Hospitals Services

Chapter 1. General Provisions

§119. Coverage of Genetic Testing of Critically Ill Infants

A. Pursuant to Act 501 of the 2022 Regular Session of the Louisiana Legislature, effective for dates of service on or after January 1, 2023, the Medicaid Program shall provide reimbursement to inpatient hospitals for rapid whole genome sequencing testing of a Medicaid enrolled infant who meets all of the following criteria:

1. is one year of age or younger;
2. has a complex illness of unknown etiology; and
3. is receiving inpatient hospital services in an intensive care unit or in a pediatric care unit.

B. For the purposes of this Section, rapid whole genome sequencing testing includes individual sequencing, trio sequencing of the parents of the infant, and ultra-rapid sequencing.

C. Reimbursement. Reimbursement will be made as an add-on service in addition to the hospital payment for the inpatient hospital stay.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 49:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have a positive impact on family functioning, stability and autonomy as described in R.S. 49:972, as it provides access to genetic testing, which may result in faster diagnosis for beneficiaries with rare conditions and allow parents to join physicians in making informed care decisions to avoid unnecessary additional testing and treatments.

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have a positive impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973, as it provides reimbursement for genetic testing that may result in faster diagnosis of rare conditions and avoid unnecessary additional testing and treatments, and other costly procedures.

Small Business Analysis

In compliance with the Small Business Protection Act, the economic impact of this proposed Rule on small businesses has been considered. It is anticipated that this proposed Rule will have no impact on small businesses.

Provider Impact Statement

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, but may reduce the total direct and indirect cost to the provider to provide the same level of service, and may enhance the provider's ability to provide the same level of service as described in HCR 170, since this proposed rule provides reimbursement outside of the inpatient hospital per diem for genetic testing of hospitalized infants.

Public Comments

Interested persons may submit written comments to Tara A. LeBlanc, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. Ms. LeBlanc is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on January 30, 2023.

Public Hearing

Interested persons may submit a written request to conduct a public hearing by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on January

9, 2023. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on January 26, 2023 in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after January 9, 2023. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage, which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Dr. Courtney N. Phillips
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Inpatient Hospital Services Coverage of Genetic Testing of Critically Ill Infants

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

It is anticipated that the implementation of this proposed rule will result in estimated state programmatic costs of approximately \$913,770 for FY 22-23, \$1,161,679 for FY 23-24, and \$1,339,617 for FY 24-25. It is anticipated that \$540 (\$270 SGF and \$270 FED) will be expended in FY 22-23 for the state's administrative expense for promulgation of this proposed rule and the final rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that the implementation of this proposed Rule will increase statutory dedicated revenue collections from the Medical Assistance Trust Fund by approximately \$61,168 for FY 22-23, \$194,119 for FY 23-24, and \$223,598 for FY 24-25. In addition, it is anticipated that the implementation of this proposed rule will increase federal revenue collections by approximately \$2,190,745 for FY 22-23, \$2,420,433 for FY 23-24, and \$2,791,178 for FY 24-25. It is anticipated that \$270 will be collected in FY 22-23 for the federal share of the expense for promulgation of this proposed rule and the final rule.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS (Summary)

This proposed rule adopts provisions governing coverage of genetic testing of critically ill infants participating in the Medical Assistance Program and provides Medicaid reimbursement outside of the inpatient hospital per diem, in compliance with Act 501 of the 2022 Regular Session of the Louisiana Legislature. Implementation of this proposed rule will provide access to genetic testing which may result in faster diagnosis for beneficiaries with rare conditions and allow parents to join physicians in making informed care decisions to avoid unnecessary additional testing and treatments. Implementation of this proposed rule is anticipated to increase payments for inpatient hospital services by \$3,103,975 for FY 22-23, \$3,582,112 for FY 23-24, and \$4,130,795 for FY 24-25, for genetic testing of critically ill infants.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT
(Summary)

This rule has no known effect on competition and employment.

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