



State of Louisiana
Louisiana Department of Health
Office of the Secretary

June 9, 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: Stephen R. Russo, JD
Secretary

Re: Second Report to LAC 48:1.401 – List of Conditions that Shall Deem an Unborn Child “Medically Futile”

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Office of Public Health, submits its second report regarding the List of Conditions that Shall Deem an Unborn Child “Medically Futile”, LAC 48:1.401.

A Notice of Intent on the proposed amendments was published in the September 20, 2022 issue of the *Louisiana Register* (LR 49:2445). Written comments were received and there was a public hearing held on October 25, 2022. 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 September 20, 2022, Notice of Intent when it is published as a final rule in the July 20, 2023, issue of the *Louisiana Register*.

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

Cc: Joseph Kanter, MD, MPH, State Health Officer
Doris Brown, OPH Assistant Secretary, LDH
Aliya Rubenstein, OPH Rulemaking Liaison, LDH
Bethany Blackson, Legislative Liaison, LDH
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

49:972 by ensuring continued provider participation in the Medicaid Program.

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 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 increases payments to providers for the services they already render.

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 October 31, 2022.

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 October 10, 2022. 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 October 27, 2022 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 October 10, 2022. 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: Targeted Case Management Reimbursement Methodology Workforce Retention Bonus Payments

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

It is anticipated that implementation of this proposed rule will have state programmatic fiscal costs of approximately \$252,896 for FY 22-23 and \$103,392 for FY 23-24. It is anticipated that \$756 (\$378 SGF and \$378 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 \$562,960 for FY 22-23 and \$210,108 for FY 23-24. It is anticipated that \$378 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 OR NONGOVERNMENTAL GROUPS (Summary)

This proposed rule continues the provisions of the July 31, 2022 Emergency Rule which established workforce retention bonus payments for targeted case management (TCM) provided to the early and periodic screening, diagnosis and treatment (EPSDT) population and New Opportunities Waiver (NOW) participants, along with audit procedures and sanctions. The U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) approved the use of bonus payments under Section 9817 of the American Rescue Plan Act of 2021. These increased payments will ensure that TCM providers continue rendering services to EPSDT beneficiaries and NOW participants in the Medicaid Program. Implementation of this proposed rule is anticipated to increase expenditures for TCM services by approximately \$815,100 for FY 22-23 and \$313,500 for FY 23-24.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Tara A. LeBlanc
Medicaid Executive Director
2209#055

Alan M. Boxberger
Interim Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health Office of Public Health

List of Conditions that Shall Deem an Unborn Child "Medically Futile" (LAC 48:I.401)

Under the authority of R.S. 14:87.1, and in accordance with R.S. 49:950 et seq., the Administrative Procedure Act, notice is hereby given that the Louisiana Department of Health, Office of Public Health (LDH-OPH), intends to promulgate the following Section in LAC 48:I.Chapter 4. As required by Act 545 of the 2022 regular session of the Louisiana Legislature, the following Rule establishes the

exclusive list of anomalies, diseases, disorders, and other conditions that shall deem an unborn child “medically futile” for purposes of R.S. Title 14, Chapter 1, Part V, Subpart A.

Title 48

PUBLIC HEALTH—GENERAL

Part I. General Administration

Subpart 1. General

Chapter 4. Medically Futile Pregnancies

§401. Conditions that Shall Deem an Unborn Child “Medically Futile”

A. Pursuant to Act 545 of the 2022 regular session of the Louisiana Legislature, the Department of Health establishes the following exclusive list of anomalies, diseases, disorders, and other conditions that shall deem an unborn child “medically futile” for purposes of R.S. Title 14, Chapter 1, Part V, Subpart A:

1. achondrogenesis;
2. acrania;
3. anencephaly;
4. arcadia;
5. body stalk anomaly;
6. campomelic dysplasia;
7. craniorachischisis;
8. dysencephalia splanchnocystica (Meckel-Gruber syndrome);
9. ectopia cordis;
10. exencephaly;
11. gestational trophoblastic neoplasia;
12. holoprosencephaly;
13. hydrops fetalis;
14. iniencephaly;
15. perinatal hypophosphatasia;
16. osteogenesis imperfecta (type 2);
17. renal agenesis (bilateral);
18. short rib polydactyly syndrome;
19. sirenomelia;
20. thanatophoric dysplasia;
21. triploidy;
22. trisomy 13;
23. trisomy 16 (full);
24. trisomy 18;
25. trisomy 22; and
26. a profound and irremediable congenital or chromosomal anomaly existing in the unborn child that is incompatible with sustaining life after birth in reasonable medical judgment as certified by two physicians that are licensed to practice in the State of Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 14:87.1

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:

Family Impact Statement

The proposed Rule should not have any known or foreseeable impact on family formation, stability, and autonomy. In particular, the proposed Rule has no known or foreseeable impact on:

1. the stability of the family;
2. the authority and rights of persons regarding the education and supervision of their children;

3. the functioning of the family;
4. family earnings and family budget;
5. the behavior and personal responsibility of children;
6. the ability of the family or a local government to perform the function as contained in the proposed Rule.

Poverty Impact Statement

The proposed Rule should not have any known or foreseeable impact on any child, individual or family as defined by R.S. 49:973(B). In particular, there should be no known or foreseeable effect on:

1. the effect on household income, assets, and financial security;
2. the effect on early childhood development and preschool through postsecondary education development;
3. the effect on employment and workforce development;
4. the effect on taxes and tax credits;
5. the effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

Small Business Analysis

The proposed Rule should have no adverse impact on small businesses as defined in the Regulatory Flexibility Act.

Provider Impact Statement

The proposed Rule should not have any known or foreseeable impact on providers as defined by HCR 170 of the 2014 Regular Legislative Session. In particular, there should be no known or foreseeable effect on:

1. the effect on the staffing level requirements or qualifications required to provide the same level of service;
2. the total direct and indirect effect on the cost to the providers to provide the same level of service; or
3. the overall effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments on the proposed Rule. Such comments must be received no later than Tuesday, October 25, 2022 at COB, 4:30 pm, and should be addressed to David McCay, Louisiana Department of Health, P.O. Box 629, Baton Rouge, LA 70802.

Public Hearing

Interested persons may submit a written request to conduct a public hearing either 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 Monday, October 10, 2022. If the criteria set forth in R.S. 49:961(B)(1) are satisfied, LDH will conduct a public hearing at 9:00 a.m. on October 25, 2022 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 October 10, 2022. 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: List of Conditions that Shall
Deem an Unborn Child "Medically Futile"**

- I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)
The Louisiana Department of Health will incur \$213 SGF in expenses associated with the publication of this proposed rule change.
In accordance with Act 545 of the 2022 RLS, the following rule establishes the exclusive list of anomalies, diseases, disorders, and other conditions that shall deem an unborn child "medically futile."
- II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)
The proposed rule change will not affect revenue collections for state or local governmental units.
- III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)
The proposed rule is not anticipated to result in costs to or have economic impacts on directly affected persons, small businesses, or non-governmental groups.
- IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)
The proposed rule will not impact competition or employment.

Doris Gray Brown
Assistant Secretary
2209#037

Alan M. Boxberger
Interim Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

**Department of Health
Office of Public Health**

**Medical Marijuana Regulation
(LAC 51:XXIX.101-907)**

Under the authority of R.S. 40:4 and 40:5, and in accordance with R.S. 49:950 et seq., the Administrative Procedure Act, notice is hereby given that state health officer, acting through the Department of Health, Office of Public Health (LDH/OPH), intends to enact a new Part of Title 51 of the *Louisiana Administrative Code* (also known as the *Louisiana State Sanitary Code*) as a consequence of changes made to medical marijuana regulations under Act No. 491 and Act No. 492 of the 2022 Louisiana Legislature. The following changes will authorize the LDH/OPH the ability to transition to conducting oversight of the manufacture and distribution of medical marijuana products, which could affect the health of Louisiana's citizens and visitors. Further, this Notice of Intent will provide the state health officer the ability to make critical decisions that protect human health.

This Rule adds a new Part, Part XXIX, to Title 51 of the *Louisiana Administrative Code*, consisting of nine Chapters enumerating the various provisions of the regulation of medical marijuana. Chapter 1 explains definitions that are unique to this regulation. Chapter 3 specifies the enabling legislation and notes that the products to be regulated herein are subject to federal law. Chapter 5 describes the permitting process for contractors and the licensure process for the two statutorily-prescribed licensees. Chapter 7 lists the inspection requirements for medical marijuana facilities and the operational requirements for the firms. Chapter 9 indicates the requirements for medical marijuana testing laboratories.

Title 51

PUBLIC HEALTH—SANITARY CODE

Part XXIX. Medical Marijuana

Chapter 1. General Requirements

§101. Definitions

A. Except as may be otherwise defined in any provision of this Part, and unless the context or use thereof clearly indicates otherwise, the following words and terms used in this Part of the *Sanitary Code* are defined for the purposes thereof, and for purposes of any other Parts which are adopted or may hereafter be adopted, as follows:

Immature Plant—nonflowering medical marijuana (as defined below) plant that is no taller than eight inches produced from a cutting, clipping or seedling.

Licensee—as defined in La. R.S. 40:1046(H)(2)(a), the Louisiana State University Agricultural Center or the Southern University Agricultural Center.

Louisiana Medical Marijuana Tracking System (LMMTS)—the required seed-to-sale tracking system that tracks medical marijuana from either the seed or immature plant stage until the plant material is sold as a finished product to a licensed medical marijuana pharmacy or destroyed.

Medical Marijuana—any parts of the plant genus *Cannabis* and all derivatives of all strains of this genus, whether growing or not; the seeds thereof; the resin extracted therefrom; any compound, mixture, or preparation of such plant, its seeds, or resin, including tetrahydrocannabinol (THC), cannabidiol (CBD), and all other naturally-occurring phytocannabinoids, whether produced directly or indirectly by extraction. This term does not include the mature stalks of such plant; fiber produced from such stalks; oil or cake made from the seeds of such plant; any other compound, salt, derivative, mixture, or preparation of such mature stalks (except for the resin extracted therefrom); fiber, oil, or cake; or sterilized seed incapable of germination.

Medical Marijuana Waste—medical marijuana that is unusable or that cannot be processed into a useable form.

Permittee—contractor employed by the licensee to grow, cultivate, process, transport, and distribute medical marijuana.

Therapeutic Marijuana—see *Medical Marijuana*.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:

Summary of Comments:

NOI: List of Conditions that Shall Deem an Unborn Child "Medically Futile" (LAC 48:I.401), published in Louisiana Register, September 2023

All abortions should be illegal with no exceptions for medically futile conditions

Physicians should be able to make decisions for their patients' healthcare without input from legislatures

The conditions omphalocele, monosomy, tay sachs, potters syndrome, hydrocephalus, hydatiform mole, & spina bifida should be added to the list of conditions that deem a pregnancy medically futile

The list should be broadened to include clinically significant abnormalities and conditions that are genetic, anatomic, infectious, and metabolic along with those that are congenital or chromosomal

The list should include a broader list of categories and should include telehealth

Physicians should be able to make decisions for their patients' healthcare without input from legislatures

The AMA says that medically futile cannot be meaningfully defined

Keep all abortions in Louisiana illegal

The list should be broadened to include miscarriages, ectopic pregnancies, and other common occurrences

The list needs to be broadened to include spina bifida, tay sachs, potters syndrome, monosomy, etc. It should also include all anomalies, not just congenital or chromosomal. The regulation should also be edited to include telehealth. Abortions should be covered by Medicaid in certain instances.

The list should be broadened to include hydraencephaly, severe hydrocephalus, homozygous achondroplasia, limb body wall, pentalogy of Cantrell, encephalocele, any open neural tube defect, arthrogryposis/fetal akinesia deformation sequence, anhydramnios due to any cause, bilateral pulmonary agenesis, severe congenital diaphragmatic hernia, congenital high airway obstruction, conjoined twins, & Dandy walker malformation

Trisomy 18 should be removed from the list of conditions

Louisiana should recruit medical professionals to Louisiana who are anti-abortion and all abortions should remain illegal



State of Louisiana
Department of Health and Hospitals
Office of the Secretary

June 8, 2023

Dear Commenter:

LDH appreciates your submitting comments regarding the Notice of Intent ("NOI"), entitled "List of Conditions that Shall Deem an Unborn Child "Medically Futile" (LAC 48:1.401), published in the September 20, 2022 edition of the Louisiana Register. LDH has reviewed and considered all of the comments it received in connection with that NOI. The comments broadly fall into three categories, and LDH offers the following responses to each:

Category I. A list (of conditions) is neither necessary nor advantageous

LDH is required to promulgate the list per Act 545 (2022 Regular Session). Specifically, the Act states, in pertinent part:

The Louisiana Department of Health shall promulgate, in accordance with the Administrative Procedure Act, administrative rules establishing an exclusive list of anomalies, diseases, disorders, and other conditions which shall be deemed "medically futile" for purposes of this Subpart.

Category II. The list omits certain conditions that should be included, and includes certain conditions that should be omitted

The definition of "medically futile" in the Act covers only profound and irremediable *congenital* or *chromosomal* anomalies that are incompatible with sustaining life after birth. Conditions that are not congenital or chromosomal do not meet the Act's definition of "medically futile". Likewise, conditions that are not both *profound* and *irremediable* and *incompatible with sustaining life after birth* do not meet the Act's definition of "medically futile".

Many of the additional conditions proposed in the comments for inclusion are disqualified from inclusion due to failure to meet such criteria. Further, LDH has concluded that Item #26 (§401.A.26) in the NOI sufficiently addresses other conditions at this time.

Additionally, LDH has concluded that all of the conditions proposed in the comments for deletion (from the list of conditions) should remain thereon, as it is LDH's decision that all of such conditions meet the definition of "medically futile" in the Act.

Category III. §401.A.26 should not be limited to congenital or chromosomal anomalies

The definition of "medically futile" in the Act covers only congenital or chromosomal anomalies. Anomalies resulting from other underlying causes do not meet the Act's definition of "medically futile".

Sincerely,

Louisiana Department of Health