John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Office of the Secretary

December 9, 2019

Via Statutorily Prescribed Email

To: The Honorable Fred H. Mills, Jr. Chairman, Senate Health & Welfare Committee
The Honorable Frank A. Hoffmann, Chairman, House Health & Welfare Committee

From: Rebekah E. Gee, MD, MPH
Secretary

By Cindy Rives for

Re: Second Report on Proposed Amendments to LAC 50:XXXIII.Chapters 151-157 – Treatment for Opioid Use Disorder in Opioid Treatment Programs

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Bureau of Health Services Financing, submits its second report regarding the proposed amendments to the rules concerning Treatment for Opioid Use Disorder in Opioid Treatment Programs

A Notice of Intent on the proposed amendments was published in the October 20, 2019 issue of the *Louisiana Register* (LR 45:1526). No written comments or 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. Additionally, no substantive changes were made to the proposed amendments since the report provide for in R.S. 49:968B-C was submitted.

Unless otherwise directed, the Department anticipates adopting the October 20, 2019, Notice of Intent when it is published as a final rule in the December 20, 2019, issue of the *Louisiana Register*.

Should you have any questions or need additional information, please contact Jen Katzman, Medicaid Deputy Director, at Jennifer.Katzman@la.gov.

Cc: Jen Katzman, Deputy Medicaid Director, Department of Health
Veronica Dent, Medicaid Program Manager, Department of Health
Anita Dupuy, Legislative Liaison, Department of Health
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing
and
Office of Behavioral Health

Behavioral Health Services
Treatment for Opioid Use Disorder in Opioid Treatment Programs
(LAC 50:XXXIII.Chapters 151-157)

The Department of Health, Bureau of Health Services Financing and the Office of Behavioral Health propose to adopt LAC 50:XXXIII.Chapters 151-157 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.

Section 1006(b) of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act amended Section 1902(a)(10)(A) of the Social Security Act to add medication-assisted treatment as a mandatory Medicaid benefit, defined as all drugs approved by the Food and Drug Administration (FDA), including methadone.

The Department of Health, Bureau of Health Service Financing and the Office of Behavioral Health propose to adopt provisions governing medication-assisted opioid use disorder (OUD) treatment in Opioid Treatment Programs, for Medicaid-eligible recipients ages 18 and over, diagnosed with OUD.

TITLE 50

PUBLIC HEALTH-MEDICAL ASSISTANCE
Part XXXIII. Behavioral Health Services
Subpart 16. Coverage for Treatment for Opioid Use Disorder in Opioid Treatment Programs

Chapter 151. General Provisions

§15101. Introduction

A. The Medicaid Program hereby adopts provisions to provide coverage for medication-assisted treatment provided in Opioid Treatment Programs, including but not limited to, methadone treatment, to all Medicaid-eligible adults and children with opioid use disorder (OUD).

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 Behavioral Health, LR 46:

§15103. Recipient Qualifications

A. Adults and children who meet Medicaid eligibility and clinical criteria shall qualify to receive medically necessary OUD services in Opioid Treatment Programs.

B. Qualifying recipients must meet the following criteria:

1. are at least 18 years old, unless the recipient has consent from a parent or legal guardian, if applicable; and

2. meet the federal requirements regarding admission to the Opioid Treatment Program.

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 Behavioral Health, LR 46:

Chapter 153. Services

§15301. General Provisions

A. All treatment services must be medically necessary.

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 Behavioral Health, LR 46:

§15303. Covered Services

A. The following services provided by Opioid Treatment Programs shall be reimbursed under the Medicaid Program:

1. the administration and dispensing of medications; and

2. treatment phases outlined in LAC 48:I.5725.

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 Behavioral Health, LR 46:

Chapter 155. Provider Participation

§15501. Provider Responsibilities

A. Each Opioid Treatment Program shall enter into a contract with the managed care organizations (MCOs) and the coordinated system of care (CSoC) contractor in order to receive reimbursement for Medicaid covered services.

B. Opioid treatment programs shall deliver all services in accordance with federal and state laws and regulations, and the provisions of this Rule.

C. Opioid Treatment Programs must be licensed in accordance with state laws and regulations, in addition to operating within their scope of practice license.

D. Opioid Treatment Programs shall retain all records necessary to fully disclose the extent of services provided to recipients for five years from the date of service and furnish such records, and any payments claimed for services, to the Medicaid program upon request.

E. Opioid Treatment Programs shall maintain compliance with state and federal regulatory authorities for operation, including but not limited to the Substance Abuse and Mental Health Services Administration (SAMHSA), the Drug Enforcement Administration (DEA), and the State Opioid Treatment Authority.

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 Behavioral Health, LR 46:

Chapter 157. Reimbursement

§15701. Reimbursement Methodology

A. Reimbursement rates for Opioid Treatment Programs shall be a bundled rate included in the Specialized Behavioral Health Fee Schedule as determined by the department.

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 Behavioral Health, LR 46:

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 as it increases access to medication-assisted opioid use disorder treatment services for eligible recipients in need of these services.

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. 49:973972 as it provides Medicaid reimbursement for medication-assisted opioid use disorder treatment services that were previously cash-based only for recipients in need of these services.

Small Business Analysis

In compliance with Act 820 of the 2008 Regular Session of the Louisiana Legislature, 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, as described in R.S. 49:965.2 et seq.

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 it provides Medicaid reimbursement for the provision of medication-assisted opioid use disorder treatment services to eligible recipients.

Public Comments

Interested persons may submit written comments to Jen Steele, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821—9030. Ms. Steele is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on November 29, 2019.

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 November 12, 2019. 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 November 27, 2019 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 November 12, 2019. 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.

Rebekah E. Gee MD, MPH

Secretary

John Bel Edwards
GOVERNOR

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SECRETARY

State of Louisiana

Louisiana Department of Health
Office of the Secretary

December 9, 2019

Via Statutorily Prescribed Email

To: The Honorable Fred H. Mills, Jr. Chairman, Senate Health & Welfare Committee
The Honorable Frank A. Hoffmann, Chairman, House Health & Welfare Committee

From: Rebekah E. Gee, MD, MPH
Secretary

By Cindy Rivera for

Re: Second Report on Proposed Amendments to LAC 50:VII.32917 – ICF-IID Dedicated Program Funding Pool Payments

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Bureau of Health Services Financing, submits its second report regarding the proposed amendments to the rules concerning ICF-IID Dedicated Program Funding Pool Payments.

A Notice of Intent on the proposed amendments was published in the October 20, 2019 issue of the *Louisiana Register* (LR 45:1514). No written comments or 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. Additionally, no substantive changes were made to the proposed amendments since the report provide for in R.S. 49:968B-C was submitted.

Unless otherwise directed, the Department anticipates adopting the October 20, 2019, Notice of Intent when it is published as a final rule in the December 20, 2019, issue of the *Louisiana Register*.

Should you have any questions or need additional information, please contact Jen Katzman, Medicaid Deputy Director, at Jennifer.Katzman@la.gov.

Cc: Jen Katzman, Deputy Medicaid Director, Department of Health
Veronica Dent, Medicaid Program Manager, Department of Health
Anita Dupuy, Legislative Liaison, Department of Health
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Intermediate Care Facilities for Persons with Intellectual Disabilities
Dedicated Program Funding Pool Payments
(LAC 50:VII.32917)

The Department of Health, Bureau of Health Services Financing proposes to adopt LAC 50:VII.32917 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 50 of the 2019 Regular Session of the Louisiana Legislature appropriated funds to the Department of Health for supplemental payments to non-state providers for rate restorations for home and community-based services and enhancing reimbursements for adult day health services and intermediate care facilities for individuals with intellectual disabilities (ICFs/IID). The department elected to carry forward funds for use in State Fiscal Year 2020 to comply with the legislation's directive to allocate the funding in a manner that maximizes the payments to providers to the greatest extent possible.

In compliance with the requirements of Act 50, the department hereby proposes to adopt provisions governing

reimbursement to non-state ICFs/IID to allow one-time, lump sum payments from the dedicated program funding pool.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE
Part VII. Long Term Care
Subpart 3. Intermediate Care Facilities for Persons with Intellectual Disabilities

Chapter 329. Reimbursement Methodology

Subchapter A. Non-State Facilities

§32917. Dedicated Program Funding Pool Payments

A. Effective for providers active and Medicaid certified as of September 1, 2019; a one-time lump sum payment will be made to intermediate care facilities for individuals with intellectual disabilities (ICFs/IID).

B. Methodology

1. Payment will be based on each provider's specific pro-rated share of an additional dedicated program funding pool totaling $4,665,635.

2. The pro-rated share for each provider will be determined utilizing the provider's percentage of total annualized program Medicaid days. Annualized program Medicaid days will be calculated utilizing the most recently desk reviewed or audited cost reports as of July 1, 2019.

3. The additional dedicated program funding pool lump sum payments shall not exceed the Medicare upper payment limit in the aggregate for the provider class.

4. The one-time payment will be made on or before June 30, 2020.

5. Payment of the one-time lump sum payment is subject to approval by the U.S. Department of Health and Human Services, Centers for Medicaid and Medicare Services (CMS).

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 46:

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 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 Statement

In compliance with Act 820 of the 2008 Regular Session of the Louisiana Legislature, 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, as described in R.S. 49:965.2 et seq.

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 permits one-time, lump sum supplemental payments to non-state ICF/IID providers.

Public Comments

Interested persons may submit written comments to Jen Steele, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821–9030. Ms. Steele is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on November 29, 2019.

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 November 12, 2019. 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 November 27, 2019 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 November 12, 2019. 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.

Rebekah E. Gee MD, MPH

Secretary

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Office of the Secretary

December 9, 2019

Via Statutorily Prescribed Email

To: The Honorable Fred H. Mills, Jr. Chairman, Senate Health & Welfare Committee
The Honorable Frank A. Hoffmann, Chairman, House Health & Welfare Committee

From: Rebekah E. Gee, MD, MPH
Secretary

By Cindy Rucker

Re: Second Report on Proposed Amendments to LAC 50:VII.32901 – ICF-IID Reimbursement Methodology Direct Care Floor

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Bureau of Health Services Financing, submits its second report regarding the proposed amendments to the rules concerning ICF-IID Reimbursement Methodology Direct Care Floor.

A Notice of Intent on the proposed amendments was published in the October 20, 2019 issue of the *Louisiana Register* (LR 45:1515). No written comments or 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. Additionally, no substantive changes were made to the proposed amendments since the report provide for in R.S. 49:968B-C was submitted.

Unless otherwise directed, the Department anticipates adopting the October 20, 2019, Notice of Intent when it is published as a final rule in the December 20, 2019, issue of the *Louisiana Register*.

Should you have any questions or need additional information, please contact Jen Katzman, Medicaid Deputy Director, at Jennifer.Katzman@la.gov.

Cc: Jen Katzman, Deputy Medicaid Director, Department of Health
Veronica Dent, Medicaid Program Manager, Department of Health
Anita Dupuy, Legislative Liaison, Department of Health
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Intermediate Care Facilities for
Persons with Intellectual Disabilities
Reimbursement Methodology
Direct Care Floor
(LAC 50:VII.32901)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:VII.32901 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

The Department of Health, Bureau of Health Services Financing proposes to amend the provisions governing reimbursement for intermediate care facilities for persons with intellectual disabilities in order to correct an invalid citation in the direct care floor language and ensure that these provisions are appropriately promulgated in the *Louisiana Administrative Code*.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE
Part VII. Long Term Care
Subpart 3. Intermediate Care Facilities for Persons with Intellectual Disabilities

Chapter 329. Reimbursement Methodology

Subchapter A. Non-State Facilities

§32901. Cost Reports

A. - B.2. ...

C. Direct Care Floor

1. A facility wide direct care floor may be enforced upon deficiencies related to direct care staffing requirements ~~noted~~cited during the HSS annual review or ~~during a~~resulting from an HSS complaint investigation~~in accordance with LAC 50:I.5501 et seq~~.

2. - 5. ...

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, Office of the Secretary, Bureau of Health Services Financing, LR 31:1592 (July 2005), repromulgated LR 31:2252 (September 2005), amended LR 33:461 (March 2007), amended by the Department of Health, Bureau of Health Services Financing, LR 44:1446 (August 2018), LR 46:

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 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 Statement

In compliance with Act 820 of the 2008 Regular Session of the Louisiana Legislature, 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, as described in R.S. 49:965.2 et seq.

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, no direct or indirect cost to the provider 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 Jen Steele, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. Ms. Steele is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on November 29, 2019.

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 November 12, 2019. 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 November 27, 2019 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 November 12, 2019. 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.

Rebekah E. Gee MD, MPH

Secretary

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State of Louisiana

Louisiana Department of Health
Office of the Secretary

December 9, 2019

Via Statutorily Prescribed Email

To: The Honorable Fred H. Mills, Jr. Chairman, Senate Health & Welfare Committee
The Honorable Frank A. Hoffmann, Chairman, House Health & Welfare Committee

From: Rebekah E. Gee, MD, MPH By Cindy Rives for
Secretary

Re: Second Report on Proposed Amendments to LAC 50:III.10307 – Medicaid Eligibility – Modified Adjusted Gross Income Groups

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Bureau of Health Services Financing, submits its second report regarding the proposed amendments to the rules concerning Medicaid Eligibility – Modified Adjusted Gross Income Groups.

A Notice of Intent on the proposed amendments was published in the October 20, 2019 issue of the *Louisiana Register* (LR 45:1516). No written comments or 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. Additionally, no substantive changes were made to the proposed amendments since the report provide for in R.S. 49:968B-C was submitted.

Unless otherwise directed, the Department anticipates adopting the October 20, 2019, Notice of Intent when it is published as a final rule in the December 20, 2019, issue of the *Louisiana Register*.

Should you have any questions or need additional information, please contact Jen Katzman, Medicaid Deputy Director, at Jennifer.Katzman@la.gov.

Cc: Jen Katzman, Deputy Medicaid Director, Department of Health
Veronica Dent, Medicaid Program Manager, Department of Health
Anita Dupuy, Legislative Liaison, Department of Health
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Medicaid Eligibility
Modified Adjusted Gross Income Groups
(LAC 50:III.10307)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:III.10307 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 Affordable Care Act of 2010 (ACA) requires that eligibility for all Medicaid and Children's Health Insurance Program (CHIP) eligibility groups be calculated using a household's modified adjusted gross income (MAGI). Temporary census income is taxable as employment income and must now be counted when calculating household income for MAGI-based Medicaid and CHIP eligibility groups.

In compliance with the ACA, the Department of Health, Bureau of Health Services Financing now proposes to amend the provisions governing Medicaid eligibility for modified adjusted gross income (MAGI) groups and income factors in order to clarify and align these provisions with current Federal regulations.

Title 50
PUBLIC HEALTH-MEDICAL ASSISTANCE
Part III. Eligibility

Subpart 5. Financial Eligibility

Chapter 103. Income

§10307. Modified Adjusted Gross Income (MAGI) Groups

A. MAGI-based

1. Income shall be calculated in accordance with 42 CFR §435.603 and §457.315.

2. - 29.z.ii. Repealed.

B. - B.1.b.iii. ...

2. The net countable income for the individual's household shall be compared to the applicable income standard for the household size to determine eligibility.

a. If the countable income is below the income standard for the applicable MAGI group, the individual is income eligible.

b. If the countable income is above the income standard for the applicable MAGI group, the individual is income ineligible.

3. - 5.b. Repealed.

C. Federal Poverty Income Guidelines (FPIG). Eligibility shall be based upon the following guidelines using the federal poverty income guidelines and adjusted to account for the 5 percent disregard:

1. - 4. ...

5. LaCHIP IV (unborn option), income is less or equal to 214 percent FPIG;

6. LaCHIP Affordable Plan, income is less or equal to 255 percent FPIG;

7. Adult Group, income is less than or equal to 138 percent FPIG; and

8. Take Charge Plus, income is less than or equal to 138 percent FPIG.

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, LR 41:947 (May 2015), amended by the Department of Health, Bureau of Health Services Financing, LR 46:

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 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 Statement

In compliance with Act 820 of the 2008 Regular Session of the Louisiana Legislature, 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, as described in R.S. 49:965.2 et seq.

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, no direct or indirect cost to the provider 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 Jen Steele, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821–9030. Ms. Steele is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on November 29, 2019.

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 November 12, 2019. 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 November 27, 2019 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 November 12, 2019. 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.

Rebekah E. Gee MD, MPH

Secretary

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State of Louisiana

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December 9, 2019

Via Statutorily Prescribed Email

To: The Honorable Fred H. Mills, Jr. Chairman, Senate Health & Welfare Committee
The Honorable Frank A. Hoffmann, Chairman, House Health & Welfare Committee

By Rebekah Rives for

From: Rebekah E. Gee, MD, MPH
Secretary

Re: Second Report on Proposed Amendments to LAC 48:I.Chapter 100 – Medication Attendant Certified – Licensing Standards

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Health Standards Section, submits its second report regarding the proposed Direct Service Worker Registry rule amendment. A Notice of Intent on the proposed amendments was published in the October 20, 2019, issue of the *Louisiana Register* (LR 45:1518). No written comments during the public comment period. A public hearing was held on November 27, 2019, however no members from the public attended the hearing and no oral testimony was given at the hearing. Additionally, no substantive changes were made to the proposed amendments since the report provided for in R.S. 49:968B-C was submitted.

Unless otherwise directed, the Department anticipates adopting the October 20, 2019, Notice of Intent as a final rule when it is published in the December 20, 2019, issue of the *Louisiana Register*.

Should you have any questions or need additional information, please contact Brenda Blanchard, BSN, RN, LNCC at (225) 342-2471 or Cecile Castello, BSN, RN, Director of the Health Standards Section, at (225) 342-4997.

Cc: Brenda Blanchard, BSN, RN, LNCC, Health Standards Section
Cecile Castello, BSN, RN, Director, Health Standards Section
Veronica Dent, Medicaid Program Manager 1B, Policy and Waivers
Anita Dupuy, Legislative Liaison, Louisiana Department of Health
Catherine Brindley, *Louisiana Register* Editor, Office of the State Register

NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Medication Attendant Certified
Licensing Standards
(LAC 48:I.Chapter 100)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 48:I.Chapter 100 as authorized by R.S. 36:254 and R.S. 37:1026.1 et seq. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

The Department of Health, Bureau of Health Services Financing proposes to amend the provisions governing the licensing of individuals certified by the department to administer medications to nursing facility residents, hereafter referred to as "medication attendants certified" (MACs). The department now proposes to amend the MAC licensing standards to revise and update the training and certification requirements.

Title 48

PUBLIC HEALTH - GENERAL
PART I. General Administration
Subpart 3. Licensing

Chapter 100. Nurse Aide Training and Competency Evaluation Program

Subchapter G. Medication Attendant Certified

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Department—the Louisiana Department of Health ~~and Hospitals~~ (~~DHH~~LDH).

***

Licensed Nurse—a licensed registered nurse or a licensed practical nurse or a RN or LPN practicing in the state under a multistate license from a compact state with a privilege to practice (PTP) in Louisiana in accordance with applicable state statutes and regulations.

Licensed Practical Nurse—a person licensed by the LSBPNE to practice practical nursing in Louisiana or a RN or LPN practicing in the state under a multistate license from a compact state with a PTP in Louisiana.

Medication Attendant Certified (MAC)—a person certified by ~~DHH~~ LDH to administer medications to nursing facility residents, hereafter referred to as a ~~medication attendant certified~~ MAC.

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Nursing ~~Home~~Facility—an institution licensed pursuant to R.S. 40:2009.1-2009.10.

Pilot—~~a program administered by the Department of Health and Hospitals to authorize the certification of medication attendants on a trial basis to perform certain functions in nursing homes licensed and in good standing with DHH and who~~

~~agree to comply with established criteria to measure the outcome of the program.~~Repealed.

Registered Nurse (RN)—a person licensed by the LSBN to practice professional nursing in Louisiana or practicing in Louisiana under a PTP.

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AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 37:1026.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:1413 (July 2008), amended by the Department of Health, Bureau of Health Services Financing, LR 46:

§10081. General Provisions

A. The Department of Health ~~and Hospitals~~ (~~DHH~~LDH) establishes provisions for the use of medication attendants certified (MACs) in licensed nursing facilities. The department shall maintain a registry of individuals who have, at a minimum, successfully ~~completed a state-approved medication attendant certified training course and competency evaluation, and criminal background check.~~:

1. completed a state-approved MAC training course;

2. passed a competency evaluation administered by a state-approved testing source; and

3. passed drug screening/testing and a statewide criminal background/security check conducted by the Louisiana State Police, or its designee.

B. The ~~medication attendant certified~~ MAC registry shall contain the following items:

1. a list of individuals who have successfully completed ~~a medication attendant certified~~ an approved MAC training curriculum and competency evaluation. Each individual listed shall have the following information maintained on the registry:

a. - c. ...

d. ~~phone~~telephone number;

e. - g. ...

h. state-issued certification number;

i. documentation of any investigation, if applicable, including ~~codes for specific~~ findings of:

i. - v. ...

j. ...

k. a current, monitored e-mail address.

C. Registry. Employers shall use the registry to determine if a prospective hire is a ~~medication attendant~~

~~certified~~ MAC and if there is a finding that he/she has abused or neglected an individual being supported or misappropriated the individual's property or funds.

D. Change of Information. A certificate holder shall notify the department ~~within~~ as soon as possible but no later than 30 days after changing his or her address, telephone number, e-mail address, or name.

E. Arrest. A ~~medication attendant certified~~MAC, or his or her employer, if aware, shall immediately notify the department of any arrest in any state.

F. Reciprocity. A person who holds a valid license, registration or certificate as a medication attendant issued by another state shall also be certified in Louisiana if the transferring state's training program is at least ~~100~~120 hours or more and the applicant passes the ~~State~~ state-approved MAC competency examination.

1. ...

2. The application shall include a ~~current copy of the rules of the other state governing its licensing and regulation of medication aides, a copy of the legal authority (law, act, code, or other) for the state's licensing program, and a~~ certified copy of the license or certificate for which the reciprocal certificate is requested.

3. ...

G. When issued, an initial certificate shall be valid for 12 months from the date of issue. The registry will renew the certificate if:

1. a certificate holder has completed four hours of state-approved continuing education administered by an approved institution focusing on medication administration prior to expiration of the certificate; and

2. a certificate holder has worked at least 400 hours per year in a licensed nursing facility.

H. Denial of Renewal. The department shall deny renewal of the certificate of a ~~medication attendant certified~~ MAC who is in violation of this Chapter at the time of the application renewal.

I. ...

J. A ~~medication attendant certified~~ MAC shall function under the direct supervision of a licensed registered or practical nurse on duty at the nursing facility. ~~A certificate holder must:~~ Although the performance of selected medication administration tasks are delegated to the MAC by the registered nurse, the registered nurse retains the accountability for the total nursing care of the resident, regardless of whether the care is provided solely by the registered nurse or by the

registered nurse in conjunction with other licensed or unlicensed assistive personnel. The MAC shall:

1. ...

2. comply with the department's rules applicable to such personnel used in a nursing facility.

K. Persons employed as ~~medication attendants certified~~ MACs in a nursing facility shall comply with the requirements relating to nurse aides as set forth in the Omnibus Budget Reconciliation Act of 1987, Public Law 100-203~~, the department's rule governing the Standards for Payment for Nursing Homes~~ and ~~Minimum Licensure Standards for Nursing Homes~~minimum licensure standards for nursing facilities or subsequent amendments. Requirements are met if the individual is:

1. - 2. ...

L. Restriction. While on duty, a MAC's sole function shall be to administer medications to residents. Persons employed as medication attendants in a nursing facility may not be assigned additional responsibilities. If medication administration has been completed, they may assist in other areas.

M. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 37:1026.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:1413 (July 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:1248 (May 2012), repromulgated LR 38:1412 (June 2012), amended by the Department of Health, Bureau of Health Services Financing, LR 46:

§10082. General Requirements

A. Prior to application for a certificate under this Chapter, all persons shall:

1. be proficient in reading, writing, speaking, and understanding the English language at a minimum eighth grade level as evidenced by the ~~following COMPASS~~ MAC training program's required entry placement test scores~~:~~.

~~a. reading, 64;~~

~~b. writing, 25; and~~

~~c. pre-algebra, 31;~~a. - c. Repealed.

2. be a citizen of the United States or a legal alien with appropriate documentation from the U.S. Department of Homeland Security;

3. - 5. ...

6. be currently employed in a facility as a certified nurse aide (CNA) on the first official day of an

applicant's medication attendant training program or be a graduate of a nursing program; ~~and~~

7. ~~successfully pass a statewide criminal history background check and verification of the results sent to the training entity.~~have a minimum of one year experience in a nursing home as a CNA or be a graduate of a nursing program; and

8. successfully pass a statewide criminal background/security check conducted by the State Police, or its designee, within 90 days of an applicant starting the MAC program and be free of abused substances as evidenced by periodic drug testing in accordance with the NF's policies and procedures. Verification of these results must be received by the training entity, documented, and maintained in the personnel file.

B. A ~~medication attendant certified~~ MAC may not administer medication to a resident in a nursing facility unless he/she:

B.1. - F. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 37:1026.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:1414 (July 2008), amended by the

Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:1249 (May 2012), amended by the Department of Health, Bureau of Health Services Financing, LR 46:

§10083. ~~Trainee Responsibilities~~Coordinators, Instructors, and Trainers

A. ~~Each medication attendant trainee shall be clearly identified as a trainee during all clinical portions of the training. Identification should be recognizable to residents, family members, visitors and staff~~ Program Coordinator. Every MAC training program shall have a program coordinator who provides general supervision of the training received by the MAC trainees.

1. The program coordinator shall be a registered nurse (RN) and shall have the following experience and qualifications:

a. a minimum of two years of nursing experience, of which at least one year must be in caring for the elderly or chronically ill, obtained through employment in any of the following:

i. a nursing facility/unit;

ii. a geriatrics department;

iii. a chronic care hospital;

iv. other long-term care setting; or

v. experience in varied responsibilities including, but not limited to, direct resident care or supervision and staff education; and

b. completion of Vocational Trade and Industrial Education (VTIE) or Career and Technical Trade and Industrial Education (CTTIE) licensure, "train the trainer" type program, or a master's degree or higher.

2. The program coordinator shall supervise no more than two MAC training programs simultaneously and shall be on the premises where the program is being conducted for at least 50 percent of the duration of the program.

B. ~~Trainees shall take the competency evaluation (through skills demonstration and written examination) within 30 days after completion of the training program. Trainees will be given a maximum of two opportunities within 90 days following completion of the training program to successfully complete the competency evaluation program.~~Instructors. Instructors shall be RNs or LPNs in a ratio such that not less than 50 percent of the instructors are RNs and shall hold a current, unencumbered Louisiana nursing license or PTP. Licensed practical (vocational) nurses, under the direct supervision of the coordinator, may provide classroom and clinical skills instruction and supervision of trainees if they have two years

of experience in caring for the elderly and/or chronically ill of any age or have equivalent experience.

1. Such experience may be obtained through employment in:

a. a nursing facility;

b. a geriatrics department;

c. a chronic care hospital; or

d. another long-term care setting.

2. Experience in resident care, supervision and staff education is preferred.

3. The ratio of instructors to trainees in clinical training shall not exceed 1:5 and the ratio of instructors to trainees in the classroom shall not exceed 1:15.

C. ~~If a trainee fails to successfully complete the competency evaluation program, he or she shall re-enroll in a training program~~ Program Trainers. Qualified resource personnel from the health field may participate as program trainers as needed for discussion or demonstration of specialized medication procedures.

1. Qualified resource personnel shall have a minimum of one year of experience in their health care field and shall be licensed, registered and/or certified, if applicable, and may include:

a. registered nurses;

b. licensed practical/vocational nurses;

c. pharmacists;

d. dietitians;

e. nursing home administrators;

f. gerontologists;

g. physical therapists and occupational therapists;

h. activities specialists; and

i. speech/language/hearing therapists.

2. All program trainers shall have a minimum of one year of current experience in caring for the elderly and/or chronically ill of any age or have equivalent experience.

3. The training program may utilize other persons such as residents, experienced aides, and ombudsmen as resource personnel if these persons are needed to meet the planned program objectives or a specific unit of training.

D. Trainees

1. Each medication attendant trainee shall be clearly identified as a trainee during all clinical portions of the training. Identification should be recognizable to residents, family members, visitors and staff.

2. Trainees shall take the competency evaluation (through skills demonstration and written examination) within 30 days after completion of the training program. Trainees will be given a maximum of two opportunities within 90 days following completion of the training program to successfully complete the competency evaluation program.

3. If a trainee fails to successfully complete the competency evaluation program, he or she shall re-enroll in a training program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 37:1026.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:1415 (July 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:1249 (May 2012), amended by the Department of Health, Bureau of Health Services Financing, LR 46:.

§10084. Training Curriculum

A. - A.4. ...

B. Each medication attendant training program shall provide all trainees with a nursing facility orientation that is not included in the required minimum ~~100~~120 hours of core

curriculum. The orientation program shall include, but is not limited to:

1. 4. ...

5. employee ~~rules~~ policies and procedures.

C. ...

1. The core curriculum shall be a minimum of ~~100~~120 hours in length with a minimum of ~~40~~45 clinical hours.

C.2. - D.12.b. ...

13. appropriate procedures to follow when the resident is NPO "nothing by mouth", dysphagic, refuses the medication, vomits the medication, or has allergies;

14. - 30. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 37:1026.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:1415 (July 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:1250 (May 2012), amended by the Department of Health, Bureau of Health Services Financing, LR 46:

§10085. Competency Evaluation

A. A competency evaluation shall be developed by the training entity and conducted to ensure that each trainee, at a

minimum, is able to demonstrate competencies taught in each part of the training curriculum.

B. ...

C. The entity responsible for the training and competency evaluation shall report to the registry the names of all individuals who have satisfactorily completed the curriculum after the training is completed. Within 15 days after a ~~medication attendant certified~~ MAC has successfully completed the training and competency evaluation, the training entity shall notify the registry.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 37:1026.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:1416 (July 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:1250 (May 2012), amended by the Department of Health, Bureau of Health Services Financing, LR 46:

§10086. Authorized Duties

A. The ~~medication attendant certified~~ MAC may perform certain duties and functions under the direct supervision of a licensed nurse. These authorized duties shall apply to medication attendant trainees under the supervision of the

clinical instructor. The ratio of ~~medication attendants certified~~ MACs to licensed nurses shall not exceed two medication attendants to one licensed nurse at any given time.

B. ~~Medication attendants certified~~ MACs may:

1. observe and report to the licensed nurse a resident's adverse reaction to a medication;

2. - 12. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 37:1026.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:1416 (July 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:1250 (May 2012), amended by the Department of Health, Bureau of Health Services Financing, LR 46:

§10087. Prohibited Duties

A. Medication attendants certified shall not:

1. ...

2. administer any medications by the following parenteral routes:

a. intramuscular;

b. intravenous;

c. subcutaneous; ~~or~~

d. intradermal; or

e. other routes restricted in department rules;

3. administer any medication used for intermittent positive pressure breathing (IPPB) treatments;

4. - 16. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 37:1026.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:1416 (July 2008), amended by the Department of Health, Bureau of Health Services Financing, LR 46:

§10088. Provider Participation and Responsibilities

A. A nursing facility ~~shall~~ with a license that is in good standing with the department may apply to the department to utilize ~~medication attendants certified~~MACs. Upon receipt of a facility's application, the department shall review the facility's compliance history.

B. If a facility is non-compliant with program regulations, the department shall take into consideration the findings that resulted in the facility's noncompliance before making a determination whether or not to allow the facility to utilize ~~medication attendants certified~~MACs. Emphasis shall be

placed on deficiencies cited in the area of medication administration such as significant medication errors, medication error rates and repeat deficiencies of such.

C. The department may deny a facility's request to use ~~medication attendants~~MACs if it is determined that, based upon the compliance history, the safety and well-being of residents would be jeopardized. If the facility is denied participation, the facility may ask for a reconsideration and review of the circumstances which contributed to the denial of the application.

D. The following information shall be provided prior to acceptance in the program:

1. - 2. ...

3. the ~~staffing levels per shift~~plan for orientation and utilization of MACs, including orientation of all staff to the role of MACs;

4. the ~~turnover rate~~number and type of ~~staff~~medication errors in the year prior to the utilization of MACs; and

5. a ~~plan for orientation and utilization of medication attendants certified, including orientation of all staff to the role of medication attendants;~~statement that the nursing facility will utilize the MACs in accordance with the

department's rules and regulation and will provide evaluation information as indicated.

~~6. the number and type of medication errors in the year prior to the utilization of medication attendants certified;~~

~~7. a survey of patient satisfaction, including the patient's perception of receiving medications, prior to the utilization of medication attendants certified; and~~

~~8. a statement that the nursing home will utilize the medication attendants certified in accordance with the accepted rules and regulations and will provide evaluation information as indicated.~~6. - 8. Repealed

E. A facility's application that is not complete within 90 days of receipt by the department shall be ~~closed~~considered null and void.

F. The department may sanction a facility and/or revoke a facility's participation in the MAC program if it is determined by the department that, based upon the facility's compliance history, the safety and well-being of residents is jeopardized by the facility's non-compliance with licensing standards. If the facility's participation is revoked, the facility may ask for a reconsideration and review of the circumstances which

contributed to the revocation of participation in the MAC program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 37:1026.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:1417 (July 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:1250 (May 2012), amended by the Department of Health, Bureau of Health Services Financing, LR 46:

§10089. Allegations of Medication Attendant Certified Wrong-Doing

A. The department, through its Division of Administrative Law or successor entity, has provided for a process of the review and investigation of all allegations of resident abuse, neglect or misappropriation of residents' property or funds by ~~medication attendants certified~~ MACs.

B. In the event of an allegation of wrong-doing, ~~medication attendants certified~~ MACs shall be bound by the department's established:

1. ...

2. informal dispute resolution policies; and

3. ~~preliminary conference requirements; and~~appeal and administrative hearing provisions:

a. the formal hearing shall be conducted according to formal hearing procedures set forth in the Administrative Procedure Act.

~~4. appeal and administrative hearing provisions:~~

~~a. the formal hearing shall be conducted according to formal hearing procedures set forth in the Administrative Procedure Act.~~4.- 4.a. Repealed.

C. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 37:1026.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:1417 (July 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:1250 (May 2012), amended by the Department of Health, Bureau of Health Services Financing, LR 46:

§10090. Suspension, Revocation or ~~Non-Renewal~~Denial of Renewal

A. The department may revoke, suspend or ~~refuse to renew~~deny renewal of a certificate or reprimand a certificate holder for a violation of this Chapter.

B. - B.3. ...

C. Prior to institution of formal proceedings to revoke or suspend a ~~permit~~certificate, the department shall give written notice to the certificate holder of the facts or conduct alleged to warrant revocation, suspension or rescission. The certificate holder shall be given an opportunity to ~~show compliance with all requirements of this Chapter~~participate in an informal dispute resolution process.

D. - F. ...

1. If a suspension overlaps a certificate renewal date, the suspended certificate holder shall be subject to the renewal procedures ~~stated in §8603.G~~ pursuant to the provisions of this Subchapter. However, the department shall not renew the certificate until it determines that the reason for suspension no longer exists.

G. If the department revokes or ~~does not renew~~ denies renewal of a certificate, a person may reapply for a certificate by complying with the provisions of this Chapter at the time of reapplication. The department may refuse to issue a certificate if the reason for revocation or ~~non-renewal~~ denial of renewal continues to exist.

1. If a certificate is revoked or ~~not renewed~~denied renewal, the certificate holder shall immediately return the certificate to the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 37:1026.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:1417 (July 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:1250 (May 2012), amended by the Department of Health, Bureau of Health Services Financing, LR 46:

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 Act 820 of the 2008 Regular Session of the Louisiana Legislature, 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, as described in R.S. 49:965.2 et seq.

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, no direct or indirect cost to the provider 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 Cecile Castello, Health Standards Section, P.O. Box 3767, Baton Rouge, LA 70821. Ms. Castello is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on November 29, 2019.

The department will conduct a public hearing at 9:30 a.m. on November 27, 2019 in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. All interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. 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.

Rebekah E. Gee MD, MPH

Secretary

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

PUBLIC HEARING CERTIFICATION
November 27, 2019
9:30 a.m.

RE: Medication Attendant Certified
Licensing Standards
Docket # 11272019-01
Department of Health
State of Louisiana

CERTIFICATION

In accordance with LA R.S. 49:950 et seq., the attached public hearing agenda, together with one digital recording of the public hearing conducted on November 27, 2019 in Baton Rouge, Louisiana constitute the official record of the above-referenced public hearing.

Medicaid Policy and Compliance
Section

11/27/19
Date

LDH/BHSF PUBLIC HEARING

Medication Attendant Certified—Licensing Standards

November 27, 2019

PERSONS IN ATTENDANCE

Name	Address	Telephone Number	AGENCY or GROUP you represent
1. Brenda Blanchard	LDH-HSS Bunville	(225) 342-3204	HSS
2. Rhea Davis	LDH / OPH / 3rd Fl.	(225) 922-3047	OPH
3. Allen Enger	LDH/OS	225-892-2455	LDH
4.			
5.			
6.			

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Office of the Secretary

December 9, 2019

Via Statutorily Prescribed Email

To: The Honorable Fred H. Mills, Jr. Chairman, Senate Health & Welfare Committee
The Honorable Frank A. Hoffmann, Chairman, House Health & Welfare Committee

By Cindy Rivera

From: Rebekah E. Gee, MD, MPH
Secretary

Re: Second Report on Proposed Amendments to LAC 50:XXIX.Chapters 1,5,7,9, and 11 – Pharmacy Benefits Management Program – Dispense as Written Electronic Prescribing

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Bureau of Health Services Financing, submits its second report regarding the proposed amendments to the rules concerning Pharmacy Benefits Management Program – Dispense as Written Electronic Prescribing.

A Notice of Intent on the proposed amendments was published in the October 20, 2019 issue of the *Louisiana Register* (LR 45:1523). No written comments or 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. Additionally, no substantive changes were made to the proposed amendments since the report provide for in R.S. 49:968B-C was submitted.

Unless otherwise directed, the Department anticipates adopting the October 20, 2019, Notice of Intent when it is published as a final rule in the December 20, 2019, issue of the *Louisiana Register*.

Should you have any questions or need additional information, please contact Jen Katzman, Medicaid Deputy Director, at Jennifer.Katzman@la.gov.

Cc: Jen Katzman, Deputy Medicaid Director, Department of Health
Veronica Dent, Medicaid Program Manager, Department of Health
Anita Dupuy, Legislative Liaison, Department of Health
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Pharmacy Benefits Management Program
Dispense as Written Electronic Prescribing
(LAC 50:XXIX.Chapters 1,5,7,9 and 11)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XXIX.Chapters 1,2,7,9 and 11 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 Department of Health, Bureau of Health Services Financing currently only allows handwritten "brand necessary" notation of the medical necessity of brand drugs by prescribing providers in the Pharmacy Benefits Management Program. The department has determined that electronic prescriptions are safer in preventing prescription drug errors from the misreading of handwriting, eliminate the ability to alter or manipulate the prescription, and speed up the workflow process. The department now proposes to amend the provisions governing the Pharmacy Benefits Management Program in order to allow notation of the medical necessity of brand drugs using electronic prescriptions, to allow the state to pursue outcomes-based agreements with manufacturers, and to align the provisions with the current Medicaid State Plan.

Title 50

PUBLIC HEALTH MEDICAL ASSISTANCE

Part XXIX. Pharmacy

Chapter 1. General Provisions

§107. Prior Authorization

A. - C.3. ...

D. Drugs Excluded from Coverage. As provided by §1927(d)(2) of the Social Security Act, the following drugs are excluded from program coverage:

1. ~~experimental drugs and investigational drugs~~ select agents when used for anorexia, weight loss, or weight gain, except Orlistat (Xenical®);

2. ~~drugs~~ select agents when used to ~~treat weight loss~~promote fertility, except ~~Orlistat~~vaginal progesterone when used for high-risk pregnancy to prevent premature births;

3. select agents when used for symptomatic relief of cough and cold ~~preparations~~, except ~~some~~ prescription antihistamine and antihistamine/decongestant combination products;

4. ~~cosmetic drugs, except Isotretinoin~~select prescription vitamins and mineral products, except:

a. prenatal vitamins;

b. fluoride preparations;

c. vitamin A injection;

d. vitamin B injection;

e. vitamin D (prescription only);

f. vitamin K (prescription only);

g. vitamin B12 injection;

h. folic acid (prescription only);

i. niacin (prescription only);

j. vitamin B6 injection;

k. vitamin B1 injection;

l. multivitamin (prescription only);

m. magnesium injections;

n. calcium injection; and

o. urinary PH modifiers (phosphorus, specifically K Phos Neutral and Phospha Neutral);

5. ~~compounded prescriptions (mixtures of two or more ingredients the individual~~ select nonprescription drugs ~~will continue to be reimbursed)~~ except OTC antihistamines and antihistamine/decongestant combinations and polyethylene glycol 3350 (Miralax®);

~~6. medications which are included in the reimbursement to a facility, i.e.:~~

~~a. hospitals;~~

~~b. skilled nursing facility for recipients receiving benefits under Part A of Title XVIII;~~

~~c. mental hospitals; or~~

~~d. some other nursing facilities;~~

~~7. non-legend drugs with some exceptions;~~

~~8. fertility drugs when used for fertility treatment;~~

~~9. vaccines covered in other programs, except influenza vaccine; and~~

~~10. DESI Drugs (see Subsection E below).~~6 - 10. Repealed.

E. ~~DESI Drugs. Those drugs that are subject to a notice of opportunity for hearing, as prescribed by section 1927(k)(2)(A) of the Social Security Act for which the Food and Drug Administration has proposed to withdraw from the market.~~Otherwise Restricted Drugs

1. The state will cover agents when used for cosmetic purposes or hair growth only when the state has determined that use to be medically necessary.

2. Select drugs for erectile dysfunction, except when used for the treatment of conditions, or indications approved by the FDA, other than erectile dysfunction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254, Title XIX of the Social Security Act, and the 1995-96 General Appropriate Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health

Services Financing, LR 32:1053 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1180 (June 2017), LR 43:1553 (August 2017), LR 45:665 (May 2019), LR 46:

§111. Copayment

A. - A.1. ...

* * *

2. The pharmacy provider shall collect a copayment from the Medicaid recipient for each drug dispensed ~~by the provider~~ and covered by Medicaid. The following pharmacy services are exempt from the copayment requirements:

a. - d. ...

3. The following population groups are exempt from copayment requirements:

a. individuals under the age of 21;

b. individuals residing in a long-term care facility;

c. individuals receiving hospice care;

d. Native Americans and Alaskan Eskimos;

e. women whose basis for Medicaid eligibility is breast or cervical cancer; and

f. home and community-based services waiver recipients.

B. ~~The~~ In accordance with federal regulations, the following ~~population groups are exempt from copayment requirements:~~provisions apply.

1. ~~individuals under the age of 21;~~The provider may not deny services to any eligible individual on account of the individual's inability to pay the copayment amount. However, this service statement does not apply to an individual who is able to pay, nor does an individual's inability to pay eliminate his or her liability for the copayment.

2. ~~individuals residing in a long-term care facility;~~Providers shall not waive the recipient copayment liability.

3. ~~individuals receiving hospice care;~~Departmental monitoring and auditing will be conducted to determine provider compliance.

4. ~~Native Americans and Alaskan Eskimos;~~Violators of this Section maybe subject to a penalty, including but not limited to, termination from the Medicaid Program.

5. ~~women whose basis for~~ The state will ensure Medicaid premiums and cost sharing incurred by all individuals in the Medicaid ~~eligibility is breast or cervical cancer; and~~household do not exceed an aggregate limit of 5 percent of the family's income applied on a monthly basis.

~~6. home and community-based services waiver recipients.~~

~~C. In accordance with federal regulations, the following provisions apply.~~

~~1. The provider may not deny services to any eligible individual on account of the individual's inability to pay the copayment amount. However, this service statement does not apply to an individual who is able to pay, nor does an individual's inability to pay eliminate his or her liability for the copayment.~~

~~2. Providers shall not waive the recipient copayment liability.~~

~~3. Departmental monitoring and auditing will be conducted to determine provider compliance.~~

~~4. Violators of this §111 will be subject to a penalty such as suspension from the Medicaid Program.~~B.6 - C.4. 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 Hospitals, Office of the Secretary, LR 32:1055 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1181 (June 2017), LR 43:1553 (August 2017), LR 46:

§115. Drug Coverage Limits

A. - 5.c. ...

6. The prescribed drug is ~~not a cosmetic drug, anorexic, cough and cold preparation, or selected nonprescription drug~~ an excluded or otherwise restricted drug.

7. ...

8. The prescribed drug is not an immunosuppresant drug prescribed and billed to Medicare ~~within one year from the date of the transplant~~ for a Title XIX transplant recipient who has Medicare Part B coverage.

9. The prescribed drug is not an immunosuppressant drug covered by Medicare Part B which is prescribed for a nontransplant patient with Medicare Part B coverage and identified in the Title XIX provider manual as subject to special billing procedures. ~~Payment shall be made only when billing requirements are met. Requirements may include provision of a physician statement (or copy) verifying the diagnosis attached to each claim submitted.~~

B. Drug Listing

1. - 2. ...

C. ~~Erectile Dysfunction Drugs. Prescription drugs for the treatment of sexual or erectile dysfunction shall not be covered or reimbursed under the Medicaid Program.~~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 Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1055 (June 2006), LR 32:2083 (November 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1182 (June 2017), LR 46:

§119. Maximum Quantity

A. ...

B. When maintenance drugs are prescribed and dispensed for chronic illnesses they shall be in quantities sufficient to effect economy in dispensing and yet be medically sound. ~~Listed below are drugs the agency considers to be maintenance~~ Maintenance type drugs ~~and which~~ should be prescribed and dispensed in a month's supply~~:~~ after the initial fill.

~~1. anti-coagulants;~~

~~2. anti-convulsants;~~

~~3. oral anti-diabetics;~~

~~4. calcium gluconate, calcium lactate, and calcium phosphate;~~

~~5. cardiovascular drugs including:~~

~~a. diuretics;~~

~~b. antihypertensives; and~~

~~c. antihyperlipidemics;~~

~~6. estrogens;~~

~~7. ferrous gluconate and ferrous sulfate;~~

~~8. potassium supplements;~~

~~9. thyroid and antithyroid drugs;~~

~~10. Vitamins~~

~~a. A, D, K, B12 injection;~~

~~b. Folic Acid; and~~

~~c. Nicotinic Acid.~~1. - 10.c. Repealed.

C. ...

D. ~~Payment will not be made for narcotics other than opioid agonists/antagonists prescribed only for narcotic addiction.~~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 Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1056 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1182 (June 2017), LR 46:

Chapter 5. Narcotics and Controlled Substances

§501. Schedule II Narcotic Analgesic Prescriptions

A. ...

B. ~~Payment will not be made for narcotics other than opioid agonists/antagonists prescribed only for narcotic addiction.~~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 Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1058 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1183 (June 2017), LR 46:

Chapter 7. Parenteral Nutrition Therapy

§701. Introduction

~~A. Parenteral nutrition (PN) therapy is the introduction of nutrients by some means other than through the gastrointestinal tract, in particular intravenous, subcutaneous, intramuscular, or intramedullary injection. Intravenous nutrition is also referred to as TPN (Total Parenteral Nutrition) or Hyperalimentation Therapy.~~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 Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1058 (June 2006), repealed LR 46:

§703. Medical Necessity

~~A. The department's published medical necessity criteria must be met.~~

~~B. Parenteral nutrition is considered to be medically necessary when any of the following conditions exists. The conditions must be deemed to be severe enough that the recipient would not be able to maintain his/her weight and strength on only oral intake or tube enteral nutrition. The recipient:~~

~~1. has undergone recent (within the past three months) massive small bowel resection leaving less than or equal to 5 feet of small bowel beyond the ligament of Treitz; or~~

~~2. has a short bowel syndrome that is severe enough that the recipient has net gastrointestinal fluid and electrolyte malabsorption such that on an oral intake of 2.5-3 liters/day the enteral losses exceed 50 percent of the oral/enteral intake and the urine output is less than 1 liter/day; or~~

~~3. requires bowel rest for at least three months and is receiving intravenously 20-35 cal/kg/day for treatment of symptomatic pancreatitis with/without pancreatic pseudocyst, severe exacerbation of regional enteritis, or a proximal enterocutaneous fistula where tube feeding distal to the fistula is not possible; or~~

~~4. has complete mechanical small bowel obstruction where surgery is not an option; or~~

5. is significantly malnourished (10 percent weight loss over three months or less and serum albumin less than or equal to 3.4 gm/dl) and has very severe fat malabsorption (fecal fat exceeds 50 percent of oral/enteral intake on a diet of at least 50 gm of fat/day as measured by a standard 72 hour fecal fat test); or

6. is significantly malnourished (10 percent weight loss over three months or less and serum albumin less than or equal to 3.4 gm/dl) and has a severe motility disturbance of the small intestine and/or stomach which is unresponsive to prokinetic medication. Prokinetic medication is defined as the presence of daily symptoms of nausea and vomiting while taking maximal doses and is demonstrated either:

a. scintigraphically (solid meal gastric emptying study demonstrates that the isotope fails to reach the right colon by six hours following ingestion); or

b. radiographically (barium or radiopaque pellets fail to reach the right colon by six hours following administration).

NOTE: These studies must be performed when the recipient is not acutely ill and is not on any medication which would decrease bowel motility.

C. Maintenance of weight and strength commensurate with the recipient's overall health status must require intravenous

~~nutrition and must not be possible utilizing all of the following approaches:~~

~~1. modifying the nutrient composition of the enteral diet (e.g., lactose free, gluten free, low in long chain triglycerides, substitution with medium chain triglycerides, provision of protein as peptides or amino acids, etc.); and~~

~~2. utilizing pharmacologic means to treat the etiology of the malabsorption (e.g., pancreatic enzymes or bile salts, broad spectrum antibiotics for bacterial overgrowth, prokinetic medication for reduced motility, etc.).~~

~~D. Recipients who do not meet the criteria in B.1-6 must meet criteria in C.1-2 (modification of diet and pharmacologic intervention) in addition to the following criteria:~~

~~1. the recipient is malnourished (10 percent weight loss over three months or less and serum albumin less than or equal to 3.4 gm/dl); and~~

~~2. a disease and clinical condition has been documented as being present and it has not responded to altering the manner of delivery of appropriate nutrients (e.g., slow infusion of nutrients through a tube with the tip located in the stomach or jejunum).~~

~~E. The following are some examples of moderate abnormalities which would require a failed trial of tube enteral nutrition before PN would be covered:~~

1. moderate fat malabsorption - fecal fat exceeds 25 percent of oral/enteral intake on a diet of at least 50 gm fat/day as measured by a standard 72 hour fecal fat test;

2. diagnosis of malabsorption with objective confirmation by methods other than 72 hour fecal fat test (e.g., Sudan stain of stool, dxylose test, etc.);

3. gastroparesis which has been demonstrated:

a. radiographically or scintigraphically as described in Subsection B above with the isotope or pellets failing to reach the jejunum in three to six hours; or

b. by manometric motility studies with results consistent with an abnormal gastric emptying, and which is unresponsive to prokinetic medication;

4. a small bowel motility disturbance which is unresponsive to prokinetic medication, demonstrated with a gastric to right colon transit time between three to six hours;

5. small bowel resection leaving greater than 5 feet of small bowel beyond the ligament of Treitz;

6. short bowel syndrome which is not severe (as defined in B.2);

7. mild to moderate exacerbation of regional enteritis, or an enterocutaneous fistula;

8. partial mechanical small bowel obstruction where surgery is not an option.

F. Documentation must support that a concerted effort has been made to place a tube. For gastroparesis, tube placement must be post-pylorus, preferably in the jejunum. Use of a double lumen tube should be considered. Placement of the tube in the jejunum must be objectively verified by radiographic studies or fluoroscopy. Placement via endoscopy or open surgical procedure would also verify location of the tube.

G. A trial with enteral nutrition must be documented, with appropriate attention to dilution, rate, and alternative formulas to address side effects of diarrhea.

H. PN can be covered in a recipient with the ability to obtain partial nutrition from oral intake or a combination of oral/enteral or oral/enteral/parenteral intake as long as the following criteria are met:

1. a permanent condition of the alimentary tract is present which has been deemed to require parenteral therapy because of its severity;

2. a permanent condition of the alimentary tract is present which is unresponsive to standard medical management; and

3. the person is unable to maintain weight and strength.

I. If the medical necessity criteria for parenteral nutrition are met, medically necessary nutrients, administration

~~supplies and equipment are covered. PN solutions containing little or no amino acids and/or carbohydrates would be covered only in situations stated in B.1, 2, or 4 above.~~

~~J. Documentation Requirements~~

~~1. Recipients covered under Paragraph B.4 must have documentation of the persistence of their condition. Recipients covered under B.5-D.2 must have documentation that sufficient improvement of their underlying condition has not occurred which would permit discontinuation of parenteral nutrition. Coverage for these recipients would be continued if the treatment has been effective as evidenced by an improvement of weight and/or serum albumin. If there has been no improvement, subsequent claims will be denied unless the physician clearly documents the medical necessity for continued parenteral nutrition and any changes to the therapeutic regimen that are planned, e.g., an increase in the quantity of parenteral nutrients provided.~~

~~2. A total caloric daily intake (parenteral, enteral and oral) of 20-35 cal/kg/day is considered sufficient to achieve or maintain appropriate body weight. The ordering physician must document in the medical record the medical necessity for a caloric intake outside this range in an individual recipient.~~

~~3. Parenteral nutrition would usually be noncovered for recipients who do not meet criteria in H.1-3, but will be~~

~~considered on an individual case basis if detailed documentation is submitted.~~

~~4. Recipients covered under criteria in B.1 or 2 must have documentation that adequate small bowel adaptation had not occurred which would permit tube enteral or oral feedings.~~

~~5. Recipients covered under B.3 must have documentation of worsening of their underlying condition during attempts to resume oral feedings.~~

~~6. The ordering physician must document the medical necessity for protein orders outside of the range of 0.8-1.5 gm/kg/day, dextrose concentration less than 10 percent, or lipid use greater than 15 units of a 20 percent solution or 30 units of a 10 percent solution per month.~~

~~7. If the medical necessity for special parenteral formulas is not substantiated, authorization of payment will be denied.~~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 Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1058 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1183 (June 2017), repealed LR 46:

§707. Prior Authorization

~~A. Parenteral nutrition therapy may be approved by the Prior Authorization Unit (PAU) at periodic intervals not to exceed six months.~~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 Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1060 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1184 (June 2017), repealed LR 46:

§709. Intradialytic Parenteral Nutrition

~~A. Intradialytic parenteral nutrition therapy (IDPN) is parenteral nutrition therapy provided to a recipient with end stage renal disease (ESRD) while the recipient is being dialyzed. IPDN may be approved by the Prior Authorization Unit at periodic intervals not to exceed six months.~~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 Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1061 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1184 (June 2017), repealed LR 46:

§713. Equipment and Supplies

~~A. An infusion pump is used to deliver nutritional requirements intravenously. Infusion pumps are covered for the delivery of parenteral nutrition for those recipients who cannot absorb nutrients by the gastrointestinal tract. Only one pump (ambulatory or stationary) will be covered at any one time. Additional pumps will be denied as not medically necessary.~~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 Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1061 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1184 (June 2017), repealed LR 46:

§715. Reimbursement

~~A. The reimbursement rate for parenteral nutrition formula is 80 percent of the Medicare Fee Schedule amount or billed charges, whichever is the lesser amount.~~

~~B. The reimbursement rate for parenteral equipment and supplies is 70 percent of the Medicare Fee Schedule amount or billed charges, whichever is the lesser amount. If an item is not available at 70 percent of the Medicare Fee Schedule amount, the flat fee that will be utilized is the lowest cost at which~~

~~the item has been determined to be widely available by analyzing usual and customary fees charged in the community.~~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 Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1061 (June 2006), repealed LR 46:

Chapter 9. Methods of Payment

Subchapter D. Maximum Allowable Costs

§949. Fee for Service Cost Limits

A. - C.3.c. ...

D. Physician Certifications

1. Limits on payments for multiple source drugs shall not be applicable when the prescriber certifies ~~in his own handwriting that a specified~~ that the brand name drug is medically necessary for the care and treatment of a recipient in his own handwriting or via an electronic prescription. Such certification ~~may~~ shall be written directly on the prescription, ~~or~~ on a separate sheet which is dated and attached to the prescription, or submitted electronically. A standard phrase ~~in the prescriber's handwriting,~~ such as "brand necessary" indicating the medical necessity of the brand will be acceptable.

~~2. Any practice which precludes the prescriber's handwritten statement shall not be accepted as a valid certification. Such practices include, but are not limited to:~~

~~a. a printed box on the prescription blank that could be checked by the prescriber to indicate brand necessity;~~

~~b. a handwritten statement transferred to a rubber stamp and then stamped on the prescription blank; or~~

~~c. preprinted prescription forms using a facsimile of the prescriber's handwritten statement.~~2. - 2.c. Repealed.

E. - 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, Office of the Secretary, Bureau of Health Services Financing, LR 32:1065 (June 2006), amended LR 34:88 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1561 (July 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1185 (June 2017), LR 43:1554 (August 2017), LR 44:1020 (June 2018), LR 45:571 (April 2019), LR 45:665 (May 2019), amended LR 46:

Chapter 11. ~~State Supplemental Rebate~~ Value-based Agreement ~~Program~~Programs

Subchapter E. 340B Program

§1101. General Provisions

A. ...

B. LDH may enter into an agreement with a pharmaceutical manufacturer for outcomes-based contracts. Participation by a pharmaceutical manufacturer in an outcomes-based agreement with the department is voluntary.

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 43:966 (May 2017), amended LR 45:909 (July 2019), LR 46:

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 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 Act 820 of the 2008 Regular Session of the Louisiana Legislature, 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, as described in R.S. 49:965.2 et seq.

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, no direct or indirect cost to the provider 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 Jen Steele, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. Ms. Steele is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on November 29, 2019.

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 November 12, 2019. 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 November 27, 2019 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 November 12, 2019. 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.

Rebekah E. Gee MD, MPH

Secretary