John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Office of the Secretary

February 8, 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 Cindy Rowe for

Re: Second Report on Proposed Amendments to LAC 48:I.Chapter 96 – Crisis Receiving Centers – Licensing Standards

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Health Standards Section, submits its second report regarding the proposed Crisis Receiving Centers – Licensing Standards rule amendment. A Notice of Intent on the proposed amendments was published in the January 20, 2019, issue of the *Louisiana Register* (LR 45:125). 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 provided for in R.S. 49:968B-C was submitted.

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

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

Cc: Cecile Castello, Director, RN, Health Standards Section
Brenda Blanchard, BSN, RN, LNCC, Medical Certification Program Manager
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

Crisis Receiving Centers
Licensing Standards
(LAC 48:I.Chapter 96)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 48:I.Chapter 96 as authorized by R.S. 36:254 and R.S. 40:2100-2115. 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 proposes to amend the provisions governing the licensing of hospital crisis receiving centers in order to adopt provisions to allow free-standing psychiatric hospitals which do not have dedicated emergency departments (EDs) to designate crisis receiving center-specialty units (CRC-SUs) as EDs for patients in need of psychiatric crisis treatment, if the CRC-SU meets all of the same regulations as a hospital ED.

Title 48
PUBLIC HEALTH—GENERAL
Part I. General Administration
Subpart 3. Licensing and Certification

Chapter 96. Hospitals—Crisis Receiving Centers

Subchapter A. General Provisions

§9601. Introduction

A. A hospital crisis receiving center is a specialty unit of a hospital that provides health care services to individuals who are experiencing a behavioral health crisis.

B. ...

§9603. Licensure Requirements

A. All crisis receiving center specialty units ~~must~~ shall be licensed by the department and shall comply with the provisions of §9333 of these hospital licensing standards.

B. A crisis receiving center specialty unit (CRC-SU) shall have approval from the Office of ~~Mental~~ Behavioral Health ~~(OMH)~~ (OBH) and/or the appropriate human service district or authority before applying to become licensed as part of the hospital.

C. Prior to securing licensure and operating the CRC-SU, the hospital shall submit architectural plans of the CRC-SU to the ~~department's Division of Engineering~~ Office of the State Fire Marshal (OSFM) for licensing approval.

D. – F. ...

G. If the CRC-SU is located at an offsite campus or is at a free-standing psychiatric hospital which does not have a dedicated emergency department, the CRC-SU shall be considered a dedicated emergency department. The CRC-SU shall comply with all EMTALA regulations if the unit meets one of the following criteria:

1. the entity is licensed by the state as an emergency department of the hospital;

2. - 3. ...

H. The following levels of a CRC-SU may be licensed as an optional service of the hospital:

1. Level I CRC-SU only; ~~and~~or

2. Level I CRC-SU and Level II CRC-SU.

I. A CRC-SU shall ~~comply~~ maintain compliance ~~with~~with the:

1. Office of Public Health (OPH) regulations; and

2. Office of State Fire Marshal regulations~~;~~. ~~and~~

3. ~~the physical plant requirements of this Chapter.~~Repealed.

J. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:513 (March 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

§9605. Licensing Process

A. The hospital shall submit the following items to the department in order to add a CRC-SU to its existing license:

1. ...

2. the ~~appropriate~~ required licensing fee, if applicable;

3. a copy of the prerequisite approval from ~~OMH~~OBH and/or the appropriate human service district or authority; and

4. other documentation as required by the department, including a current Office of Public Health (OPH)/Sanitation approval~~, Division of Engineering approval~~ and Office of State Fire Marshal approval for occupancy and licensing plan review.

B. – C. ...

1. The sub-license/certificate shall designate the level of the CRC-SU and the ~~number of beds~~ licensed capacity ~~in~~of the CRC-SU.

C.2. – E. ...

F. The sub-license/certificate shall be valid only for the designated ~~geographical~~geographic location and shall be issued only for the person/premises named in the application. The ~~geographical~~geographic location of the CRC-SU shall not be moved, changed, or relocated without notification to HSS, approval by HSS, and the re-issuance of the sub-license/certificate.

G. The~~ sub-license/certificate shall not be transferable or assignable. If the hospital undergoes a change of ownership, the new owning entity shall obtain written consent from OMH~~

~~and/or the appropriate human service district, and shall submit a new license application to the~~ department ~~for~~ may conduct on-site surveys and inspections at the CRC-SU as necessary to ensure compliance with these licensing standards.

H. ~~The department may conduct on-site surveys and inspections at the CRC-SU as necessary to ensure compliance with these licensing standards.~~Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:513 (March 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

§9607. Discharges, Referrals or Transfers

A. Patients ~~that~~ who are discharged home from the CRC-SU shall be given verbal and written discharge instructions and any referral information, including information for ~~appointment~~appointments regarding follow-up care and treatment.

B. – C. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:514

(March 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

§9609. Training Requirements

A. A CRC-SU shall ensure that all staff providing direct patient care has documentation of successful completion of crisis services and intervention training in accordance with this Chapter.

B. Crisis services and intervention training shall include, but is not limited to the following:

1. an organized training program that includes an initial 40 hours of training to be completed upon hire and a minimum of 12 hours of training to be completed annually thereafter. Required training includes, but is not limited to the following areas:

a. – j. ...

k. an overview of mental illness and substance abuse diagnoses and treatment;

l. – n. ...

o. confidentiality and Health Insurance Portability and Accountability Act (~~HIPPA~~HIPAA) regulations; and

p. ...

C. All formal training shall be provided by a licensed mental health professional (LMHP) or other qualified licensed behavioral health personnel with extensive experience in the

field in which they provide training. Nonviolent physical interventions shall be taught by a trainer with documented current certification by a nationally established crisis intervention program (e.g. Crisis Prevention and Intervention, Tactical Crisis Intervention, Crisis Intervention Training, etc.).

1. An LMHP is an individual who is currently licensed to practice independently and in good standing in the state of Louisiana to practice within the scope of all applicable state laws, practice acts, and the individual's professional license, as one of the following:

a. medical psychologist;

b. licensed psychologist;

c. licensed clinical social worker (LCSW);

d. licensed professional counselor (LPC);

e. licensed marriage and family therapist (LMFT);

f. licensed addiction counselor (LAC);

g. advance practice registered nurse (APRN); or

h. licensed rehabilitation counselor (LRC).

D. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:514 (March 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

Subchapter B. Level I Crisis Receiving Centers

§9615. General Provisions

A. ...

B. The length of a patient stay for a Level I CRC-SU shall not exceed 24 hours, unless there is documented evidence of the CRC-SU's measures taken to transfer the patient to the appropriate level of needed care and the reasons the transfer of the patient exceeds 24 hours.

C. Services required of a Level I CRC-SU include, but are not limited to:

1. – 2. ...

3. assessment services, including medication management;

4. brief intervention and stabilization; and

5. ...

D. The Level I CRC-SU shall develop and implement policies and procedures for instituting an increased level of supervision for patients at risk for suicide and other ~~self injurious~~ self-injurious behaviors.

E. – F. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:514 (March 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

§9617. Level I Services

A. – B.3. ...

4. The triage/screening shall include:

a. – e. ...

f. a medical screening including at a minimum, vital signs and a medical history, ~~whenever possible~~ as soon as the patient's condition permits.

5. The triage/screening shall be conducted by licensed professionals in the medical or behavioral health fields that have the training and experience to triage/screen individuals for both behavioral and medical emergent needs in accordance with the scope of practice of their licensed discipline.

B.6. – C.2. ...

3. The assessment shall be initiated within two hours of the triage/screening evaluation and shall include:

a. a full ~~behavioral health~~psychiatric assessment;

b. – c. ...

4. A full ~~behavioral health~~psychiatric assessment shall include:

a. patient interviews by board certified/eligible licensed psychiatrist(s)or psychiatric nurse practitioner(s) trained in emergency psychiatric assessment and treatment;

b. a review of the medical and psychiatric records of current and past diagnoses, treatments, medications and dose response, side-effects and compliance, if available;

c. contact with current ~~mental~~ behavioral health providers whenever possible;

d. – g. ...

h. a detailed assessment of substance use, abuse~~/~~, and misuse~~.~~; and

i. an assessment for possible abuse and neglect; such assessment shall be conducted by an LMHP trained in how to conduct an assessment to determine abuse and neglect. The CRC-SU shall ensure that every patient is assessed for sexual, physical, emotional, and verbal abuse and/or neglect.

5. All individuals shall ~~see a~~ be seen by a licensed psychiatrist or a licensed APRN within eight hours of the triage/screening. The board certified/eligible psychiatrist or

APRN shall formulate a preliminary psychiatric diagnosis based on review of the assessment data collected.

a. The APRN must be a nurse practitioner specialist in adult psychiatric and mental health, family psychiatric and mental health, or a certified nurse specialist in psychosocial, gerontological psychiatric mental health, adult psychiatric and mental health, or child-adolescent mental health and may practice to the extent that services are within the APRN's scope of practice.

6. A physical health assessment shall be conducted by a licensed physician, licensed advanced nurse practitioner, or a licensed physician's assistant and shall include the following:

a. - d. ...

e. pregnancy test in all ~~fertile~~ women of child-bearing age, as applicable;

f. - h. ...

7. ~~An assessment for possible abuse and neglect shall be conducted (at the minimum) by a crisis worker trained in how to conduct an assessment to determine abuse and neglect. The CRC-SU must ensure that every patient is assessed for sexual, physical, emotional, and verbal abuse and/or neglect~~Repealed.

D. Brief Intervention and Stabilization

1. If an assessment reveals that immediate stabilization services are required, the Level I CRC-SU shall provide behavioral health interventions and stabilization which may include the use of psychotropic medications ~~which can be administered and benefits generally realized within a 24-hour period~~.

2. Following behavioral health interventions and stabilization measures, the Level I CRC-SU shall assess the patient to determine if referral to community based behavioral health services is appropriate~~;~~ or a higher level of care is required.

E. Linking/Referral Services

1. If an assessment reveals a need for emergency or continuing care for a patient, the Level I CRC-SU shall make arrangements to place the patient into the appropriate higher level of care. Patients in a Level I CRC-SU shall be transitioned out of the Level I CRC-SU within 24 hours unless there is documented evidence of the CRC-SU's measures taken to transfer the patient to the higher level of needed care and the reasons the transfer of the patient exceeds 24 hours.

2. If the assessment reveals no need for a higher level of care, the Level I CRC-SU shall provide:

a. referrals, and make appointments where possible, to appropriate community-based behavioral health

services for individuals with developmental disabilities, addiction disorders, and mental health issues; and

b. brief behavioral health interventions to stabilize the crises until referrals to appropriate community-based behavioral health services are established or contact is made with the individual's existing provider and a referral is made back to the existing provider in the form of a follow-up appointment or other contact.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:515 (March 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

§9619. Staffing Requirements

A. – B.2. ...

C. A Level I CRC-SU shall have the following staff on call at all times and available to be onsite at the CRC-SU within one hour and who meets the following criteria:

1. is a ~~behavioral~~ licensed mental health professional (LMHP) ~~counselor~~ who ~~meets the following criteria:~~ has one year of documented crisis services and intervention experience; or

~~a. has a master's degree in psychology, social work or counseling;~~

~~b. has one year of experiencein the field of behavioral health; and~~

~~c. has documented crisis services and intervention training in accordance with this Chapter;~~a. - c. Repealed.

C.2. - E. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:516 (March 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

§9621. Physical Environment

A. - C. ...

D. Interior finishes, lighting, and furnishings shall ~~suggest a residential, rather than institutional setting, while conforming~~ conform to applicable fire safety codes. Security and safety devices shall not be presented in a manner to attract or challenge tampering by patients.

E. Grab bars, if provided, ~~must~~ shall meet the following specifications:

1. - 2. ...

3. ~~must~~ shall be securely fastened with tamper-proof screw heads;

4. ...

5. if mounted adjacent to a wall, the space between the wall and the grab bar shall be ~~one and one-half inches~~filled completely to prevent a cord or string being tied around the grab bar and used for hanging.

F. Towel racks, closet and shower curtain rods~~, if provided, must be the breakaway type~~ are not permitted.

G. – M.2. ...

3. The doors on the bathroom/toilet rooms shall swing out or be double hinged.

M.4. - O. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:516 (March 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

Subchapter C. Level II Crisis Receiving Centers

§9631. General Provisions

A. A Level II CRC-SU is an intermediate level of care unit that provides for:

1. – 5. ...

6. an appropriate referral and coordination of care for extended services as necessary.

B. – E. ...

F. The ~~beds~~ licensed capacity in a Level II CRC-SU shall not be licensed as hospital beds and shall not be counted in the aggregate number of licensed hospital beds.

G. – K.1. ...

L. The Level II CRC-SU shall develop and implement policies and procedures for instituting an increased level of supervision for patients at risk for suicide and other ~~self injurious~~ self-injurious behaviors.

M. – M.1. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:517 (March 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

§9633. Level II Services

A. In addition to the services required in §9617 of this Chapter, the Level II CRC-SU ~~must~~ shall provide the following services.

1. – 3.c. ...

4. The Level II CRC-SU shall conduct a psychosocial assessment on each patient within 24 hours of admission. This assessment shall be conducted by a~~:~~ licensed LMHP who has one year of documented crisis services and intervention experience.

~~a. behavioral health counselor who has:~~

~~i. a master's degree in psychology, social work or counseling;~~

~~ii. one year of experience in the field of behavioral health; and~~

~~iii. training in crisis services and intervention.~~a. - a.iii. Repealed.

5. - 5.g. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:518 (March 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

§9635. Staffing Requirements

A. - A.1. ...

2. The Level II CRC-SU shall have sufficient numbers and types of qualified staff on duty and available at all times to provide necessary care, services, treatment and safety, based on the acuity of the patients, the mix of the patients present

in the CRC-SU, ~~and~~ the need for extraordinary levels of care and to meet the needs of the patient throughout the length of any patient stay in the CRC-SU.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:518 (March 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

§9637. Physical Environment

A. – F. ...

G. Bathrooms

1. The Level II CRC-SU shall have a minimum of two ~~toilet rooms~~bathrooms that contain all of the following:

a. – c.i. ...

2. If the Level II CRC-SU has more than a capacity for 12 ~~patient~~ patients~~beds~~, there shall be one additional bathroom for each additional capacity for four ~~beds~~ patients.

3. – 4. ...

H. The Level II CRC-SU shall have a ~~toilet room~~ separate bathroom and a break room designated for staff use.

I. Separate and apart from the seclusion room required in a Level I CRC-SU, the Level II CRC-SU shall have a minimum of one seclusion room for ~~every~~ each capacity for 12 ~~beds~~ patients.

1. – 2. ...

J. The Level II CRC-SU shall have separate consultation room(s) with a minimum floor space of 100 square feet each, provided at a room-to-bed ratio of one consultation room for each capacity for 12 ~~beds~~patients. Consultation rooms within the unit shall be ~~used~~ available for use for interviews with the patient and/or their families. The consultation room(s) shall be designed for acoustical and visual privacy.

K. – M. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:518 (March 2010) amended by the Department of Health, Bureau of Health Services Financing, LR 45:

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 effect on the stability of the family functioning and autonomy as described in R.S. 49:972 by ensuring that recipients in need of psychiatric crisis treatment have increased access to appropriate services without delay and ensuring the safe and effective operation of hospital crisis receiving center specialty units.

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 effect on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973 by ensuring that recipients in need of psychiatric crisis treatment have increased access to appropriate services.

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.

Interested persons may submit written comments to Cecile Castello, Health Standards Section, P.O. Box 3767, Baton Rouge, LA 70821 or by email to MedicaidPolicy@la.gov. Ms. Castello is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at close of business, 4:30 p.m., on March 1, 2019.

Interested persons may submit a written request to conduct a public hearing either by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629, fax to (225) 342-5568, or email to LDHRulemaking@la.gov; however, such request must be received no later than 4:30 p.m. on February 9, 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 February 28, 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 Stanley Bordelon at (225) 219-3454 after February 9, 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

February 8, 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
The Honorable Eric LaFleur, Chairman, Senate Finance Committee
The Honorable Cameron Henry, Chairman, House Appropriations Committee

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

Re: Second Report on Proposed Amendments to LAC 50:XXIX. 105 and Chapter 9 – Pharmacy Benefits Management Program – Pharmacy Ingredient Cost Reimbursement

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Health Standards Section, submits its second report regarding the proposed Pharmacy Benefits Management Program – Pharmacy Ingredient Cost Reimbursement rule amendment. A Notice of Intent on the proposed amendments was published in the January 20, 2019, issue of the *Louisiana Register* (LR 45:129). 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 provided for in R.S. 49:968B-C was submitted.

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

Should you have any questions or need additional information, please contact Sue Fontenot, at (225) 342-2768 or Sue.Fontenot@la.gov.

Cc: Jen Katzman, Medicaid Deputy Director, Bureau of Health Services Financing
Sue Fontenot, Pharmacist 4, Bureau of Health Services Financing
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

Pharmacy Benefits Management Program
Pharmacy Ingredient Cost Reimbursement
(LAC 50:XXIX.105 and Chapter 9)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XXIX.105 and Chapter 9 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 proposes to amend the provisions governing reimbursement in the Pharmacy Benefits Management Program in order to change the pharmacy ingredient cost reimbursement methodology from average acquisition cost to the national average drug acquisition cost.

Title 50
PUBLIC HEALTH-MEDICAL ASSISTANCE
Part XXIX. Pharmacy

Chapter 1. General Provisions

§105. Medicaid Pharmacy Benefits Management System Point of Sale—Prospective Drug Utilization Program

A. – B. ...

C. Covered Drug List. The list of covered drugs is managed through multiple mechanisms. Drugs in which the manufacturer entered into the Medicaid Drug Rebate Program with CMS are

included in the list of covered drugs. ~~Average acquisition costs, federal upper payment limits (FUL)~~ National average drug acquisition cost (NADAC) and usual and customary charges assist in managing costs on the covered drug list. ~~Federal upper limits provide for dispensing of multiple source drugs at established limitations unless the prescribing practitioner specifies that the brand product is medically necessary for a patient.~~ Establishment of co-payments also provides for management.

D. Reimbursement Management. The cost of pharmaceutical care is managed through ~~average acquisition cost (AAC)~~ NADAC of the ingredient or through wholesale acquisition cost (WAC) when no ~~AAC~~ NADAC is assigned~~, and compliance with FUL regulations,~~ and the establishment of the professional dispensing fee, drug rebates and copayments. Usual and customary charges are compared to other reimbursement methodologies and the "lesser of" is reimbursed.

E. – L. ...

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:

Chapter 9. Methods of Payment

Subchapter A. General Provisions

§901. Definitions

Average Acquisition Cost (AAC)—~~the average of net payments that pharmacists made to purchase a drug product, after taking into account such items as purchasing allowances, discounts and rebates as determined through the collection and review of pharmacy invoices and other information deemed necessary by the Medicaid Program, and in accordance with applicable state and federal law.~~Repealed.

***

National Average Drug Acquisition Cost (NADAC)—a national pricing benchmark that is reflective of actual invoice costs that pharmacies pay to acquire prescription and over-the-counter drugs. It is based upon invoice cost data collected from retail community pharmacies and reflects actual drug purchases.

***

Usual and Customary Charge—the lowest price the ~~provider most frequently charges the general public for the same~~ pharmacy would charge to a particular customer if such customer were paying cash for the identical prescription drug or prescription drug services on the date dispensed.

***

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 LR 34:87 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1558 (July 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1184 (June 2017), LR 43:1554 (August 2017), LR 45:

Subchapter C. Estimated Acquisition Cost

§935. Estimated Acquisition Cost Formula

A. Estimated acquisition cost (EAC) is the ~~average acquisition~~ national average drug acquisition cost (NADAC) of the drug dispensed. If there is not a~~n~~ ~~AAC~~ NADAC available, the EAC is equal to the wholesale acquisition cost, as reported in the drug pricing compendia utilized by the department's fiscal intermediary/pharmacy benefits manager (PBM).

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 32:1064 (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 43:1184 (June 2017), LR 45:

Subchapter D. Maximum Allowable Costs

§945. Reimbursement Methodology

A. – A.1. ...

B. Payment will be made for medications in accordance with the payment procedures for any fee-for-service (FFS) Medicaid eligible person. ~~On a periodic basis as ingredient costs change, the department will post a link on its website containing average acquisition cost of drugs.~~

C. – F. ...

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 32:1064 (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 43:1184 (June 2017), LR 45:

§949. Fee for Service Cost Limits

A. Brand Drugs. The department shall make payments for single source drugs (brand drugs) based on the lower of:

1. ~~average acquisition cost (AAC)~~national average drug acquisition cost~~s~~ (NADAC) plus the professional dispensing fee:

a. if no ~~AAC~~ NADAC is available, use the wholesale acquisition cost (WAC) plus the professional dispensing fee; or

2. – 2.a. ...

B. Generic Drugs. The department shall make payments for multiple source drugs (generic drugs), other than drugs subject to "physician certifications", based on the lower of:

1. ~~AAC~~NADAC plus the professional dispensing fee:

a. if no ~~AAC~~ NADAC is available, use the WAC plus the professional dispensing fee; or

2. ~~federal upper payment limits plus the professional dispensing fee; or~~the provider's usual and customary charges to the general public not to exceed the department's "maximum payment allowed."

a. For purposes of these provisions, the term general public does not include any person whose prescriptions are paid by third-party payors, including health insurers, governmental entities and Louisiana Medicaid.

~~3. the provider's usual and customary charges to the general public not to exceed the department's "maximum payment allowed."~~

~~a. For purposes of these provisions, the term general public does not include any person whose prescriptions are paid by third-party payors, including health insurers, governmental entities, and Louisiana Medicaid.~~3. - 3.a. Repealed.

C. ~~Federal Upper Payment Limits for Multiple Source Drugs~~Physician Certifications

1. ~~Except for drugs subject to "physician certification", the Medicaid Program shall utilize listings established by the Centers for Medicare and Medicaid Services (CMS) that identify and set upper limits~~ Limits on payments for multiple source drugs~~ that meet the following requirements~~ shall not be applicable when the prescriber certifies in his own handwriting that a specified brand name drug is medically necessary for the care and treatment of a recipient. Such certification may be written directly on the prescription or on a separate sheet which is dated and attached to the prescription. A standard phrase in the prescriber's handwriting, such as "brand necessary" will be acceptable.

~~a. All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of their publication, Approved Drug Products with Therapeutic Equivalence Evaluations (including supplements or in successor publications).~~

~~b. At least three suppliers list the drug, which has been classified by the FDA as category "A" in the aforementioned publication based on listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.~~a. - b. Repealed.

2. ~~Medicaid shall utilize the maximum acquisition cost established by CMS in determining multiple source drug cost.~~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; and

c. preprinted prescription forms using a facsimile of the prescriber's handwritten statement.

~~3. The Medicaid Program shall provide pharmacists who participate in Medicaid reimbursement with updated lists reflecting:~~

~~a. the multiple source drugs subject to federal multiple source drug cost requirements;~~

~~b. the maximum reimbursement amount per unit; and~~

~~c. the date such costs shall become effective.~~3. - 3.c. Repealed.

D. ~~Physician Certifications~~Fee-for-Service 340B Purchased Drugs. The department shall make payments for self-administered drugs that are purchased by a covered entity through the 340B program at the actual acquisition cost which can be no more than the 340B ceiling price plus the professional dispensing fee, unless the covered entity has implemented the Medicaid carve-out option, in which case 340B drugs should not be billed to or reimbursed by Medicaid. 340B contract pharmacies are not permitted to bill 340B stock to Medicaid. Fee-for-service outpatient hospital claims for 340B drugs shall use a cost to charge methodology on the interim and settled at cost during final settlement. Federally qualified health center (FQHC) and rural health clinic (RHC) claims for physician-administered drugs shall be included in the all-inclusive T1015 encounter rate.

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

~~c. preprinted prescription forms using a facsimile of the prescriber's handwritten statement.~~1. - 2.c. Repealed.

E. ~~Fee-for-Service 340B Purchased~~ Federal Supply Schedule Drugs. ~~The department shall make payments for self-administered drugs that are purchased by a covered entity through the 340B program at the actual acquisition cost which can be no more than the 340B ceiling price~~ Drugs acquired at federal supply schedule (FSS) and at nominal price shall be reimbursed at actual acquisition cost plus ~~the~~ a professional dispensing fee~~, unless the covered entity has implemented the Medicaid carve-out option, in which case 340B drugs should not be billed to or reimbursed by Medicaid. 340B contract pharmacies are not permitted to bill 340B stock to Medicaid. Fee-for-service outpatient hospital claims for 340B drugs shall use a cost to charge methodology on the interim and settled at cost during final settlement. Federally qualified health center (FQHC) and rural health clinic (RHC) claims for~~

~~physician administered drugs shall be included in the all-inclusive T1015 encounter rate~~.

F. ~~Fee-for-Service Drugs. Drugs acquired at federal supply schedule (FSS) and at nominal price shall be reimbursed at actual acquisition cost plus a professional dispensing fee.~~Indian Health Service All-Inclusive Encounter Rate. Pharmacy services provided by the Indian Health Service (IHS) shall be included in the encounter rate. No individual pharmacy claims shall be reimbursed to IHS providers.

G. ~~Indian Health Service All-Inclusive Encounter Rate.~~ Mail Order, Long-Term Care and Specialty Pharmacy. ~~services provided by the Indian Health Service (IHS) shall be included in the encounter rate. No individual~~ Drugs dispensed by mail order, long-term care and/or specialty pharmacies (drugs not distributed by a retail community pharmacy) ~~claims shall be reimbursed to IHS providers~~ will be reimbursed using the brand/generic drug reimbursement methodology.

H. ~~Mail Order, Long-Term Care and Specialty Pharmacy. Drugs dispensed by mail order, long-term care and/or specialty pharmacies (drugs not distributed by a retail community pharmacy) will be reimbursed using the brand/generic drug reimbursement~~ Physician-Administered Drugs. Medicaid-covered physician-administered drugs shall be reimbursed according to the Louisiana professional services fee schedule. Reimbursement shall be

determined utilizing the following methodology, and periodic updates to the rates shall be made in accordance with the approved Louisiana Medicaid State Plan provisions governing physician-administered drugs in a physician office setting.

1. Reimbursement for Medicaid-covered physician-administered drugs in a physician office setting shall be established at the current Louisiana Medicare rate, which is average sales price (ASP) plus 6 percent, for drugs appearing on the Medicare file.

2. Reimbursement rates for physician-administered drugs in a physician office setting that do not appear on the Medicare file shall be determined utilizing the following alternative methods:

a. the wholesale acquisition cost (WAC) of the drug, if available;

b. If the drug has no WAC available, one of the following methods shall be used:

i. the provider's actual cost of the drug as documented by invoice or other acceptable documentation as deemed appropriate by the department;

ii. Medicaid rate of other states;

iii. commercial payer rate; or

iv. medical consultant recommendation.

I. ~~Physician-Administered Drugs. Medicaid-covered physician-administered drugs shall~~ Clotting Factor. Pharmacy claims for clotting factor will be reimbursed~~ according to the Louisiana professional services fee schedule. Reimbursement shall be determined utilizing the following methodology, and periodic updates to the rates shall be made in accordance with the approved Louisiana Medicaid State Plan provisions governing physician-administered drugs in a physician office setting~~ using the brand/generic drug reimbursement methodology.

~~1. Reimbursement for Medicaid-covered physician-administered drugs in a physician office setting shall be established at the current Louisiana Medicare rate, which is average sales price (ASP) plus 6 percent, for drugs appearing on the Medicare file.~~

~~2. Reimbursement rates for physician-administered drugs in a physician office setting that do not appear on the Medicare file shall be determined utilizing the following alternative methods:~~

~~a. the wholesale acquisition cost (WAC) of the drug, if available;~~

~~b. If the drug has no WAC available, one of the following methods shall be used:~~

~~i. the provider's actual cost of the drug as documented by invoice or other acceptable documentation as deemed appropriate by the department;~~

~~ii. Medicaid rate of other states;~~

~~iii. commercial payer rate; or~~

~~iv. medical consultant recommendation.~~1. – 2.b.iv. Repealed.

J. ~~Clotting Factor. Pharmacy claims for clotting factor will~~ Investigational or Experimental Drugs. Investigational or experimental drugs shall not be reimbursed ~~using the brand/generic drug reimbursement methodology~~ by Medicaid.

K. ~~Investigational or Experimental Drugs. Investigational or experimental drugs shall not be reimbursed by Medicaid.~~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 32:1065 (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:

Subchapter E. 340B Program

§961. Definitions

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Estimated Acquisition Cost (EAC)—the ~~average acquisition~~ national average drug acquisition cost (NADAC) of the drug dispensed. If there is not a~~n~~ ~~AAC~~NADAC available, the EAC is equal to the wholesale acquisition cost, as reported in the drug pricing compendia utilized by the department's fiscal intermediary.

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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 32:1066 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1186 (June 2017), LR 43:1555 (August 2017), LR 45:

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.

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.

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.

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, but may reduce the total direct and indirect cost to the provider to provide the same level of service, and may enhance the provider's ability to provide the same level of service as described in HCR 170 since this proposed Rule increases payments to providers for the same services they already render.

Interested persons may submit written comments about the proposed Rule to Jen Steele, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030 or by email to MedicaidPolicy@la.gov. Ms. Steele is responsible for responding to inquiries regarding this proposed Rule. The deadline for

submitting written comments is at close of business, 4:30 p.m., on March 1, 2019.

Interested persons may submit a written request to conduct a public hearing either by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629, fax to (225) 342-5568, or email to LDHRulemaking@la.gov; however, such request must be received no later than 4:30 p.m. on February 9, 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 February 28, 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 Stanley Bordelon at (225) 219-3454 after February 9, 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