



State of Louisiana
Louisiana Department of Health
Office of the Secretary

April 5, 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 Ruff

Re: Second Report on Proposed Amendments to LAC 48:I.Chapter 92 – Direct Service Worker Registry

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 February 20, 2019, issue of the *Louisiana Register* (LR 45:291). No written comments during the public comment period. A public hearing was held on March 28, 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 February 20, 2019, Notice of Intent as a final rule when it is published in the May 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

Direct Service Worker Registry (LAC 48:I.Chapter 92)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 48:I.Chapter 92 as authorized by R.S. 36:254 and 40:2179-2179.1. 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 Direct Service Worker (DSW) Registry in order to 1) provide a process for direct service workers who have been placed on the DSW Registry with a negative finding of neglect of a client to request removal, under certain conditions, and to provide for appeal opportunities if the reinstatement request is denied; and 2) clarify and ensure that the provisions for the DSW Registry are promulgated in a clear and concise manner in the *Louisiana Administrative Code*.

Title 48

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

Chapter 92. Direct Service Worker Registry

Subchapter A. General Provisions

§9201. Definitions

Assistance with Activities of Daily Living~~-services that provide assistance with activities of daily living.~~ Such assistance may be the actual performance of the task for the individual, or may provide hands-on assistance with the performance of the tasks, or may ~~be~~ include supervision and prompting to allow the individual to self-perform such tasks.

Daily Monitoring~~-activities pursued on a daily basis by a family member, direct service worker and/or other health care providers for the purposes of collecting critical information needed to assure the individual's welfare. Monitoring activities may include, but are not limited to face-to-face home visits with the person receiving assistance or services and/or daily telephone calls with the individual~~ or communication by other electronic means.

Department~~-the Louisiana Department of Health and Hospitals~~
(~~DHHL~~LDH).

Direct Service Worker Registry~~-the negative database,~~
maintained by the department, or its designee, of unlicensed persons who have a finding placed against them of abuse,

neglect, misappropriation, exploitation, or extortion while employed as a DSW at a licensed health care facility or entity who are ineligible to be employed, or have continued employment, as a direct service worker.

Finding—allegations of abuse, neglect, misappropriation, exploitation or extortion that are placed against the DSW on the registry by the department for the following reasons:

1. - 2. ...

Health Care Provider—any health care facility, agency, or entity licensed and/or certified by ~~DHHL~~DH. Such entities may be referred to in other laws, statutes and regulations as providers, agencies, clinics, residential care units, homes or facilities. Health care providers include, but are not limited to, the following:

1. - 10. ...

Health Standards Section (HSS)—the section of the Department of Health ~~and Hospitals~~ responsible for the licensing and/or certification of health care providers.

Home and Community-Based Services—those services as defined in R.S. 40:2120.2 or a successor statute. For the purposes of this Rule, home and community-based services do not include services provided in day or residential congregate care settings including, but not limited to, the following:

1. - 6. ...

7. any other 24-hour facility licensed by the department, Department of Education or the Department of Children and Family Services, exclusive of center-based respite facilities.

Mental Abuse-Emotional or mental abuse may involve any activity that is designed to blame, shame, humiliate, or intimidate an individual and includes, but is not limited to abuse that is facilitated or caused by taking or using photographs or recordings in any manner that would demean or humiliate a client using any type of equipment (e.g., cameras, smart phones, and other electronic devices) and/or keeping or distributing them through multimedia messages or on social media sites.

1. Mental abuse may occur through either verbal or nonverbal conduct which causes or has the potential to cause the client to experience humiliation, intimidation, fear, shame, agitation, or degradation, regardless of whether the client provided consent and regardless of the client's cognitive status. This may include, but is not limited to:

a. photographs and recordings of clients that contain nudity;

b. sexual and intimate relations;

- c. bathing, showering or toileting;
- d. providing perineal care, such as after an incontinence episode;
- e. agitating a client to solicit a response;
- f. derogatory statements directed to the client;
- g. showing a body part of the client without the client's face, whether it is the chest, limbs or back;
- h. labeling a client's pictures and/or providing comments in a demeaning manner;
- i. directing a client to use inappropriate language; and/or
- j. showing a client in a compromised position.

~~Neglect—the failure, or willful forsaking of an adult~~ by a caregiver responsible for an adult's care or by other parties, to provide the proper or necessary support or medical, surgical, or any other care necessary for his/her well-being, unless the resident exercises his/her right to refuse the necessary care.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2179-2179.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:2058 (November 2006), amended LR 33:95 (January 2007), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:3175 (December 2012), LR 42:893 (June 2016), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

§9202. Introduction

A. The Department of Health ~~and Hospitals~~ (~~DHHL~~LDH) shall maintain a registry of individuals for whom specific findings of abuse, neglect, misappropriation, exploitation or extortion have been substantiated by the department, an administrative law judge, or a court of law.

B. The Direct Service Worker Registry will contain the following items on each individual for whom a finding has been placed:

1. - 3. ...

4. ~~state registration number~~an accurate summary of finding(s); and

5. ~~an accurate summary of finding(s); and~~information relative to registry status which will be available through procedures established by the Health Standards Section (HSS).

6. ~~information relative to registry status which will be available through procedures established by the Health Standards Section (HSS).~~Repealed.

C. Licensed and/or certified health care providers shall access the registry to determine if there is a finding that a prospective hire, or currently employed or contracted ~~direct service worker~~DSW, has been determined to have committed exploitation, extortion, abuse or neglect of an individual being supported, or misappropriated the individual's property or funds. If there is such a finding on the registry, the prospective employee shall not be hired as a DSW nor shall a current employee have continued employment as a DSW with the licensed and/or certified health care provider.

1. Access to the registry shall be limited to an inquiry for a specific DSW.

D. - D.1. ...

E. The provisions of this Chapter shall apply to ~~direct service workers~~DSWs who are compensated, either by direct employment or through contract, regardless of the setting, and specifically do not apply to those DSWs listed on the Certified Nurse Aide Registry established under rules promulgated by the ~~Department of Health and Hospitals~~LDH.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2179-2179.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:2059 (November 2006), amended LR 33:95 (January 2007), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:3176 (December 2012), LR 42:894 (June 2016), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

Subchapter B. Reserved.

Subchapter C. Provider Participation

§9231. Health Care Provider Responsibilities

A. Prior to hiring any ~~direct service worker~~DSW or trainee, the licensed and/or certified health care provider shall:

1. ~~assure~~ensure that the individual is at least 18 years of age, ~~and that they have the ability to read, write and comprehend the English language;~~and

2. ~~access the registry in accordance with the provisions of §9202.C.~~document that the individual is able to read, write and comprehend the English language; and

3. access the registry in accordance with the provisions of §9202.C-C.1.

B. The health care provider shall have a written policy/process to check the DSW registry on the department's

designated database at least every six months to determine if
any currently employed or contracted ~~direct service worker~~DSW or
trainee has been placed on the registry with a finding that
he/she has been determined to have committed abuse or neglect of
an individual being supported or misappropriated the
individual's property or funds or committed exploitation or
extortion of an individual being supported.

1. ...

2. If there is such a finding on the registry, the
employee shall not have continued employment as a DSW with the
licensed and/or certified health care provider in accordance
with the provisions of §9202.C.

NOTE: The DSW Registry is maintained on the department's
designated database which may also contain other
exclusionary information on a DSW. The provider's
responsibility to access the database shall also be
conducted in accordance with other departmental rules and
regulations, as applicable.

D. Criminal History. In accordance with RS 40:1203.1-5 et
seq., the provider shall have a written policy and process to
request in writing a security check and the criminal history of
an employee, either contracted or directly employed, conducted
by the Louisiana State Police or authorized agency, upon offer
of employment or contract.

1. An employer may make an offer of temporary employment to a non-licensed person pending the results of the criminal history and security check on the person. In such instances, the employer shall provide to the Louisiana State Police, or authorized agency, the name and relevant information relating to the person within 72 hours after the date the person accepts temporary employment.

2. The security check shall consist of the use of personal identifiers, such as name, social security number, date of birth, and driver's license number, to search the national sex offender public registry. The provider shall obtain from the Louisiana State Police or the authorized agency the results of the security check to verify if an applicant is listed in the national sex offender public registry.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2179-2179.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:2061 (November 2006), amended LR 33:97 (January 2007), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:3176 (December 2012), LR 42:894 (June 2016), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

Subchapter D. Medication Administration and Noncomplex Tasks in Home and Community-Based Settings

§9243. General Requirements for the Performance of Medication Administration and Noncomplex Tasks in Home and Community-Based Settings

A. A registered nurse shall authorize and monitor medication administration and noncomplex tasks performed by the direct service workers. In order for the RN to authorize these tasks, the direct service worker shall:

1. ...

2. attend to an individual who:

a. - c. ...

d. receives periodic assessment by a RN based on the person's health status and specified within the plan of care; in no case shall the periodic assessment be less than annually. A comprehensive assessment performed for a client in accordance with policies and procedures established by Medicaid or by a ~~DHH~~-LDH program office may serve as the basis of the RN assessment but may not be used in lieu of the RN assessment.

B. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1031-1034.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:3177

(December 2012), amended LR 42:895 (June 2016), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

§9245. Training Requirements for the Performance of Medication Administration and Noncomplex Tasks in Home and Community-Based Settings

A. - A.2. ...

3. Based on the nursing assessment and clinical judgment, the RN shall provide additional person-specific training when the person receiving care has a change in health status or physician orders and yet remains in a stable, predictable condition. The RN may make a determination based upon his/her assessment of the worker's competency that training can be safely performed via telephone contact, other means of electronic communication, or face-to-face contact with the worker. Examples include, but are not limited to:

A.3.a. - B.3.b.iv. ...

C. A direct service worker who has not completed didactic training and demonstrated competency in accordance with guidelines established and approved by the Department of Health ~~and Hospitals~~ and the Louisiana Board of Nursing shall not be allowed to perform medication administration or any noncomplex tasks covered by this Rule.

D. ...

AUTHORITY NOTE: Promulgated in accordance with R.S.
37:1031-1034.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Bureau of Health Services Financing, LR 38:3177
(December 2012), amended LR 42:895 (June 2016), amended by the
Department of Health, Bureau of Health Services Financing, LR
45:

**§9249. Authorized Medication Administration and Noncomplex
Tasks in Home and Community-Based Settings**

A. - A.2. ...

3. other noncomplex tasks as identified by
guidelines established and approved by the Department of Health
~~and Hospitals~~ and the Louisiana Board of Nursing.

AUTHORITY NOTE: Promulgated in accordance with R.S.
37:1031-1034.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Bureau of Health Services Financing, LR 38:3178
(December 2012), amended by the Department of Health, Bureau of
Health Services Financing, LR 45:

Subchapter E. Violations

**§9273. ~~Allegations of Prohibited~~ Direct Service Worker Wrong-
Doing Conduct**

A. The department, ~~through the Division of Administrative
Law, or its successor,~~ provides a process for the review, and

~~investigation, and appeal of all allegations of wrong-doing by direct service workers DSWs. Direct service workers and trainees shall not~~
The following constitutes prohibited DSW conduct:

1. ~~use verbal, mental, sexual or physical abuse, corporal punishment or involuntary seclusion on an individual being supported; nor~~
2. ~~neglect of an individual or commit exploitation, extortion, or misappropriation of the individual's property or funds.~~
being supported; or
3. exploitation, extortion, or misappropriation of the individual's person, property or funds, inclusive of, but not limited to, the following:
 - a. credit card fraud;
 - b. theft of a firearm;
 - c. identity theft;
 - d. fraudulent acquisition of a credit card; or
 - e. theft of a vehicle.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2179-2179.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:2061 (November 2006), amended LR 33:98 (January 2007), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:3180

(December 2012), LR 42:895 (June 2016), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

§9275. Notice of Violation

A. When there are substantiated allegations against the direct service worker, either through oral or written evidence, the department will notify the individual(s) implicated in the investigation of the following:

1. - 2. ...

3. ~~the right to request from HSS an informal discussion (informal dispute resolution process); and~~appeal rights/opportunities:

a. the right to request from HSS an informal discussion (informal dispute resolution process); and

b. the right to request from the Division of Administrative Law an administrative hearing (appeal); or

c. the right to bypass the informal dispute resolution process and request appeal with the Division of Administrative Law.

4. ~~the right to request from the Division of Administrative Law an administrative hearing (appeal).~~Repealed.

B. The specified timeframe, up to and including permanent status, to cease employment as a DSW in a licensed health care

facility will be indicated in the notice letter of placement of the finding against the DSW.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2179-2179.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:2061 (November 2006), amended LR 33:98 (January 2007), LR 42:895 (June 2016), amended by the Department of Health, Bureau of Health Services Financing, LR 45:

Subchapter F. Administrative Hearings

§9285. General Provisions

A. - A.3. ...

a. Notification of the finding of abuse, neglect, exploitation, extortion, and/or misappropriation will then be sent to the DSW Registry to be recorded.

B. - C. ...

D. If there is a final and binding administrative hearing decision to place a finding on the DSW Registry against the direct service worker, the department shall place the direct service worker's name and the adverse findings on the DSW Registry. The ~~occurrence and findings~~ finding(s) ~~will~~ may remain on the DSW Registry against the DSW for a specified length of time up to and including permanently dependent on the severity and nature of the offense.

1. The specified timeframe, up to and including permanent status, to cease employment as a DSW in a licensed health care facility will be stated in the notice letter of placement of the finding against the DSW.

E. Removal of the DSW's name from the DSW Registry.

1. For those DSWs who only have a placement of finding of neglect, HSS will consider removal of the DSW's name from the Registry only upon the DSW's written request to the department for reinstatement and in accordance with the following:

a. the employment and personal history of the DSW does not reflect a pattern of abusive behavior or neglect or instances of misappropriation, exploitation or extortion of an individual being supported;

b. the neglect involved in the original finding was a singular occurrence; and

c. a period of no less than one year has passed since the DSW's name was placed on the Registry barring employment in a licensed health care facility as a DSW.

3. If the DSW successfully petitions the department to remove the DSW's name from the Registry, the DSW will be notified in writing of such determination and date of removal.

4. If the DSW unsuccessfully petitions the department to remove the DSW's name from the Registry, the DSW

will be notified in writing of the department's decision and their right to an administrative appeal in accordance with §9275.A(3)a-c.

5. There shall be only one opportunity for a DSW to request removal of their name from the DSW Registry.

6. There is no opportunity afforded for a DSW to request removal of a finding of abuse, extortion, misappropriation or exploitation placed against them on the Registry.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2179-2179.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:2062 (November 2006), amended LR 33:98 (January 2007), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:3180 (December 2012), LR 42:896 (June 2016), amended by the Department of Health and Hospitals, 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 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, 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 April 1, 2019.

The department will conduct a public hearing at 9:30 a.m. on March 28, 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



State of Louisiana
Louisiana Department of Health
Office of the Secretary

April 5, 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 Ruff

Re: Second Report on Proposed Amendments to LAC 50:XXIX. 105 and 949 – Pharmacy Benefits Management Program – Federal Upper Payment Limits and Physician-Administered Drugs

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Bureau of Health Services Financing, submits its second report regarding the proposed Pharmacy Benefits Management Program – Federal Upper Payment Limits and Physician-Administered Drugs rule amendment. A Notice of Intent on the proposed amendments was published in the February 20, 2019, issue of the *Louisiana Register* (LR 45:295). 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 February 20, 2019, Notice of Intent as a final rule when it is published in the May 20, 2019, issue of the *Louisiana Register*.

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

Cc: Jen Katzman, Medicaid Deputy Director, Bureau of Health Services Financing
Sue Fontenot, B Pharm, 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 Federal Upper Payment Limits and Physician-Administered Drugs Reimbursement (LAC 50:XXIX.105 and 949)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XXIX.105 and §949 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 amended the provisions governing the Pharmacy Benefits Management Program in order to revise the reimbursement methodology for physician-administered drugs in a physician office setting to bring the rates current and to incorporate a mechanism for periodic updates to the rates in compliance with U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) requirements (*Louisiana Register*, Volume 44, Number 6). The department promulgated a Notice of Intent which proposed to amend the provisions governing pharmacy ingredient cost reimbursement in order to change the reimbursement methodology from average acquisition cost to the national average drug acquisition cost (*Louisiana*

Register, Volume 45, Number 1). The department subsequently determined that the Notice of Intent published in the January 20, 2019 edition of the *Louisiana Register* erroneously repealed the provisions governing federal upper payment limits.

The department now proposes to amend the provisions governing reimbursement in the Pharmacy Benefits Management Program in order to: 1) reinstate the federal upper payment limits provisions; 2) align the reimbursement methodology for physician-administered drugs in a physician office setting with the corresponding CMS-approved State Plan Amendment; and 3) ensure that these provisions are appropriately promulgated in the *Louisiana Administrative Code*.

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. 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 NADAC of the ingredient or through wholesale acquisition cost (WAC) when no 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 D. Maximum Allowable Costs

§949. Fee for Service Cost Limits

A. - B.1.a. ...

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

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.~~Repealed.

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.

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

1. ~~Limits on payments~~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 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 that~~
meet all of the following requirements-:

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.

2. ~~Any practice which precludes the prescriber's handwritten statement~~ Medicaid ~~shall not be accepted as a valid certification. Such practices include, but are not limited to:~~
utilize the maximum acquisition cost established by CMS in determining multiple source drug cost.

~~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.~~a. - c.

Repealed.

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.

~~D. 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.~~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 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; or

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

E. ~~Federal Supply Schedule~~ Fee for Service 340B Purchased Drugs. ~~Drugs acquired at federal supply schedule (FSS) and at nominal price~~ The department shall be reimbursed 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 a 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 shall not bill 340B stock to Medicaid. Fee-for-service outpatient hospital claims for 340B drugs shall use a cost to charge methodology on the interim cost report and settled during final cost 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. ~~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~~ Federal Supply Schedule Drugs. Drugs acquired at federal supply schedule (FSS) and at a nominal price shall be reimbursed to IHS providers at actual acquisition cost plus a professional dispensing fee.

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

~~H. Physician-Administered Drugs. Medicaid-covered physician-administered drugs shall~~ 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 according to the Louisiana professional services fee schedule. Reimbursement shall be determined utilizing using the following brand/generic drug reimbursement 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.~~1. -

2.b.iv. Repealed.

I. Clotting Factor. Pharmacy claims for clotting factor will Physician-Administered Drugs. Medicaid-covered physician-administered drugs shall be reimbursed using according to the brand/generic drug reimbursement methodology 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. Average sales price (ASP) plus 6 percent, for drugs appearing on the Medicare file.

2. Reimbursement rates for drugs 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 there is no WAC available, the reimbursement rate will be 100 percent of the provider's current invoice for the dosage administered.

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

K. Investigational or Experimental Drugs. Investigational or experimental drugs shall not be reimbursed by Medicaid.

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:

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 and no direct or indirect cost

to the provider to provide the same level of service. These provisions will have no impact the provider's ability to provide the same level of service as described in HCR 170.

Interested persons may submit written comments 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 April 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 March 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 March 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 March 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