POLICY AND PROCEDURE

POLICY NAME: PHARMACY PROGRAM	POLICY ID: LA.PHAR.OP.09	
BUSINESS UNIT:- Louisiana Healthcare Connections	FUNCTIONAL AREA: PHARMACY	
EFFECTIVE DATE: 11/12	PRODUCT(S): MEDICAID	
REVIEWED/REVISED DATE: 10/13, 4/14, 11/14, 11/15, 9/16, 1/17, 7/17, 7/18, 10/18, 10/19, 12/21, 1/22, 5/22, 4/23,		
6/23, 4/24, 2/25 <u>,-12/25</u>		
REGULATOR MOST RECENT APPROVAL DATE(S): n/a		

POLICY STATEMENT:

It is the policy of Louisiana Healthcare Connections to have a comprehensive and high-quality pharmacy program.

PURPOSE:

To ensure that Louisiana Healthcare Connections (LHCC), Centene Pharmacy Services (CPS), and the Louisiana Singlecontracted Pharmacy Benefits Manager (PBM), to whom pharmaceutical management has been delegated, develop, and annually review and update policies and procedures for pharmaceutical management, using sound clinical evidence.

SCOPE:

This policy applies to Louisiana Healthcare Connections Pharmacy Department, Centene Pharmacy Services, Louisiana Healthcare Connections Medical Management Department, Centene Corporate Pharmacy and Therapeutics Committee, and the Louisiana contracted Medicaid Single Pharmacy Benefits Manager (PBM)

DEFINITIONS: (Acronyms section)

BOD - Board of Directors

CAD – Clinical Administered Drugs

CFR - Code of Federal Regulations

CMR - Comprehensive Medication Review

DAA - Direct Acting Anti-viral

DESI - Drug Efficacy Study Implementation

DUR - Drug Utilization Review

HEDIS - Healthcare Effectiveness Data and Information Set

HRSA - Health Resources and Services Administration

LDH - Louisiana Department of Health

LHCC – Louisiana Health Care Connections

MCO - Managed Care Organization

MN - Medical Necessity

MTM - Medication Therapy Management

NCQA - National Committee for Quality Assurance

NPDL - Non-Preferred Drug List

OPA - Office of Pharmacy Affairs

P&T - Pharmaceutical and Therapeutics

PA - Prior Authorization

PBM - Pharmacy Benefit Manager

PDL - Preferred Drug List

POS - Point of Sale

QAPIC - Quality Assurance and Process Improvement Committee

QI - Quality Improvement

ST - Step Therapy

UM – Utilization Management

PROCEDURE:

I. INTRODUCTION

A. PURPOSE

The purpose of the Louisiana Healthcare Connections (LHCC) Pharmacy Program is to provide access to pharmaceutical services to eligible Medicaid members, and to ensure that these services are a covered benefit, medically necessary, appropriate to the patient's condition, rendered in the appropriate setting, and meets professionally recognized standards of pharmaceutical care and aligns to the guidance set forth by the Louisiana Department of Health (LDH). In addition, the LHCC Pharmacy Program seeks to educate providers regarding the

cost-effective usage of drugs and to provide useful feedback about current prescribing patterns to improve the quality of patient care.

B. SCOPE

The Pharmacy Program applies to all members eligible to receive the pharmacy benefit. The scope of the program is to:

- First and foremost, align to LDH guidance and requirements for our managed care program
- Ensure that pharmacy benefit services provided are medically necessary
- Promote safe and cost-effective drug therapy
- Manage pharmacy benefit resources effectively and efficiently while ensuring that quality care is provided
- Ensure that members can easily access prescription services
- Actively monitor utilization to guard against over-utilization of services and fraud or abuse and to address gaps in care or underutilization of needed medication
- Work with the LHCC Quality Department to initiate and manage programs that increase the quality of pharmaceutical care for LHCC members.
- Champion and support efforts to ensure proper utilization of medications such as but not limited to opiates, supports efforts to curb opioid addiction and support education of medication-assisted treatment (MAT) in the treatment of opioid use disorders (OUD) to help member recovery.
- Champion review for fraud, waste, and abuse in our healthcare system
- Support the lock-in program

C. AUTHORITY

Centene Corporation is a fully-integrated government services managed care company with health plans in several states, including Louisiana Health Care Connections (LHCC). Due to differences in state regulations, Centene's Board of Directors (BOD) delegates the responsibility of the pharmacy program to LHCC's President/CEO who coordinates the provision of pharmacy services with Centene Pharmacy Services Department. The Louisiana Single contracted PBM is responsible for implementing benefit design, drug utilization review (DUR), the prior authorization (PA) process, pharmacy network management, pharmacy claims processing, pharmacy help desk, customer service functions, clinical reviews, and reporting. The dedicated LHCC Pharmacy team, along with Vendor Management, provides oversight of the contracted Louisiana Single Pharmacy Benefit Manger (PBM) to ensure all required functions are being met and the pharmacy benefit is being appropriately administered to our members consistent to LDH guidance and requirements.

<u>LHCC</u>, Centene, and/or its subsidiaries does not discriminate on the basis of race, color, national origin, sex, age, or disability, nor exclude from participation in, deny the benefits of, or otherwise subject to discrimination under any applicable Company health program or activity.

II. UTILIZATION MANAGEMENT GOALS AND FUNCTIONS

A. GOALS

The goals of the Pharmacy Program are to:

- Promote pharmaceutical utilization to support/improve clinical outcomes and ensure all program provisions are consistent to LDH guidance and requirements.
- Continuously expand access to services and care to ensure improved patient centered health outcomes, safety and optimize patient care using evidence-based clinical guidelines.
- Monitor and evaluate the quality, efficiency, and effectiveness of the pharmacy program
- Conduct DUR activities to monitor appropriate drug use, including but not limited to addressing gaps in care, inappropriate dosing, under or over prescribing via LDH approved DUR programs
- Ensure there are appropriate prospective, concurrent, and retrospective DUR programs in place consistent to LDH guidance and requirements.
- · Promote cost containment without compromising quality of care
- Identify, assess, and refer members who could benefit from case management/disease management or behavioral health
- Optimize patient care through use of evidence-based clinical guidelines
- Ensure confidentiality of member and practitioner information
- · Be a resource to other departments, Providers and Members regarding pharmacy benefits
- Ensure timely reviews of requests for drug prior authorization
- Be a resource regarding pharmacy appeals and grievances as needed

- Provide Provider and Member consultations related to drug therapy
- Identify and report cases of fraud, waste, and/or abuse to appropriate departments
- Review Members for the Lock-In program and perform required reassessments pursuant to LDH guidance
- Support all NCQA and HEDIS measures and requirements

B. FUNCTIONS

The key function of the Pharmacy Program is to promote the appropriate use of the pharmacy benefit. Components of the Pharmacy Program include:

- Use of prior authorization (PA) using medical necessity (MN) criteria and consistent to any LDH criteria provided for use
- Concurrent and retrospective DUR review and point of sale edits as approved by LDH
- Analysis of utilization data
- Develop, review and update policies and procedures that govern the various aspects of the pharmacy benefit consistent with contractual requirements
- Identify opportunities to improve quality of care and services
- Interface with other LHCC departments including Medical Management, Behavioral Health, Member Services, Provider Services, Provider Performance and Quality Improvement, etc. to support opportunities for case management, chronic care management, behavioral health management, and member and provider education
- Provide feedback to providers who demonstrate inappropriate prescribing patterns that deviate from recognized practice standards and guidelines.
- Lock-In initiatives and reviews

III. ACCOUNTABILITY AND ORGANIZATIONAL STRUCTURE

LHCC's Board of Directors has the ultimate authority and responsibility for the LHCC Pharmacy Program. The Board delegates the responsibility for the oversight of the Pharmacy Program to LHCC's Plan President/CEO. The CEO works closely with our LA based and state licensed pharmacist serving as Pharmacy Director to oversight all provisions of the pharmacy program. The pharmacy program activities are integrated with the LHCC's Utilization Management (UM) and Quality Improvement (QI) Programs. The utilization and quality issues and trends identified as part of the Pharmacy Program are reported to the LHCC's Quality Assurance and Process Improvement Committee (QAPIC).

IV. PHARMACY AND THERAPEUTICS COMMITTEE

The Centene P&T Committee presents policies, procedures and lists of pharmaceuticals and seeks feedback and input from the practitioners who are participating on the committee. Those participating practitioners are also involved in the development of pharmaceutical procedures that are used throughout the organization. The LHCC Pharmacy program will always default to LDH guidance and requirements in lieu of any company offered program or criteria to remain compliant to LDH contractual requirements.

LHCC's Director of Pharmacy is responsible for the oversight of the Pharmacy Program with the Chief Medical Officer (CMO) and works closely with the CEO and the <u>Single-contracted</u> PBM to ensure all contractual and regulatory obligations of the pharmacy program are met. Responsibilities include working with Centene Pharmacy Services staff and <u>Single-contracted</u> PBM Pharmacy Staff to:

- Review pharmacy policies to assure compliance with state rules and regulations.
- Review clinical drug criteria, used in the prior authorization and medical necessity review process, for appropriateness.
- Review policies and procedures developed by the corporate liaison from the Pharmacy Solutions Group and make suggestions for changes consistent with state regulations.
- Provide oversight of the state-mandated Singlecontracted PBM and their delegated responsibilities and programming as it applies to PA, medical necessity, and other pharmaceutical management edits.
- Support resolution of questions about the Pharmacy Program and educate providers on Pharmacy Program to promote provider satisfaction.
- Contact providers as necessary to discuss Pharmacy Program issues and provider complaints.
- Review and analyze LHCC's pharmacy cost, utilization reports and reports on trends and initiatives for costcontainment.
- Monitor practitioner prescribing patterns and suggest corrective action, as appropriate, for providers identified with prescribing concerns related to the provision of quality care.

 Serve as a liaison between the Pharmacy Department and other Louisiana Healthcare Connections departments and provide support to the Medical Management staff in the performance of their responsibilities.

VI. REVIEW OF PROGRAM ELEMENTS

A. DRUG UTILIZATION REVIEW (DUR) PROGRAM

LHCC maintains a DUR Program as outlined in LA.PHAR.OP.04 Drug Utilization Review.

B. LOCK-IN PROGRAM

LHCC maintains a Lock-In Program as outlined in LA.PHAR.OP.14 Lock-In Program.

C. PRIOR AUTHORIZATIONS

LHCC maintains a Prior Authorization (PA) Process as outlined in LA.PHAR.OP.08 Prior Authorization and Medical Necessity.

D. APPEALS AND GRIEVANCES

LHCC maintains a separate internal appeal processing department for the benefit of its members and provides members affected by an adverse coverage decision with a written explanation on how they or an authorized representative can access the appeals options. Providers may also appeal an unfavorable coverage decision on behalf of members.

E. PREFERRED DRUG LIST (PDL)

LHCC follows a single PDL which is approved by LDH's P&T committee. The PDL is posted on LHCC's website and can be downloaded and printed. It includes information on pharmaceutical management procedures, explanations of drug therapy limitations, PDL preferred product selection as determined by LDH, Prior Authorization (PA) and step therapy (ST) protocols, etc. The Process is outlined in *Preferred Drug List*, *LA.PHAR.OP.10*.

There are also excluded drugs and/or therapeutic categories which will not be included in the state's PDL nor in LHCC's provided coverage through use of the Single-contracted PBM. This includes, but is not limited to:

- a. Select agents when used for symptomatic relief of cough and colds, not including prescription antihistamines, and antihistamine/decongestant combination products
- b. Select agents when used for anorexia, weight loss or weight gain, not including orlistat
- c. Select agents when used to promote fertility, not including vaginal progesterone when used for high-risk pregnancy to prevent premature births
- d. Drug Efficacy Study Implementation (DESI) drugs, select non-prescription drugs, not including over-the-counter (OTC) antihistamines, antihistamine/decongestant combinations, or polyethylene glycol, etc.
- e. Select agents when used solely for erectile dysfunction
- f. Select agents when solely used for cosmetic purposes
- g. Non-legend or OTC drugs or items with some exceptions
- h. For a full listing of drugs excluded from coverage, LHCC references guidance posted by LDH in resources such as the MCO Manual, Pharmacy Benefit Management Services Manual, and the PDL.

F. SPECIALTY DRUGS

LHCC recognizes the importance of providing adequate access to specialty drugs to our members while ensuring proper management of handling and utilization. LHCC, through use of the Single PBM, follows PDL and criteria guidance provided by LDH for providing specialty drugs and works to ensure the drugs can be provided within our network to our members who may need them. LHCC complies with the specialty drug and specialty pharmacy requirements specified in the MCO Manual and pursuant to contractual requirements. LHCC maintains a *Specialty Pharmacy Program Policy* as outlined in *LA.PHAR.OP.12*.

G. SAFETY ISSUES

LHCC delegates real time adjudication of drug claims to the state-mandated Singlecontracted PBM's processing platform and to generate electronic alerts to dispensing pharmacies via standard point of sale (POS) messaging when potential drug conflicts exist consistent to LDH guidance. The PBM will utilize when consistent to any LDH guidance a passive notification to augment the dispensing pharmacy's internal DUR dispensing application and to avoid interruption or delays in drug therapy. LHCC will work with works with the

<u>contracted PBM</u> the <u>state-mandated Single PBM</u> to identify and notify appropriate parties of drug alerts and drug recalls which have the potential to cause serious health problems. LHCC's Drug recall process is outlined in *LA.PHAR.OP.02 FDA Drug Alert and Recall Notifications*.

H. EXCEPTIONS

Louisiana Department of Health (LDH) P&T Committee reviews and makes determination on PDL placement and clinical criteria for MCO use. This information is shared on our website and will be provided in any prior authorization adverse determination to direct to next steps as appropriate to receive the medication. A pharmacist or appropriate practitioner at the state-mandated Single PBM-reviews the exception requests received within turnaround times and against specific criteria following any LDH guidance. Clinical urgency is respected. Prescribers and members are notified of denials, and that an appeal process is available. For this reason, the state-mandated PBM who is delegated the responsibility of completing the reviews is held to strict protocols regarding the timeliness of clinical reviews. A 72-hour supply policy is in place to allow for interim therapy while a clinical review can be completed. In addition, if a member tries to obtain a non-PDL drug after hours or on holidays, the member is allowed a 72-hour supply until Single PBM Call Center LHCC resumes normal business hours.

I. CONTINUITY OF CARE

The continuity of care process, through use of the Single PBM, promotes the appropriate, safe, and effective transition of medication when applicable.

The transition of care program ensures:

- Members can continue treatment of maintenance medications (non-behavioral health) for at least 60 days
 after launch of pharmacy services, enrollment into the LHCC or switching from one plan to another
 through the capabilities of the Single PBM. LHCC, through the use of the Single PBM, does continue any
 treatment of behavioral health medications (such as but not limited to antidepressants, antipsychotics,
 etc.) for at least 60 days after enrollment into LHCC.
- An enrollee that is at the time of enrollment in LHCC receiving a prescription drug that is not on LDH's PDL, will be permitted to continue to receive that prescription drug if medically necessary for at least 60 days through the use of the Single PBM.
- 3. LHCC, through the use of the Single PBM, will continues the behavioral health therapeutic classes (Including long-acting injectable antipsychotics), and other medication assisted treatment (including Suboxone and naloxone) prescribed to the enrollee in a state mental health treatment facility for at least 60 days after the facility discharges the enrollee, unless the plan's psychiatrist, in consultation and agreement with the facility's prescribing physician, determines that the medications are not medically necessary, or potentially harmful to the enrollee.
- 4. An enrollee receiving a prescription drug that was on LHCC's PDL and subsequently removed or changed, is permitted to continue to receive that prescription drug if determined to be medically necessary for at least 60, as specified above. LHCC or the Single PBM will make a determination in consultation with the prescriber.

J. MEDICATION THERAPY MANAGEMENT (MTM) PROGRAM

Members eligible for the MTM program receive a Comprehensive Medication Review (CMR) that focuses on (i) safety, (ii) cost savings, (iii) care gaps such as non-adherence and omissions in care, and (iv) preventive care and lifestyle recommendations. The MTM service includes participation from community pharmacists and is conducted either face-to-face or telephonic at the member's discretion. The MTM program targets members who met criteria which includes:

- Specified disease states
- Minimum number of covered medications
- Projected annual medication spend

The MTM Process is maintained in *Medication Therapy Management Program*, LA.PHAR.OP.41.

K. 340B PROGRAM

The 340B program is a federal program administered by the Health Resources and Services Administration (HRSA). HRSA's Office of Pharmacy Affairs (OPA) maintains a searchable database of all healthcare providers enrolled as 340B covered entities (http://www.hrsa.gov/opa/). Medicaid and Managed Care Medicaid claims billed by 340B covered entities that self-attest to HRSA that their Medicaid populations are carved into their 340B programs are removed from Federal Medicaid Rebate invoicing. This means the provider attests that their Medicaid claims are all 340B discount stock and are not eligible for Federal Rebate collection. LDH sends a pharmacy provider file to LHCC on a quarterly basis indicating those pharmacies who qualified for 340 B status by HRSA.

Orphan drug regulations and 340B drug stock shortages are examples of isolated instances when a 340B covered entity's claims are not exclusively 340B.

2. Louisiana Medicaid requires a claim-level indicator be used by the billing provider in order to denote a drug claim's status as 340B.

The following values should be submitted on a pharmacy claim by a 340B covered entities to identify a 340B claim:

Pharmacy 340B Drug Claims:

- NCPDP: Bill value of "20" in the Submission Clarification Code field (420-DK)
- NCPDP: Bill value of "08" in the Basis of Cost Determination field (423-DN)
- LDH and LHCC direct the Single PBM to denyLHCC denies 340 B claims for all Hepatitis C direct acting anti-viral (DAA) agents. The denials should be based on the 340 B pharmacy list provided by LDH quarterly.

LHCC maintains a 340B Pharmacy Program Policy in LA.PHAR.OP.28 340B Pharmacy Policy.

L. REIMBURSMENT

The Single PBM_LHCC does not make or allow any direct or indirect reduction of payment to a pharmacist or pharmacy for a drug, device, or service under a reconciliation process to an effective rate of reimbursement, including, but not limited to, generic effective rates, brand effective rates, direct and indirect remuneration fees, or any other reduction or aggregate reduction of payment. This revision is to ensure transparent payments are made to Medicaid pharmacy providers.

M. COST SHARING

- 1. Louisiana Healthcare Connections, through use of the Single PBM, may impose cost sharing on Members in accordance with 42 CFR §447.50 §447.82 provided that it does not exceed Cost Sharing amounts in the state plan. The Copayment tiers in the state plan shall be based on the total amount reimbursed to the Pharmacy for the claim.
- 2. Louisiana Healthcare Connections, through use of the Single PBM, shall insures cost sharing incurred by all individuals in the Louisiana Medicaid Program household does not exceed an aggregate limit of five percent (5%) of the household's income applied on a quarterly or monthly basis as instructed by the state.
- 3. The State reserves the right to amend cost sharing requirements.
- Louisiana Healthcare Connections , through use of the Single PBM, may does not:
 - a. Deny services to a member who is eligible for services because of the members inability to pay the cost sharing
 - b. Restrict Members access to needed drugs and related pharmaceuticals products by requiring Members to use mail-order pharmacy providers
 - c. Impose Copayments for services specified in the state's Managed Care Organization (MCO) Manual

N. MAIL ORDER/MAIL SERVICE PHARMACY

LHCC does not require Members to use mail service pharmacy. LHCC does not exceed more than one percent (1%) of all pharmacy Claims for mail service pharmacy claims. LHCC Members are not charged any amounts above applicable copays for mail order (e.g., shipping and handling fees).

References:

Louisiana Healthcare Connections Louisiana Department of Health Contract Louisiana Medicaid Managed Care Organization (MCO) Manual

ATTACHMENTS:

ROLES & RESPONSIBILITIES:

REGULATORY REPORTING REQUIREMENTS:

La R.S. 46:460.54 applies to material changes for this policy

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Annual Review	Annual Review – Changes were not necessary	10/2013
Ad-hoc Review	Updated "goals" to include "Promote pharmaceutical utilization known to improve clinical outcomes."	04/24/14
Ad-hoc Review	LA Procurement 2015 Policy Update	11/2014
Annual Review	Clarified COC language due to BH requirements, Added Psychiatric Facility Discharge Medication Procedure, Added Dose Change Procedure, Clarified MTM language to include Community Pharmacist Involvement	12/2015
Annual Review	Changed 2015 to 2016	09/26/16
Annual Review	Remove the year. Changed US Script to Envolve Pharmacy Solutions; Under F. Safety Issues: indicated that Envolve Pharmacy Solutions can be designated to carry out member and provider notifications for drug recalls; Under G. Exceptions: added information for 72-hour supply after hours and on holidays.	01/24/17
Ad-hoc Review	Added section for 340B Program	07/24/17
Annual Review	Annual Review – changed policy reference from USS.PHARM.02 to EPS.PHARM.02.	07/24/18
Ad-hoc Review	Updated contract section numbers Changed Product Type from Louisiana Healthcare Connections to Medicaid	10/24/18
Annual Review	Added discrimination clause in section I.C. Added the name of LHCC policies to policy numbers Updated the PDL paragraph to reflect the State mandated Single PDL, Section IV.E Updated the Safety issues, IV. F to reflect changes from corporate policy Updated the 340 B language to include denials of Hepatitis C direct acting anti-viral (DAA) agents to be in compliance with MCO contract amendment 18 Changed "The Plan" to "LHCC"	10/24/19
Annual Review	Annual Review- No changes noted.	12/29/21
Annual Review	Annual Review- Added to the GOALS section: Continuously expand access to services and care to ensure improved patient centered health outcomes and safety; Monitor and evaluate the efficiency and effectiveness of the pharmacy program; and Optimize patient care through the use of evidence-based clinical guidelines. Added copyright language.	01/31/22
Ad hoc Review	Updated new RFP reference number to 2.12.7.4.1 to Reference and Continuity of Care header. Took out all reference to LHCC P&T Committee. Changed Director to VP of Pharmacy. Updated Amendment 11- 11: 17.11.5.4.6 Effective May 1, 2022, The PBM shall not make or allow any direct or indirect reduction of payment to a pharmacist or pharmacy for a drug, device, or service under a reconciliation process to an effective rate of reimbursement, including, but not limited to, generic effective rates, brand effective rates, direct and indirect remuneration fees, or any other reduction or aggregate reduction of payment. This revision is to ensure transparent payments are made to Medicaid pharmacy providers. Updated name change Envolve Pharmacy Solutions to Centene Pharmacy Services.	05/27/22
Annual Review	Updated to new P&P template. Updated per new LHCC Model Contract and LDH MCO Manual 2023. Updated Purpose Statement, Scope Statement, Acronyms Section, Procedure Purpose Statement, Procedure Scope Statement, Procedure Authority Section, Utilization Management Goals and Function sections, Accountability and Organizational Structure section, Pharmacy and Therapeutics Committee section, and updated Review of Program Elements sections A through M.	04/11/23
Ad hoc Review	Corrected grammar and formatting elements as suggested by LDH upon review, updated bulleted list describing drugs excluded from coverage, rearranged 340B information to improve readability – incorporated under reimbursement section. Updated policy title to include "OP" designation in alignment with edits to previous operational policies issued by LHCC.	06/13/23

Annual Review	Updated template to reflect implementation of Louisiana Medicaid Single PBM, added language to clarify that single PBM is held responsible for many of the contract requirements between LHCC and LDH (i.e. continuity of care, POS processing and messaging, pharmacy call center for all emergencies or override needs, reviewing of PA requests). Updated BH Continuity of Care section to reflect the MCO Manual's change from 90-day allowance to 60-day allowance. Updated names of all other pharmacy policies references to policy name updates throughout 2023 to include "OP". References section updated with hyperlinks to references on LDH website.	04/09/24
Annual Review	Adjusted numbering for V. Pharmacy Director Responsibilities and VI. Review of Program Elements, as one heading appeared to have been in the wrong section. Added name of Drug Recall Policy for reference (LA.PHAR.OP.02) in Safety Issues. Removed bulk of Specialty Pharmacy section since separate operational policy is maintained (LA.PHAR.OP.12). Revised grammar.	02/11/25
Annual Review	Updated policy to reflect transition away from Single PBM in October 2025. Grammar updates. Added reference to detailed 340B Pharmacy Policy (LA.PHAR.OP.28) in Section K. Minor formatting updates.	12/098/25

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.

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