Policy and Procedure

Title:	Policy and Procedure number:	Version number:
Recipient Management Lock-In Program (RMLP) - NC	RX LOCK 28150	23.1
Responsible department:	**Author:**	**Content Owner:**
Pharmacy Management/Oversight	Rodney Granlund	Samantha McKinley
Effective Date:	**Date of Policy Retirement: *URAC requirement**	**Last Reviewed Date:**
01/01/2023	N/A	05/08/2023
Regulatory information		
Resources and references		
Federal or state regulations and/or accreditation requirements:	• Code of Federal Regulations, Title 42, §431.54(e), which provides the state Medicaid agency with the authority to restrict a Medicaid recipient to a designated provider if the agency finds that a recipient has utilized Medicaid services at a frequency or amount that is not medically necessary, as determined in accordance with utilization guidelines established by the state. • §1927. [42 U.S.C.1396r-8] of the Social Security Act. • 42 C.F.R. § 456 subpart K of the Social Security Act. • 42 C.F.R. § 438.3(s)(2) and 42 C.F.R. § 438.3(s)(3). • Health Insurance Portability and Accountability Act (HIPAA) 42 USC [sect] 1320d. • BCBS PHP Contract 30-190029-DHB_Base Contract 2019 and all amendments • N.C. Gen. Stat. § 108A-68.2.12 • NC Medicaid Outpatient Pharmacy, Clinical Coverage Policy No. 9, Section 5.14: Beneficiary Management Lock-In Program • Strengthen Opioid Misuse Prevention (STOP) Act Overview, found on www at: www. ncbop.org/PDF/GuidanceImplementationsSTOPACTJuly2017.pdf • ATTACHMENT WLP to the WELLPOINT, INC. AMENDED AND RESTATED MASTER ADMINISTRATIVE SERVICES AGREEMENT, effective January 1, 2004. • MEMORANDUM OF UNDERSTANDING RELATED TO THE WELLPOINT, INC. AMENDED AND RESTATED MASTER ADMINISTRATIVE SERVICES AGREEMENT AND INGENIORX, INC. SERVICES, effective May 1, 2019.	

A01965MUWENCRX 06/22
Template Version Number: 24.0

Policy and Procedure

LOB & Product		
☐ Commercial ☐ Large Group ☐ Small Group ☐ Individual ☐ Health Insurance Exchange ☐ Multiple Employer Welfare Arrangement (MEWA)	☐ Medicare ☐ Part C (Part B Drugs) ☐ Part D ☐ Medicare Medicaid Plan/Duals (MMP)	☒ Medicaid ☐ Children's Health Ins. Program (CHIP) ☐ Essential Plan (EP)

Table of contents

I. Purpose

The North Carolina Medicaid Pharmacy Lock-In Program is designed to identify North Carolina Healthy Blue (Healthy Blue) members who may be over-utilizing prescribers, medications, and pharmacies.

This restriction program reduces inappropriate utilization, reduces costs, and improves quality of life through enhanced coordination of care.

II. Background and scope

This policy is specific to North Carolina Healthy Blue Medicaid membership as identified by the requirements defined in this policy and is specific to restrictions related to the pharmacy program.

III. Acronyms/definitions

AMH: Advanced Medical Home is a program that provides delegated care management services to certain North Carolina Medicaid members.

Appeal: A formal request to an organization by a practitioner or member for reconsideration of a decision (e.g., utilization review recommendation, benefit payment, administrative action, quality of care or service issue) with the goal of finding a mutually acceptable solution.

Case Manager: a nurse within Health Care Management (HCM) who coordinates care for enrolled members who have been identified as requiring it.

CCR: Customer Care Representative

A01965MUWENCRX 06/22
Template Version Number: 24.0

Policy and Procedure

CSRS: The Controlled Substances Reporting System is an electronic system used by licensed doctors and pharmacists to monitor the dispensing of Schedule II, III and IV controlled substance prescription drugs.

DMA: Division of Medical Assistance within the NC Department of Health and Human Services also referred to as “the Department”.

Good Cause: acceptable reasons to allow the member to permanently change their assigned providers (e.g., pharmacy or prescriber)

HCM: Health Care Management is the directorate within Healthy Blue in charge of planning, administration, and management of healthcare programs.

HIC: Hierarchical Ingredient Code is a means of identifying drugs based on their active ingredients developed by First Drug Databank; a full HIC is 6 characters in length; a HIC3 code refers to a HIC truncated to its first 3 characters that captures the therapeutic use.

Medicaid Lock-In: The department within Government Business Division that assists HCM with Lock-In administration and reporting.

PBM: A Pharmacy Benefit Manager refers to a business, organization, or service vendor that is contracted to administer/manage pharmacy benefits or the drugs of a medical benefit offered by a health plan. This acronym applies to companies such as CarelonRx who proactively manage drug benefits through various cost-containment efforts for health plans and managed care organizations. PBM’s generally act as a service vendor or health care consultant; provide member education; provide competitive pricing; and many other economic and service programs to manage the prescription drug spend.

PCP: Primary Care Provider

Permanent Change: a permanent re-assignment of a member to another designated pharmacy or prescriber for the duration of the original restriction.

PHS (Pharmacy Home System): an enterprise application owned by Lock-In Operations that automates certain processes within the program including candidate identification, letter generation, Lock-In load, and state reporting. It differentiates users by access levels, allowing them to interact within their assigned roles, such as (HCM) selecting enrollees and (Lock-In) changing locks.

Pharmacy Member Services: the call center that initially receives all pharmacy benefit calls.

Pharmacy Second Level: the call center that responds to escalated calls from Pharmacy Member Services.

A01965MUWENCRX 06/22
Template Version Number: 24.0

Policy and Procedure

PHP: Prepaid Health Plan

Provider: a registered pharmacy or a prescriber (physician, nurse practitioner, or physician's assistant).

RMLP: Recipient Management Lock-In Program the name of Healthy Blue's Lock-In program.

SFH: State Fair Hearing, also referred to as an "external appeal"

Temporary Override: a short-term (usually one (1) calendar day) authorization that enables a member to temporarily receive restricted medication written by a prescriber or filled at a pharmacy other than the one permanently assigned for a defined good cause reason (e.g., designated prescriber or pharmacy is unwilling or unable to see the member, the assigned pharmacy is closed or out of stock of needed medication when due for fill).

Utilization Review: a review and analysis by HCM, whether initial or periodic, to determine if misuse/overuse of designated controlled substance medications and/or controlled substances providers has occurred.

IV. Policy

To establish a policy and procedure for identifying Healthy Blue members for enrollment in the Recipient Management Lock-In Program (RMLP). The purpose of the RMLP is to manage members at risk for possible overuse or improper use of certain pain medications (opioid analgesics) and certain nerve medications (benzodiazepines anxiolytics), and those receiving these prescriptions from multiple prescribers.

V. Procedure

1) Identification of members for enrollment in the RMLP include the following:
   a. Reports provided by the Department identifying members previously locked in while in fee-for-service or other PHP.
   b. Members identified as meeting any one of following criteria:
      i. At least six (6) benzodiazepine anxiolytic claims in a period of two (2) consecutive months.
      ii. At least six (6) opioid analgesic claims in a period of two (2) consecutive months.
      iii. At least three (3) prescribers writing claims for opiate analgesics and/or benzodiazepine anxiolytics in a period of two (2) consecutive months.

Note: Identification and restriction is accomplished by use of a Drug List supplied by the Department in the form of HIC3 codes. The current Drug List provided by the Department contains the following HIC3 codes: S7G, H3A, H3H, H3J, H3M, H3N, H3U, H3X, H4A, AND H20. Effective 2/1/2022, we removed H3W as per the Department. These are drugs used to treat opioid dependence such as Suboxone®, Subutex®, Zubsolv®, and Probuphine®.

   c. Members identified by direct referrals to the Department or to Healthy Blue made by medical providers or social service agencies.

2) Members identified as having potential drug utilization issues will have their utilization claims forwarded to HCM for review. HCM will conduct a review to determine if there is any significant reason to not enroll a member in the RMLP such as an active cancer diagnosis, see Exclusions paragraph below. For members whom HCM decides to enroll in the RMLP, the following communications occur.

3) Communications:
   a. Member Letter – The member will be notified in writing via certified mail of this enrollment decision sixty (60) days prior to restriction. The letter will contain, at a minimum, the following information:
      i. General information on the RMLP - The purpose of the program, reason(s) for selection, and medications being restricted to designated providers (currently, opioid analgesics and benzodiazepine anxiolytics).
      ii. The start and end dates of the restriction.
      iii. Selection process for providers – The name and address of one frequently used pharmacy and prescriber will be provided to the member, along with instructions on how to choose different ones if the member responds back within the prescribed time, prior to restriction.
      iv. Timeframe available to the member to select a provider other than the identified providers. If there is no response from the member within sixty (60) calendar days from the date of the letter, the member will be locked into the designated pharmacy and prescriber listed on the 61st day.
      v. Lock-In change/override process – Description of allowable changes and phone number to call.
      vi. Member appeal information – Required appeal information, including address, phone/fax number, and time limit for filing.
      vii. Any additional state specific information required.
   b. Provider Letter – On the 61st day, the member's PCP or AMH and their designated providers (pharmacy/prescriber) will be notified of our decision to enroll the member in the RMLP under the care of the designated providers for restricted medications. The provider letter will contain, at a minimum, the following information:
      i. General information on the RMLP – the purpose of the program and reason(s) for selection.
      ii. The designated pharmacy(ies) and prescriber(s) for restricted medications (currently, opioid analgesics and benzodiazepine anxiolytics).
      iii. The start date and period of the restriction.
      iv. The claims used to identify the member, with the exception of Substance Use Disorder (SUD) medications such as Suboxone. As, pursuant to 42 C.F.R. Part 2 which prohibits disclosure of Substance Use Disorder (SUD) information without the member's written consent, allowing nonconsensual disclosure only with a disclosure statement in very limited circumstances, such as responding to member safety issues or reporting on fraud/waste/abuse, any claims data going to external providers will exclude all medications indicated exclusively for SUD (e.g., Suboxone).
      v. Education piece on the RMLP for the prescriber(s) to review with the member on the benefits of utilizing a single pharmacy and prescriber for all opioid and benzodiazepine prescriptions. The Education piece will also include, at a minimum, the following information:

a) The purpose of the program.
b) Description of the selection process.
c) Description of the services to be restricted.

4) Restriction:
   a. Once enrolled, the member will be restricted to receiving certain medications (opioid analgesics and benzodiazepine anxiolytics) from designated provider(s) only unless approved in advance by HCM (see "Provider Change/Override" below) except in the event of an emergency (see "Emergency Lock-In Override" below).
      i. For situations in which two (2) prescribers need to be utilized (e.g., psychiatrist prescribes benzodiazepines and pain management specialist prescribes opioids), HCM may be requested to allow up to two (2) designated prescribers.
      ii. For situations in which two (2) pharmacies need to be utilized (e.g., one (1) retail pharmacy and one (1) specialty pharmacy for medications unavailable via retail), HCM may be requested to allow up to two (2) designated pharmacies.

5) Exclusions: Healthy Blue Members who meet any one (1) of the following conditions are excluded from enrollment in the RMLP:
   a. Under age eighteen (18).
   b. Residing in a nursing facility, group home or personal care home.
   c. Receiving services through a home and community-based waiver program.
   d. Receiving hospice services.
   e. Having Cancer or Sickle Cell Disease diagnoses.
   f. Having utilized healthcare services at a frequency or amount which is medically necessary to treat a complex, life threatening medical condition, as determined by the HCM.
   g. Those who the Department has determined are exempt due to its belief that it is not in the best interest of the member.

6) Appeal Rights:
   a. Members have the right to appeal within sixty (60) days of the date of the initial letter if they disagree with HCM's decision to enroll them in the RMLP.
      i. Members may initiate an appeal by phone or in writing.
         1. Verbal Appeals - Members may initiate an appeal over the phone by calling Member Services toll-free at 844-594-5070 (TTY 711). Oral filings will be treated as appeals to establish the earliest filing date. To confirm the member's verbal appeal request, the Appeals Department will send the member an acknowledgement letter.
         2. Written appeals – Appeal Request Forms are available on our web portal at https://www.healthybluenc.com/north-carolina/benefits/appeal-grievances.html Members may elect to write a letter instead, including all appropriate identification information, the reason removal from restriction is desired, a copy of the lock-in notification letter if possible, and any desired supporting documentation. Written appeals may be sent by:

a) Mail:

N.C. Healthy Blue Appeals
P.O. Box 62429
Virginia Beach, VA 23466

b) Fax – (844) 429-9635
c) Email – ncmedicaidgrievances@nchealthyblue.com

7) State Fair Hearing Rights:
   a. Members may also request a State Fair Hearing (SFH) if they are unsatisfied with Healthy Blue's decision regarding their internal appeal. If an internal appeal is denied, members or their representatives have one hundred twenty (120) days from the date of the adverse determination letter to request a State Fair Hearing (SFH). SFH requests should be mailed or faxed to:

Office of Administrative Hearing (OAH)
Attention: Clerk of Court
6714 Mail Service Center
Raleigh, NC 27699-6714
Telephone: 919-431-3000
Fax: 919-431-3100

8) Program Administration:
   a. Length of Restriction:
      i. Initial period of restriction is two (2) years.
      ii. Sixty (60) days prior to the end of the two (2) year restriction period, PHS will generate unlock letters which will be mailed to members within thirty (30) days notifying them of unlock at the end of their restriction period. PHS will continue to review pharmacy claims data to identify members who meet criteria. If the member again meets criteria, after HCM and approves them as per the initial Lock-In process, the member will be notified of RMLP enrollment for another two (2) year period.
   b. Prescriber Changes/Overrides:
      i. Requests for permanent prescriber changes and temporary prescriber overrides may be made by calling Pharmacy Member Services at 844-594-5084 (TTY 711).
      ii. Permanent prescriber change - defined as a long-term change of designated prescriber, normally from the date of request to the end date of the original Lock-In period. Permanent prescriber changes will be reviewed by a Case Manager within one (1) workday. The outcome will be documented, and the member will be notified by phone or in writing. The member may request one (1) prescriber change per year without cause. More frequent changes may be permitted for good cause, as determined by HCM. Defined good cause reasons includes the following:
         1. The designated prescriber no longer wishes to be a provider for the member.
         2. The member has taken legal action against the designated prescriber or the designated prescriber has taken legal action against the member.
         3. The member requires specialized care for an acute or chronic condition, and the member and HCM agree that reassignment to a different Lock-In provider is in the member's best interest.

4. The designated prescriber closes, changes location, or the member is reassigned.
5. The member relocates outside of the designated prescriber's area.
6. The designated prescriber ceases to participate with Medicaid and/or with Healthy Blue.
7. The designated prescriber has been suspended, terminated, excluded or otherwise disqualified from participation in DMA and/or federal health care programs.

iii. Temporary prescriber override: defined as a short-term change of designated prescriber, normally from the date of request for a twenty-four (24) to seventy-two (72) hour period. The member may request a temporary prescriber change for good cause which will be reviewed by HCM during normal work hours (8 am to 5 pm EST Mon – Fri). Defined good cause reasons include the following:

1. The member's designated prescriber is temporarily unavailable.
2. The member's PCP or designated prescriber referred the member to another prescriber for a restricted medication.
3. The member was seen in a hospital or emergency room for an urgent injury or illness that could not wait for their designated prescriber and that resulted in a prescription for a restricted medication.

iv. After hours temporary prescriber override: in limited circumstances defined below, the CCR may place a temporary prescriber override and notify HCM by email for review the next workday:

1. Member is new to the RMLP (defined as within 30 days Lock-In start date), is assigned to a controlled-drug prescriber whom they say they don't know or see and presents a controlled drug prescription after normal HCM work hours (above). CCR may enter one override per plan year of a four (4) day supply of restricted medication(s) and notify HCM by email for review the next workday.
2. Member presents a controlled drug prescription after normal HCM work hours (above) which originated from a hospital, emergency room or urgent care center. CCR will first confirm the origin of the prescription with the pharmacist. CCR may enter one (1) override of a four (4) day supply of restricted medication(s) and notify HCM by email for review the next workday.

c. Pharmacy Changes/Overrides: Requests for permanent pharmacy changes and temporary pharmacy overrides may be made by calling Pharmacy Member Services at 844-594-5084 (TTY 711).

i. Permanent Pharmacy Change: Defined as a long-term change of pharmacy, normally from the date of request to the end date of the original period. Permanent pharmacy change requests will be reviewed by a Lock-In associate within one (1) workday. The outcome will be documented, and the member will be notified of the decision via mail the following week. Members may request one (1) pharmacy change per year without cause. More frequent changes are only permitted for good cause. Good cause for permanent pharmacy change is defined as:

1. The designated pharmacy no longer wishes to be a provider for the member.
2. The member has taken legal action against the designated pharmacy, or the designated pharmacy has taken legal action against the member.

3. The designated pharmacy closes, changes location, or the member is reassigned.
4. The member relocates outside of designated pharmacy's area.
5. The designated pharmacy is consistently unable to provide the need medication at the time of fill.
6. The designated pharmacy ceases to participate with Medicaid and/or with Healthy Blue.

ii. Temporary Pharmacy Override: Defined as a short-term change of pharmacy, normally for a twenty-four (24) to seventy-two (72) hour period. Requests will be reviewed by the CCR receiving the call while on the line with the member, the call will be documented, and the override will be approved/entered or denied/not entered based on one of the good cause reasons below:

1. The member does not have access to the designated pharmacy at the time of fill.
2. The designated pharmacy is temporarily out of the needed medication at the time of fill.

d. Emergency Lock-In Overrides: One (1) four (4) day emergency override of pharmacy and prescriber Lock-In is allowed to be entered by the pharmacist at point-of-sale once per restricted medication per member per plan year. Plan year is defined as each one (1) year of the member's two (2) year enrollment period (e.g., If the two (2) year enrollment period is 4/1/2022-3/31/2024, plan year one (1) is 4/1/2022-3/31/2023, and plan year two (2) is 4/1/2023-3/31/2024). If the pharmacist determines that an emergency exists, they

may enter a "03" (Emergency) in the Level of Service field of the pharmacy claims transaction to override the Lock-In. The pharmacy will only be reimbursed for the cost of the drug itself and a standard dispensing fee as determined by the Department, and the member will still have a copay.

9) Care Management:

During the administration of the program, HCM will work with the member and their providers to provide care management and education reinforcement as necessary. If deemed necessary, a Care Manager will educate members regarding appropriate pharmacy utilization, risks of the pattern of use of current medications, coordination of care among physicians, the importance of regular medication renewal and the importance of complying with provider visits and established treatment plan. They will also inform the member of the availability and process for accessing mental health and substance abuse services.

10) Regulatory Reporting:

a. Reports regarding RMLP-enrolled members with provider restrictions are sent to Regulatory Compliance for submission to State agencies as required by State contract.
b. Medicaid Lock-In will communicate membership changes, Lock-In effective dates, and provider changes/overrides to NC Tracks as required by State contract.

VI. Exceptions

There are no exceptions for this policy.

Policy and Procedure

VII. Revision history

Version number:	Approval date:	Prepared by:	Description of change(s):
23.1	06/17/2023	PnP Admin	• NC State Approved 6/17/23 (Annual Review)
23.1	05/08/2023	Rodney Granlund	• Annual Review • Purpose/Background & Scope: added to complete new template • Definitions: added PHS • Procedure: transferred Exceptions to Exclusions, expanded temporary and after-hours prescriber override
23.0	01/01/2023	Coralie Draper	• New policy created for CarelonRx – see A91 for archived version.