Policy and Procedure

Title:	Policy and Procedure number:	Version number:
Recipient Management Lock-In Program (RMLP) - NC	RX LOCK 28150	24.1
Responsible department:	**Author:**	**Content Owner:**
Primary: Pharmacy Lock-In Secondary: Pharmacy Management/Oversight	[redacted]	[redacted]
Effective Date:	**Date of Policy Retirement:** ***URAC requirement**	**Last Reviewed Date:**
01/01/2023	N/A	10/01/2024
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: https://www.ncbop.org/downloads/GuidanceImplementationSTOPACTUpdatedJune2023.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.	

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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)

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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 Medicaid pharmacy benefit program for these members.

Healthy Blue is a Medicaid plan offered by Blue Cross and Blue Shield of North Carolina ("Blue Cross NC"). Certain administrative services for Healthy Blue are provided by Amerigroup Partnership Plan, LLC. ("Amerigroup") pursuant to a strategic alliance with Blue Cross NC. Blue Cross NC and/or Amerigroup are hereinafter referred to as the Health Plan.

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.

CarelonRx: CarelonRx is contracted to manage pharmacy benefits for health plan members and may herein be referred to as the Pharmacy Benefit Manager. No individuals have an ownership or controlling interest in CarelonRx, Inc., a wholly owned (100%) subsidiary of Carelon Holdings, Inc., which is a wholly owned (100%) subsidiary of Elevance Health, Inc., formerly

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

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 six (6) characters in length; a HIC3 code refers to a HIC truncated to its first three (3) characters that captures the therapeutic use.

Lock-In Ops: Lock-In Operations is a division within CarelonRx that supports Government Business with Lock-In program administration and reporting.

MCO: Managed Care Organization, also referred to as a "Prepaid Health Plan." A Managed Care Organization (MCO), Managed Care Entity (MCE), Managed Care Plan (MCP) or Care Management Organization (CMO) is an organization that provides health care insurance (i.e., medical, dental, pharmaceutical, etc.) designed to provide high quality care at the lowest possible cost by using a variety of utilization/quality control and cost containment methods. For purposes of this policy, MCO/MCE/MCP/CMO refers to the applicable health plan as appropriate.

NC DHHS: North Carolina Department of Health and Human Services, also referred to as the Department

PBM: A Pharmacy Benefit Manager refers to a business, organization, or service vendor that is contracted to administer/manage pharmacy benefits and/or certain physician administered drugs.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. PBMs 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 is an enterprise application owned by Lock-In Ops 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 Ops) changing locks.

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

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.

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SFH: State Fair Hearing offers a Medicaid beneficiary the opportunity to appear before an administrative law judge when an MCO has taken an action to deny, reduce, suspend, or terminate Medicaid services. It may be filed after an "internal appeal" has been denied and is 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

This policy outlines the procedures used 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.

CarelonRx is the contracted PBM for North Carolina Healthy Blue and will perform its duties in support of the MCO's contractual obligations listed below.

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 Medicaid Direct or another Prepaid Health Plan (PHP).
   b. Members identified as meeting any of following criteria:
      i. Received 10 or more claims for benzodiazepines in 2 consecutive months when not medically necessary.
      ii. Received 10 or more claims for opiates in 2 consecutive months when not medically necessary.
      iii. Received prescriptions for opiates from four (4) or more prescribers in two (2) consecutive months when not medically necessary.
      iv. Received prescriptions for benzodiazepines from four (4) or more prescribers in two (2) consecutive months when not medically necessary.
      v. Received prescriptions for a combination of opiates and benzodiazepines from four (4) or more prescribers in two (2) consecutive months when not medically necessary.

Note: Identification and restriction are 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, H3W was removed per NC DHHS requirements. H3W includes drugs used to treat opioid dependence such as Suboxone®, Subutex®, Zubsolv®, and Probuphine®.

2) Members identified as having potential drug utilization issues will have their utilization

claims forwarded to HCM for 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, Lock-In Ops will notify the member and providers (pharmacy/prescriber).

3) Communications:
   a. Member Letter – The member will be notified in writing via certified mail of this enrollment decision at least 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, and the appeal end date (sixty [60] days from the date of notice).
      iii. Selection process for providers – The name and address of one (1) 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 no later than the seventieth (70^{th}) 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 – The member's Primary Care Provider (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(s) 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, except for 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.

c. Other Letters – sent as appropriate:
   i. Final Member Selection Letter
   Confirms designated pharmacy and prescriber selections after the 60 (sixty) day appeal window has ended. If the member has not responded by then, they will be locked into the designated pharmacy and prescriber listed no later than the seventieth (70th) day from the date of the initial member letter.
   ii. Member Pharmacy Change Granted or Denied Letters
   Notifies member of approval or denial of pharmacy change request based on predefined criteria. The approval letter informs the member of the need to use the new pharmacy for all restricted medications going forward. The denial letter lists general denial reasons.
   iii. Transition of Care (TOC) Letter
   Notifies TOC members of continuation of previous restriction until the original program end date (noted). Identifies designated pharmacy(s) and prescriber(s), provider change and temporary override processes, and toll-free point of contact.
   iv. Network Disruption Letter
   Informs member that their pharmacy is closing or going out of network, identifies an alternative pharmacy, and informs member of the Lock-In start date of the newly designated pharmacy if they do not respond back to change by the date listed.

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 one (1) of the following conditions are excluded from enrollment in the RMLP:
   a. Under age eighteen (18).
   b. Residing in a skilled nursing facility.
   c. Receiving hospice services.
   d. Prescribed drugs containing buprenorphine that are specifically indicated for the treatment of Opioid Use Disorder (OUD)

e. Having a Cancer diagnosis within the past year, or a Sickle Cell Disease diagnosis.
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.

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 24/7 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 toll-free 24/7 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 DHB 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 Customer Care Representative (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 thirty (30) days of Lock-In start date), is assigned to a controlled-drug prescriber whom they say they do not know or see and presents a controlled drug prescription after normal HCM work hours (above). CCR may enter one (1) 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 toll-free 24/7 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 (1) 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 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, Lock-In Ops may request the CM to outreach a member and/or their provider for care management and education reinforcement, as necessary. For example:

a. Lock-In Ops may receive notification that the member is believed to have requested excessive temporary overrides. Lock-In Ops will investigate log notes to determine if the override reasons given met good cause criteria and will report findings to HCM for member outreach as the CM deems appropriate. If good cause criteria is met, the CM may determine that no action is required, or that the member requires a second provider be added. If good cause criteria is not met, the CM may elect to education the member on appropriate pharmacy utilization, risks of the pattern of use of current medications, coordination of care among physicians, the importance of regular medication renewal and of complying with provider visits and established treatment plan, or of the availability of and process for accessing mental health and substance abuse services.
b. Lock-In Ops may receive notification that a member's claims are rejecting because their provider is no longer enrolled in NC Medicaid. If a pharmacy, Lock-In Ops will identify a nearby network pharmacy that is enrolled in NC Medicaid and will request HCM to attempt member outreach. If a prescriber, Lock-In Ops will forward the non-enrolled prescriber information to HCM for HCM to attempt member outreach to identify an enrolled prescriber.

10) Reporting Requirements:
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.

VII. Revision history

Version number:	Approval date:	Prepared by:	Description of change(s):
24.1	10/01/2024	[redacted]	• Off-Cycle update • Procedure: 1 b criteria change per State Mandate for Opioid Misuse Prevention Program.
24.0	04/22/2024	[redacted]	• Annual Review • Definitions: Removed: CCR, DHB, Pharmacy Second Level.

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			Added: CarelonRx, NC • Procedure: Added #3 c, toll-free 24/7 to several paragraphs, re-worded # 9 to align with state policy.
23.3	10/30/2023	[redacted]	• NC State Approved 10/30/2023 (Off-cycle update)
23.3	10/13/2023	[redacted]	• Off-cycle update • Definitions: changed DMA to DHB • Procedure: updated acronym
23.2	09/13/2023	[redacted]	• Off-cycle update • Definitions: Removed CSRS and PHP • Procedure: Communications updated Appeal End Date to member letter and clarified lock-in effective date
23.1	06/17/2023	[redacted]	• NC State Approved 6/17/23 (Annual Review)
23.1	05/08/2023	[redacted]	• 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	[redacted]	• New policy created for CarelonRx – see A91 for archived version.

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