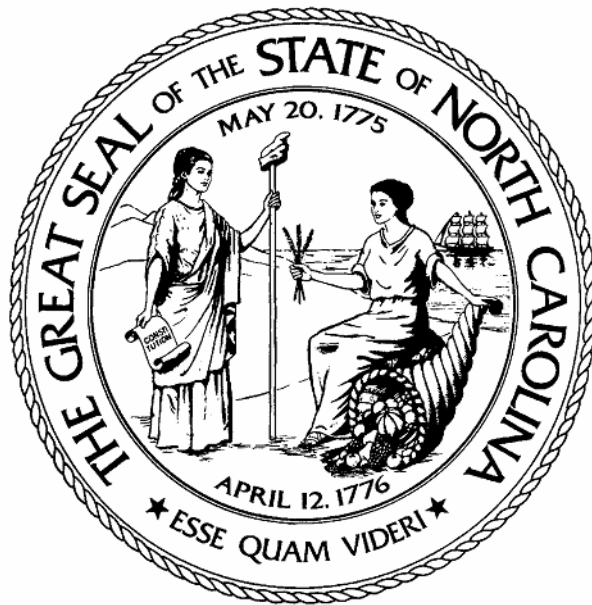


Medicaid Beneficiary Management Lock-in Program

Session Law 2015-268, Section 4.4



Report to

**The Joint Legislative Program Evaluation
Oversight Committee**

By

North Carolina Department of Health and Human Services

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I. INTRODUCTION

The North Carolina Administrative Code, 10A NCAC 22F .0704 and 10A NCAC 22F .0104, Session Law 2015-241, Section 12F.16.(l), along with 42 CFR 431.54 and the Medicaid State Plan support the State's development of procedures for the control of beneficiary overutilization of Medicaid benefits, including development and implementation of a Medicaid Beneficiary Management Lock-in Program ("Lock-in Program"). The purpose of the Lock-in Program is to monitor and prevent the overutilization and abuse of prescribed controlled substances, including opioids and benzodiazepines, by Medicaid beneficiaries. The program works by restricting beneficiaries who qualify for the program to one prescriber and one pharmacy for those prescriptions. The program is intended to improve beneficiary safety, encourage coordination of care, and decrease inappropriate or unnecessary utilization.

The Division of Medical Assistance ("DMA") first implemented the program in July 2010 with beneficiary enrollment beginning in October 2010. Under the current program, beneficiaries are identified as qualifying based on Medicaid claims data, using the following criteria:

- (a) receipt of greater than six (6) claims in two (2) consecutive months for benzodiazepines and/or certain anxiolytics;
- (b) receipt of greater than six (6) claims in two (2) consecutive months of opioid analgesics; or
- (c) receipt of prescriptions for opiates and/or benzodiazepines and certain anxiolytics from greater than three (3) prescribers in two (2) consecutive months.

Based on these patterns of utilization, beneficiaries identified for the Lock-in Program are restricted to a single prescriber and pharmacy in order to obtain narcotic analgesics, benzodiazepines, and certain anxiolytics covered through the Medicaid Outpatient Pharmacy Program. Those identified for the program are mailed a notification letter which explains the reason they qualified for the program. Beneficiaries are given the right to appeal DMA's decision to place them in the Lock-in Program per federal regulations. Beneficiaries are permitted to select their prescriber and pharmacy and given a toll free number to call if they have questions. The prescriber and pharmacy chosen by the beneficiary each receive a letter notifying them that NCTracks will reflect that they are the chosen provider for the particular beneficiary.

Session Law 2015-268, Section 4.4. expands the Lock-in Program by increasing the time period for beneficiary lock-in from one year to two years and raising program enrollment capacity. This report is intended to provide an update on implementation of these changes. DMA is presently working with its fiscal agent, CSRA, to implement program changes. The anticipated date of implementation is December 4, 2016. Per legislation, DMA will conduct an audit within six months of implementation of the program changes and report on fiscal impact within one year of implementation. Please see **Appendix A** for the text of Session Law 2015-268, Section 4.4.

II. PROGRESS TOWARD IMPLEMENTATION

1) ESTABLISHING WRITTEN PROCEDURES FOR OPERATION

DMA and its claims processing contractor, CSRA, have established written procedures for the operation of the Lock-In Program. Two Customer Service Requests (“CSRs”) have been generated to implement the program in NCTracks. These CSRs convert program requirements into working processes that meet program needs, such as the process for claims adjudication and operation of the call center. DMA vets the CSRs, but CSRA is ultimately responsible for determining financial, programmatic, and staffing needs.

Below is a partial summary of responsibilities under these CSRs. For a more detailed description, please see *Appendix B* for Business Requirements for CSR 1078 and *Appendix C* for Business Requirements for CSR 1927.

DMA Responsibilities

- Oversee the Lock-in Program.
- Develop and revise lock-in policies and procedures, as appropriate.
- Enforce lock-in policies and procedures via the Medicaid Management Information System (MMIS) and CSRA.
- Serve as the subject matter expert for stakeholders and gateway for stakeholder questions and concerns regarding the program. Provide information on the program, including publishing informational bulletins related to the program.
- Conduct a monthly clinical review of beneficiaries recommended by CSRA for participation in the Lock-in Program.
- Oversee the appeals process for the program via a state contract with the Office of Administrative Hearings.
- Ensure the program is analyzed annually by an actuarial service.

CSRA Responsibilities

- Develop and maintain, through NCTracks MMIS, the system requirements for managing the Lock-in Program, including:
 - Capability for beneficiaries to be locked-in **to** and locked-out **from** a specific pharmacy and/or prescriber.
 - Capability for beneficiaries to be locked into the program for a 2 year period.
 - Capability to allow one 4-day emergency fill event per year.
 - Capability to provide notification letters to beneficiaries and providers.
 - Capability to adjudicate claims in accordance with program requirements.
- Provide “Call Center” coverage from 7:00 am until 11:00 pm Eastern Standard Time on State business days, Monday through Friday, and from 7:00 a.m. until 6:00 p.m. Eastern Standard Time on Saturday and Sunday.
- Review and recommend beneficiaries to be locked-in monthly based on utilization data.
- Participate in the appeals process, including mediations and hearings.

2) ESTABLISHING PROCEDURES FOR DATA SHARING WITH THE CONTROLLED SUBSTANCES REGULATORY BRANCH

The Drug Control Unit is housed under the Department's Division of Mental Health, Developmental Disabilities, and Substance Abuse Services. The Drug Control Unit administers the Controlled Substances Reporting System (CSRS), an electronic database that contains data on prescribed controlled substances dispensed in the State. CSRS was established by North Carolina law to improve the state's ability to identify individuals who abuse prescription drugs classified as Schedule II-V controlled substances. It is also intended to assist clinicians in identifying and treating patients misusing controlled substances.

DMA does not currently interface with CSRS. However, DMA has met with the Controlled Substances Regulatory Branch to discuss the potential for data sharing and noted some potential obstacles, including the following:

- i. It may require extensive IT resources to establish bulk data sharing.
- ii. CSRS entries and Medicaid beneficiaries are not always easy to match. NCTracks adjudicates claims based on the Medicaid ID, whereas CSRS data is based on name and date of birth.
- iii. CSRS does not require pharmacies to submit reversed or adjusted claims. Claims that are reversed may show up as paid in CSRS, creating false positives.

Funds appropriated by Session Law 2016-94, Section 12F.7.(a) to improve CSRS may assist in overcoming these obstacles. DMA will continue to discuss the potential for data sharing with the Drug Control Unit. .

3) REVISING LOCK-IN DURATION AND ELIGIBILITY CRITERIA AND REPORTING COSTS

- i. DMA worked with the Physician Advisory Group (PAG) to amend DMA Clinical Coverage Policy No. 9, Outpatient Pharmacy, in order to extend the lock-in duration from one year to two years. PAG is a charitable, nonprofit organization that was created for the purpose of advising the North Carolina Department of Health and Human Services on ways to improve the health of the state's vulnerable populations by expanding access to quality, cost-effective health care services. NCGS § 108A-54.2 requires DMA to consult with and seek the advice of PAG during the development or amendment of clinical coverage policies. Following PAG acceptance of the update, the policy was posted for 45 days for public notice and comment. No public comments were received. The final, revised policy is now posted on DMA's website. Please see *Appendix D* for the updated policy language found in Section 5.14 of the policy.
- ii. No revisions were made to the Lock-in program eligibility criteria. However, DMA continues to monitor the use of narcotic medications dispensed through the Outpatient Pharmacy Program and to align with the CDC's guidance on best practices for the treatment of chronic pain. In addition to changes to the Lock-in Program, DMA is working to revise its narcotics analgesics policy to align with statewide and national strategic goals for preventing prescription drug abuse. Key components of the policy are to decrease the maximum morphine equivalent doses allowed and to decrease the length of use of these

medications without a Prior Authorization. This approach allows DMA to more broadly impact prescription drug abuse in the Medicaid population, rather than only among Lock-in participants.

- iii. Since the updated program has not yet been implemented, a fiscal analysis has not yet been conducted. Per the requirements of Section 4.4.(3), DMA will report on fiscal impact within one year of implementation. It is expected that the fiscal analysis will provide valuable feedback on program performance as well as estimated cost savings of the program, if any. Please see **Appendix E** for a Proposed Work Plan created by DMA's contracted actuarial service, Myers and Stauffer.

4) DEVELOPING WEBSITE AND COMMUNICATION MATERIALS

DMA has developed a number of communication materials to inform lock-in enrollees, prescribers, pharmacies, and providers (including emergency room health care providers) about the program. Many of these materials already exist and are being updated based on changes to the program.

- **DMA Clinical Coverage Policy No. 9, Outpatient Pharmacy**
 - As noted above, this policy has been amended to address changes to the Lock-in Program and is posted on DMA's website.
 - Please see **Appendix D** for the revised language.
- **Article in Pharmacy Newsletter and Medicaid Bulletin**
 - An article outlining the changes will be posted in both the DMA Pharmacy Newsletter and the Medicaid Bulletin. This article will be published just prior to going live with the proposed changes outlined in CSR 1927.
- **Lock-in Letters to Beneficiaries, Selected Prescribers, and Selected Pharmacies**
 - Beneficiaries selected to participate in the program receive an initial notice in the form of a trackable letter that informs them about the program, gives them the opportunity to select a prescriber and pharmacy, and provides information on appeal rights. Please see **Appendix F** for the initial beneficiary notice.
 - Just prior to the lock-in begin date, beneficiaries receive a second notice as a reminder. Please see **Appendix G** for the second beneficiary notice.
 - Once a beneficiary has selected a prescriber and pharmacy, a notice also goes out to each of the selected providers. Please see **Appendix H** for the notice to the selected prescriber and **Appendix I** for the notice to the selected pharmacy.
- **DMA Outpatient Pharmacy Website**
 - DMA's outpatient pharmacy website contains a link to Clinical Coverage Policy No. 9. It will also contain links to the article in the Pharmacy Newsletter and Medicaid Bulletin once those articles are published. The articles will include the Lock-in Call Center toll free phone number at CSRA.
 - The website can be found at this web address:

5) INCREASING PROGRAM CAPACITY

Following final implementation of CSR 1927, program capacity will increase from 200 to 600 Medicaid beneficiaries per month. At the end of one year, it is expected that approximately 7,200 beneficiaries will have been identified for the Lock-in Program, compared to the 2,400 beneficiaries currently being identified. Additionally, once locked into the program, enrollees will remain locked in for the longer time period of two years. By the end of year two, the program could have as many as 14,400 participants.

6) CONDUCTING AN AUDIT

Since the updated program has not yet been implemented, an audit has not yet been conducted. Per the requirements of Section 4.4.(6), DMA will conduct an audit within six months of implementation. The audit will: (1) evaluate the effectiveness of the program in preventing overutilization of controlled substances; (2) identify program vulnerabilities; and (3) address whether there is suspicion of fraud or abuse within the program. Please see **Appendix E** for a Proposed Work Plan created by DMA's contracted actuarial service, Myers and Stauffer.

III. CONCLUSION

The Medicaid Beneficiary Management Lock-in Program supports North Carolina's statewide initiative for preventing prescription drug abuse through coordination of care with a single prescriber and pharmacy for the use of narcotic analgesics and benzodiazepines. This program encourages safer practices and improved outcomes for beneficiaries who need these types of medications and has the potential to deter overutilization. DMA continues to work diligently with CSRA to expand program capacity and comply with the legislation that authorizes this program.

IV. APPENDICES

Please see the appendices that follow for documentation referenced in the report.

Appendix A: Session Law 2015-268, Section 4.4.

"The Division of Medical Assistance of the Department of Health and Human Services (DMA) shall take the following steps to improve the effectiveness and efficiency of the Medicaid lock-in program:

- (1) Establish written procedures for the operation of the lock-in program, including specifying the responsibilities of DMA and the program contractor.
- (2) Establish procedures for the sharing of bulk data with the Controlled Substances Regulatory Branch.
- (3) In consultation with the Physicians Advisory Group, extend lock-in duration to two years and revise program eligibility criteria to align the program with the statewide strategic goals for preventing prescription drug abuse. DMA shall report an estimate of the cost-savings from the revisions to the eligibility criteria to the Joint Legislative Program Evaluation Oversight Committee and the Joint Legislative Oversight Committee on Health and Human Services within one year of the lock-in program again becoming operational.
- (4) Develop a Web site and communication materials to inform lock-in enrollees, prescribers, pharmacists, and emergency room health care providers about the program.
- (5) Increase program capacity to ensure that all individuals who meet program criteria are locked in.
- (6) Conduct an audit of the lock-in program within six months after the effective date of this act in order to evaluate the effectiveness of program restrictions in preventing overutilization of controlled substances, identify any program vulnerabilities, and address whether there is evidence of any fraud or abuse within the program.

DMA shall report to the Joint Legislative Program Evaluation Oversight Committee by September 30, 2016, on its progress toward implementing all items included in this section."

Appendix B: “Business Requirements” Section from PDD for CSR 1078

1. Business Requirements

The purpose of this Project Design Document (PDD) is to describe the scope, approach, assumptions, and design changes needed in NCTracks to support the following business requirements for the North Carolina Recipient Management Lock-in Program.

1.1 Requirements

The following table lists the State-defined requirement(s) established for this project.

Requirement Number	Description
40.2.1.114	Provides capability for recipient lock-in/lock-out from a specific pharmacy and/or primary care provider and/or prescriber.
40.2.1.115	Provides capability for claims exceptions to process automatically when prior authorized by the lock-in/lock-out primary care provider or prescriber in accordance with State policy.
40.2.1.116	Provides capability for historical begin and end dates for each lock-in and lock-out segment, as well as the reason for lock-in/lock-out.
40.2.1.117	Provides capability for an unlimited number of lock-in/lock-out segments per recipient.
40.2.1.118	Provides capability for multiple concurrent active lock-in/lock-out segments of any type.
40.2.1.119	Provides capability for online inquiry and update into lock-in/lock-out segments.
40.2.1.120	Provides capability to maintain an audit trail of all changes to lock-in/lock-out segments.
40.8.1.75	Provides capability to edit against lock-in/lock-out recipient data for pharmacy, primary care provider, and/or prescriber.
40.8.1.150	Provides capability to allow for exceptions to pharmacy lock-ins.
40.8.1.217	Provides capability for claims exceptions to process automatically when prior authorized by the lock-in primary care provider or prescriber in accordance with State policy.
40.8.1.428	Provides capability to display the recipient, the pharmacy provider, and the prescriber the recipient is locked into, along with the effective dates and end dates, on a user interface screen.
40.8.1.429	Provides capability to display a secondary pharmacy provider and a secondary prescriber on the user interface screen.
40.8.1.430	Provides capability to apply lock-in to specific drug General Classification Code 3 (GC3) classes with a schedule drug indicator of 2, 3, 4, or 5.
40.8.1.431	Provides capability to implement two new Legacy edits (1140, 1141).
40.8.1.432	Provides capability to activate one Legacy audit (2485) associated with lock-in.
40.8.1.433	Provides capability to allow only one emergency fill event during a 1-year period.
40.8.1.434	Provides capability to include information on the Lock-in Program in the Automated Voice Response System (AVRS) and web query responses.
40.2.2.15	After ranking the candidate recipients as required by Requirement 40.2.2.17, each month the Fiscal Agent shall identify a list of the 200 highest ranking candidates for the Recipient Management Lock-in Program.
40.2.2.16	The Fiscal Agent shall identify additional recipients on a monthly basis for the Recipient Management Lock-in Program based on referrals from a provider, DMA, or CCNC.
40.2.2.17	The Fiscal Agent shall score and rank the list of candidate recipients who meet the criteria for the Recipient Management Lock-in Program based on scoring guidelines approved by the State.
40.2.2.18	The Fiscal Agent shall provide profiles of recipients recommended for participation in the Recipient Management Lock-in Program to DMA for validation and approval every month.
40.2.1.182	The system shall provide the capability to capture a prescriber's information in NCTracks even though the prescriber is not enrolled as a provider in NCTracks.
40.2.1.183	The system shall provide the capability to generate and send letters on a monthly basis to recipients notifying them of the lock-in decision.

Requirement Number	Description
40.2.2.19	The Fiscal Agent shall receive letters from recipients identifying their selected lock-in pharmacy and prescriber and ensure selections are recorded on the lock-in file.
40.2.2.20	The Fiscal Agent shall select a lock-in prescriber and pharmacy if one is not selected by the recipient or if the recipient does not return the selection form.
40.2.2.21	The Fiscal Agent shall allow candidates for the Recipient Management Lock-in Program to appeal the lock-in decision.
40.2.2.22	The Fiscal Agent shall allow candidates selected for the Recipient Management Lock-in Program to enroll in a secondary pharmacy and prescriber in addition to the primary pharmacy and prescriber when it is determined to be medically appropriate.
40.2.2.23	The Fiscal Agent shall allow recipients participating in the Recipient Management Lock-in Program to change lock-in pharmacy or lock-in provider when deemed medically appropriate as directed by the State.
40.2.1.184	The system shall provide the capability to generate and send letters on a monthly basis to pharmacies notifying them of the recipients that are locked in to the pharmacy. The letters must be sent within a minimum of five (5) State business days prior to the begin date of the lock-in period for the beneficiary.
40.2.1.185	The system shall provide the capability to generate and send letters on a monthly basis to prescribers notifying them of the recipients that are locked in to the prescriber. The letters must be sent within a minimum of five (5) State business days prior to the begin date of the lock-in period for the beneficiary.
40.2.2.24	The Fiscal Agent shall create a comprehensive recipient profile that identifies the criteria the recipient has met including diagnosis codes, descriptions, procedure codes and claims marked by date of service and grouped by category for easy review. Pharmacies and prescribers must also be identified on the profile.
40.2.2.25	The Fiscal Agent shall maintain the recipient profiles for clinical review, including review comments and copies of all letters sent to the recipient, prescriber, and pharmacy along with the recommended designation for the recipient reviewed (lock-in recommended, no action, lock-in not recommended, etc).
40.2.2.26	The Fiscal Agent shall represent the State in mediation and hearings in accordance with federal and State requirements and the Division's policies regarding the beneficiary's right to appeal a decision.
40.2.1.186	The system shall provide the capability to remove the recipients from the lock-in program automatically after one (1) year.
40.2.2.27	The Fiscal Agent shall generate and send the lock-in recipient letter to a recipient's Authorized Representative if one exists.
40.2.2.28	The Fiscal Agent shall end-date the lock-in segment in the event of a recipient's death.

Appendix C: Business Requirements” Section from PDD for CSR 1927

1. Business Requirements

Customer Service Request (CSR) 1927 requests that CSRA continue the performance of all tasks related to the operation of the Division of Medical Assistance (DMA) Pharmacy Lock-in Program (Lock-in Program) and to incorporate the updates documented in the numbered memo MP16.340 into those procedures and processes.

CSRA is requested to update all Lock-in Program correspondence templates to reflect the change from a 1-year lock-in period to a 2-year lock-in period.

CSRA will also modify the existing Lock-in Program functionality to allow a beneficiary's program participation to be put on hold if the appeal is received by CSRA prior to the beneficiary's Lock-in Program begin date or if a beneficiary's previously closed Lock-in Program appeal is reopened.

1.1 Requirements

The following table lists the State-defined requirement(s) established for this project.

Requirement Number	Description
40.2.1.113	Provides capability for recipient lock-in/lock-out to a specific pharmacy and/or primary care provider and/or prescriber.
40.2.1.114	Provides capability for recipient lock-in/lock-out from a specific pharmacy and/or primary care provider and/or prescriber.
40.2.1.186 (Updated)	The system shall provide the capability to remove the recipients from the lock-in program automatically after two (2) years.
40.2.1.206 (New)	The system shall provide the capability to allow a user to modify the lock-in program begin dates and end-dates.
40.2.1.207 (New)	The system shall provide the capability to delay the generation of letter 2, 3 and 4 when an appeal is in process.
40.2.2.15 (Updated)	Each month, after ranking the candidate recipients as required by Requirement 40.2.2.17, the Fiscal Agent shall review the lock-in report and lock-in 600 individuals or, if fewer than 600 individuals are identified, lock-in all of the individuals indicated on the report.
40.2.2.20	The Fiscal Agent shall select a lock-in prescriber and pharmacy if one is not selected by the recipient or if the recipient does not return the selection form.
40.2.2.38 (New)	The Fiscal Agent shall ensure that any beneficiary locked in for one (1) year under the previous program rules will continue to be locked in for only one (1) year and must run concurrent with the revised timeline.
40.2.2.39 (New)	The Fiscal Agent shall ensure that any beneficiary who previously participated in the lock-in program and becomes qualified to participate again shall be locked-in for a two (2) year period.
40.2.2.40 (New)	The Fiscal Agent shall be responsible for monitoring the utilization of General Classification Code 3s (GC3s) and identify those individuals who meet the following criteria: <ol style="list-style-type: none">Opiates where more than six (6) claims are submitted in two (2) consecutive months.<ul style="list-style-type: none">GC3s: H3A, H3H, H3J, H3M, H3N, H3U, H3W, H3XBenzodiazepines and certain anxiolytics where more than six (6) claims are submitted in two (2) consecutive months.<ul style="list-style-type: none">GC3: H2F (to exclude Buspar/buspirone products with Generic Code Number (GCN) 13037, 28890, 28891, 28892, 92121)GC3: H4B (to include only Klonopin/clonazepam products with GCN 17470, 17471, 17472, 19467, 19468, 19470, 19472)Received prescriptions for opiates and/or benzodiazepines and certain anxiolytics (any of the GC3s and GCNs noted for inclusion above) from more than three (3) prescribers in two (2) consecutive months.
40.2.2.41 (New)	The Fiscal Agent shall update all lock-in program correspondence templates to reflect the change from a 1-year lock-in period to a 2-year lock-in period.

Requirement Number	Description
40.2.2.42 (New)	The Fiscal Agent shall ensure that all current reporting for the Lock-in Program is updated to capture and display data when the begin date or end date that has been modified.
40.6.1.82	Provides capability to handle recipient opt-in to specified lock-in pharmacies according to State policy and business rules.
40.7.2.16	Fiscal Agent shall ensure that the Pharmacy Fiscal Agent shall ensure that the Pharmacy PA Customer Service Call Center is available from 7:00 a.m. until 11:00 p.m. Eastern Time on State business days Monday through Friday, and from 7:00 a.m. until 6:00 p.m. Eastern Time on Saturday and Sunday.
40.7.2.67 (New)	Fiscal Agent shall represent the State throughout the hearing/appeals process for all Recipient Lock-in Program decisions. The Fiscal Agent's pharmacist shall attend mediations and The Fiscal Agent's pharmacist shall attend mediations and Office of Administrative Hearings (OAH) hearings.
40.7.2.68 (New)	Fiscal Agent shall monitor the market for any additions, deletions or changes of GC3s or GCNs meeting the definition of the drugs included for lock-in and recommend changes to the State as appropriate.
40.7.3.37 (New)	Fiscal Agent shall provide coverage through the Pharmacy PA Customer Service Call Center for the Recipient Lock-in Program ninety-nine and nine-tenths (99.9) percent of the time.
40.7.3.38 (New)	Calls from providers and beneficiaries with lock-in changes and inquiries that are routed to the Fiscal Agent's Pharmacy routed to the Fiscal Agent's Pharmacy PA Customer Service Call Center shall be responded to within two (2) hours of receipt.
40.8.1.75	Provides capability to edit against lock-in/lock-out recipient data for pharmacy, primary care provider, and/or prescriber.
40.8.1.150	Provides capability to allow for the following exceptions to pharmacy lock-ins: <ul style="list-style-type: none"> • NC Health Choice beneficiaries • Medicaid beneficiaries under the age of 18 • Medicaid beneficiaries who are deceased • Medicaid beneficiaries who are in a skilled nursing bed (living arrangement code 50) • Medicaid beneficiaries who are in hospice care • Medicaid beneficiaries who have a cancer diagnosis indicated on a medical claim within the past 12 months
40.8.1.433 (Updated)	Provides capability to allow only one 4-day emergency fill event per year for each year of the two-year period.
40.7.1.146 (New)	The system shall provide the capability to track a lock-in appeal if the appeal is submitted by the beneficiary after his participation in the program.
40.7.2.68 (New)	The Fiscal Agency shall not place a beneficiary's program participation on hold if an appeal is submitted after the participation begin date has been entered into the system. The following action shall be taken when an appeal decision has been rendered: <ul style="list-style-type: none"> • If the beneficiary loses the appeal, no action is needed. • If the beneficiary wins the appeal, the Fiscal Agent shall enter the appropriate program participation end status and end date.
40.7.1.147 (New)	The system shall provide the capability for a lock-in appeal to be reopened and for the beneficiary's participation to be placed on hold.
40.7.2.69 (New)	The Fiscal Agency shall place a beneficiary's program participation on hold if an appeal is reopened. The following action shall be taken when an appeal decision has been rendered: <ul style="list-style-type: none"> • If the beneficiary loses the appeal, the Fiscal Agent shall enter the appropriate program participation status and end date. The total participation period should be 24 months (the original begin date to the new end date minus the time the program participation was on hold). • If the beneficiary wins the appeal, the Fiscal Agent shall enter the appropriate program participation end status and end date.

Appendix D: DMA Clinical Coverage Policy No. 9, Outpatient Pharmacy, Section 5.14

5.14 Beneficiary Management Lock-In Program

The North Carolina Administrative Code, 10A NCAC 22F .0704 and 10A NCAC 22F .0104, Session Law 2015-241, Section 12F.16.(1), along with 42 CFR 431.54 and the State Plan Amendment supports the State's development of procedures for the control of beneficiary overutilization of Medicaid benefits which includes implementing a Beneficiary Management Lock-In program. The Beneficiary Management Lock-In Program does not apply to the NCHC program. DMA has developed criteria for inclusion in the Beneficiary Management Lock-In Program.

A Medicaid beneficiary identified for the lock-in program is restricted to a single prescriber and pharmacy to obtain opioid analgesics, benzodiazepines and certain anxiolytics. The beneficiary must obtain all prescriptions for these medications from their lock-in prescriber and lock-in pharmacy for the claim to pay. Claims submitted that are written by a prescriber or filled at a pharmacy other than those listed on the lock-in file are denied.

A beneficiary who qualifies for the program shall be notified and locked in for two (2) years after which time they will be removed from the program if they no longer meet the criteria. A beneficiary who continues to meet the criteria is locked in for another two years. Once released from the lock-in program, prescription claims continue to be monitored. If a beneficiary meets the criteria again after being released from the program, they will be re-identified for the lock-in program. The beneficiary cannot change their lock-in prescriber or pharmacy without authorization from DMA.

5.14.1 Inclusion in the Beneficiary Management Lock-In Program

A NC Medicaid beneficiary shall be locked-in to one prescriber and one pharmacy for controlled substances categorized as opiates or benzodiazepines and certain anxiolytics when one or more of the following criteria are met:

1. Beneficiary who has at least ONE of the following:
 - a. Benzodiazepines and certain anxiolytics: greater than six (6) claims in two (2) consecutive months.
 - b. Opiates greater than six (6) claims in two (2) consecutive months.
2. Receiving prescriptions for opiates and/or benzodiazepines and certain anxiolytics from greater than three (3) prescribers in two (2) consecutive months.

5.14.2 Exclusion from the Beneficiary Management Lock-In Program

Health Choice beneficiaries will not be part of the Lock-In Program

5.14.3 Emergency Supplies for the Beneficiary Management Lock-In Program

The N.C. Medicaid Program shall reimburse an enrolled Medicaid pharmacy for a four (4)-day supply of a prescription dispensed to a beneficiary locked into a different pharmacy and prescriber in response to an emergent situation. The provider shall be paid for the drug cost only and the beneficiary shall be responsible for the appropriate copayment. One emergency occurrence is reimbursed per beneficiary during each year of the two (2) year lock-in period. Paid quantities for more than a four (4)-day supply are subject to recoupment.



**North Carolina Division of Medical Assistance (DMA)
BENEFICIARY MANAGEMENT LOCK-IN PROGRAM ANALYSIS
PROPOSED WORKPLAN**

August 31, 2016

The North Carolina Division of Medical Assistance (DMA) requested Myers and Stauffer develop a work plan that outlines the completion of fiscal analyses related to the Beneficiary Management Lock-In Program (MLIP). The initial time period under review begins with the re-implementation of the MLIP in March 2015 and runs through June 30, 2016. Following the initial review period, each subsequent analyses will cover the next state fiscal year. In addition to these fiscal analyses, the Joint Legislative Program Evaluation Oversight Committee has requested a study of the MLIP that coincides with programmatic changes to extend lock-in duration to two years and revise program eligibility criteria to align the program with the statewide strategic goals for preventing prescription drug abuse. These changes are anticipated to be implemented on or about December 4, 2016. The time period for this study should include a minimum of six months post implementation, and the report will be delivered to the committee on or about October 31, 2017.

Completion of each fiscal analysis will provide valuable feedback regarding program performance, including the estimated cost-savings of the program, and provide DMA with useful information to evaluate future changes to the MLIP. The ad hoc study, as requested by the Joint Oversight Committee, will evaluate the program revisions and include the following information:

- Evaluate the effectiveness of program restrictions in preventing overutilization of controlled substances;
- Identify program vulnerabilities; and,
- Address whether there is suspicion of fraud or abuse within the MLIP.

Presented below is an outline of the proposed time period and focus of each planned fiscal analysis as well as the requested MLIP ad hoc study. Select factors may influence proposal timeframes such as the actual implementation date of systematic changes (anticipated on or about December 4, 2016) and the availability of key data elements (e.g. lock-in tables, program cost information).

Fiscal Analysis and Audit Review Work Plan North Carolina Medicaid Beneficiary Management Lock-In Program		
Time Period of Review	Focus of Review	Deliverable Date
March 1, 2015 – June 30, 2016	Initial Fiscal Analysis, including evaluation of program since re-implementation	December 31, 2016
December 4, 2016 (or date of implementation) – May 31, 2017	Ad Hoc MLIP Program Study, providing analysis of program changes implemented	September 30, 2017
July 1, 2016 – June 30, 2017	SFY 2017 Annual Fiscal Analysis	December 31, 2017
July 1, 2017 – June 30, 2018	SFY 2018 Annual Fiscal Analysis	December 31, 2018

Appendix F: Initial Notice to Beneficiary (Template)

[Date of Letter Field 3]

[Recipient Name Field 35 Field 37 Field 36]

[Recipient Address Field 97, Field 98]

[Recipient City, State Zip Field 99, Field 100 Field 101]

Dear [Recipient Name, Recipient ID Field 35 Field 37 Field 36, Field 32],

Medicaid started the Recipient Management Lock-in Program which helps identify patients at risk for possible overuse or improper use of pain medications (opioid analgesics) and nerve medications (benzodiazepines and certain anxiolytics), as well as helps identify those who receive these medications from multiple prescribers (doctor, nurse practitioner, or physician's assistant). The N.C. Administrative Code 10A NCAC 22F.0704 and 10A NCAC 22F.0104, along with 42 CFR 431.54 and the Medicaid State Plan supports the State's development of procedures for the control of recipient overutilization of Medicaid benefits, which includes implementing a recipient management lock-in program.

Your recent Medicaid prescriptions qualify you for the Recipient Management Lock-in Program because

- [Field 120]
- [Field 121]
- [Field 122]

You are qualified for this program; therefore, starting on [Program Start Date Field 116] Medicaid will only pay for your pain medications and nerve medications when dispensed from one pharmacy. In addition, prescriptions for these medications must be written by the same prescriber (doctor, nurse practitioner, physician's assistant).

You must choose one N.C. Medicaid prescriber to write prescriptions for your pain medications and nerve medications. You must also choose one pharmacy to fill these prescriptions. You will be locked into the pharmacy and prescriber that you chose for [LCKNPER] months. In response to an emergent situation, Medicaid will reimburse an enrolled Medicaid pharmacy for a one time four-day supply of a prescription medication during each of the 12 month periods. For good cause (e.g., pharmacy closed or moved, prescriber moved or no longer in practice), change of your lock-in prescriber or pharmacy may be authorized by Medicaid.

Si desea apelar esta decisión, debe responder a no más tardar de 30 días a partir de la fecha que esta carta fue enviada. Si necesitas ayuda para leer y entender la carta, por favor contáctese con el 1-800-662-7030. DIGA AL OPERADOR QUE LA NOTIFICATION DMA 2001RML.

Please complete the enclosed PHARMACY AND PRESCRIBER SELECTION FORM with the name and address of the pharmacy and prescriber you want to use. Please also choose a second pharmacy and prescriber in case Medicaid is unable to give you your first choice. You have thirty (30) days from the date on this letter to complete and mail the form to:

CSC
ATTN: Recipient Lock-in Program
PO Box XXXX
Raleigh, NC XXXXX-XXXX
1-866-246-8505

If the Pharmacy and Prescriber Selection Form is not received from you within thirty (30) days from the date on this letter, a pharmacy and a prescriber will be chosen for you. This will be the only notice you receive about choosing a prescriber and pharmacy.

YOU HAVE THE RIGHT TO APPEAL THIS DECISION. To appeal, you must complete and file the attached Medicaid Recipient Services Hearing Request form asking for a hearing with the Office of Administrative Hearings. **YOU HAVE 30 DAYS FROM THE DATE OF THIS LETTER TO FILE THE REQUEST FOR HEARING.**

To learn more about the hearing process, please call the Office of Administrative Hearings at 919-431-3000, Medicaid at 919-855-4260, or the toll free CARE-LINE at 1-800-662-7030, Monday-Friday, 8:00 a.m.-5:00 p.m. To speak with a Medicaid staff person about this decision, call the name and telephone number listed at the end of this notice.

FILING THE APPEAL REQUEST:

- To file for a hearing, you must submit **a completed hearing request form** (enclosed only in the recipient's mailing). You can also get a duplicate hearing request form by calling the Division of Medical Assistance at 919-855-4260 or the toll free CARE-LINE at 1-800-662-7030 and ask for your call to be transferred to Clinical Policy and Programs, the Appeals Unit.
- Mail or fax the completed hearing request form to Clerk of Court, Office of Administrative Hearings. The address and fax number are on the hearing request form.

THE HEARING PROCESS

- If you decide to appeal this decision and once you file with the Office of Administrative Hearings, OAH will send you a letter by trackable mail stating the date and time of your hearing. OAH will also refer your case to the Mediation Network of North Carolina.
- The Mediation Network of North Carolina will contact you to offer you a free mediation with Medicaid to try to settle your appeal. You may accept or reject this offer.
- If you or your representative accept an offer of mediation and then fail to attend mediation without good cause, your case will be dismissed.
- You may participate in the mediation process by telephone or in person. Medicaid representatives will participate by telephone. You may invite anyone to participate in the mediation process as long as all parties involved in the mediation agree to their participation.
- At the mediation, you may present new evidence, including medical records and documentation from doctors and other providers about why you need the requested services.
- If mediation resolves your case, your hearing will be dismissed, and services will be provided as agreed to during the mediation.
- If you do not accept the offer of mediation or if the mediation does not succeed, you may still proceed with your hearing.
- You can have a hearing by telephone or in person or you can have the hearing by videoconferencing if you have access to a computer with a camera and videoconferencing software. The hearing will be conducted by telephone unless you specifically request an in-person or video hearing. The in-person hearing will be held at the OAH main location in Wake County (Raleigh) unless you can show good cause why you cannot come to Wake County.
- Hearings are conducted by an administrative law judge with OAH.
- You have the right to see Medicaid's entire file about your case before the date of the hearing.
- At the hearing, you may present new evidence, including medical records and testimony from doctors and other providers about why you need the requested services (even if you obtained it after Medicaid made its decision).
- You may represent yourself in the hearing process, hire an attorney or use a legal aid attorney, or ask a relative, friend, or other spokesperson (e.g. case manager) to speak for you.
- The administrative law judge will make a decision and will send that decision to you via mail.
- If you lose your appeal, you can appeal the final decision in Superior Court.

Free legal aid may be available to assist with your appeal. Contact your nearest Legal Aid of North Carolina office or call 919-856-2564 or **toll-free at 1-866-369-6923** to obtain the telephone number of the office that serves your community. If the recipient is a person with a disability, you may also contact Disability Rights North Carolina at 919-856-2195 or **toll-free at 1-877-235-4210**.

Sincerely,

NCTracks- Operations
1-866-246-8505

Enclosure: Pharmacy and Prescriber Selection Form
Recipient Hearing Request Form, DMA 2003

MEDICAID SERVICES RECIPIENT HEARING REQUEST FORM
COMPLETE AND SEND THIS FORM IF YOU WANT TO APPEAL MEDICAID'S DECISION

Date: [Date of Letter Field 3]

Decision made by: ☐ DMA ☐ CCME ☐ MedSolutions ☐ Murdoch ☐ PBH ☐ VO ☒ CSCRML ☐ Crossroads ☐ Durham Center ☐ Eastpointe ☐ Pathways ☐ Other (Specify) _____

Type of Request: ☒ Initial/No Service in Place ☐ Continuing/Reauthorization

Type of Notice Issued: ☐ 2001 ☐ 2001A ☐ 2001E ☒ 2001RML2002 ☐ 2002A ☐ 2002E ☐ 2002 CAP UR

<p>SEND COPY OF FORM TO:</p> <p>Office of Administrative Hearings (OAH)</p> <p>Attention: Clerk of Court</p> <p>6714 Mail Service Center</p>
--

[Recipient Name Field 35 Field 37 Field 36] (RID Field 32)

[Recipient Address Field 97, Field 98]

[Recipient City, State Zip Field 99, Field 100 Field 101]

DIRECTIONS: Please complete this form. Send the completed form by mail or fax to OAH at the address or fax number in the above box. The hearing request form must be received by OAH within **30 days of the date this notice was mailed to me**.

I would like to appeal the decision to be placed in the Recipient Management Lock-in Program.

I have the right to a hearing conducted telephonically, by video technology, or in person. The hearing will be conducted by telephone unless I request an in-person or video hearing. If I request an in-person hearing, I understand it will be held at the Office of Administrative Hearings in Wake County (Raleigh) unless I can show good cause why I cannot come to Wake County.

I am requesting a hearing **(please check one)**:

☐ **by telephone** ☐ **by videoconference** ☐ **in-person in Raleigh** ☐ **in-person in my county of residence** because _____.

I may represent myself during the appeal process, hire an attorney or use a legal aid attorney, or ask a relative, friend, my case manager, or another spokesperson to represent me. By signing this form, I authorize any person listed below to represent me during the appeal, to discuss my case, and to have access to my Medicaid file, including medical records and other confidential information about my case. I understand that I can file this appeal form now and still ask a representative to help me at a later time.

I will (please check one): ☐ Represent myself. ☐ Be represented by someone else, If yes, complete box below.

Name of Representative	Relationship to Recipient	Address	Telephone Number
			() _____ - _____

I understand if I am appealing a CHANGE notice and I submit a request for hearing within **30 days of the date this notice was mailed** and my provider submitted the service request before the last authorization expired **and** as long as I remain otherwise Medicaid eligible, unless I give up this right, I will continue to receive services until my appeal is decided. Should I have been receiving services and appeal within **10 days of the date this notice was mailed**, my services will continue without interruption. If I appeal within **30 days of the date this notice was mailed** to me and services were stopped or reduced, services will be reinstated. Services will be provided at the same level I was receiving the day before the decision or the level requested by my provider, whichever is less. **I will continue to be authorized to receive my current service(s) even if I change providers.** If I lose my appeal, I understand that I (the recipient) may be required to pay for the services that continue because of the appeal.

Signature of Medicaid Recipient/Applicant or Legal Guardian Date () _____
Telephone Number

PHARMACY AND PRESCRIBER SELECTION FORM
Division of Medical Assistance Recipient Management Lock-in Program

Mail this completed form to:

CSC
ATTN: Recipient Lock-in Program
PO Box XXXX
Raleigh, NC XXXXX-XXXX
1-866-246-8505

Please print clearly, spell the names correctly, and provide the correct addresses.

	I have chosen the following pharmacy as my first choice.	I have chosen the following pharmacy as my second choice if my first choice is not acceptable at this time.
Pharmacy Name:	_____	_____
Address:	_____	_____
	_____	_____
Telephone Number:	_____	_____
	I have chosen the following prescriber as my first choice:	I have chosen the following prescriber as my second choice if my first choice is not acceptable at this time.
Prescriber Name:	_____	_____
Address:	_____	_____
	_____	_____
Telephone Number:	_____	_____
My Name:	_____	
My Address:	_____	

My Telephone Number:	_____	
Signature	_____	Date: _____

Patient ID: [RID Field 32]
Case #: [RID-Program Start Date Field 32-Field116]
Date: [Date of Letter Field 3]

Appendix G: Second Notice to Beneficiary (Template)

[Date of Letter Field 3]

[Recipient Name Field 35 Field 37 Field 36]

[Recipient Address Field 124, Field 125]

[Recipient City, State Zip Field 126, Field 127 Field 128]

Dear [Recipient Name Field 35 Field 37 Field 36],

You were notified by Medicaid on [Notification Letter Mail Date Field 102] that you qualified for the

Recipient Management Lock-in Program. Under this program you are limited to using one pharmacy and one prescriber (doctor, nurse practitioner, physician's assistant) to obtain pain medications (opioid analgesics) and nerve medications (benzodiazepines and certain anxiolytics).

Prescriptions for pain and nerve medications must be written by the prescriber listed on the card below and filled at the pharmacy listed on the card below. Please show the card below when you see your doctor and when you fill these medications at your pharmacy. This card does not take the place of your Medicaid card but will be needed in order for Medicaid to pay for your prescriptions for pain and nerve medications. If your prescription for pain or nerve medication is written by a prescriber other than the prescriber listed on the card below, then Medicaid will not pay for that prescription. If you try to fill your prescription for pain or nerve medication at a pharmacy other than the one listed on your card below, Medicaid will not pay for the prescription. This only applies to pain and nerve medications. This card will be in effect for [LCKNPER] months from the lock-in date listed on the card below.

Sincerely,

NCTracks- Operations

1-866-246-8505

Recip ID: [RID Field 32]

Cut here to detach your card

N.C. Department of Health and Human Services

Division of Medical Assistance

Recipient Management Lock-in Program

Toll-Free Phone: 1-866-246-8505

Patient Name / Patient ID: [Field 35 Field 37 Field 36 / Field 32]

Lock-in Date: [Field 116]

Effective Period: [Field 116 – Field 117]

Prescriber:

NAME [Field 24 Field 23]

ADDRESS 1 [Field 25]

ADDRESS 2 [Field 26]

CITY/STATE/ZIP [Fields 27-29]

Pharmacy:

NAME [Field 20]

ADDRESS 1 [Field 97]

ADDRESS 2 [Field 98]

CITY/STATE/ZIP [Fields 99-101]

Appendix H: Notice to Selected Prescriber (Template)

[Date of Letter Field 3]

NAME [Field 10, Field 12, Field11]

ADDRESS 1 [Field 13]

ADDRESS 2 [Field 14]

CITY/STATE/ZIP [Fields 15-17]

RE: [Recipient Name, Recipient ID Field 35 Field 37 Field 36, Field 32]

Lock in Confirmation Effective date: [Field 116 – Field 117]

Dear [Field 10, Field 12, Field11]

Your Provider ID: [Field 18]

The North Carolina Division of Medical Assistance (DMA) implemented the Recipient Management

Lock-in Program. The purpose of this program is to identify recipients who may be at risk for health-related issues due to potential overutilization of opioid analgesics, benzodiazepines, and certain anxiolytics. DMA developed criteria which looks for patterns that may indicate issues such as excessive or improper use of controlled substances as well as individuals who have received selected controlled substances from multiple prescribers. An analysis of available Medicaid claims data indicated potential recipient overutilization resulting in a decision by the Division to lock-in your patient to a single pharmacy and prescriber. More information regarding the Recipient Management Lock-in Program is located at <http://www.ncdhhs.gov/dma/pharmacy> or refer to the **August 2010** General Medicaid Bulletin.

For the patient named above, Medicaid will pay for prescriptions for opioid analgesics, benzodiazepines, and certain anxiolytics if the prescription is written by the prescriber listed below and is filled at the pharmacy listed below. The lock in period is for **LCKNPER** months. In order for the prescription to pay at the pharmacy, **your NPI number will be required on the prescription**. The prescription will be denied by Medicaid if only your DEA number is provided. Prescriptions for these selected medications written by a prescriber or filled at a pharmacy other than what is listed below will also be denied. The recipient may not change their lock-in prescriber or pharmacy without authorization from DMA.

Selected N.C. Medicaid Enrolled Prescriber	Selected N.C. Medicaid Enrolled Pharmacy
NAME [Field 10, Field 12, Field11]	CLINICAL PHARMACY [Field 23]
ADDRESS 1 [Field 13]	ADDRESS 1 [Field 25]
ADDRESS 2 [Field 14]	ADDRESS 2 [Field 26]
CITY/STATE/ZIP [Fields 15-17]	CITY/STATE/ZIP [Fields 27-29]

The N.C. Administrative Codes 10A NCAC 22F.0704 and 10A NCAC 22F.0104, along with 42 CFR 431.54 and the Medicaid State Plan support the State's development of procedures for the control of recipient overutilization of Medicaid benefits, which includes implementing a recipient management lock-in program.

Prescribers and pharmacists are also reminded that the Controlled Substances Reporting System is a statewide reporting system established by North Carolina law to improve the state's ability to identify people who abuse and misuse prescription drugs, classified as Schedule II-V controlled substances, and also to assist clinicians in identifying and referring for treatment patients who are misusing controlled substances. More information regarding the program goals, use and access to this system is located at <http://www.ncdhhs.gov/providers/provider-info/mental-health/nc-controlled-substances-reporting-system>.

If you have any questions about this letter or the enclosed materials, please call us at our special phone number for the Recipient Management Lock-in Program: 1-866-246-8505 (Monday through Friday 7 AM to 11 PM, Saturday – Sunday 7 AM to 6 PM, and Holidays 7 AM to 6 PM).

Thank you for your cooperation and assistance.

Sincerely,

NCTracks- Operations

Appendix I: Notice to Selected Pharmacy (Template)

[Date of Letter Field 3]

CLINIC PHARMACY [Field 11]

ADDRESS [Field 13] [Field 14]

CITY, STATE, ZIP [Fields 15-17]

RE: [Recipient Name, Recipient ID Field 35 Field 37 Field 36, Field 32]

Lock in Confirmation Effective date: [Field 116 – Field 117]

Dear Pharmacist:

The North Carolina Division of Medical Assistance (DMA) implemented the Recipient Management

Lock-in Program. The purpose of this program is to identify recipients who may be at risk for health-related issues due to potential overutilization of opioid analgesics, benzodiazepines, and certain anxiolytics. DMA developed criteria which looks for patterns that may indicate issues such as excessive or improper use of controlled substances as well as individuals who have received selected controlled substances from multiple prescribers. An analysis of available Medicaid claims data indicated potential recipient overutilization resulting in a decision by the Division to lock-in your patient to a single pharmacy and prescriber. More information regarding the Recipient Management Lock-in Program is located at <http://www.ncdhhs.gov/dma/pharmacy> or refer to the **July 2010** Pharmacy Bulletin.

For the patient named above, Medicaid will pay for prescriptions for opioid analgesics, benzodiazepines, and certain anxiolytics if the prescription is written by the prescriber listed below and is filled at the pharmacy listed below. The lock in period is for **LCKNPER** months. In order for the claim to pay, the **prescriber's NPI will be required on the pharmacy claim**. Submitting the prescriber's DEA will cause the claim to be denied. Claims for these selected drugs written by a prescriber or filled at a pharmacy other than the providers listed below will be denied. The recipient may not change their lock-in prescriber or pharmacy without authorization from DMA.

Selected N.C. Medicaid Enrolled Prescriber	Selected N.C. Medicaid Enrolled Pharmacy
NAME [Field 24, Field 23]	CLINICAL PHARMACY [Field 11]
ADDRESS 1 [Field 25]	ADDRESS 1 [Field 13]
ADDRESS 2 [Field 26]	ADDRESS 2 [Field 14]
CITY/STATE/ZIP [Fields 27-29]	CITY/STATE/ZIP [Fields 15-17]

The N.C. Administrative Codes 10A NCAC 22F.0704 and 10A NCAC 22F.0104, along with 42 CFR 431.54 and the Medicaid State Plan support the State's development of procedures for the control of recipient overutilization of Medicaid benefits, which includes implementing a recipient management lock-in program.

Prescribers and pharmacist are also reminded that the Controlled Substances Reporting System is a statewide reporting system established by North Carolina law to improve the state's ability to identify people who abuse and misuse prescription drugs, classified as Schedule II-V controlled substances, and also to assist clinicians in identifying and referring for treatment patients who are misusing controlled substances. More information regarding the program goals, use and access to this system is located at.

<http://www.ncdhhs.gov/providers/provider-info/mental-health/nc-controlled-substances-reporting-system>.

If you have any questions about this letter or the enclosed materials, please call us at our special phone number for the Recipient Management Lock-in Program: 1-866-246-8505 (Monday through Friday 7 AM to 11 PM, Saturday – Sunday 7 AM to 6 PM, and Holidays 7 AM to 6 PM).

Thank you for your cooperation and assistance.

Sincerely,

NCTracks- Operations