# 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

## March 1, 2018

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## I. INTRODUCTION

The Medicaid Beneficiary Management Lock-in Program ("Lock-in Program" or "MLIP") monitors and prevents the overutilization and abuse of prescribed controlled substances, including opioids and benzodiazepines, by restricting Medicaid beneficiaries who qualify for the program to one prescriber and one pharmacy for those prescriptions. The program improves beneficiary safety, encourages coordination of care, and decreases inappropriate or unnecessary utilization.

The Division of Medical Assistance ("DMA") implemented the program in July 2010 with beneficiary enrollment beginning in October 2010. Beneficiaries are enrolled in the Lock-in Program 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 to obtain opioid analgesics, benzodiazepines, and certain anxiolytics covered by the N.C. Medicaid Outpatient Pharmacy Program. Beneficiaries receive a notification letter explaining the reason(s) they qualify for the program, and are given the right to appeal DMA's decision to place them in the Lock-in Program per federal regulations. Beneficiaries select their prescriber and pharmacy and are provided 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 provider selected by the beneficiary.

Session Law 2015-268, Section 4.4. increased the time-period for beneficiary lock-in from one year to two years and increased program enrollment capacity. The State implemented the first two-year lock-in period on March 1, 2017. This report provides an update on the implementation of the program enhancements and provides a post-implementation audit 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. Please see ***Appendix A*** for the text of Session Law 2015-268, Section 4.4.

## II. AUDIT

Per the requirements of Session Law 2015-268, Section 4.4.(6), DMA requested a currently contracted actuarial service to perform an audit to: (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 B*** for the complete audit report created by DMA's contracted actuarial service, Myers and Stauffer.

## III. CONCLUSION

### 1. PROGRAM EFFECTIVENESS

Myers and Stauffer evaluated the utilization patterns of beneficiaries within the lock-in program. They looked at claims for the six-month period prior to the increase from a one- to a two-year lock-in period and at claims for the following six months for those beneficiaries locked in beginning March 2017. Focusing on the population that continued to use targeted drugs after lock-in (page 24), total pharmacy claims for these beneficiaries decreased by 38 percent, the total number of prescribers decreased by 65 percent, and the total pharmacies used decreased by 50 percent. Additionally, the average number of pharmacy claims, average number of prescribers, and average number of pharmacies per beneficiary decreased, demonstrating the effectiveness of the lock-in program in preventing overutilization.

There were beneficiaries who discontinued use of the targeted drugs after lock-in but continued to remain in the program. Myers and Stauffer lists possible explanations for the beneficiaries no longer receiving targeted drugs on page 23 of the audit, including that these beneficiaries may have started receiving appropriate care and clinical management so that they no longer needed the targeted drugs. While not noted in the audit report, some beneficiaries may also have switched to illicit drug use following their lock-in as recent data reports a decrease in overdoses related to prescription opioids and an increase in overdoses related to illicit drug use. Myers and Stauffer was unable to determine the total effect of increasing the lock-in period from a one- to two-year period since the enhanced program had been operational for less than a year at the time of the evaluation. However, a review of a similar program with a two-year lock-in period found that beneficiaries were more likely to achieve stable outcomes the longer they remained enrolled in the lock-in program.

Pharmacy claims for the lock-in beneficiaries were analyzed to determine if beneficiaries were taking opioid dependence treatment drugs concurrently with other targeted drugs (opioids, benzodiazepines and certain anxiolytics), as it is generally contraindicated. For the audit, concurrent use was defined as having one claim for an opioid dependence treatment drug with an overlapping date of service of any other targeted drug. Myers and Stauffer identified beneficiaries that were concurrently receiving both types of drugs in both the pre- and post-lock-in groups and found a 2.5-fold decrease in the number of beneficiaries with overlapping drug claims occurred after lock-in compared to before lock-in. This decrease may be due to improved care and clinical management of the opioid dependence treatment of these lock-in beneficiaries, which would demonstrate that the program does positively impact the safety and treatment outcomes of the beneficiaries in the program. Myers and Stauffer found the percentage of lock-in beneficiaries with opioid dependence treatment drug claims increased from the pre-lock-in period to the post-lock-in period, which may indicate more beneficiaries are committing to treatment for opioid dependence. Additionally, the implementation of the STOP Act should decrease the number of beneficiaries on opioids or benzodiazepines and drugs for opioid dependence treatment with overlapping dates of service as prescribers and pharmacists increase utilization of the N.C. Controlled Substance Reporting System (CSRS).

The audit also evaluated the utilization of opioids and benzodiazepines, excluding drugs for the treatment of opioid dependence, in the population that continued to utilize targeted drugs and found this group had the most significant reduction in targeted drug usage, with an 18 percent reduction in the number of beneficiaries taking these drugs after lock-in. In addition, there was a 46 percent reduction in targeted drug pharmacy prescription count, a 69 percent reduction in the number of prescribers, and a 59 percent reduction in the number of pharmacies used.

Additionally, Myers and Stauffer provided the cost savings for the lock-in beneficiary population based on the data available at the time of audit for drug utilization, only as it relates to the targeted drugs. An overall targeted drug savings of $92,407.62 was observed during the six-month period after lock-in and the average cost per lock-in beneficiary decreased by $140.10. This cost savings does not take into consideration program operational costs or any other extrapolated cost savings due to a decrease in utilization of other services because of the lock-in program. A fiscal analysis of the lock-in program will be completed by Myers and Stauffer in the coming months.

In general, Myers and Stauffer states, **"This analysis found the current NC MLIP design is effectively identifying beneficiaries for lock-in based on its criteria and is operating primarily as designed."**

## 2. Program Vulnerabilities

Myers and Stauffer compared the criteria and program design of our four bordering states (Georgia, South Carolina, Tennessee, and Virginia) to evaluate potential vulnerabilities of the program and possible ways to improve the program. A complete analysis of potential program vulnerabilities can be found beginning on page 11.

The basic design elements of North Carolina's MLIP are like those of its bordering states. All four programs lock-in periods reviewed are for a minimum of two years, except for Tennessee which utilizes an indefinite lock-in period. All four programs currently lock into one pharmacy provider. However, only two programs, South Carolina and Tennessee, do not lock into one prescriber.

It was reported that all four of the bordering state programs are more restrictive and use more criteria for participation in their respective lock-in programs. DMA intends to evaluate criteria used by other states to determine if the N.C. lock-in program would benefit from implementing any of the noted criteria. Opportunities to be considered to improve the N.C. lock-in program are listed on page 19, Table C.

The utilization of the N.C. CSRS would aid in both identifying beneficiaries for lock-in and monitoring targeted drug use activity of lock-in beneficiaries, but does present some operational challenges. There is no match to a beneficiary's Medicaid ID in the N.C. CSRS. Instead matches would be made using name, birthdate, and address as potential identifiers. While pharmacies are required to report in all paid claims for controlled substances, there is no requirement that pharmacies report claims that are reversed and not dispensed. This could lead to false positives.

The report noted that a portion of lock-in beneficiaries may possibly be obtaining targeted drugs outside of Medicaid by paying cash. The STOP Act should assist in curbing this behavior, as there

are requirements for pharmacists to check the N.C. CSRS when individuals present at the pharmacy requesting to pay cash when they have a third-party payor on file.

Another opportunity to improve the program is the use of morphine milligram equivalents (MME) as an inclusion criteria. The Center for Disease Control (CDC) finds that patients receiving higher doses of opioids have an increased likelihood of adverse outcomes, so DMA established opioid dosage limits in opioid clinical coverage policy. Currently, DMA opioid clinical coverage policy requires all beneficiaries receiving an opioid dosage exceeding 120 mg MME have a prior authorization requested by their prescriber before N.C. Medicaid will make payment. A recent analysis of opioid utilization data by the N.C. Medicaid Drug Utilization Review Board reported a decrease in prescribed opioid MMEs since the implementation of the policy in August 2017.

DMA will need to consider coordination with the Prepaid Health Plans (PHPs) as the Medicaid program transitions to managed care or consider operating one statewide lock-in program administered by DMA to prevent beneficiaries from bypassing the lock-in program by changing from one managed care plan to another.

### 3. Fraud and Abuse

Per the audit, "Myers and Stauffer has carefully evaluated patterns of behavior to identify whether any evidence was identified of potential fraud or abuse within the MLIP and did not identify indications that fraud or abuse exist within the MLIP." The Top 25 prescribers of targeted drugs were identified by reviewing pharmacy claims for the six (6) month period post-lock-in. Five of the top prescribers identified had previously entered into consent orders (negotiated settlement agreements) with the N.C. Medical Board, as a result of Board investigations finding concerns about the prescribers' practices relating to controlled substances. The audit suggests there may be benefit in referring these providers to Program Integrity for review. DHHS is also carefully reviewing prescribing patterns across Medicaid to determine potential interventions.

Beneficiaries are allowed one emergent fill for up to a 4-day supply of the targeted medications not written by the prescriber on file or not filled at the pharmacy on file per year while in the lock-in program. An attempt to evaluate the use of the Emergency Override was inconclusive due to the complexity of the system edits. However, in a sample of claims, there was no evidence of beneficiaries receiving more than one emergency fill per year.

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 opioid analgesics and benzodiazepines. The 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 its fiscal agent, CSRA, to ensure the program complies 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: Myers and Stauffer's Beneficiary Management Lock-in Program Ad Hoc Analysis**

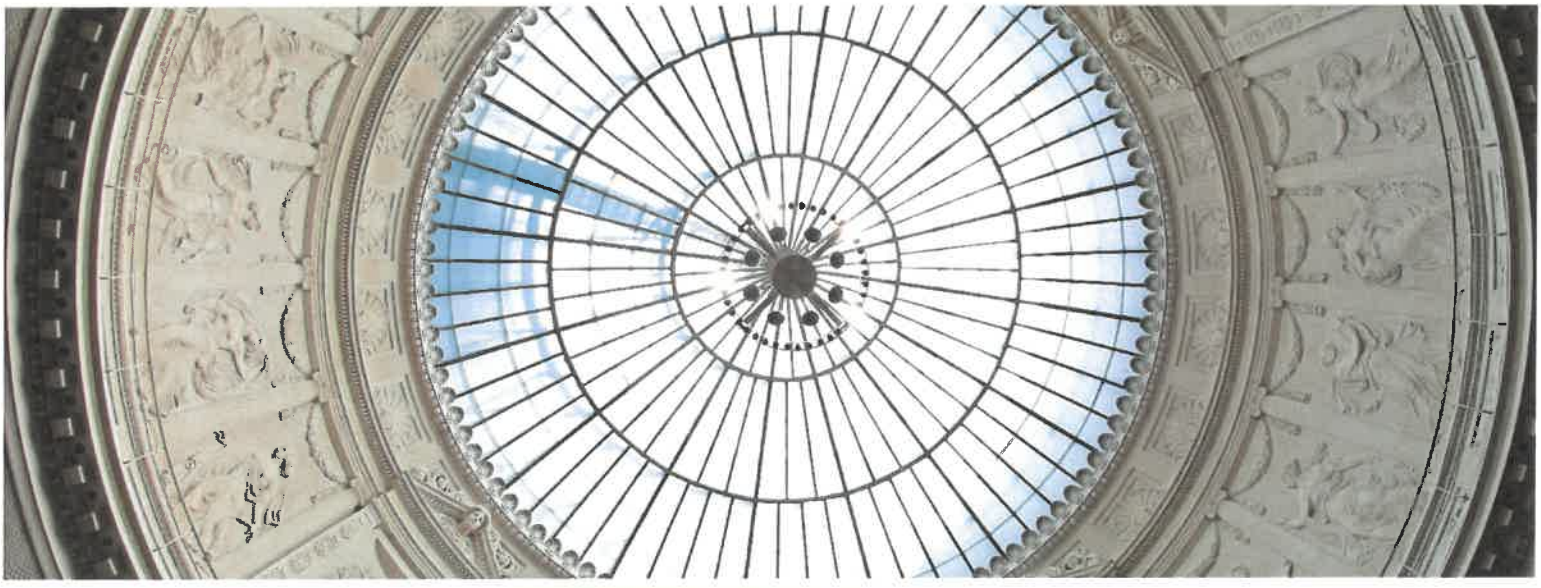
MYERS AND STAUFFER LC
1977 - 2017
CERTIFIED PUBLIC ACCOUNTANTS

# NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
# DIVISION OF MEDICAL ASSISTANCE

Beneficiary Management Lock-In Program

AD HOC Analysis

February 5, 2018



DEDICATED TO GOVERNMENT HEALTH PROGRAMS

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# *Executive Summary*

North Carolina's Division of Medical Assistance (Division or DMA) engaged Myers and Stauffer to perform an ad hoc analysis of the State's Beneficiary Management Lock-In Program (MLIP) to satisfy Section 12F.16(l) of S.L. 2015-241, as amended by Sec. 4.4 of S.L. 2015-268, which requires the Division of Medical Assistance of the Department of Health and Human Services (DMA) to "take the following steps to improve the effectiveness and efficiency of the Medicaid lock-in program: (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…"

As required by Session Law (S.L.) 2015-268, Section 4.4, key changes were made to the MLIP effective January 2017. The changes include program revisions to extend the lock-in duration to two (2) years and to increase MLIP capacity to ensure that all individuals who meet revised program criteria are locked in. These changes applied to beneficiaries receiving notification letters beginning January 2017, with revisions to the program implemented operationally within the NCTracks system in March 2017. Therefore, the observation period for this analysis was limited to March 2017 – August 2017 to provide a six month view of operations based on the new MLIP criteria, as outlined.

**This analysis found the current NC MLIP design is effectively identifying beneficiaries for lock-in based on its criteria and is operating primarily as designed.** From the data available and within the time period allotted to perform this review, no specific evidence of fraud or abuse was identified within the MLIP as a result of this analysis.

Program vulnerabilities were identified with opportunities for improvement or revision as outlined below.

- *Enhancement of program operation to consider utilization of the North Carolina Prescription Drug Monitoring Program (PDMP) to aid in both identifying candidates for lock-in and monitoring targeted drug use activity of lock-in beneficiaries. It is possible that a portion of MLIP beneficiaries may be obtaining targeted drugs outside of Medicaid to circumvent the MLIP restrictions. Select bordering state lock-in programs currently utilize PDMP data as part of their criteria for inclusion in their lock-in program, as well as to identify lock-in beneficiaries who are non-compliant with program guidelines. PDMP data may also be used to explain MLIP behavior when MLIP beneficiaries cease to obtain targeted drugs via Medicaid. Per the North Carolina Controlled Substances Reporting System Act, the North Carolina Department of Health and Human Services shall release data in the controlled substances reporting system to the Division of Medical Assistance for purposes of administering the State Medical Assistance Plan.[1] Several limitations have prevented current use of the PDMP in the MLIP. The first*

[1] N.C. Gen. Stat. § 90-113.74, https://www.ncga.state.nc.us/enactedlegislation/statutes/html/byarticle/chapter_90/article_5e.html, Accessed November 16, 2017.

*limitation is that there is no way to match the member identification numbers used in the NC Medicaid Program and PDMP. Current identification requires matching beneficiary names, birthdates, addresses, etc. The second limitation is that data in the PDMP may not be standing paid claims. Claims reversed at the pharmacy because the beneficiary did not pick up the medication are not required to be submitted to the PDMP.*

- *Expansion of the MLIP criteria for inclusion/selection to include additional resources related to targeted drug use as discussed in* ***Table C****. This would assist with identifying candidates who may have misutilized the NC Medicaid system via misutilization of services beyond the current targeted drug use monitoring that occurs.*
- *Consider lowering the priority of potential candidates who receive opioid dependence treatment drugs consistently from the same prescriber and same pharmacy without other targeted drug use, as these are indicators these beneficiaries are appropriately managed. This would allow capturing a larger number of potential candidates, who are not actively managed, to be considered for lock-in.*
- *Investigation of lock-in beneficiaries who cease targeted drug activity after lock-in, but maintain Medicaid eligibility would allow for the identification of program vulnerabilities and provide a means of recapturing those beneficiaries to improve management of their drug treatment, when applicable.*
- *Monitoring lock-in beneficiaries for potential transfer of misutilization post lock-in to other members of the same household or case.*
- *NCTracks Updates/Enhancements*
    - *Update the field in NCTracks used to track/document when beneficiaries change their lock-in provider to utilize standard reasons (along with the ability to add free text, when appropriate) so that useful reports can be generated to identify trends about why members change lock-in providers, what reasons are appropriate to drive such changes, etc.*
    - *Modify MLIP reports exported from NCTracks to include a text description of the field code and/or the notes entered by individual reviewers on MLIP hearing and appeal cases.*
- *Re-evaluate CSRA approach which utilizes the same pharmacist staff to perform the work that currently supports MLIP evaluations as well as prior authorization reviews.*
- *Provide more beneficiary and provider education regarding the MLIP.*
- *Develop and implement a formal referral process from CSRA staff to NC DMA and/or NC Program Integrity.*
- *In consideration of the State's upcoming transition to managed care, a vulnerability may occur should the lock-in program be operated separately by various managed care organizations (MCOs). Maintaining central operation and oversight of the MLIP within NC DMA will prevent lock-in beneficiaries from bypassing lock-in requirements by changing coverage between managed care organizations.*

# *Background*

The Beneficiary Management Lock-In Program (MLIP) was originally implemented in October 2010, per the State's Outpatient Pharmacy Program Clinical Coverage Policy No: 9, Section 5.15; the North Carolina Administrative Code, 10 A NCAC 22F .0704 and 10A NCAC 22F .0104. Additionally, 42 CFR 431.54 and the North Carolina Medicaid State Plan Amendment support the State's development of procedures for the control of beneficiary overutilization of Medicaid benefits. Further, Session Law (S.L.) 2015-241, Section 12F.16. (l) as found at *http://www.ncga.state.nc.us/Sessions/2015/Bills/House/PDF/H97v9.pdf*, 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.

Beneficiaries who have potentially misutilized Medicaid services and would benefit from a more detailed level of program involvement are locked into one physician/prescriber and one pharmacy to obtain program-targeted drugs which are controlled substances such as opiates, benzodiazepines and certain anxiolytics.

The lock-in period, effective for lock-in implementations beginning March 1, 2017, is two years. A beneficiary will be removed from the program after two years if he/she no longer meets the criteria. 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, he/she will be re-identified for the lock-in program. The beneficiary cannot change their lock-in prescriber or pharmacy without authorization from DMA.

Requirements in effect throughout the period of analysis outline that North Carolina Medicaid beneficiaries will be locked into one prescriber and one pharmacy for controlled substances categorized as opiates, benzodiazepines and certain anxiolytics when one or more of the following criteria are met:

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

After notification of enrollment, a beneficiary is given 30 days to select a lock-in physician and pharmacy. If the beneficiary does not provide these preferences, the vendor CSRA (formerly Computer Sciences Corporation (CSC) – now operating as CSRA) automatically selects the lock-in physician/prescriber and pharmacy providers, notifies the beneficiary and providers of the selection and relays this information to NCTracks, the State's MMIS. A physician/prescriber or pharmacy can opt to not provide services to the beneficiary through the lock-in program.

Beneficiaries who are locked in must obtain all targeted drug prescriptions from the lock-in prescriber and lock-in pharmacy in order for the claim to be paid by NC Medicaid. Claims

submitted by any prescriber or filled by any pharmacy other than the one listed on the lock-in file are to be denied.

The program allows for a single emergency fill of medication for an emergent situation once per year during each year of the two-year lock-in period for a beneficiary who uses a physician or pharmacy outside of their lock-in providers. This emergency fill is limited to a four-day supply and is indicated by the pharmacy reporting a "3" in the level of service field. The State will reimburse for the drug cost only and the beneficiary is responsible for all applicable copayments.

# *Methodology*

The State of North Carolina Division of Medical Assistance (DMA) may be referred to as either "the State" or "DMA" or "Division" interchangeably throughout this report with all referring to the DMA as part of the State.

As reviewed with the Division, this analysis was focused on North Carolina Medicaid beneficiaries locked into the MLIP beginning in March 2017 and ending with the final cohort locked in during August 2017. Due to the short timeframe of this review, **only that data which was available at the start of the analysis was utilized.**

Myers and Stauffer evaluated overall program effectiveness for each element of the Medicaid and Health Choice Clinical Coverage Policy No. 9 related to Section 5.14 Beneficiary Management Lock-In Program. In order to validate the appropriateness of the identification of the beneficiaries for lock-in consideration based on the criteria provided, Myers and Stauffer developed and implemented a process which allowed generating a list of beneficiaries potentially eligible for lock-in and compared it with the list of beneficiaries who were actually locked into the MLIP.

For the purpose of evaluating MLIP effectiveness from a data perspective, the analysis focused primarily on the MLIP cohorts of March and April 2017 as those cohorts contain the most complete dataset at the time of this review. In addition, the August 2017 cohort was referenced in select scenarios where comparison between initial MLIP operations and most recent operations or impact was sought.

A list of program-targeted drugs provided by the State was used to isolate pharmacy claims meeting lock-in criteria. Final paid targeted drug claims, with dates of service between March 1, 2017 and April 30, 2017, were used to identify beneficiaries who had not been locked into the program prior to May 1, 2017 and met at least one of the lock-in criteria, as outlined above in the background section. Eligibility data and institutional and outpatient medical claims with dates of service between March 1, 2016 and April 30, 2017 were used (for historical reference period) to exclude recipients who met one of the program exclusion criteria outlined below.

MLIP Beneficiary Exclusion Criteria:

- *NC Health Choice beneficiaries.*
- *Medicaid beneficiaries under the age of 18.*
- *Medicaid beneficiaries deceased prior to the date of evaluation.*
- *Medicaid beneficiaries who are in a skilled nursing bed.*
- *Medicaid beneficiaries who are in hospice care.*
- *Medicaid beneficiaries who have a qualifying cancer diagnosis, as provided by the State, on a medical claim within the past 12 months.*

The total number of adult beneficiaries who met at least one of the lock-in criteria based on the March 2017 and April 2017 targeted drug claims was 2,587, of which one (1) beneficiary had a date of death on file by the end of April 2017 resulting in exclusion from this analysis. The number of recipients excluded due to a qualifying cancer diagnosis within the past 12 months was 260. Additionally, 99 beneficiaries were excluded due to being in a skilled nursing bed or hospice care between March 2017 and April 2017. The total number of beneficiaries for lock-in program consideration who did not meet any of the exclusion criteria outlined above was 2,227. After removal of the currently locked-in beneficiaries (prior to May 1, 2017) this number decreased to 1,729.

Once the list of beneficiaries identified as potential candidates for lock-in consideration was complete, Myers and Stauffer used CSRA's Lock-in Profile Scoring and Ranking Algorithm *(as outlined by NCMMIS Project Design Document CSRs 1078 and 1148, V1.0, Section 4.4.2.6 Lock-in Profile Scoring and Ranking for Beneficiary)* to identify the top 600 beneficiaries for monthly lock-in consideration, outlined below.

- *Recipients who had a targeted drug claim count of seven (7) received six (6) points (applied for both Opiate and Benzodiazepine/Anxiolytics drug groups separately). One (1) point was added to this score for each subsequent claim.*
- *Recipients who had a prescriber count of four (4) received four (4) points. Two point one (2.1) points were added to the score for each prescriber over four (4).*
- *The overall Component score was a sum of the three sub-component scores.*
- *Two (2) points were added to the overall Component score for beneficiaries who met all three criteria and had each of the sub-component scores greater than zero (0).*

After the combined score was calculated for each potential candidate, the total payment amount on the targeted drug claims was calculated to determine the final increase in the combined Component score, based on the following logic:

- *Add 0.20 points for total payments amounts of $0 – $150.99.*
- *Add 0.40 points for total payments amounts of $151 – $300.99.*
- *Add 0.60 points for total payments amounts of $301 – $450.99.*
- *Add 0.80 points for total payments amounts of $451 – $600.99.*

- *Add 1.1 points for total payments amounts greater than $600.99.*

In order to identify the top 600 beneficiaries, the potential candidates were ranked based on the Component score with a highest value assigned rank one (1). The potential candidates were ordered by the Component score as the first sorting criterion and total payment amount as a secondary one. Therefore, the rank of the beneficiaries with the same Component score was assigned based on the total payment amount with the highest value assigned the highest ranking (with one (1) being the highest). The list of the top 600 beneficiaries generated upon completion of the identification process described above was then compared with the list of beneficiaries who were actually locked in. Please refer to the Program Effectiveness Evaluation section for the results of this comparison.

Evaluation of specific subsets of beneficiaries inside and outside the MLIP was performed to further evaluate program effectiveness. The first cohort included beneficiaries who were not locked in and had at least one targeted drug dispensed within the study period (dates of service between March 1, 2017 and August 31, 2017). Beneficiaries who met any of the exclusion criteria listed on the previous page, were excluded from the analysis. The total number of adult beneficiaries after applying all of the exclusion criteria was 140,188. The second cohort included beneficiaries who were enrolled in the program between September 2016 and March 2017 and were locked-in every month within the study period (March 2017 – August 2017). A few examples of the records reviewed include:

- *Highest number of targeted drugs by beneficiary and prescriber.*
- *Top beneficiaries by total number of prescribers.*
- *Top prescribers by the average number of claims per beneficiary.*

Beneficiary utilization was also evaluated through review of medication/prescription and medical profiles six (6) months prior and six (6) months post/after lock-in start date. Beneficiaries locked into the program in March 2017 who were not locked in within six (6) months prior to this month, were included in the analysis. Select recipients with dates of death on file between March 2017 and August 2017 were excluded from the data pull. Examples of the key outcomes compared for these two cohorts include, but are not limited to the below:

- *Average number of claims per beneficiary.*
- *Average number of claims per prescriber.*
- *Average number of prescribers per beneficiary.*
- *Average number of pharmacies per beneficiary.*
- *Average cost per claim.*
- *Average cost per beneficiary.*

The total number of beneficiaries included in this analysis was 574. The majority (459 out of 574; 80 percent) of these beneficiaries stayed in the MLIP program, as evidenced by having at least one (1) targeted drug dispensed within six (6) months after their lock-in start date on March 1, 2017. Approximately 20 percent (115 out of 574) of MLIP beneficiaries received no targeted drugs after their lock-in start date. This included 10 beneficiaries whose Medicaid eligibility

ended prior to March 1, 2017 and, therefore, they were excluded from the "Ceased Targeted Drug Activity" cohort.

With the purpose of identification of any potential transfer of behavior/misutilization upon lock-in, utilization was reviewed based on case head status when the beneficiary being locked in was a case head with the potential to transfer behavior to a related party in the same case or household. In the absence of household ID field, potentially related beneficiary pairs where at least one individual was locked in were identified based on the case head last name and address. A total of 165 pairs were identified; please refer to the section titled Case Head/Household: Analysis of Targeted Drug Usage on page 35 for the results of this review.

Averages throughout this analysis (average claims/prescribers/pharmacies/costs per beneficiary, etc.) were calculated as total number of unique items (claims/prescribers/pharmacies/costs) divided by the unique beneficiary count.

## Assumptions, Exclusions and Limitations of Analysis

The following assumptions, exclusions and limitations of analysis are noted relative to issues encountered or considerations made in compilation of this fiscal analysis.

**NOTE:** Throughout this document terms such as "review" or "audit" may be utilized. These terms are defined by the North Carolina Legislature and/or the Division of Medical Assistance and do not imply an audit or examination as those terms are used and defined in the accounting profession.

- *Myers and Stauffer's analysis was based on outpatient pharmacy and medical claims data with dates of service from March 2015 through August 2017, paid through October 2017. Additional paid claims data would alter the results of this analysis.*
- *Although the cohorts of specific focus for this analysis were March through August 2017, claims data was not complete at the time of analysis for these beneficiaries. Therefore, any observations regarding claims data should be considered to be subject to change based on potential additional claims, claim voids or adjustments which may not have been received within the timeframe of completion of this review.*
- *All estimates are based upon information available or provided at a point in time and are subject to unforeseen and random events. Therefore, any projection must be interpreted as having a likely range of variability from the estimate. Any estimate or projection may not be used or relied upon by any party or for any other purpose than for which it was issued by Myers and Stauffer. Myers and Stauffer is not responsible for the consequences of any unauthorized use.*
- *For this analysis, Myers and Stauffer relied upon data, as well as other sources of information as described in this report. We relied upon this data without independent audit. Although the data was reviewed for reasonableness and consistency, we have not audited or otherwise verified this data.*
- *Myers and Stauffer's review may not identify all data imperfections. We assume the data provided is both accurate and complete. The results of our analysis are dependent upon*

*this assumption. If the data or information provided is inaccurate or incomplete, our findings and conclusions may require revision.*

- *Data Limitations: Myers and Stauffer used the State's Beneficiary Management Lock-in Program enrollment tables, as provided by the Division, to determine the lock-in beneficiary universe (by month) that were included in this analysis.*
- *Lock-in provider demographics for each lock-in beneficiary were utilized in this analysis; however, neither the reason for lock-in provider changes nor the timestamps and effective/end dates of these changes were received. Therefore, claims were matched only to the lock-in provider of record, not to the lock-in provider active at the moment of claim adjudication.*
- *During the course of the analysis, it was determined that the Prescriber ID field had missing values on about two (2) percent of the claims. This was discussed with the State which resulted in the agreement that the Prescriber National Provider Identifier field will be included in the data feed for any future analyses.*
- *Myers and Stauffer did not have access to the Household ID or any other field which would allow capturing all household members. Using case head last name and address does not allow for identification of all potential household beneficiaries and limited the scope of the analysis.*
- *Myers and Stauffer relied upon a list of program-targeted drugs as provided by the State for this analysis.*

## Two-Year Lock-In Program Impact

Since the NC MLIP program with the two-year lock-in period has been operational for less than a year at the time of this evaluation, the impact of this program change (extending the duration of lock-in), cannot yet be measured. However, a review of a similar programs, with a two-year lock-in period, found that beneficiaries who remained enrolled in the program were more likely to achieve stable outcomes the longer they spent in the program. Stable outcomes were defined as having either decreased or no use of prescription opioids, maintained steady use, or entered a maintenance replacement program.[2] Based on the results of this study, the NC MLIP could reasonably expect to see its participants achieve similar stable outcomes resulting from the longer lock-in period.

[2] Dreyer, R.F., Michalski, T., & Williams B.C. Patient Outcomes in a Medicaid Managed Care Lock-In Program. J Manag Care Spec Pharm 2015;21(11):1006-12.

# *Program Vulnerabilities*

Myers and Stauffer identified two areas of vulnerabilities in North Carolina's Medicaid Lock-In Program (NC MLIP). These vulnerabilities involve coordination with Federal and State agencies and program design and criteria compared to adjoining or bordering state lock-in programs.

## State/Federal Coordination

As currently written, the NC MLIP does not require coordination between the North Carolina Division of Medical Assistance and other North Carolina State and/or Federal agencies. Such coordination would provide for the identification of Medicaid beneficiaries who would benefit from the program, but may not currently meet criteria.

The most significant vulnerability of the NC MLIP observed by this analysis is the current lack of coordination with (or use of) the North Carolina PDMP. The North Carolina Controlled Substances Reporting System Act, Chapter 90, Article 5E, Section § 90-113.743, allows the North Carolina Department of Health and Human Services to release data in the controlled substances reporting system to the Division of Medical Assistance for purposes of administering the State Medical Assistance Plan. Obtaining access to and including consideration of targeted drugs obtained outside of Medicaid will help identify those Medicaid beneficiaries who circumvent program guidelines and may assist in monitoring those individuals enabling the State to help them remain in the program to prevent overutilization of other areas of Medicaid. PDMP data could also be used to identify Medicaid beneficiaries who would have met criteria had they been receiving targeted drugs solely through Medicaid. This would require revision of MLIP criteria. Limitations have been identified that may prevent reliable use of the PDMP in the MLIP. The first limitation is that there is no way to match the member identification numbers used in the the NC Medicaid Program and PDMP. Current identification requires matching beneficiary names, birthdates, addresses, etc. The second limitation is that data in the PDMP may not be standing paid claims. Claims reversed at the pharmacy because the beneficiary did not pick up the medication are not required to be submitted to the PDMP. These limitations would need to be evaluated and addressed. A study conducted by Roberts, Farley, Holmes, et al on the NC MLIP population specifically identified this area for improvement in the NC MLIP.[4] This study found that MLIP beneficiaries shifted to obtaining targeted drugs outside of the MLIP, mitigating the effectiveness of program restrictions.

A second area to consider is the coordination that will be needed as North Carolina Medicaid transitions to managed care. Without coordination between the State and the managed care organizations, individuals may be able to bypass the system by changing from one managed care organization to another.

[3] N.C. Gen. Stat. § 90-113.74, https://www.ncga.state.nc.us/enactedlegislation/statutes/html/byarticle/chapter_90/article_5e.html, Accessed November 16, 2017.
[4] Roberts, A. W., Farley, J. F., Holmes, G. M., Oramasionwu, C. U., Ringwalt, C., Sleath, B., & Skinner, A. C.. Controlled substance lock-in programs: Examining an unintended consequence of a prescription drug abuse policy. Health Affairs 2016,35(10), 1884-1892. DOI: 10.1377/hlthaff.2016.0355.

In a study conducted on a Michigan Medicaid managed care lock-in population, over half of its lock-in beneficiaries dropped coverage post lock-in.[5] This study did not discuss whether all Michigan Medicaid managed care organizations operate lock-in programs with the same criteria and/or processes. In addition, it did not report what happened to beneficiaries who disenrolled from the managed care organization. According to a 2014 report by the National Association of Medicaid Directors, contract oversight and administration of pharmacy data collection can be difficult when managed care organizations are responsible for lock-in programs.[6] Currently, South Carolina Department of Health and Human Services (SC DHHS) operates a statewide lock-in program. A secure website is utilized to house live beneficiary data and is required to be updated by its managed care organizations during a beneficiary's lock-in period.[7] This website allows the SC DHHS to manage its lock-in program with its various managed care organizations. Continued oversight by the NC DMA of the lock-in program will reduce the ability of beneficiaries to bypass the lock-in program by switching between managed care organizations.

## Program Design and Criteria Vulnerabilities

As part of the vulnerability identification process, Myers and Stauffer compared the design and criteria of bordering state lock-in programs to the NC MLIP. These states included Georgia, South Carolina, Tennessee and Virginia. Please refer to ***Table A*** for the design elements of North Carolina's MLIP and the programs of its four bordering states. Overall, the basic design elements of North Carolina's MLIP are similar to those of its bordering states. All program lock-in periods reviewed are for a minimum of two years, except for Tennessee which utilizes an indefinite lock-in period. All programs currently lock into one pharmacy provider. Only two programs, South Carolina and Tennessee, do not lock into a prescriber.

Myers and Stauffer also compared the lock-in criteria of the NC MLIP to the criteria of its bordering states' programs (***Table B***). Bordering state programs are more restrictive and use more criteria for participation in their respective lock-in programs. The NC MLIP uses only three criteria for lock-in compared to its bordering state programs, which utilize between nine to 17 criteria. A beneficiary must meet at least one of the criteria in these programs, except for South Carolina which applies weight to criteria, to be considered for lock-in.

Bordering state programs have a higher number of criteria for lock-in because they utilize additional resources and types of criteria outside of pharmacy claims data. For example, most of the states utilize emergency room visit data to identify beneficiaries with frequent emergency room visits for the purpose of obtaining controlled substances and/or non-emergency care, which is absent from the NC MLIP evaluation process. While there may be a lag time of the

[5] Centers for Disease Control and Prevention, "Patient Review & Restriction Programs: Lessons Learned From State Medicaid Programs" (2012), http://www.cdc.gov/drugoverdose/pdf/pdo_patient_review_meeting-a.pdf.
[6] National Association of Medical Directors, "State Medicaid Interventions for Preventing Prescription Drug Abuse and Overdose" (2014), https://www.integration.samhsa.gov/namd_rx_abuse_report_october_2014.pdf.
[7] State of South Carolina. Managed Care Organizations Policy and Procedure Guide, Section 11.9, October 2017, https://msp.scdhhs.gov/managedcare/sites/default/files/MCO%20October%202017_Final%20Post%2009-30-17.pdf, Accessed November 13, 2017.

availability of emergency room data if applying the same two-month period of review as that employed under the current MLIP, criteria related to emergency room data for a longer timeframe could be utilized. Including emergency room data in identifying and locking in beneficiaries would be expected to result in a potential decrease in unnecessary Medicaid emergency room visit costs. According to the Patient Review and Restriction Programs[8] report issued by the Centers for Disease Control and Prevention, a study of Oklahoma's Medicaid Lock-in Program identified a reduction in emergency department visits after beneficiaries were enrolled in lock-in.

The following are criteria present in select bordering state programs, which illustrates the diversity in their criteria. Inclusion of these criteria in the NC MLIP would require consideration of each criterion individually, including their potential impact on expanding the identification of the most egregious misutilizers of Medicaid services. Bordering state programs criteria include the identification of beneficiaries who obtain controlled substance schedule II prescriptions without corresponding professional claims, beneficiaries with services/medications outside their county of residence, beneficiaries with duplicate drug therapies from multiple prescribers, and beneficiaries who obtain narcotics without appropriate diagnoses. Additional notable criteria include identifying beneficiaries who fill prescriptions for more than 120 morphine milligram equivalents per day, beneficiaries with suspected drug abuse/fraudulent activities, beneficiaries with a history of drug-related offenses, beneficiaries with diagnoses of narcotic poisoning/abuse with/without benzodiazepine/opioid prescriptions, and/or beneficiaries with documentation of any type of abuse of the Medicaid system, e.g. financial or eligibility violations (***Table B***). By including a wider variety of criteria in their programs, bordering states are able to identify beneficiaries with drug-seeking behavior that would not be identified through pharmacy claims data alone, such as the review performed for the NC MLIP.

There is an opportunity to improve the NC MLIP through an expansion of the program's lock-in criteria and requirements. ***Table C*** lists potential program criteria that would provide the NC MLIP potential to achieve an inclusion list similar to its bordering states and would allow for the identification of beneficiaries who would benefit from lock-in restriction, but are not being captured using the current criteria.

[8] Centers for Disease Control and Prevention, "Patient Review & Restriction Programs: Lessons Learned From State Medicaid Programs" (2012), http://www.cdc.gov/drugoverdose/pdf/pdo_patient_review_meeting-a.pdf.

## Table A: Pharmacy Lock-In Program Design Elements of North Carolina and its Bordering States*

| | North Carolina[1,2] | Georgia[3,4] | South Carolina[5] | Tennessee[6] | Virginia[7] |
|---|---|---|---|---|---|
| **Lock-in period** | 2 years | 24 months | 24 months (regardless of beneficiary's movement between MCOs) | Indefinite, but disenroll if meet 4 criteria for 6 consecutive months | 24 months |
| **Lock into one pharmacy** | Yes | Yes | Yes | Yes | Yes |
| **Lock into one prescriber** | Yes | Yes or physician group | No | No | Yes or physician group, except for members with dual eligibility for Medicaid and Medicare |
| **Additional criteria beyond Medicaid enrollment to be a lock-in provider** | No | Not indicated | Not indicated | Yes | Yes |
| **Member appeal rights** | Yes | Yes | Yes | Yes | Yes |
| **Lock-in remains during appeal** | Yes, if appeal submitted after enrollment | Yes | No | No | No |
| **Prohibit cash pharmacy payment for controlled substances** | No | Yes, pharmacies with knowledge of lock-in are prohibited from accepting cash payments for controlled substance prescriptions that do not adjudicate | Not indicated | No, but will continue lock-in if beneficiary paid cash. May be escalated to prior approval status if beneficiary pays cash for ≥ 3 controlled substances and meets two other criteria | No, but documented cash payments are criteria for lock-in and program continuation |
| **Period of review** | Run reports of pharmacy claims (60 days) | Assess monthly and period of review varies | Quarterly report of all claims for a designated 6 month period | 90 days | Not indicated |
| **Exclusions** | -NC Health Choice<br>-Beneficiaries < age 18<br>-Deceased beneficiaries<br>-Beneficiaries in a skilled nursing bed<br>-Beneficiaries in hospice<br>-Beneficiaries with a qualifying cancer diagnosis | Not indicated | -Voids<br>-In hospice, with date of death or no longer Medicaid eligible<br>-Currently in lock-in<br>-Age ≤ 16 and Aid Category=57 or RSP in approved list | Not indicated | -MCO members<br>-Institutionalized long-term care residents |
| **Emergency supply amount** | One 4-day supply during each year of the 2-year lock-in period | Amount not specified, but indicates lock-in does not apply to emergency services | -After regular business hours, weekends or holidays, allow a 3-day supply<br>-If medication not in stock, a coordinating pharmacy may dispense up to a 30-day supply | Amount not specified, but available with approval | Amount not specified, but available with approval |

*Information in this table regarding Georgia, South Carolina, Tennessee and Virginia lock-in programs, referenced below, was obtained from publically available sources as noted. This table was not supplied to the respective States for their review.*

1. North Carolina Division of Medical Assistance. Medicaid and Health Choice Clinical Coverage Policy No. 9, Section 5.14, May 2017.
2. North Carolina Department of Health and Human Services. North Carolina Medicaid Management Information System Project Design Document CSR 1927, Version D1.1.1, March 2017.
3. Georgia Department of Community Health, Division of Medical Assistance. Part I Policies and Procedures for Medicaid/Peachcare for Kids, Section 109.1, January 1, 2018. https://www.mmis.georgia.gov/portal/Portals/0/StaticContent/Public/ALL/HANDBOOKS/Part%201%20Polices%20and%20Procedures%20for%20Medicaid_PeachCare%20for%20Kids%2020180105183803.pdf, Accessed January 9, 2018.
4. Georgia Department of Community Health, Division of Medical Assistance. Part II Policies and Procedures for Pharmacy Services Manual, Sections 606 and 606.1, October 2017. https://www.mmis.georgia.gov/portal/Portals/0/StaticContent/Public/ALL/HANDBOOKS/Pharmacy%20Services%2020171016161310.pdf, Accessed November 16, 2017.
5. State of South Carolina. Managed Care Organizations Policy and Procedure Guide, Section 11.9, October 2017, https://msp.scdhhs.gov/managedcare/sites/default/files/MCO%20October%202017_Final%20Post%2009-30-17.pdf, Accessed November 13, 2017.
6. State of Tennessee. Rules of Tennessee Department of Finance and Administration Bureau of TennCare, Chapter 1200-13-13, Section 13, October 2017, http://publications.tnsosfiles.com/rules/1200/1200-13/1200-13-13.20171001.pdf , Accessed November 16, 2017.
7. State of Virginia Department of Medical Assistant Services. Virginia Administrative Code, Title 12, Agency 30, Chapter 130, Sections 800-820, December 2015, https://law.lis.virginia.gov/admincode/title12/agency30/chapter130/section810/ ,Accessed November 20, 2017.

**Table B: Pharmacy Lock-In Program Criteria of North Carolina and its Bordering States***

| | North Carolina[1] | Georgia[2] | South Carolina[3] | Tennessee[4] | Virginia[5] |
|---|---|---|---|---|---|
| **Number of criteria used for lock-in** | 3 criteria | 12 criteria | 20 criteria | 2 criteria considered appropriate for lock-in and 7 criteria considered potentially appropriate for lock-in | 17 Criteria |
| **Criteria method** | Meet 1 criteria | Meet 1 criteria | Criteria are weighted, total score and rank assigned for enrollment selection | Referred if meet 1 criteria, but approved subsequent to clinical review | Meet 1 criteria |
| **Emergency room services** | | Member seen in hospital emergency room > 2 times/year | Two or more ER visits in 30 days and controlled prescription | Multiple controlled substance prescriptions filled at ≥ 2 pharmacies and written during ≥ 3 emergency room visits (potentially appropriate) | ≥ 3 emergency room visits for non-emergency care in 3 month period |
| **Prescriber/pharmacy** | | Services/medications received outside of member's county of residence | CII without professional claim | Multiple controlled substance prescriptions filled at ≥ 3 pharmacies and written by ≥ 3 prescribers in a 90-day period (potentially appropriate) | Utilized ≥ 3 prescribers and ≥ 3 pharmacies in a 3 month period |
| | | | | Multiple controlled substance prescriptions filled at ≥ 1 targeted pharmacies and written by ≥ 2 prescribers in a 90-day period (potentially appropriate) | ≥ 2 drugs (duplicative or potentially addictive) from > 1 pharmacy or > 1 prescriber for a period > 4 weeks |
| | | | | Multiple controlled substance prescriptions filled at ≥ 2 targeted pharmacies and written by ≥ 1 prescribers in a 90-day period (potentially appropriate) | Exceeded max therapeutic dosage of same drug or multiple drugs in same therapeutic class prescribed by ≥ 2 prescribers for a period > 4 weeks |
| | | | | Multiple controlled substance prescriptions filled at ≥ 1 targeted pharmacies and written by ≥ 1 targeted prescribers in a 90-day period (potentially appropriate) | |

| | North Carolina[1] | Georgia[2] | South Carolina[3] | Tennessee[4] | Virginia[5] |
|---|---|---|---|---|---|
| **Pharmacy** | > 6 claims for benzodiazepines and certain anxiolytics in 2 consecutive months | Filled >3 controlled substances/month | Four or more pharmacies | Used buprenorphine-containing products for office based opioid addiction treatment within previous 6 months (appropriate) | ≥ 12 psychotropic prescriptions or ≥ 12 analgesic prescriptions or ≥ 12 controlled substance prescriptions with potential for abuse in 3 month period |
| | > 6 claims for opiates in 2 consecutive months | Total number of controlled substance prescriptions exceeds 10% of total prescriptions filled by member | Five or more controlled substances in 30 days | | ≥ 1 occurrences of paying cash for controlled substances, analgesic drugs, or psychotropic drugs |
| | | Paid cash for drugs of abuse | Ten or more pills per day for controlled prescriptions | | 2 occurrences of having the same drug filled ≥ 2 times the same day or subsequent day |
| | | Filled prescriptions at > 2 pharmacies/month or > 5 pharmacies/year | Two or more out of state pharmacies for controlled prescriptions | | ≥ 24 prescriptions in a 3 month period |
| | | | Two controlled prescriptions from 2 pharmacies within 2 days | | |
| | | | Controlled substances dispensed at 2 or more pharmacies | | |
| | | | Three or more controlled substances and drugs of concern (tramadol, cyclobenzaprine, methocarbamol, tizanidine and metaxalone) | | |
| | | | Fifteen or more prescriptions in 30 days | | |
| | | | > 3,600mg of oxycodone in a rolling 30 days | | |
| | | | Opioid prescription within 30 days after a Suboxone prescription | | |
| | | | On Cocktail Reports (at least 1 opioid, a benzodiazepine and a muscle relaxant) | | |
| | | | Pill count > 600 for all DEA Schedule II-V prescriptions | | |
| | | | Suboxone prescription | | |

| | North Carolina[1] | Georgia[2] | South Carolina[3] | Tennessee[4] | Virginia[5] |
|---|---|---|---|---|---|
| **Prescriber** | Prescriptions for targeted drugs from > 3 prescribers in 2 consecutive months | Duplicate therapies from different physicians | Two or more opioid prescribers | | Narcotics from > 2 prescribers without appropriate diagnoses |
| | | | Five or more prescribers | | ≥ 3 different physicians of same type in 3 month period for treatment of similar condition |
| | | | Three or more prescribers for a controlled substance | | ≥ 2 occurrences of seeing ≥ 2 physicians of same type/specialty on same or subsequent day for same/similar diagnosis |
| | | | | | ≥ 1 provider recommend restriction due to demonstration of inappropriate utilization practices |
| **Other** | | Appropriate diagnosis | History of drug dependence diagnosis code and a benzodiazepine or opiate prescription | Identified by the TennCare OIG as having been convicted of TennCare fraud or a drug-related offense (appropriate) | Pattern of noncompliance inconsistent with sound fiscal or medical practices |
| | | Previously participated in lock-in while enrolled in CMO | History of a poisoning/overdose diagnosis code and a benzodiazepine or opiate prescription | Has been arrested for TennCare fraud (potentially appropriate) | Documentation of use of eligibility card under false pretenses, including attempt to purchase drugs via forged/ altered prescription[i] |
| | | Taking > 120 MME per day | | Arrested for a drug-related offense (potentially appropriate) | Documented alteration of recipient eligibility card |
| | | Suspected of drug abuse or fraudulent activities | | | Documented use of card-sharing |
| | | Diagnosis of narcotic poisoning or abuse | | | Duplicative, excessive or contraindicated utilization of medications, medical supplies or appliances dispensed/ prescribed by > 1 provider for DMAS specified time period |

*i. Examples include: 1. Failure to disclose any treatment or services provided by another provider to a provider; 2. Failure to follow drug regimen/treatment; 3. Requests for non-medically necessary medical services/medications; 4. Self-referral for non-acute medical treatment to emergency rooms; and 5. Underutilization of medically necessary services that result in higher costs of a medication condition.*

**Information in this table regarding Georgia, South Carolina, Tennessee and Virginia lock-in programs, referenced below, were obtained from publically available sources as noted. This table was not supplied to the respective States for their review.*

1. North Carolina Division of Medical Assistance. Medicaid and Health Choice Clinical Coverage Policy No. 9, Section 5.14, May 2017.
2. Georgia Department of Community Health, Division of Medical Assistance. Part II Policies and Procedures for Pharmacy Services Manual, Sections 606 and 606.1, October 2017.
3. State of South Carolina. Managed Care Organizations Policy and Procedure Guide, Section 11.9, October 2017.
4. State of Tennessee. Rules of Tennessee Department of Finance and Administration Bureau of TennCare, Chapter 1200-13-13, Section 13, October 2017.
5. State of Virginia Department of Medical Assistant Services. Virginia Administrative Code, Title 12, Agency 30, Chapter 130, Sections 800-820, December 2015, Accessed November 20, 2017.

**Table C: Potential Criteria and Requirement Additions for Program Improvement**

| Criteria | Benefits of Inclusion |
|---|---|
| Emergency room visits for non-emergency care, targeted drug usage, and/or drug overdose related diagnoses | ■ *Allows identification of Medicaid beneficiaries with drug-seeking behavior and/or a history of drug abuse*<br>■ *Allows for identification of potential lock-in participants that do not meet current pharmacy claim-driven criteria, but do burden other areas of Medicaid services*<br>■ *May lead to reduction in unnecessary emergency visits/costs for beneficiaries post lock-in* |
| Incorporate comparison of medical claims with pharmacy claims to ensure appropriate diagnoses | ■ *Allows identification of potential lock-in participants with drug-seeking behavior and/or a history of drug abuse who may be obtaining targeted drugs outside of the lock-in program*<br>■ *May allow for the identification of fraud conducted by pharmacies and/or prescribers*<br>■ *May lead to a reduction in Medicaid professional claim payments after lock-in* |
| Morphine milligram equivalents (MME) per day (>50 MME/day) | ■ *Allows for identification of potential lock-in participants using 50-120 MME per day currently not captured by the prior authorization process (>120 MME per day) and may be taking opioids that are not medically necessary*<br>■ *Allows for identification of potential lock-in participants obtaining large quantities of opioids and a small number of prescriptions currently not identified by the program criteria* |
| Duplicate therapy from multiple prescribers or different prescribers within the same specialty | ■ *Allows for identification of potential lock-in participants who may not meet the current program criteria, but obtain duplicate prescriptions from prescribers*<br>■ *Allows for identification of Medicaid beneficiaries with drug seeking behavior and/or a history of drug abuse* |
| Utilize PDMP data to identify potential lock-in candidates and/or monitor current MLIP beneficiaries | ■ *Allows for identification of Medicaid beneficiaries that may be misutilizing Medicaid services, but are not identified because their targeted drug prescription activity through Medicaid does not meet current criteria*<br>■ *Allows for management of current MLIP beneficiaries who may continue to misutilize Medicaid services outside of pharmacy claims, but cease obtaining targeted drugs via Medicaid after lock-in* |
| Central management of MLIP by NC DMA during and after transition to managed care | ■ *Allows for NC DMA to ensure the MLIP is properly administered by managed care organizations*<br>■ *Prevents lock-in beneficiaries from bypassing the program by switching between managed care organizations to avoid MLIP participation* |

# *Program Effectiveness Evaluation*

## Observations of Operations – Meetings with NC Program Integrity and CSRA MLIP Staff

To gather information regarding operational issues related to the MLIP, meetings were held September 26, 2017, with the NC program integrity (PI) unit, NC DMA and key staff from the vendor CSRA that are involved in MLIP operations.

### North Carolina Program Integrity Unit

One vulnerability noted during the meeting with NC PI was that when beneficiaries change their lock-in prescriber, the field in NCTracks used to note such change is currently free text. It was reported by NC PI staff that this free text entry method precludes the State from being able to summarize/analyze data regarding changes in lock-in providers and/or generate useful reports. This field could be updated to include standard reasons (along with the ability to add free text, when appropriate) so that useful reports can be generated to identify trends about why members change lock-in providers, what reasons are appropriate to drive such changes, etc.

A similar observation regarding the NCTracks fields for hearings related to MLIP appeals was noted. NC PI reported that the fields for reasons and outcomes related to the hearings are recently standardized; however, the exported report that is currently available for evaluation of hearing reasons does not contain a text description of the field code and/or the notes entered by individual reviewers on the hearing cases. This prevents useful report generation to evaluate the hearing process related to MLIP beneficiaries.

In order to provide meaningful reports, an update to NCTracks is essential. Reports currently provided require time and expense because the NCTracks system lacks the capability to generate such reports.

### CSRA MLIP Operations

Myers and Stauffer was able to meet with CSRA and gain a basic understanding of the operation of MLIP. During the meeting with CSRA, pharmacist staff who perform the work supporting the MLIP were noted to also be the same staff who evaluate pharmacy prior approvals. There seemed to be concern for the volume received, especially in light of recent increases related to the implementation of prior authorization requirements related to criteria for morphine milligram equivalents (MMEs). An opportunity may exist to re-evaluate this approach and allocate appropriate staff to each program based on volume.

A second area discussed during the meeting involved provider communication and education. CSRA shared MLIP letters utilized, which included standard program notification and response letters. CSRA emphasized that all material that is sent to the provider community is done so with the approval of DMA. Review of literature, other state programs and federal recommendations suggests an opportunity to provide more beneficiary and provider education regarding the NC MLIP.

One vulnerability pointed out by CSRA was the ability of lock-in beneficiaries to pay cash for targeted drug prescriptions and that identifying those individuals is not within CSRA's scope of work. NC DMA has indicated that access to the state-wide PDMP is pending and should help address this

vulnerability. However, once access is granted, staff resources will need to be made available to review this system and incorporate the results into program operations. The Strengthen Opioid Misuse Prevention Act of 2017 (STOP Act) may assist in the reduction of lock-in beneficiaries' ability to pay cash for targeted drug prescriptions.[9] Under this Act, dispensers shall review the PDMP and document if they have a reasonable belief that the ultimate user may be seeking a targeted controlled substance for any reason other than the treatment of an existing medical condition or if they pay for the prescription with cash when there is prescription insurance on file with the dispenser. Even though this Act may reduce the ability of the MLIP beneficiaries to obtain targeted drugs outside of Medicaid, it does not allow for the identification and monitoring of Medicaid beneficiaries who may be misutilizing Medicaid services.

One final vulnerability and resulting opportunity for improvement was noted in regards to the referral process between CSRA and DMA/NC PI. CSRA indicated that they call with a referral regarding potential fraud or abuse, but do not submit anything in writing to the State. This is observed to be a vulnerability with a clear opportunity for improvement to develop and implement a formal referral process. Such processes are readily available from other NC PI activities and could be easily modified by CSRA to accommodate their referrals.

## Effectiveness of Beneficiary Identification for Lock-In Analysis

Analysis of the pharmacy data with consideration of the exclusion criteria reflected that the majority of beneficiaries who meet the lock-in criteria are currently being identified for MLIP participation. ***Table D*** depicts the lock-in analysis results. Myers and Stauffer identified 593 potential candidates for lock-in consideration out of the top 600 actual locked in beneficiaries (98.8 percent). Approximately 93 percent of these potential candidates (553 out of 593) met lock-in criteria based on filling more than six targeted drug opioid prescriptions, 29.8 percent of the beneficiaries (177 out of 593) received targeted drug prescriptions from more than three prescribers and only 1.5 percent (9 out of 593) had more than six pharmacy prescriptions for targeted benzodiazepines and certain anxiolytics within two consecutive months. Five beneficiaries had more than six pharmacy claims consisting of both targeted opioids and targeted benzodiazepines and certain anxiolytics. The Component scores ranged from 7.1 to 25.7 with the average value of 9.77. The highest ranked beneficiary had 11 opioid prescriptions from nine unique prescribers. The total payment amount ranged from $38.43 to $4,273.61 with the average amount per beneficiary of $631.66.

[9] N.C. Gen. Stat. Session Law 2017-74, House Bill 243, https://www.ncleg.net/Sessions/2017/Bills/House/PDF/H243v7.pdf, Accessed January 11, 2018.

**Table D: Lock-In Analysis Results of Identified Potential Lock-In Candidates Who Were Locked into the MLIP**

| Key Outcomes of Pharmacy Claims Data (March 2017 - April 2017) | Met Criteria of > Six Opioid Claims in Two Consecutive Months | Met Criteria of > Three Prescribers in Two Consecutive Months | Met Criteria of > Six Benzodiazepines and Certain Anxiolytics Claims in Two Consecutive Months | Met At Least One of the Three Criteria* |
|---|---|---|---|---|
| Unique Beneficiary Count | 553 | 177 | 9 | 593 |
| Number of Targeted Drug Claims | 4,721 | N/A | 72 | N/A |
| Unique Number of Prescribers | N/A | 913 | N/A | N/A |
| Targeted Drug Spend | $355,481.06 | $47,482.04 | $455.72 | $374,575.33 |
| Average Number of Claims per Beneficiary | 8.54 | N/A | 8 | N/A |
| Average Number of Prescribers per Beneficiary | N/A | 5.16 | N/A | N/A |
| Average Cost per Claim | $75.30 | N/A | $6.33 | N/A |
| Average Cost per Beneficiary | $642.82 | $268.26 | $50.64 | $631.66 |
| Average Component Score | 9.86 | 12.48 | 12.93 | 9.77 |

*Some beneficiaries met more than one of the three criteria and therefore the totals in the last column are not equal to the sum of the three criteria.

Evaluation identified seven beneficiaries who met criteria, but were not locked in. Based on how the criteria were weighted, these beneficiaries appeared lower on the potential lock-in list which may have contributed to them not being identified for lock-in. Further research identified that two of these beneficiaries passed away within the 90 day window for MLIP determination or decision-making and one was later diagnosed with cancer, which are exclusions for participation. Furthermore, these beneficiaries may not have been identified within this review timeframe, but could be pending lock-in in a subsequent period.

Due to the time period of this analysis being so recent and claims still being actively filed and updated by providers (via adjustments, voids and potential late submissions), reproducing the point in time analysis to replicate exactly what CSRA would have utilized is not possible.

## Analysis of Targeted Drug Usage Pre- and Post-Lock-In

After validating that appropriate members were locked in, based on the provided criteria, Myers and Stauffer further evaluated pharmacy claims for beneficiaries of the March 2017 cohort. Pharmacy claims for these beneficiaries during the six month period prior to lock-in were compared to the pharmacy claims six months after lock-in. A small number of beneficiaries were enrolled in the MLIP during part of the six month period prior to March 2017. These beneficiaries were excluded from the analysis to allow a true comparison of targeted drug use prior to and after lock-in. ***Table E*** depicts the comparison of pre- and post-lock-in pharmacy claims for beneficiaries of the March 2017 cohort.

Analysis identified that approximately 20 percent or 115 of the beneficiaries locked in March 2017 had no pharmacy claims for targeted drugs after their lock-in effective date. In this report, this group will be referred as the Ceased Targeted Drug Activity group. Analysis of the Ceased Targeted Drug Activity group identified that 10 of these MLIP beneficiaries became ineligible for Medicaid. Of the remaining 105 MLIP beneficiaries, 79 beneficiaries did receive non-targeted drugs or had institutional claims after lock-in. The remaining 26 beneficiaries had no professional, institutional or pharmacy claims after lock-in, but remained eligible for Medicaid and did not have a date of death on file. Beneficiaries receiving opioid dependence treatment drugs upon enrollment were less likely to be in the Ceased Targeted Drug Activity group than those beneficiaries taking other targeted drugs.

Possible explanations for MLIP beneficiaries who no longer obtained targeted drug prescriptions through Medicaid may include 1) beneficiaries may have been identified for program inclusion with targeted drug use; however, their targeted drug use was limited to a short duration due to acute diagnoses, 2) beneficiaries may have obtained targeted drug prescriptions via cash at pharmacies, circumventing the MLIP, 3) beneficiaries may have turned to illicit drug use, 4) beneficiaries may have shifted to obtaining targeted drugs using the Medicaid eligibility of a household or other related member, 5) beneficiaries may have become incarcerated; or 6) beneficiaries may have started receiving appropriate care and clinical management and did not require targeted drug use.

**Table E: Comparison of Usage Pre- and Post-Lock-In for Beneficiaries of the March 2017 Cohort**

| Key Outcomes | Six Months Pre-Lock-In (Sep 16 - Feb 17) | Six Months Post-Lock-In (Mar 17 - Aug 17) | Difference |
|---|---|---|---|
| Unique Beneficiary Count | 574 | 459 | (115) |
| Number of Targeted Drug Pharmacy Claims | 11,322 | 5,940 | (5,382) |
| Unique Number of Prescribers | 1,716 | 480 | (1,236) |
| Unique Number of Pharmacies | 895 | 393 | (502) |
| Targeted Drug Pharmacy Spend | $791,381.01 | $609,846.97 | $(181,534.04) |
| Average Number of Claims per Beneficiary | 19.72 | 12.94 | (6.78) |
| Average Number of Prescribers per Beneficiary | 2.99 | 1.05 | (1.94) |
| Average Number of Pharmacies per Beneficiary | 1.56 | 0.86 | (0.70) |
| **Average Cost per Beneficiary** | **$1,378.71** | **$1,328.64** | **($50.07)** |

Further analyses were conducted to compare targeted drug usage pre- and post-lock-in for beneficiaries who remained in the program, as evidence by the presence of targeted drug pharmacy claims after lock-in. ***Table F*** depicts the analysis of the 459 lock-in beneficiaries who continued to obtain targeted drugs after lock-in. During the six months after lock-in, total pharmacy claims for these beneficiaries decreased by 38 percent, the total number of prescribers decreased by 65 percent, and the total pharmacies used decreased by 50 percent. The total spend of targeted drugs for these beneficiaries decreased by $101,543.92. Decreases in average number of pharmacy claims, average number of prescribers and average number of pharmacies per beneficiary were also noted. Lastly, the average cost per beneficiary decreased by $221.23. Beneficiaries who were part of the March 2017 cohort and remained in the program after lock-in, had reduced targeted drug use and prescription cost.

**Table F: Comparison of Targeted Drug Usage Pre- and Post-Lock-In**

| Key Outcomes | Six Months Pre-Lock-In (Sep 16 - Feb 17) | Six Months Post-Lock-In (Mar 17 - Aug 17) | Difference |
|---|---|---|---|
| Unique Beneficiary Count | 459 | 459 | 0 |
| Number of Targeted Drug Pharmacy Claims | 9,510 | 5,940 | (3,570) |
| Unique Number of Prescribers | 1,357 | 480 | (877) |
| Unique Number of Pharmacies | 789 | 393 | (396) |
| Targeted Drug Pharmacy Spend | $711,390.89 | $609,846.97 | ($101,543.92) |
| Average Number of Claims per Beneficiary | 20.72 | 12.94 | (7.78) |
| Average Number of Prescribers per Beneficiary | 2.96 | 1.05 | (1.91) |
| Average Number of Pharmacies per Beneficiary | 1.72 | 0.86 | (0.86) |
| **Average Cost per Beneficiary** | **$1,549.87** | **$1,328.64** | **($221.23)** |

Myers and Stauffer reviewed the top targeted drugs grouped by name, strength and dosage form dispensed pre- and post-lock-in for the 459 beneficiaries who maintained targeted drug activity after program enrollment. ***Table G*** lists the Top 10 dispensed drugs based on claim count during the six month period pre- and post-lock-in. In both timeframes, the most frequently dispensed medications were buprenorphine/naloxone film and buprenorphine sublingual tablets, which are drugs used to treat opioid dependence. While the number of claims for these two opioid dependence treatment drugs decreased post-lock-in, this is not necessarily indicative of or correlated to decreased use of these medications. Prescribers often manage beneficiaries who are new to treatment by prescribing only a few days supply of medication at a time. Once beneficiaries are better managed or well-controlled, prescribers may increase quantities prescribed. For example, a beneficiary who used to have two claims in a week's time now only has one.

**Table G: Top 10 Targeted Drugs Dispensed Pre- and Post-Lock-In**

| Targeted Drug Claims for Six Month Period Pre-Lock-In | | | Targeted Drug Claims for Six Month Period Post-Lock-In | | |
|---|---|---|---|---|---|
| Generic Name, Strength, and Dosage Form | Claims | Spend | Generic Name, Strength, and Dosage Form | Claims | Spend |
| **BUPRENORPHINE HCL/NALOXONE HCL 8 MG-2 MG FILM** | 2,513 | $ 319,230.92 | **BUPRENORPHINE HCL/NALOXONE HCL 8 MG-2 MG FILM** | **1,728** | **$ 297,340.46** |
| **BUPRENORPHINE HCL 8 MG TAB SL** | **1,421** | **$ 49,640.58** | **BUPRENORPHINE HCL 8 MG TAB SL** | **1,061** | **$ 40,857.22** |
| TRAMADOL HCL 50 MG TABLET | 647 | $ 4,977.70 | OXYCODONE HCL/ACETAMINOPHEN 10MG-325MG TABLET | 277 | $ 11,336.95 |
| HYDROCODONE/ACETAMINOPHEN 5 MG-325MG TABLET | 536 | $ 5,948.13 | TRAMADOL HCL 50 MG TABLET | 245 | $ 2,137.83 |
| OXYCODONE HCL/ACETAMINOPHEN 5 MG-325MG TABLET | 508 | $ 5,588.68 | OXYCODONE HCL 10 MG TABLET | 206 | $ 3,438.00 |
| OXYCODONE HCL/ACETAMINOPHEN 10MG-325MG TABLET | 327 | $ 13,538.95 | ALPRAZOLAM 1 MG TABLET | 158 | $ 1,694.67 |
| OXYCODONE HCL 10 MG TABLET | 259 | $ 4,063.93 | OXYCODONE HCL/ACETAMINOPHEN 5 MG-325MG TABLET | 142 | $ 1,641.48 |
| ALPRAZOLAM 1 MG TABLET | 224 | $ 2,280.23 | CLONAZEPAM 1 MG TABLET | 140 | $ 1,250.77 |
| OXYCODONE HCL 5 MG TABLET | 222 | $ 2,615.37 | CLONAZEPAM 0.5 MG TABLET | 139 | $ 1,139.76 |
| CLONAZEPAM 1 MG TABLET | 214 | $ 1,845.31 | **BUPRENORPHINE HCL/NALOXONE HCL 8 MG-2 MG TAB SL** | **103** | **$ 12,822.45** |
| **Top 10** | **6,871** | **$ 409,729.80** | **Top 10** | **4,199** | **$ 373,659.59** |

*Opioid dependence treatment drugs in bold text above.

Because the most frequently prescribed drugs (based on highest volume of claims) pre- and post-lock-in were opioid dependence treatment drugs, an additional analysis was conducted of pharmacy claims for opioid dependence treatment drugs only versus all other targeted drugs. Opioid dependence treatment drugs were identified by the therapeutic class "narcotic withdrawal therapy agent". ***Table H*** depicts the usage of all opioid dependence treatment drugs pre- and post-lock-in for beneficiaries who continued to obtain targeted drugs after program enrollment. This analysis showed that 49 percent of beneficiaries locked in March 2017 who continued to obtain targeted drugs were taking opioid dependence treatment drugs. After lock-in, the number of beneficiaries receiving opioid dependence treatment was slightly lower. While the decrease in beneficiary count and spend was small, the number of claims and pharmacies decreased to a greater extent. This appears to be due to the prescribing patterns changing after lock-in. Both average days supply and average quantity per claim for these drugs increased after lock-in.

**Table H: Comparison of Opioid Dependence Treatment Drug Usage Pre- and Post-Lock-In**

| Key Outcomes | Six Months Pre-Lock-In (Sep 16 - Feb 17) | Six Months Post-Lock-In (Mar 17 - Aug 17) | Difference |
|---|---|---|---|
| Unique Beneficiary Count | 229 | 223 | (6) |
| Number of Targeted Drug Pharmacy Claims | 4,359 | 3,164 | (1,195) |
| Unique Number of Prescribers | 120 | 116 | (4) |
| Unique Number of Pharmacies | 322 | 187 | (135) |
| Targeted Drug Pharmacy Spend | $414,291.41 | $405,155.11 | ($9,136.30) |
| Average Number of Claims per Beneficiary | 19.03 | 14.19 | (4.84) |
| Average Number of Prescribers per Beneficiary | 0.52 | 0.52 | 0.00 |
| Average Number of Pharmacies per Beneficiary | 1.41 | 0.84 | (0.57) |
| **Average Cost per Beneficiary** | **$1,809.13** | **$1,816.84** | **$7.71** |

Additional analysis of the pharmacy claims for the lock-in beneficiaries in ***Table H*** was conducted to determine if these beneficiaries were taking opioid dependence treatment drugs concurrently with other targeted drug usage (opioids, benzodiazepines and certain anxiolytics). Examples of opioid dependence treatment drugs include buprenorphine and/or naloxone products with indications for medication assisted addiction treatment. Concurrent use was defined as having one claim for an opioid dependence treatment drug with an overlapping date of service of any other targeted drug. While short term use of opioids may be appropriate for acute pain related to trauma or surgery, repeated use of opioids and other targeted drugs with opioid dependence treatment drugs may lead to relapse or overdose and may indicate poorly coordinated opioid treatment.[10] Myers and Stauffer identified that there were beneficiaries taking both of these types of drugs concurrently in both the pre- and post-lock-in groups. However, a 2.5-fold decrease in the number of MLIP beneficiaries with overlapping drug claims occurred post-lock-in compared to

[10] Johns Hopkins Bloomberg School of Public Health. News Release, Many Patients Receive Prescription Opioids During Medication-Assisted Treatment for Opioid Addiction; 2017 Feb 23 [cited 2017 Dec 18]. Available from: https://www.jhsph.edu/news/news-releases/2017/many-patients-receive-prescription-opioids-during-medication-assisted-treatment-for-opioid-addiction.html.

pre-lock-in. This may be correlated to better management of the opioid addiction treatment of these lock-in beneficiaries.

Myers and Stauffer conducted additional analyses of targeted drug usage of beneficiaries who continued to obtain targeted drugs after lock-in. ***Table I*** depicts usage of opiates compared to usage of benzodiazepines and certain anxiolytics pre- and post-lock-in. While the total number of claims declined, the percentage of use of each category of drug remained the same.

**Table I: Targeted Drug Usage by Type Pre- and Post-Lock-In for Beneficiaries**

| Drug Type | Six Months Pre-Lock-In (Sep 16 - Feb 17) | | Six Months Post-Lock-In (Mar 17 - Aug 17) | |
|---|---|---|---|---|
| | Claim Count | Percentage | Claim Count | Percentage |
| Opiates | 8,457 | 89% | 5,250 | 88% |
| Benzodiazepines and certain anxiolytics | 1,053 | 11% | 690 | 12% |
| Total Number of Pharmacy Claims | 9,510 | | 5,940 | |

After reviewing opioid dependence treatment drug usage, Myers and Stauffer analyzed the pharmacy claims data for the remaining targeted drugs for the study population. ***Figure 1*** illustrates the targeted drug usage (with the exception of opioid dependence treatment drugs) of beneficiaries who continued to obtain targeted drugs post-lock-in. Analysis concluded that the most significant reduction in targeted drug usage occurred in this group. Evaluation identified an 18 percent reduction in the number of beneficiaries taking these drugs after lock-in. In addition, there was a 46 percent reduction in targeted drug pharmacy prescription count, a 69 percent reduction in the number of prescribers and a 59 percent reduction in the number of pharmacies used.

**Figure 1: Targeted Drug Usage Six Months Pre- and Post-Lock-In**

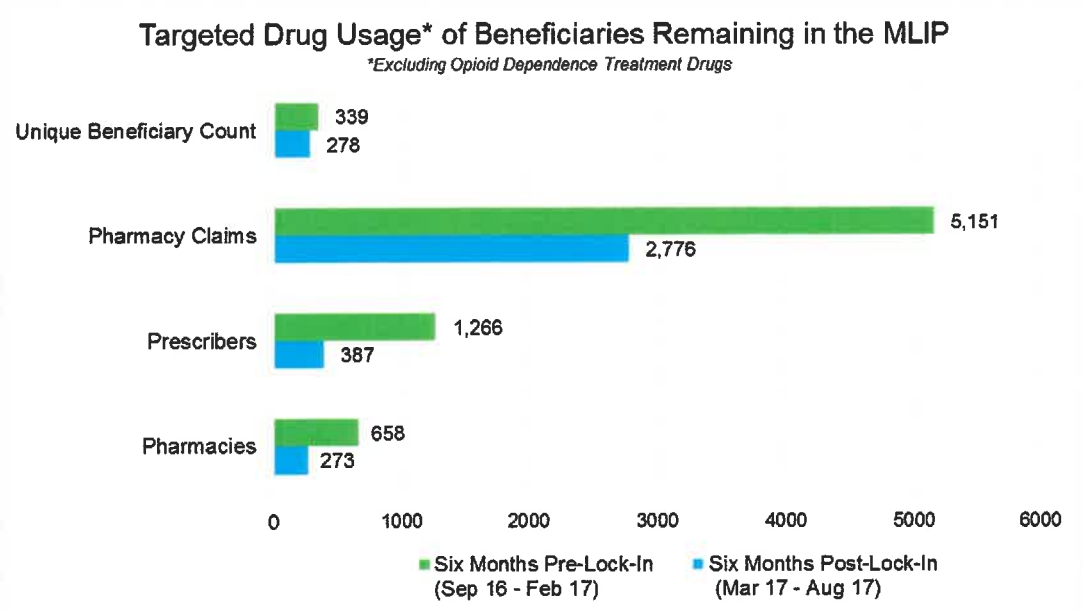


***Table J*** depicts the savings and average changes for this group. In comparing usage for these beneficiaries, an overall targeted drug savings of $92,407.62 was observed during the six month period after lock-in. The average number of claims, prescribers and pharmacies per beneficiary decreased as well. In addition, the average cost per beneficiary decreased by $140.10.

**Table J: Comparison of Targeted Drug Usage Six Months Pre- and Post-Lock-In**

| Key Outcomes | Six Months Pre-Lock-In (Sep 16 - Feb 17) | Six Months Post-Lock-In (Mar 17 - Aug 17) | Difference |
|---|---|---|---|
| Unique Beneficiary Count | 339 | 278 | (61) |
| Total Pharmacy Spend | $ 297,099.48 | $ 204,691.86 | $ (92,407.62) |
| Average Number of Pharmacy Claims per Beneficiary | 15.19 | 9.99 | (5.20) |
| Average Number of Prescribers per Beneficiary | 3.73 | 1.39 | (2.34) |
| Average Number of Pharmacies per Beneficiary | 1.94 | 0.98 | (0.96) |
| **Average Cost per Beneficiary** | **$ 876.40** | **$ 736.30** | **$ (140.10)** |

*Excluding opioid dependence treatment drugs

## Analysis of Targeted Drug Usage of Beneficiaries Outside and Inside the MLIP

Myers and Stauffer conducted additional analyses of targeted drug usage for beneficiaries outside of the MLIP compared to those inside the MLIP. Beneficiaries with at least one targeted drug dispensed between March 1, 2017 and August 31, 2017 were included in the analysis. ***Table K*** exhibits the result of this analysis, which indicated that there was a higher average number of pharmacy claims, prescribers and pharmacies per beneficiary inside the MLIP compared to those beneficiaries outside the MLIP. This illustrates that beneficiaries with the most targeted drug usage are being captured inside the MLIP.

**Table K: Targeted Drug Usage of Beneficiaries Inside and Outside the MLIP**

| Key Outcomes | Beneficiary Group Outside of MLIP | Beneficiary Group in MLIP | Difference |
|---|---|---|---|
| Average Number of Pharmacy Claims per Beneficiary | 3.88 | 12.03 | 8.15 |
| Average Number of Prescribers per Beneficiary | 0.13 | 0.89 | 0.76 |
| Average Number of Pharmacies per Beneficiary | 0.02 | 0.63 | 0.61 |
| Average Cost per Pharmacy Claim | $ 56.74 | $ 118.94 | $ 62.20 |
| **Average Cost per Beneficiary** | **$ 220.19** | **$ 1,431.34** | **$ 1,211.15** |

Further comparison was conducted for the same beneficiaries by differentiating between those beneficiaries taking opioid dependence treatment drugs versus beneficiaries who took all other targeted drugs. Analysis determined that only four percent of the beneficiaries outside of the MLIP were taking opioid dependence treatment drugs during the time period reviewed. Again, most beneficiaries taking opioid dependence treatment drugs are being captured by the MLIP criteria. ***Table L*** exhibits the key outcomes by drug type for beneficiaries outside and inside the MLIP.

It is important to note that for beneficiaries taking opioid dependence treatment drugs, the average cost per beneficiary is only 15 percent higher for those inside the MLIP. For all other targeted drugs, the average cost per beneficiary was 82 percent higher for those inside the MLIP.

The average cost per beneficiary showed less of a difference for opioid dependence treatment drugs between the outside and inside MLIP groups due to opioid dependence treatment drugs being more costly.

**Table L: Targeted Drug Usage Inside and Outside the MLIP by Beneficiary Group**

| Opioid Dependence Treatment Drug Users - Key Outcomes | Beneficiary Group Outside of MLIP | Beneficiary Group in MLIP |
|---|---|---|
| Average Number of Pharmacy Claims per Beneficiary | 6.08 | 13.12 |
| Average Number of Claims per Prescriber | 76.34 | 41.33 |
| Average Number of Prescribers per Beneficiary | 0.08 | 0.32 |
| Average Number of Pharmacies per Beneficiary | 0.22 | 0.67 |
| Average Cost per Claim | $ 269.75 | $ 147.53 |
| **Average Cost per Beneficiary** | **$ 1,639.47** | **$ 1,935.56** |
| **All Other Targeted Drug Users - Key Outcomes** | **Beneficiary Group Outside of MLIP** | **Beneficiary Group in MLIP** |
| Average Number of Pharmacy Claims per Beneficiary | 3.73 | 9.47 |
| Average Number of Prescribers per Beneficiary | 0.14 | 1.20 |
| Average Number of Pharmacies per Beneficiary | 0.02 | 0.77 |
| Average Cost per Pharmacy Claim | $ 41.19 | $ 91.87 |
| **Average Cost per Beneficiary** | **$ 153.55** | **$ 869.60** |

## Targeted Lock-In Beneficiary Analysis

In an effort to provide an additional assessment of the effectiveness of the NC MLIP, Myers and Stauffer identified a random sample of 40 beneficiaries who were locked into the NC MLIP effective March 2017. Pharmacy claims for targeted drugs filled during the six month period pre-lock-in were compared to targeted drug claims filled during the first six months post-lock-in.

***Table M*** lists the details of the comparison. Of the 40 beneficiaries reviewed, nine did not receive any prescriptions for targeted drugs post-lock-in. Seven of these beneficiaries received prescriptions for non-targeted drugs post-lock-in. The remaining two beneficiaries had no pharmacy, professional or institutional claims post-lock-in. None of these beneficiaries had a date of death on file at the time of the review. NCTracks showed one of these beneficiaries with current Medicaid eligibility; however, the other beneficiary's eligibility ended effective December 31, 2016. Five of these beneficiaries had opioid dependence treatment drugs pre-lock-in.

Of the remaining 31 beneficiaries, 68 percent obtained less prescriptions for targeted drugs, 71 percent received targeted drugs from less prescribers, and 74 percent used less pharmacies post-lock-in. Due to the decrease in numbers of claims paid post-lock-in compared to pre-lock-in, the approximate cost savings was $12,475 for all 40 beneficiaries. Review of pharmacy claims also identified that 55 percent of all 40 targeted beneficiaries received at least one prescription for an opioid dependence treatment drug.

## Table M: Targeted Drug Pharmacy Claims Analysis

| Beneficiary | No Claims After Lock-In | Difference (Pre-Lock-In vs. Post-Lock-In) | | | | Opioid Dependence Medication Claims |
|---|---|---|---|---|---|---|
| | | Claim Count | Prescribers | Pharmacies | Total Pharmacy Reimbursed Amount | |
| Beneficiary 1 | X | | | | $ (583.75) | X |
| Beneficiary 2 | X | | | | $ (148.94) | |
| Beneficiary 3 | | -1 | -2 | -2 | $ 72.71 | |
| Beneficiary 4 | X | | | | $ (1,668.33) | X |
| Beneficiary 5 | | 6 | 0 | -2 | $ 720.76 | X |
| Beneficiary 6 | | 2 | -3 | -3 | $ (113.92) | X |
| Beneficiary 7 | | -14 | -9 | -5 | $ (153.36) | |
| Beneficiary 8 | | -2 | 0 | -1 | $ 621.44 | X |
| Beneficiary 9 | X | | | | $ (492.42) | |
| Beneficiary 10 | | -14 | -5 | -2 | $ (129.22) | |
| Beneficiary 11 | | -16 | 1 | -1 | $ 46.23 | X |
| Beneficiary 12 | | -5 | -8 | -1 | $ 1,041.88 | X |
| Beneficiary 13 | | -8 | -5 | -2 | $ 13.21 | |
| Beneficiary 14 | | -3 | -1 | -1 | $ 423.88 | X |
| Beneficiary 15 | | -4 | -1 | 0 | $ 27.72 | |
| Beneficiary 16 | | -3 | -3 | 0 | $ (17.48) | |
| Beneficiary 17 | | -11 | 0 | -1 | $ (534.30) | X |
| Beneficiary 18 | | 1 | -1 | -3 | $ (83.13) | X |
| Beneficiary 19 | | 0 | 0 | 0 | $ (15.07) | X |
| Beneficiary 20 | | -3 | -4 | -3 | $ (760.80) | |
| Beneficiary 21 | X | | | | $ (1,221.41) | X |
| Beneficiary 22 | X | | | | $ (993.16) | X |
| Beneficiary 23 | | 3 | -1 | -1 | $ 4.26 | X |
| Beneficiary 24 | X | | | | $ (2,166.20) | |
| Beneficiary 25 | | -17 | 0 | -3 | $ (2,272.74) | X |
| Beneficiary 26 | X | | | | $ (1,259.91) | X |
| Beneficiary 27 | | 3 | -2 | 0 | $ 779.59 | X |
| Beneficiary 28 | | -13 | -8 | -3 | $ (222.97) | |
| Beneficiary 29 | | 8 | 0 | 0 | $ 461.93 | X |
| Beneficiary 30 | | -16 | -4 | -2 | $ (1,799.53) | X |
| Beneficiary 31 | | -3 | -2 | 0 | $ (1,439.75) | |
| Beneficiary 32 | | -12 | -4 | -2 | $ (634.52) | |
| Beneficiary 33 | | -6 | -5 | -3 | $ (71.40) | |
| Beneficiary 34 | | -6 | -7 | -1 | $ 136.61 | |
| Beneficiary 35 | | -7 | -6 | -1 | $ (68.32) | |
| Beneficiary 36 | | 6 | 3 | -1 | $ 78.98 | |
| Beneficiary 37 | | 0 | -2 | 0 | $ 65.84 | X |
| Beneficiary 38 | | 0 | -1 | 0 | $ 1,074.85 | X |
| Beneficiary 39 | | -13 | 0 | -1 | $ (1,030.14) | X |
| Beneficiary 40 | X | | | | $ (164.48) | |
| **Total** | | **-308** | **-107** | **-62** | **$ (12,475.36)** | **22** |

Overall, review identified a reduction in targeted drug use, a reduction in the number of unique prescribers and pharmacies, and reimbursement savings to the Medicaid program. The targeted review, however, identified a potential opportunity for program improvement in the pre-lock-in review of beneficiaries receiving opioid dependence treatment drugs. In situations where beneficiaries are stable in opioid dependence treatment, as illustrated by the absence of non-buprenorphine targeted drugs and utilization of one pharmacy and prescriber, overutilization of Medicaid benefits is unlikely at the time of the review. Using the same criteria for well-managed beneficiaries on opioid dependent treatment drugs may cause lock-in of beneficiaries with clear overutilization to be delayed or not occur.

Lastly, the targeted review allowed for the exploration of potential reasons for beneficiaries ceasing to obtain targeted drug prescriptions post-lock-in. Most of these beneficiaries continued to utilize the Medicaid system as identified by professional and institutional claims. The concern is that these beneficiaries may be paying cash for targeted drugs or obtaining illicit drugs while continuing to utilize the Medicaid system. In addition, impact on overutilization of all Medicaid services, not just prescription utilization, may continue to occur.

## Beneficiary Lock-In Composition Analysis

Due to the identification of a large number of lock-in beneficiaries with opioid dependence treatment drug claims, Myers and Stauffer compared the composition of targeted drug claims of beneficiaries locked in effective March 2017 and August 2017. Claims were reviewed for the three month period pre-lock-in effective date and the three month period post-lock-in.

***Figure 2*** depicts the total targeted drug pharmacy claims pre- and post-lock-in for beneficiaries locked in either March 2017 or August 2017. Beneficiaries locked in March 2017 had more pharmacy claims pre-lock-in than the August 2017 lock-in group. Both groups also experienced a reduction in total prescription count post-lock-in. This indicates that those beneficiaries who would benefit most are being prioritized and locked into the program.

**Figure 2: Targeted Drug Prescription Claim Count Pre- and Post-Lock**

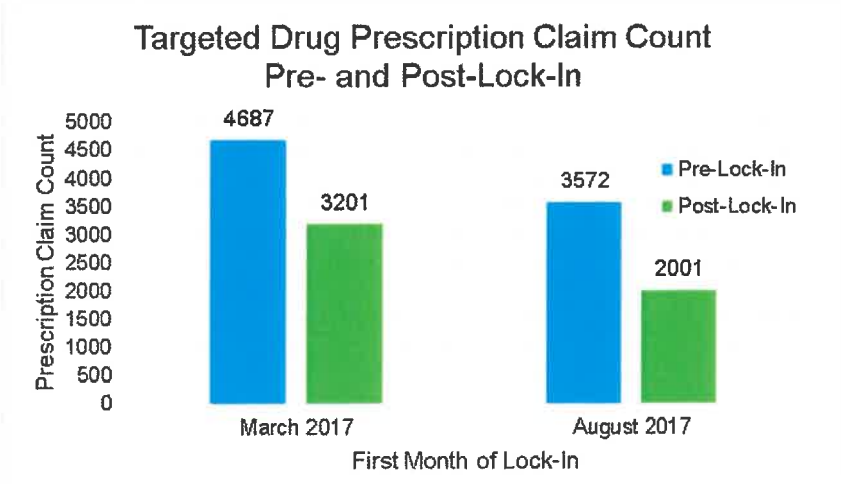


***Figure 3*** depicts the percentage of locked in beneficiaries with opioid dependence treatment drug claims pre- and post-lock-in. Less of the lock-in beneficiaries in the August 2017 cohort had a history of opioid dependence treatment compared to the March 2017 cohort. Several factors may contribute to this difference. First, criteria for lock-in prioritize beneficiaries who fill more prescriptions for smaller quantities of medication, which is common for beneficiaries undergoing opioid dependence treatment. Second, criteria prioritize drug claims with higher costs and opioid dependence drugs have higher costs per unit than most of the targeted drugs in the MLIP. The utilization of these two criteria led to more beneficiaries with opioid dependence treatment drugs locked in at the onset of the program capacity increase in March 2017. Therefore, upon implementation of the new program criteria, beneficiaries with a history of opioid dependence were locked in earlier in the program.

Post-lock-in, both groups experienced an increase in the percentage of beneficiaries with opioid dependence treatment claims. This appeared to be due to beneficiaries receiving opioid dependence treatment drugs being less likely to discontinue targeted drug usage compared to beneficiaries not receiving opioid dependence treatment. Therefore, beneficiaries receiving opioid dependence treatment drugs represented a higher proportion in the post-lock-in period.

**Figure 3: Percentage of Beneficiaries with Opioid Dependence Treatment Drug Claims During the Three Month Period Pre- and Post-Lock-In**

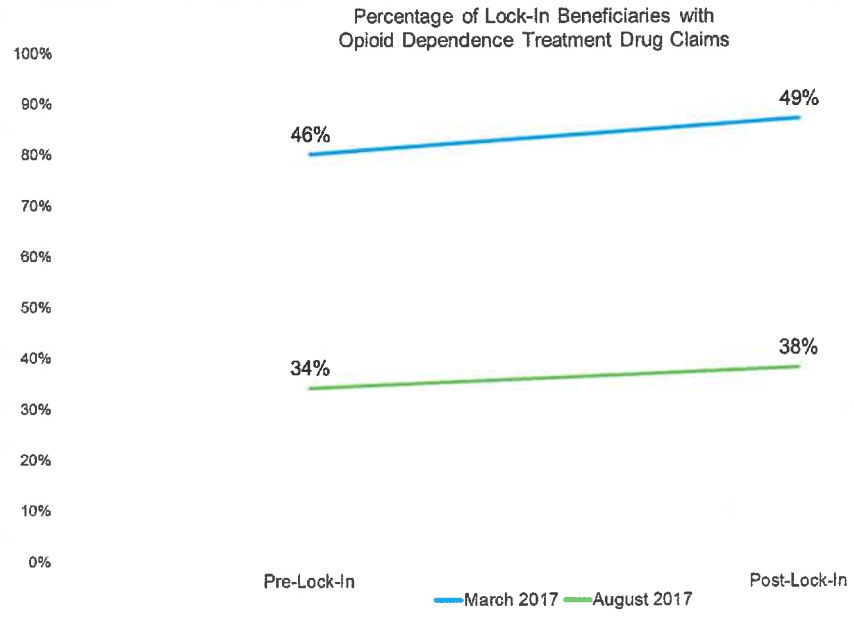


***Figure 4*** depicts the number of lock-in beneficiaries in the March 2017 and August 2017 cohorts who had no pharmacy claims for targeted drugs after their lock-in effective date. A higher number of August 2017 lock-in beneficiaries ceased receiving targeted drugs post lock-in compared to the March 2017 cohort. This could be due to a lower number of beneficiaries receiving opioid dependence treatment drugs upon enrollment in the August 2017 cohort and the increased likelihood that beneficiaries taking other targeted drugs (opiates and anxiolytics) are more like to cease targeted drug activity after enrollment. Future review of eligibility, pharmacy claims in the PDMP system, impact of prior authorization requirement for opioids exceeding 120 morphine milligram equivalents, as well as professional and institutional claims may further explain this change.

**Figure 4: Beneficiaries with No Targeted Drug Pharmacy Claims after Lock-In**

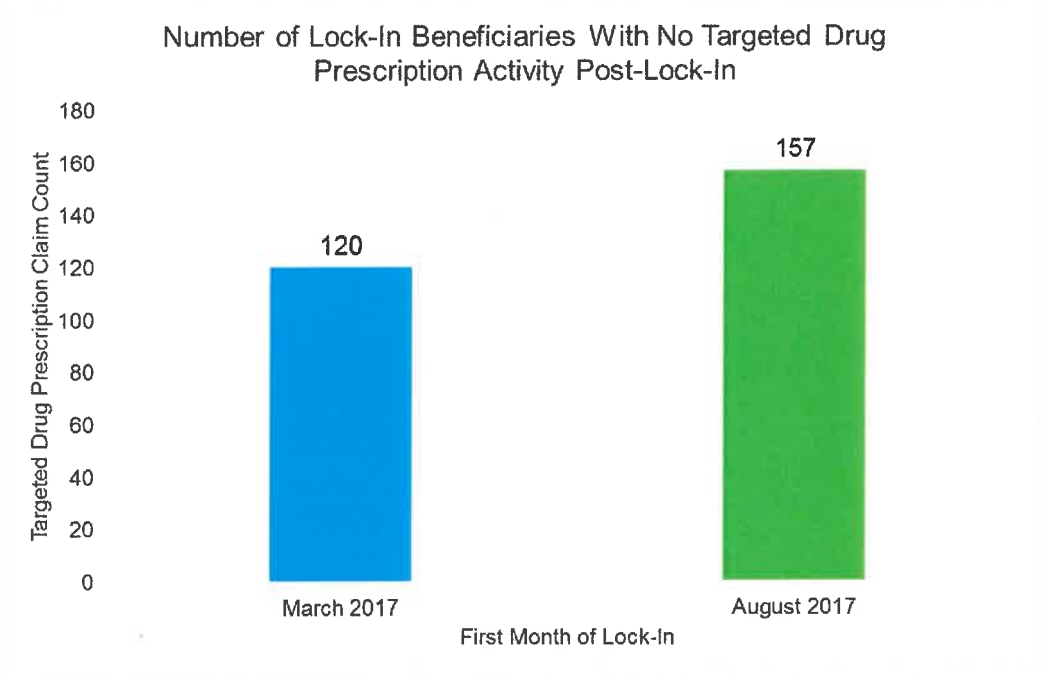
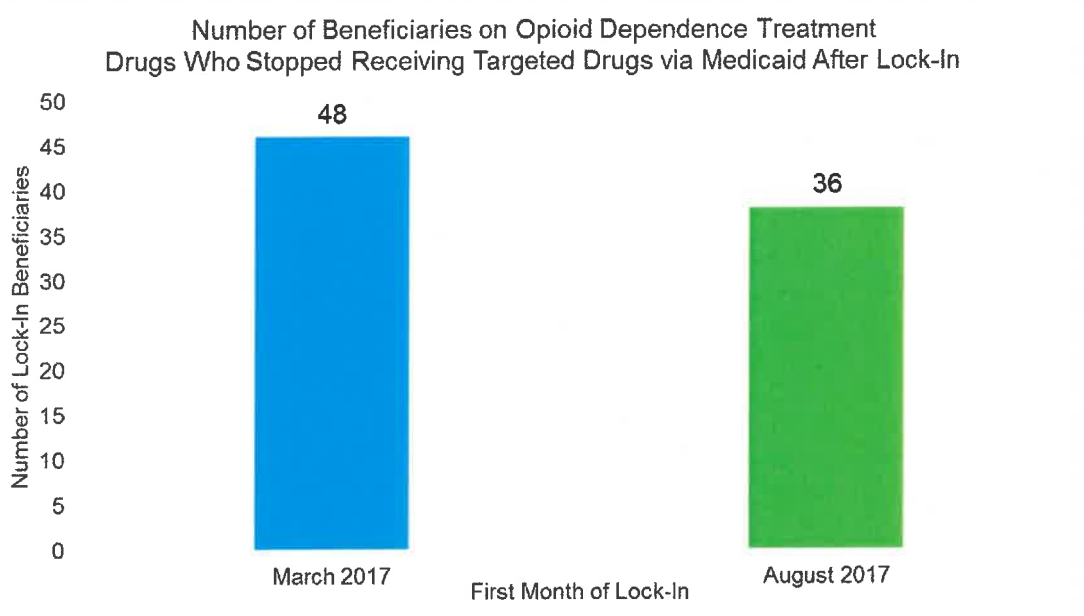


***Figure 5*** depicts the number of beneficiaries in the Ceased Targeted Drug Activity groups in the March 2017 and August 2017 lock-in cohorts that had a history of opioid dependence treatment drug claims pre-lock-in. Additional investigation identified that fewer of the August 2017 lock-in beneficiaries with a history of opioid dependence drug treatment stopped receiving targeted drugs via Medicaid after lock-in compared to the March 2017 group. Of the August 2017 Ceased Targeted Drug Activity group, only 24 percent had prior opioid treatment dependence drug claims. From the March 2017 Ceased Targeted Drug Activity group, 38 percent had prior opioid treatment dependence drug claims. This variance may indicate that more lock-in beneficiaries are being maintained and more appropriately managed for opioid treatment dependence due to their inclusion in MLIP.

**Figure 5: Beneficiaries on Opioid Dependence Treatment Drugs with No Targeted Drug Pharmacy Claims after Lock-In**




## Coordination with NC Care Management Program(s)

As part of this evaluation, we considered the interaction and potential collaboration with the NC care management programs, specifically the subprograms related to case management. Two programs (Care Coordination for Children or CC4C and Local Education Agencies) involve services to children which are already excluded from the NC MLIP. Two remaining programs, HIV Case Management and Case Management Services for Adults and Children At-Risk of Abuse, Neglect, or Exploitation, may include Medicaid beneficiaries who could potentially be identified and placed in the MLIP if they were not otherwise excluded.

We identified, via program documentation and interviews with DMA and CSRA staff, that participation or inclusion in the care management programs has no current relationship or coordination established with the NC MLIP. Care management records are maintained in a separate data system.

While not specifically identified to represent a vulnerability in the process, communication between the two programs could add value to each. It would likely be helpful for the case management program to be aware of any beneficiaries identified as meeting the MLIP criteria so that they could adjust their case management approach accordingly, to monitor and potentially address drug-seeking or MLIP-circumvention behaviors. It also would be potentially valuable for the MLIP to be aware of members identified as meeting MLIP criteria who are part of the case management program to enhance their coordination experience, optimally resulting in a more well-coordinated care response.

## Case Head/Household: Analysis of Targeted Drug Usage

Myers and Stauffer reviewed targeted drug pharmacy claims for NC Medicaid beneficiaries that potentially reside in the same household as locked in beneficiaries identified via the NCTracks system as case heads. NC Medicaid beneficiaries (potential household members) were linked to case heads, or head of household, who also had Medicaid eligibility and were MLIP beneficiaries. Review of pharmacy claims identified that after lock-in of the case head between March 2017 and August 2017, 14 potential household members experienced an increase in the number of targeted drug pharmacy claims. The previous lock-in period, October 2015 through February 2017, was also reviewed and 18 additional household members were identified with similar increases in targeted drugs when their household members were MLIP participants. Five potential household members from both lock-in time frames had no targeted pharmacy claims during prior to their case head lock-in, but received targeted drugs after case head lock-in.

An individual analysis of several potential household members with the highest increase revealed that these household members were also locked-in shortly after demonstrating increases in targeted drug prescription counts. Obtaining targeted drugs through household members on Medicaid is a potential program vulnerability. While increases in targeted drug activity were identified, further investigation of these household members may be warranted on a case-by-case basis to mitigate potential program vulnerabilities.

## Analysis of Emergency Fills

The NC MLIP allows for one four-day emergency supply of a prescription during each year of the two year lock-in period. Outpatient pharmacy claims provided as emergency fills were evaluated and identified by utilizing a level of service code of "3" in addition to one of four claim edits as provided by the Division. Because a level of service code of "3" is not unique to emergency fills for the lock-in program, and can be utilized for other emergency overrides such as for prior authorization, manual review and research was required for identified claims. Until a unique identifier is provided for emergency fills for lock-in claims, emergency fills cannot be easily identified or assessed programmatically. Five beneficiaries with claims containing a level of service code of "3" and one of the four provided claim edits were identified, researched and reviewed with DMA. Manual review of the five beneficiaries identified no cases with more than one emergency fill per lock-in year.

# *Evaluation for Evidence of Fraud or Abuse*

Identification of potential fraud, waste or abuse of the program is one of the most complex areas of evaluation which also carries the most serious potential consequences. Myers and Stauffer has carefully evaluated patterns of behavior to identify whether any evidence was identified of potential fraud or abuse within the MLIP and did not identify indications that fraud or abuse exist within the MLIP.

While no evidence of potential fraud, waste or abuse of the program by prescribers was identified in earlier analyses, further research of Top 25 prescribers by targeted drug prescription count for the Top 600 beneficiaries locked into the MLIP was completed. The Top 25 prescribers were identified by reviewing pharmacy claims for the six (6) month period post-lock-in. Of these 25 prescribers, 14 prescribers reported one of their areas of practice related to addiction medicine to the NC Medical Board.[11] This was expected as the Top 25 drugs included seven opioid dependence treatment drugs. Identification of addiction treatment providers may reflect that the correct beneficiaries are being identified for lock-in and receiving the appropriate type of care.

Additional research identified seven of these Top 25 prescribers had consent orders issued by the NC Medical Board, five of which were related to controlled substances. While identifying such information does not directly identify fraud, waste or abuse, such investigations may identify potential candidates for further examination using additional resources available through state and local agencies. Further evaluation of these seven prescribers by DMA would likely be beneficial and may result in referral to the NC program integrity unit for further work-up.

[11] North Carolina Medical Board License Search. https://wwwapps.ncmedboard.org/Clients/NCBOM/Public/LicenseeInformationSearch.aspx. Accessed December 20, 2017.