

**Department of State
Division of Publications**

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For Department of State Use Only

Sequence Number: 10-84-13
Rule ID(s): 5587
File Date: 10/3/13
Effective Date: 1/1/14

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

Agency/Board/Commission:	Tennessee Department of Finance and Administration
Division:	Bureau of TennCare
Contact Person:	George Woods
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Revision Type (check all that apply):

☒ Amendments
☐ New
☐ Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	Chapter Title
1200-13-14	TennCare Standard
Rule Number	Rule Title
1200-13-14-.01	Definitions
1200-13-14-.13	Members Abuse and Overutilization of the TennCare Program

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

The Table of Contents of Rule Chapter 1200-13-14 TennCare Standard is amended by deleting the Title of Rule Number 1200-13-14-.13 Members Abuse and Overutilization of the TennCare Program from the Table of Contents in its entirety and replacing the Rule Title in the Table of Contents as follows:

1200-13-14-.13 Member Abuse or Overutilization of the TennCare Pharmacy Program.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-109 and 71-5-146.

Rule 1200-13-14-.01 Definitions is amended by deleting Paragraph (71) Lock-In Provider and replacing it with amended Paragraph (71) Lock-In Provider as follows:

(71) Lock-In Provider. A provider, pharmacy or physician, chosen by an enrollee on pharmacy lock-in status to whom the enrollee is assigned by TennCare for the purpose of receiving covered pharmacy services.

Rule 1200-13-14-.01 Definitions is amended by deleting Paragraph (72) Lock-In Status and replacing it with amended Paragraph (72) Lock-In Status as follows:

(72) Lock-In Status. The restriction of an enrollee to a specified physician, or to a specified pharmacy provider at a specified single location.

Rule 1200-13-14-.01 Definitions is amended by deleting the word "provide" from current Paragraph (97) PBM (Pharmacy Benefits Manager) and replacing it with the word "administer" so that as amended Paragraph (97) PBM (Pharmacy Benefits Manager) reads as follows:

(97) PBM (Pharmacy Benefits Manager) shall mean an organization approved by the Tennessee Department of Finance and Administration to administer pharmacy benefits to enrollees to the extent such services are covered by the TennCare Program. A PBM may have a signed TennCare Contractor Risk Agreement with the State, or may be a subcontractor to an MCO.

Rule 1200-13-14-.01 Definitions is amended by inserting alphabetically the following new Paragraphs and numbering all definitions appropriately:

- () Controlled Substance. A drug, substance, or immediate precursor identified by the U.S. Department of Justice, Drug Enforcement Administration or by the Tennessee Drug Control Act as having the potential for abuse and the likelihood of physical or psychological dependence if used incorrectly.
- () Prescriber. An individual authorized by law to prescribe drugs.
- () Targeted Pharmacy. A pharmacy meeting one of the following criteria:
 - (a) It is located outside the State of Tennessee.
 - (b) It has had previous controlled substance violations with the Tennessee State Board of Pharmacy.
 - (c) It appears to be an outlier to the norm in its dispensing of controlled substances.
 - (d) It has filled controlled substance prescriptions that are covered by TennCare for members locked in to a different pharmacy after being notified that the member was locked in to a different pharmacy.
- () Targeted Prescriber. A prescriber with prescribing authority who is ranked as a top prescriber of controlled substances based on multiple factors which may include but are not limited to any of the following:
 - (a) The percentage of controlled substances prescribed.
 - (b) The percentage of Schedule II controlled substances prescribed.
 - (c) The percentage of Schedule III controlled substances prescribed.

- (d) The percentage of short acting single ingredient opiates prescribed.
- (e) The percentage of short acting combination product opiates prescribed.
- (f) The percentage of long acting opiates prescribed.
- (g) The average morphine equivalents per day prescribed.
- (h) The percentage of rejected claims of controlled substances.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-109 and 71-5-146.

Rule 1200-13-14-.13 "Members Abuse and Overutilization of the TennCare Program" is deleted in its entirety and replaced with the following:

1200-13-14-.13 Member Abuse or Overutilization of the TennCare Pharmacy Program.

- (1) The Bureau is authorized to implement and maintain a pharmacy lock-in program designed to address member abuse or overutilization. Activities which may indicate abuse or overutilization justifying placement on lock-in or prior approval status include but are not limited to the following:
 - (a) Forging or altering a prescription for drugs.
 - (b) Selling TennCare paid prescription drugs.
 - (c) Failing to control pharmacy overutilization activity while on lock-in status.
 - (d) Visiting multiple prescribers or pharmacies to obtain controlled substances.
 - (e) Trading, swapping or selling a TennCare card.
 - (f) Failing to promptly report the loss or theft of a TennCare card.
 - (g) Forging or altering a TennCare card.
 - (h) Knowingly providing false, incomplete, inaccurate or erroneous information to provider(s) in order to receive covered services for which the member is eligible.
 - (i) Permitting the use of a TennCare card by anyone other than the member to whom the card is assigned in order to receive or attempt to receive services.
- (2) The TennCare pharmacy lock-in program shall be administered by the Bureau. Monitoring of enrollee activities listed in Paragraph (1) shall be conducted by the Bureau, the MCCs, including the PBM, and the TennCare Office of Inspector General (OIG). When an enrollee has been identified as having participated in any abuse or overutilization activities, including but not limited to the activities listed in Paragraph (1), the enrollee's name shall be referred to the Bureau as appropriate or potentially appropriate for the lock-in program as follows:
 - (a) Appropriate for the lock-in program:
 - 1. Any enrollee who has been identified by the OIG as having been convicted of TennCare fraud or a drug-related offense.
 - 2. Any enrollee who has used buprenorphine/naloxone (Suboxone®) or buprenorphine (Subutex®) for office based opioid addiction treatment within the previous six (6) months.
 - (b) Potentially appropriate for the lock-in program:
 - 1. Any enrollee who has been arrested for TennCare fraud.

2. Any enrollee who has been arrested for a drug-related offense.
3. Any enrollee who has obtained multiple controlled substance prescriptions over a 90-day period that meet one of the following conditions:
 - (i) The prescriptions were filled at three (3) or more pharmacies and written by three (3) or more prescribers.
 - (ii) The prescriptions were filled at one (1) or more targeted pharmacies and written by two (2) or more prescribers.
 - (iii) The prescriptions were filled at two (2) or more targeted pharmacies and written by one (1) or more prescribers.
 - (iv) The prescriptions were filled at one (1) or more targeted pharmacies and written by one (1) or more targeted prescribers.
 - (v) The prescriptions were filled at two (2) or more pharmacies and written during three (3) or more emergency room visits.
- (3) Pharmacy lock-in procedures shall include:
 - (a) A determination to place an enrollee who has been referred as appropriate or potentially appropriate for the lock-in program on lock-in status shall be made by the TennCare Pharmacy Director or designee after the enrollee's relevant pharmacy claims data has been reviewed by clinical staff.
 - (b) Any enrollee determined to be appropriate for the lock-in program shall be notified by the Bureau or the MCC prior to the imposition of lock-in status. The notice shall include a brief explanation of the lock-in program, the reason for the determination to place the enrollee on lock-in status, the date the lock-in will become effective, and the information necessary for the enrollee to appeal the decision of the Bureau, pursuant to Rule 1200-13-13-.11.
 - (c) If an enrollee fails to appeal placement in the lock-in program or an appeal is not resolved in his favor, the enrollee will be provided TennCare pharmacy services only at the lock-in provider to which the enrollee is assigned.
- (4) Lock-in provider selection. A pharmacy will qualify for and may be selected by the enrollee as a lock-in provider only if it meets all the following criteria:
 - (a) It is enrolled in the TennCare Pharmacy Network;
 - (b) It is within the State of Tennessee;
 - (c) It is a full-service pharmacy that carries all medications normally carried by pharmacies;
 - (d) It is not a mail order or specialty pharmacy;
 - (e) It is not a targeted pharmacy;
 - (f) It is a single pharmacy location at a specific address. A chain pharmacy may be selected but only the specific named location may be used, not multiple locations or outlets of the chain; and
 - (g) It is in proximity to the enrollee's residence, which must be the current address on file with the Bureau.
- (5) After twelve (12) months a member may request a change of lock-in provider once each year. Additional changes are limited to the following reasons:
 - (a) The member has moved and his new address is at least fifteen (15) miles from the lock-in pharmacy and he has updated his address with the Bureau.

- (b) The member's lock-in pharmacy has permanently closed.
 - (c) The member's lock-in pharmacy has voluntarily dismissed the enrollee from its practice and has notified the Bureau and the PBM.
 - (d) The Bureau may, at its sole discretion, determine that there is a compelling need to change the member's lock-in pharmacy.
- (6) Review of lock-in status. The Bureau or the MCC shall periodically review the claims information of members on lock-in status to determine the need for continued lock-in or escalation to prior approval status.
- (a) Lock-in status will be discontinued if the Bureau determines that a member has met all of the following criteria for at least six (6) consecutive months:
 - 1. Has not paid cash for any controlled substance prescriptions covered by TennCare.
 - 2. Has not received any narcotic medications while on buprenorphine or buprenorphine/naloxone for addiction.
 - 3. Has received TennCare reimbursed controlled substance prescriptions from only one (1) provider.
 - 4. Has received TennCare reimbursed prescriptions from only one (1) pharmacy.
 - (b) If a member is removed from lock-in status, the Bureau or the MCC will monitor the member for changes in utilization patterns and return him to lock-in status if appropriate.
- (7) Prior approval status.
- (a) A member against whom criminal process alleging TennCare fraud has been issued or who has been convicted of TennCare fraud shall automatically be placed on prior approval status.
 - (b) Lock-in status shall be escalated to prior approval status if a member on lock-in status meets three (3) of the following criteria over a 90 day period:
 - 1. Has paid cash for three (3) or more controlled substance prescriptions covered by TennCare.
 - 2. Has filled prescriptions for controlled substances at two (2) or more pharmacies.
 - 3. Has received controlled substance prescriptions from two (2) or more prescribers.
 - 4. Has received a narcotic prescription while receiving buprenorphine or buprenorphine/naloxone for addiction.
 - (c) A member who has been treated in a hospital emergency department for an overdose of a controlled substance (as identified in the most recently available TennCare data) or an illicit substance identified by toxicology shall automatically be placed on prior approval status.
- (8) Emergency pharmacy services may be obtained with a TennCare or MCC override of a member's lock-in status. The PBM has clinical staff available at all times to respond to emergency situations. The PBM must verify that a genuine emergency exists, such as documented proof from the lock-in pharmacy that it is temporarily out of stock of a needed medication. A lock-in override will not be provided simply because a pharmacy is closed for the day unless a true medical emergency exists.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-109 and 71-5-146.

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Department of Finance and Administration (board/commission/ other authority) on 08/27/2013 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 06/11/13

Rulemaking Hearing(s) Conducted on: (add more dates). 08/08/13

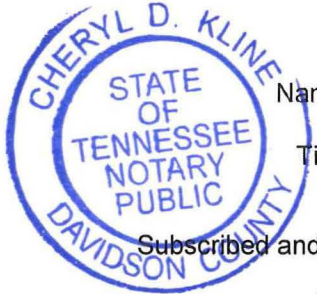
Date: 8/27/2013

Signature: D. J. Gordon

Name of Officer: Darin J. Gordon

Director, Bureau of TennCare

Title of Officer: Tennessee Department of Finance and Administration



Subscribed and sworn to before me on: 8/27/13

Notary Public Signature: Cheryl D Kline

AUG 28 2016

My commission expires on: _____

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

RE Cooper Jr

Robert E. Cooper, Jr.
Attorney General and Reporter

10-1-13

Date

Department of State Use Only

Filed with the Department of State on: 10/3/13

Effective on: 1/1/14

Tre Hargett
Secretary of State

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Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

There were no public comments on these rules.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

The rules are not anticipated to have an effect on small businesses.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

The rules are not anticipated to have an impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The rules are being updated to meet the requirements of the pharmacy lock-in program.

- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

The rules are lawfully adopted by the Bureau of TennCare in accordance with §§ 4-5-202, 71-5-105, 71-5-109 and 71-5-146.

- (C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

The persons, organizations, corporations or governmental entities most directly affected by these Rules are the TennCare enrollees, providers, and the Bureau of TennCare, Tennessee Department of Finance and Administration.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

The Rules were approved by the Tennessee Attorney General. No additional opinion was given or requested.

- (E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

The promulgation of these rules is not anticipated to have an effect on state and local government revenues and expenditures.

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Donna Tidwell
Deputy General Counsel

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Donna Tidwell
Deputy General Counsel

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

310 Great Circle Road
Nashville, TN 37243
(615) 507-6852
donna.tidwell@tn.gov

(I) Any additional information relevant to the rule proposed for continuation that the committee requests.

GW10113220

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Revision Type (check all that apply):☒ Amendments☐ New☐ Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only ONE Rule Number/Rule Title per row)

Chapter Number	Chapter Title
1200-13-14	TennCare Standard
Rule Number	Rule Title
1200-13-14-.01	Definitions
1200-13-14-.13	Members Abuse and Overutilization of the TennCare Program

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

The Table of Contents of Rule Chapter 1200-13-14 TennCare Standard is amended by deleting the Title of Rule Number 1200-13-14-.13 Members Abuse and Overutilization of the TennCare Program from the Table of Contents in its entirety and replacing the Rule Title in the Table of Contents as follows:

1200-13-14-.13 Member Abuse or and Overutilization of the TennCare Pharmacy Program.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-109 and 71-5-146.

Rule 1200-13-14-.01 Definitions is amended by deleting Paragraph (71) Lock-In Provider and replacing it with amended Paragraph (71) Lock-In Provider as follows:

(71) Lock-In Provider. A provider, pharmacy or physician, chosen by an enrollee on pharmacy lock-in status to whom the enrollee is assigned by TennCare for the purpose of receiving covered pharmacy services.

~~(71) Lock-In Provider shall mean a provider, either pharmacy or physician, who an enrollee on pharmacy lock-in status has chosen and to whom an enrollee is assigned by TennCare or the MCO for purposes of receiving covered pharmacy services.~~

Rule 1200-13-14-.01 Definitions is amended by deleting Paragraph (72) Lock-In Status and replacing it with amended Paragraph (72) Lock-In Status as follows:

(72) Lock-In Status. The restriction of an enrollee to a specified physician, or to a specified pharmacy provider at a specified single location.

~~(72) Lock-In Status shall mean the restriction of an enrollee to a specified and limited number of pharmacy providers.~~

Rule 1200-13-14-.01 Definitions is amended by deleting the word "provide" from current Paragraph (97) PBM (Pharmacy Benefits Manager) and replacing it with the word "administer" so that as amended Paragraph (97) PBM (Pharmacy Benefits Manager) reads as follows:

(97) PBM (Pharmacy Benefits Manager) shall mean an organization approved by the Tennessee Department of Finance and Administration to administer ~~provide~~ pharmacy benefits to enrollees to the extent such services are covered by the TennCare Program. A PBM may have a signed TennCare Contractor Risk Agreement with the State, or may be a subcontractor to an MCO.

Rule 1200-13-14-.01 Definitions is amended by inserting alphabetically the following new Paragraphs and numbering all definitions appropriately:

() Controlled Substance. A drug, substance, or immediate precursor identified by the U.S. Department of Justice, Drug Enforcement Administration or by the Tennessee Drug Control Act as having the potential for abuse and the likelihood of physical or psychological dependence if used incorrectly.

() Prescriber. An individual authorized by law to prescribe drugs.

() Targeted Pharmacy. A pharmacy meeting one of the following criteria:

(a) It is located outside the State of Tennessee.

(b) It has had previous controlled substance violations with the Tennessee State Board of Pharmacy.

(c) It appears to be an outlier to the norm in its dispensing of controlled substances.

(d) It has filled controlled substance prescriptions that are covered by TennCare for members locked in to a different pharmacy after being notified that the member was locked in to a different pharmacy.

() Targeted Prescriber. A prescriber with prescribing authority who is ranked as a top prescriber of controlled substances based on multiple factors which may include but are not limited to any of the following:

- (a) The percentage of controlled substances prescribed.
- (b) The percentage of Schedule II controlled substances prescribed.
- (c) The percentage of Schedule III controlled substances prescribed.
- (d) The percentage of short acting single ingredient opiates prescribed.
- (e) The percentage of short acting combination product opiates prescribed.
- (f) The percentage of long acting opiates prescribed.
- (g) The average morphine equivalents per day prescribed.
- (h) The percentage of rejected claims of controlled substances.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-109 and 71-5-146.

Rule 1200-13-14-.13 "Members Abuse and Overutilization of the TennCare Program" is deleted in its entirety and replaced with the following:

1200-13-14-.13 Member Abuse or Overutilization of the TennCare Pharmacy Program.

(1) The Bureau is authorized to implement and maintain a pharmacy lock-in program designed to address member abuse or overutilization. Activities which may indicate abuse or overutilization justifying placement on lock-in or prior approval status include but are not limited to the following:

- (a) Forging or altering a prescription for drugs.
- (b) Selling TennCare paid prescription drugs.
- (c) Failing to control pharmacy overutilization activity while on lock-in status.
- (d) Visiting multiple prescribers or pharmacies to obtain controlled substances.
- (e) Trading, swapping or selling a TennCare card.
- (f) Failing to promptly report the loss or theft of a TennCare card.
- (g) Forging or altering a TennCare card.
- (h) Knowingly providing false, incomplete, inaccurate or erroneous information to provider(s) in order to receive covered services for which the member is eligible.
- (i) Permitting the use of a TennCare card by anyone other than the member to whom the card is assigned in order to receive or attempt to receive services.

(2) The TennCare pharmacy lock-in program shall be administered by the Bureau. Monitoring of enrollee activities listed in Paragraph (1) shall be conducted by the Bureau, the MCCs, including the PBM, and the TennCare Office of Inspector General (OIG). When an enrollee has been identified as having participated in any abuse or overutilization activities, including but not limited to the activities listed in Paragraph (1), the enrollee's name shall be referred to the Bureau as appropriate or potentially appropriate for the lock-in program as follows:

- (a) Appropriate for the lock-in program:
 - 1. Any enrollee who has been identified by the OIG as having been convicted of TennCare fraud or a drug-related offense.

2. Any enrollee who has used buprenorphine/naloxone (Suboxone®) or buprenorphine (Subutex®) for office based opioid addiction treatment within the previous six (6) months.

(b) Potentially appropriate for the lock-in program:

1. Any enrollee who has been arrested for TennCare fraud.

2. Any enrollee who has been arrested for a drug-related offense.

3. Any enrollee who has obtained multiple controlled substance prescriptions over a 90-day period that meet one of the following conditions:

(i) The prescriptions were filled at three (3) or more pharmacies and written by three (3) or more prescribers.

(ii) The prescriptions were filled at one (1) or more targeted pharmacies and written by two (2) or more prescribers.

(iii) The prescriptions were filled at two (2) or more targeted pharmacies and written by one (1) or more prescribers.

(iv) The prescriptions were filled at one (1) or more targeted pharmacies and written by one (1) or more targeted prescribers.

(v) The prescriptions were filled at two (2) or more pharmacies and written during three (3) or more emergency room visits.

(3) Pharmacy lock-in procedures shall include:

(a) A determination to place an enrollee who has been referred as appropriate or potentially appropriate for the lock-in program on lock-in status shall be made by the TennCare Pharmacy Director or designee after the enrollee's relevant pharmacy claims data has been reviewed by clinical staff.

(b) Any enrollee determined to be appropriate for the lock-in program shall be notified by the Bureau or the MCC prior to the imposition of lock-in status. The notice shall include a brief explanation of the lock-in program, the reason for the determination to place the enrollee on lock-in status, the date the lock-in will become effective, and the information necessary for the enrollee to appeal the decision of the Bureau, pursuant to Rule 1200-13-13-.11.

(c) If an enrollee fails to appeal placement in the lock-in program or an appeal is not resolved in his favor, the enrollee will be provided TennCare pharmacy services only at the lock-in provider to which the enrollee is assigned.

(4) Lock-in provider selection. A pharmacy will qualify for and may be selected by the enrollee as a lock-in provider only if it meets all the following criteria:

(a) It is enrolled in the TennCare Pharmacy Network;

(b) It is within the State of Tennessee;

(c) It is a full-service pharmacy that carries all medications normally carried by pharmacies;

(d) It is not a mail order or specialty pharmacy;

(e) It is not a targeted pharmacy;

(f) It is a single pharmacy location at a specific address. A chain pharmacy may be selected but only the specific named location may be used, not multiple locations or outlets of the chain; and

(g) It is in proximity to the enrollee's residence, which must be the current address on file with the

Bureau.

- (5) After twelve (12) months a member may request a change of lock-in provider once each year. Additional changes are limited to the following reasons:
- (a) The member has moved and his new address is at least fifteen (15) miles from the lock-in pharmacy and he has updated his address with the Bureau.
 - (b) The member's lock-in pharmacy has permanently closed.
 - (c) The member's lock-in pharmacy has voluntarily dismissed the enrollee from its practice and has notified the Bureau and the PBM.
 - (d) The Bureau may, at its sole discretion, determine that there is a compelling need to change the member's lock-in pharmacy.
- (6) Review of lock-in status. The Bureau or the MCC shall periodically review the claims information of members on lock-in status to determine the need for continued lock-in or escalation to prior approval status.
- (a) Lock-in status will be discontinued if the Bureau determines that a member has met all of the following criteria for at least six (6) consecutive months:
 - 1. Has not paid cash for any controlled substance prescriptions covered by TennCare.
 - 2. Has not received any narcotic medications while on buprenorphine or buprenorphine/naloxone for addiction.
 - 3. Has received TennCare reimbursed controlled substance prescriptions from only one (1) provider.
 - 4. Has received TennCare reimbursed prescriptions from only one (1) pharmacy.
 - (b) If a member is removed from lock-in status, the Bureau or the MCC will monitor the member for changes in utilization patterns and return him to lock-in status if appropriate.
- (7) Prior approval status.
- (a) A member against whom criminal process alleging TennCare fraud has been issued or who has been convicted of TennCare fraud shall automatically be placed on prior approval status.
 - (b) Lock-in status shall be escalated to prior approval status if a member on lock-in status meets three (3) of the following criteria over a 90 day period:
 - 1. Has paid cash for three (3) or more controlled substance prescriptions covered by TennCare.
 - 2. Has filled prescriptions for controlled substances at two (2) or more pharmacies.
 - 3. Has received controlled substance prescriptions from two (2) or more prescribers.
 - 4. Has received a narcotic prescription while receiving buprenorphine or buprenorphine/naloxone for addiction.
 - (c) A member who has been treated in a hospital emergency department for an overdose of a controlled substance (as identified in the most recently available TennCare data) or an illicit substance identified by toxicology shall automatically be placed on prior approval status.
- (8) Emergency pharmacy services may be obtained with a TennCare or MCC override of a member's lock-in status. The PBM has clinical staff available at all times to respond to emergency situations. The PBM must verify that a genuine emergency exists, such as documented proof from the lock-in pharmacy that it is temporarily out of stock of a needed medication. A lock-in override will not be provided simply because a pharmacy is closed for the day unless a true medical emergency exists.

~~1200-13-14-.13 Members Abuse and Overutilization of the TennCare Program.~~

- ~~(1) The TennCare Bureau and the MCCs shall possess the authority to restrict or lock-in TennCare enrollees to a specified and limited number of pharmacy providers if the TennCare Bureau or the MCCs has determined that the enrollee has abused the TennCare Pharmacy Program. Such abuse includes, but shall not be limited to the following:
 - ~~(a) Forging or altering prescription drugs;~~
 - ~~(b) Selling TennCare paid prescription drugs;~~
 - ~~(c) Filing to control pharmacy overutilization activity while on lock-in status; or~~
 - ~~(d) Visiting multiple prescribers or pharmacies to obtain controlled substances.~~~~
- ~~(2) All pharmacy lock-in programs established by the TennCare Bureau or the MCCs must contain at least the following elements:
 - ~~(a) Criteria for selection of abusive or overutilizing enrollees — Pharmacy lock-in program must demonstrate, in detail, how the program will identify lock-in candidates.~~
 - ~~(b) Methods of evaluation of potential lock-in candidates — Pharmacy lock-in programs must describe how the program will review lock-in candidates to ensure appropriate patterns of health care utilization are not misconstrued as abusive or overutilization.~~
 - ~~(c) Lock-in status — Pharmacy lock-in programs must describe the exact process used to notify the lock-in enrollee, notify the lock-in pharmacy and physician providers, coordinate the lock-in activities with the appropriate case managers, when appropriate, and continually review the enrollee's utilization patterns.~~
 - ~~(d) Prior approval status — Pharmacy lock-in programs may include placing an enrollee in a prior approval status in which some or all prescriptions such as controlled substances, require prior authorization. The program must describe the exact process used to notify the enrollee of prior approval status, notify the pharmacy of the enrollee's prior approval status, coordinate the prior approval status activities with the appropriate case managers, when appropriate, and continually review the enrollee's utilization patterns.~~
 - ~~(e) Emergency Services — Pharmacy lock-in programs must describe, in detail, how pharmacy services will be delivered to enrollees on lock-in or prior approval status in the event of an emergency.~~~~
- ~~(3) Pharmacy lock-in program procedures shall include:
 - ~~(a) Prior to imposing lock-in status upon a TennCare enrollee, the TennCare Bureau or the MCC shall provide appropriate notice to TennCare enrollees, informing enrollees that they may only use one pharmacy provider and of their right to appeal this action.~~
 - ~~(b) If the enrollee fails to appeal this lock-in or the appeal of the lock-in is not resolved in his/her favor, the enrollee will only receive coverage for his/her prescription drugs at the lock-in pharmacy.~~
 - ~~(c) If the enrollee attempts to fill a prescription at any pharmacy other than his/her lock-in pharmacy, the PBM will deny coverage for the prescription and the enrollee will be entitled to notice and appeal rights as described in rule 1200-13-14-.11.~~
 - ~~(d) The MCC shall monitor and evaluate the TennCare enrollee subject to the lock-in in accordance with the criteria identified in paragraph (2) above.~~~~

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-109 and 71-5-146.

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Department of Finance and Administration (board/commission/ other authority) on _____ (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 06/11/13

Rulemaking Hearing(s) Conducted on: (add more dates). 08/08/13

Date: _____

Signature: _____

Name of Officer: Darin J. Gordon

Director, Bureau of TennCare

Title of Officer: Tennessee Department of Finance and Administration

Subscribed and sworn to before me on: _____

Notary Public Signature: _____

My commission expires on: _____

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Robert E. Cooper, Jr.
Attorney General and Reporter

Date

Department of State Use Only

Filed with the Department of State on: _____

Effective on: _____

Tre Hargett
Secretary of State

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

There were no public comments on these rules.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

The rules are not anticipated to have an effect on small businesses.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 “any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments.” (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

The rules are not anticipated to have an impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The rules are being updated to meet the requirements of the pharmacy lock-in program.

- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

The rules are lawfully adopted by the Bureau of TennCare in accordance with §§ 4-5-202, 71-5-105, 71-5-109 and 71-5-146.

- (C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

The persons, organizations, corporations or governmental entities most directly affected by these Rules are the TennCare enrollees, providers, and the Bureau of TennCare, Tennessee Department of Finance and Administration.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

The Rules were approved by the Tennessee Attorney General. No additional opinion was given or requested.

- (E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

The promulgation of these rules is not anticipated to have an effect on state and local government revenues and expenditures.

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Donna Tidwell
Deputy General Counsel

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Donna Tidwell
Deputy General Counsel

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

310 Great Circle Road
Nashville, TN 37243
(615) 507-6852
donna.tidwell@tn.gov

(I) Any additional information relevant to the rule proposed for continuation that the committee requests.

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