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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

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

X Amendment
___ 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**
1200-13-13	TennCare Medicaid
Rule Number	**Rule Title**
1200-13-13-.04	Covered Services
1200-13-13-.10	Exclusions
1200-13-13-.13	Member Abuse or Overutilization of the TennCare Pharmacy 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)

Rule 1200-13-13-.04 Covered Services, Paragraph (1), Subparagraph (c), Part 9 is deleted in its entirety and replaced with new Parts 9 and 10 and the current Part 10 is renumbered as Part 11, which shall read as follows:

9. Buprenorphine products for opiate addiction treatment for persons aged 21 and older are restricted as follows:

   (i) Dosage shall not exceed sixteen milligrams (16 mg) per day for a period of up to six (6) months from the initiation of therapy. For enrollees who are pregnant while receiving this dosage, the six-month period does not begin until the enrollee is no longer pregnant. At the end of either six month period, the covered dosage amount shall not exceed eight milligrams (8 mg) per day.

   (ii) Therapy shall be limited to a total lifetime period of coverage not to exceed a total of 732 therapy days, which do not have to be consecutive. For enrollees who are pregnant on day 732 of treatment, the treatment may continue until the enrollee is no longer pregnant.

   (iii) Effective October 1, 2015, enrollees who have exceeded 549 days of treatment will receive coverage for an additional 183 days of therapy prior to exhaustion of their lifetime coverage limits.

10. Sedative hypnotic medications for persons aged 21 and older shall not exceed fourteen (14) pills per month for sedative hypnotic formulations in pill form such as Ambien and Lunesta, one hundred forty milliliters (140 ml) per month of chloral hydrate, or one (1) bottle every sixty (60) days of Zolpimist.

11. Allergy medications.

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

Rule 1200-13-13-.10 Exclusions, Paragraph (3), Subparagraph (a), Part 17, Subpart (vii) is deleted in its entirety and replaced with a new Subpart (vii) which shall read as follows:

(vii) Buprenorphine-containing products used for treatment of opiate addiction in excess of the covered amounts listed below:

   (I) Dosage of sixteen milligrams (16 mg) per day for a period of up to six (6) months (183 days) from the initiation of therapy or from the conclusion of pregnancy, if the enrollee is pregnant during this initial maximum dosage therapy;

   (II) Dosage of eight milligrams (8 mg) per day after the sixth (6th) month (183rd day) of therapy;

   (III) Total lifetime coverage of 732 therapy days (24 months), which do not have to be consecutive, but if the enrollee is pregnant on day 732 of therapy, treatment may continue until the conclusion of pregnancy; and

   (IV) Effective October 1, 2015, enrollees who have exceeded 549 days (18 months) of therapy will receive coverage for an additional 183 days of therapy prior to exhaustion of their lifetime coverage limits.

Rule 1200-13-13-.10 Exclusions, Paragraph (3), Subparagraph (b), Part 88 is amended by inserting the punctuation and language ", four (4) confirmation urine screens and two (2) specific assay tests" between the number "(12)" and the word "during" so that as amended the Part shall read as follows:

88. Urine drug screens in excess of twelve (12), four (4) confirmation urine screens and two (2) specific assay tests during a calendar year.

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

Rule 1200-13-13-.13 Member Abuse or Overutilization of the TennCare Pharmacy Program, Paragraph (2), Subparagraph (a), Part 2 is deleted in its entirety and replaced with a new Part 2 which shall read as follows:

2. Any enrollee who has used buprenorphine-containing products for office based opioid addiction treatment within the previous six (6) months.

Rule 1200-13-13-.13 Member Abuse or Overutilization of the TennCare Pharmacy Program, Paragraph (6), Subparagraph (a), Part 2 is deleted in its entirety and replaced with a new Part 2 which shall read as follows:

2. Has not received any narcotic medications while on buprenorphine-containing products for addiction.

Rule 1200-13-13-.13 Member Abuse or Overutilization of the TennCare Pharmacy Program, Paragraph (7), Subparagraph (b), Part 4 is deleted in its entirety and replaced with a new Part 4 which shall read as follows:

4. Has received a narcotic prescription while receiving buprenorphine-containing products for addiction.

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

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 11/20/2015 (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: 09/09/15

Rulemaking Hearing(s) Conducted on: (add more dates). 10/28/15

Date: 11/20/2015

Signature:

Name of Officer: Darin J. Gordon

Title of Officer: Director, Bureau of TennCare
Tennessee Department of Finance and Administration

ROBIN A. PAGE NOTARY PUBLIC STATE OF TENNESSEE WILLIAMSON COUNTY

Subscribed and sworn to before me on: 11/20/2015

Notary Public Signature: Robin A Page

My commission expires on: 10/18/16

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.

Herbert H. Slatery III

Herbert H. Slatery III
Attorney General and Reporter

12/18/2015
Date

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PUBLICATIONS

Filed with the Department of State on: 12/29/15

Effective on: 3/28/16

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.

Comment: Commenter with the American Society of Addiction Medicine (ASAM) and the Tennessee Society of Addiction Medicine (TnSAM) stated in a letter that they had great concern with the proposed changes in the TennCare Medicaid and TennCare Standard rules that would limit buprenorphine coverage to 732 days in a patient's lifetime. They believe that limiting buprenorphine coverage through treatment length limits does not allow physicians to work with their patient to determine the best individual treatment. They urged TennCare not to adopt the rule, as it interferes with the physician-patient relationship and does not treat addiction as the chronic, lifelong condition that it is.

Response: Thank you for your comments regarding proposed changes to TennCare Rule Chapters 1200-13-13 and 1200-13-14 related to limitations on certain TennCare-covered services. TennCare has considered your comments and those offered by other stakeholders, but believe that the proposed changes are appropriate and necessary at this time.

Comment: A commenter wrote a personal testimony describing what Subutex had done for her in her life and that she was scared of coming off of it.

Response: Thank you for your comments at the rulemaking hearing that took place on October 28, 2015. TennCare has considered your comments and those offered by other stakeholders, but believe that the proposed changes are appropriate and necessary at this time.

Comment: There were ten commenters that offered verbal comments at the hearing. There were also several written comments without name and address that was left at the hearing. Their main concern was with the milligram dosage limit and the 732 day lifetime limit on therapy treatment.

Response: TennCare considered the comments of each and every commenter and those offered by other stakeholders, but we believe that the proposed changes in the rules are appropriate and necessary at this time.

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.

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;

These Rules replace emergency rules that were promulgated to reduce expenditures by limiting coverage for buprenorphine-containing products for treatment of opiate addiction and by limiting payments for additional urine drug test codes.

(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 and 71-5-109.

(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 and entities most directly affected by these Rules are the TennCare enrollees, providers, and managed care contractors. The governmental entity most directly affected by these Rules is 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 anticipated to decrease state government expenditures for TennCare Medicaid and TennCare Standard by $2,984,000, as reported in the Health Care Finance and Administration Fiscal Year 2016 Budget Reduction Plan and incorporated in the Appropriations Act.

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

John G. (Gabe) Roberts
General Counsel

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

John G. (Gabe) Roberts
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) 507-6936

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

GW10115292

RULES
OF
TENNESSEE DEPARTMENT OF FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE

CHAPTER 1200-13-13
TENNCARE MEDICAID

1200-13-13-.04 COVERED SERVICES.

(1) Benefits covered under the managed care program

(c) Pharmacy

TennCare is permitted under the terms and conditions of the demonstration project approved by the federal government to restrict coverage of prescription and non-prescription drugs to a TennCare-approved list of drugs known as a drug formulary. TennCare must make this list of covered drugs available to the public. Through the use of a formulary, the following drugs or classes of drugs, or their medical uses, shall be excluded from coverage or otherwise restricted by TennCare as described in Section 1927 of the Social Security Act [42 U.S.C. §1396r-8]:

9. Buprenorphine ~~and buprenorphine/naloxone~~ products ~~and sedative hypnotics~~ for opiate addiction treatment for persons aged 21 and older are restricted as follows ~~to the quantity limits specified below~~:

(i) ~~Generic buprenorphne, Subtex (buprenorphine), and Suboxone (buprenorphine/naloxone) products~~ Dosage shall not exceed sixteen milligrams (16 mg) per day for a period of up to six (6) months from the initiation of therapy. For enrollees who are pregnant while receiving this dosage, the six-month period does not begin until the enrollee is no longer pregnant. At the end of either six month period, the covered dosage amount shall not exceed eight milligrams (8 mg) per day.

(ii) Therapy shall be limited to a total lifetime period of coverage not to exceed a total of 732 therapy days, which do not have to be consecutive. For enrollees who are pregnant on day 732 of treatment, the treatment may continue until the enrollee is no longer pregnant.

(iii) Effective October 1, 2015, enrollees who have exceeded 549 days of treatment will receive coverage for an additional 183 days of therapy prior to exhaustion of their lifetime coverage limits.

~~(ii)~~10. Sedative hypnotic medications for persons aged 21 and older shall not exceed fourteen (14) pills per month for sedative hypnotic formulations in pill form such as Ambien and Lunesta, one hundred forty milliliters (140 ml) per month of chloral hydrate, or one (1) bottle every sixty (60) days of Zolpimist.

~~10~~11. Allergy medications.

1200-13-13-.10 EXCLUSIONS.

(3) Specific exclusions. The following services, products, and supplies are specifically excluded from coverage under the TennCare Section 1115 waiver program unless excepted by paragraph (2)

herein. Some of these services may be covered under the CHOICES program or outside TennCare under a Section 1915(c) Home and Community Based Services waiver when provided as part of an approved plan of care, in accordance with the appropriate TennCare Home and Community Based Services rule.

(a) Services, products, and supplies that are specifically excluded from coverage except as medically necessary for children under the age of 21.

17. Certain pharmacy items as follows:

(vii) ~~Generic b~~Buprenorphine-containing products used for treatment of opiate addiction~~, Subtex (buprenorphine), and Suboxone (buprenorphine/naloxone)~~ in ~~dosage amounts that~~ excess~~ed~~ of the covered ~~dosage~~ amounts listed below:

(I) Dosage of ~~S~~sixteen milligrams (16 mg) per day for a period of up to six (6) months (183 days) from the initiation of therapy or from the conclusion of pregnancy, if the enrollee is pregnant during this initial maximum dosage therapy; ~~or~~

(II) Dosage of ~~E~~eight milligrams (8 mg) per day after the sixth (6th) month (183rd day) of therapy;~~.~~

(III) Total lifetime coverage of 732 therapy days (24 months), which do not have to be consecutive, but if the enrollee is pregnant on day 732 of therapy, treatment may continue until the conclusion of pregnancy; and

(IV) Effective October 1, 2015, enrollees who have exceeded 549 days (18 months) of therapy will receive coverage for an additional 183 days of therapy prior to exhaustion of their lifetime coverage limits.

(b) Services, products, and supplies that are specifically excluded from coverage under the TennCare program.

88. Urine drug screens in excess of twelve (12), four (4) confirmation urine screens and two (2) specific assay tests during a calendar year.

1200-13-13-.13 MEMBER ABUSE OR OVERUTILIZATION OF THE TENNCARE PHARMACY PROGRAM.

(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-containing products ~~/naloxone (Suboxone®) or buprenorphine (Subutex®)~~ for office based opioid addiction treatment within the previous six (6) months.

(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-containing products ~~or buprenorphine/naloxone~~ for addiction.

(7) 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-containing products ~~or buprenorphine/naloxone~~ for addiction.

GW10115293