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Sequence Number: 09-15-16
Rule ID(s): 6302
File Date: 9/13/16
Effective Date: 12/12/16

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
Contact Person:	George Woods
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Zip:	37243
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Revision Type (check all that apply):

X Amendments
___ New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. 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-.04	Covered Services
1200-13-14-.10	Exclusions

(Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to http://sos.tn.gov/sites/default/files/forms/Rulemaking_Guidelines_August2014.pdf)

Rule 1200-13-14-.04 Covered Services, Paragraph (1), Subparagraph (c), Part 9 is deleted in its entirety and is replaced with a new Part 9, 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.

   (ii) For enrollees who are pregnant while receiving the sixteen milligrams (16 mg) per day dosage, the six-month period does not begin until the enrollee is no longer pregnant.

   (iii) At the end of the six-month period described in subparts (i) and (ii), the covered dosage amount shall not exceed eight milligrams (8 mg) per day.

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

Rule 1200-13-14-.10 Exclusions, Paragraph (3), Subparagraph (a), Part 18, Subpart (vii) is amended by inserting the word "and" at the conclusion of Item (I), by deleting and replacing the punctuation at the end of Item (II) with a "." and by deleting Items (III) and (IV) in their entirety 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; and

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

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 08/18/2016 (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: 05/23/16

Rulemaking Hearing(s) Conducted on: (add more dates). 07/20/16

Date: 8/18/16

Signature: Wendy Long MD

Wendy Long, M.D., M.P.H.
Director, Bureau of TennCare

Name of Officer: Tennessee Department of Finance and Administration

Title of Officer:

ROBIN A. PAGE
STATE OF TENNESSEE
NOTARY PUBLIC
WILLIAMSON COUNTY, TN

Subscribed and sworn to before me on: 8/18/16

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
Attorney General and Reporter

9/9/2016
Date

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Filed with the Department of State on: 9/13/16

Effective on: 12/12/16

Tre Hargett
Secretary of State

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PUBLICATIONS

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 Tennessee Association of Alcohol, Drug and Other Addiction Services (TAADAS) stated in a letter that they wanted to offer comments on the proposed amendment to the TN Administrative Rules governing TennCare covered services and exclusions. The comments were as follows:

TAADAS is a statewide association of alcohol and drug abuse service professionals and providers that includes several providers of Buphrenorphine. TAADAS represents over 63 treatment and recovery services providers statewide and over 15 individual member professionals.

TAADAS supports the elimination of the lifetime limits on buprenorphine in the proposed rules. Addiction is a chronic disease. Lifetime limits do not exist for other drugs used to treat other chronic diseases such as hypertension or diabetes.

TAADAS members have been staggered and overwhelmed by the ever increasing number of persons addicted to opioids. No longer is alcohol the drug of choice for Tennesseans. Instead, the drug of choice is now pills, and most of those are initially prescribed lawfully. Given the difficulty of treating those addicted to opioids, some of our members have seen the need for buprenorphine to assist our patients with the cravings brought on by opioid withdrawal—especially for those that are pregnant and using opiates. We appreciate and support the additional time permitted for pregnant women at the higher maximum daily dosage limits in the present rule. We recognize the lack of flexibility in amending a proposed rule but would advocate for additional consideration of a higher daily dose limit for pregnant women. We would hope that in the future the Bureau will consider a higher daily limit for pregnant women up to a maximum of 24mg per day on a case by case basis. Some of our advisors in the treatment community would see this higher limit as helpful for the treatment of addicted pregnant women. Buphrenorphine dosing during pregnancy can be higher given that the woman is supporting the medication needs for herself and a fetus. Higher dosing is of particular concern for women who will have multiple births. Removing this limitation will remove a barrier to effective and accessible treatment for these women—many of whom were paying for the extra medication out of pocket or getting the extra doses either from a generous provider or from a dealer on the streets. Amerigroup, for example, is paying for additional Buphrenorphine above the current dose limits for their pregnant Medication Assisted Treatment participants. Removing this dosage limitation improves the likelihood women will get appropriate dosing to maintain a healthy pregnancy while in recovery services.

Response: Thank you for your letter on the above-referenced rules pertaining to the TennCare program. We appreciate your comments in support of HCFA's decision to remove lifetime limits from the use of buprenorphine to treat opiate addiction in adults. Although your concerns about daily dosage limits during pregnancy are outside the scope of this rulemaking, they will be retained for future consideration. We appreciate the services that TAADAS and its member organizations provide for Tennesseans needing addiction treatment services, and we look forward to continuing to work with you as we seek to provide high-quality healthcare for TennCare enrollees.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

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 are being promulgated to replace emergency rules which restored the fiscal year 2015-2016 budget reduction to the Bureau of TennCare, which had reduced expenditures for Buprenorphine-containing products for treatment of opiate addiction for persons age 21 and older by imposing a lifetime coverage limit of 732 therapy days. The emergency rule amendment also deleted the lifetime coverage limit and permits the Bureau to reinstate medically necessary treatment of opiate addiction for persons age 21 and older utilizing Buprenorphine.

(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 this Rule 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 or the necessity to promulgate 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 increase state government expenditures for TennCare Medicaid and TennCare Standard by $4,541,600, of which $1,590,300 will be state appropriations. The supplemental appropriation for FY16 was included in the Appropriations Act, Public Chapter 758, effective April 21, 2016, which funds the FY17 budget.

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

Donna K. 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 K. 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

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(615) 507-6852
donna.tidwell@tn.gov

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

GW10116189

RULES
OF
TENNESSEE DEPARTMENT OF FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE

CHAPTER 1200-13-14
TENNCARE STANDARD

1200-13-14-.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 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 while receiving the sixteen milligrams (16 mg) per day dosage, the six-month period does not begin until the enrollee is no longer 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.~~ At the end of the six-month period described in subparts (i) and (ii), the covered dosage amount shall not exceed eight milligrams (8 mg) per day.

1200-13-14-.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.

18. Certain pharmacy items 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; and

(II) Dosage of eight milligrams (8mg) per day after the sixth (6^{th}) month (183^{rd} 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.~~

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