Department of State
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For Department of State Use Only

Sequence Number: 10-17-11
Rule ID(s): 5035
File Date: 10/28/2011
Effective Date: 01/26/2012

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. TCA Section 4-5-205

Agency/Board/Commission:	Tennessee Department of Finance and Administration
Division:	Bureau of TennCare
Contact Person:	George Woods
Address:	Bureau of TennCare 310 Great Circle Road Nashville, Tennessee
Zip:	37243
Phone:	(615) 507-6446
Email:	George.woods@tn.gov

Revision Type (check all that apply):

X 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**
1200-13-13	TennCare Medicaid
Rule Number	**Rule Title**
1200-13-13-.04	Covered Services
1200-13-13-.10	Exclusions

(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)

Chapter 1200-13-13
TennCare Medicaid

Emergency Rule Parts 9. and 10. of Subparagraph (c) of Paragraph (1) of Rule 1200-13-13-.04 Covered Services are deleted in their entirety and replaced with Rulemaking Hearing Rule Parts 9. and 10. which shall read as follows:

9. TennCare shall not cover drugs considered by the FDA to be Less Than Effective (LTE) and DESI drugs, or drugs considered to be Identical, Related and Similar (IRS) to DESI and LTE drugs or any other pharmacy services for which federal financial participation (FFP) is not available. The exclusion of drugs for which no FFP is available extends to all TennCare enrollees regardless of the enrollee's age. TennCare shall not cover experimental or investigational drugs which have not received final approval from the FDA.

10. Buprenorphine and buprenorphine/naloxone products and sedative hypnotics for persons aged 21 and older are restricted to the quantity limits specified below:

    (i) Generic buprenorphine, Subutex (buprenorphine), and Suboxone (buprenorphine/naloxone) products 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) Sedative hypnotic medications 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.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-109 and Public Chapter 473, Acts of 2011.

Emergency Rule Subparts (ix) and (x) of Part 20. of Subparagraph (a) of Paragraph (3) of Rule 1200-13-13-.10 Exclusions are deleted in their entirety and replaced with Rulemaking Hearing Rule Subparts (ix) and (x) so as replaced Part 20. shall read as follows:

20. Certain pharmacy items as follows:

    (i) Agents when used for anorexia or weight loss

    (ii) Agents when used to promote fertility

    (iii) Agents when used for cosmetic purposes or hair growth

    (iv) Agents when used for the symptomatic relief of cough and colds

    (v) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee

    (vi) Nonprescription drugs

    (vii) Barbiturates

    (viii) Benzodiazepines

(ix) Generic buprenorphine, Subutex (buprenorphine), and Suboxone (buprenorphine/naloxone) in dosage amounts that exceed the covered dosage amounts listed below:

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

(II) Eight milligrams (8 mg) per day after the sixth (6^{th}) month of therapy.

(x) Sedative hypnotic medications in dosage amounts that exceed the dosage amounts listed below:

(I) Fourteen (14) pills per month for sedative hypnotic formulations in pill form such as Ambien and Lunesta;

(II) One hundred forty milliliters (140 ml) per month of chloral hydrate; or

(III) One (1) bottle every sixty (60) days of Zolpimist.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-109 and Public Chapter 473, Acts of 2011.

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 10/19/11 (mm/dd/yyyy), and is in compliance with the provisions of TCA 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 08/08/2011

Rulemaking Hearing(s) Conducted on: (add more dates). 09/29/2011

Date: 10/19/2011

Signature:

Name of Officer: Darin J. Gordon

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

CHERYL D. KLINE STATE OF TENNESSEE NOTARY PUBLIC DAVIDSON COUNTY

Subscribed and sworn to before me on: 10/19/2011

Notary Public Signature: Cheryl D Kline

My commission expires on: 9/3/2012

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

10-27-11
Date

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Filed with the Department of State on: 10/28/2011

Effective on: 01/26/2012

Tre Hargett
Secretary of State

RECEIVED
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SECRETARY OF STATE
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.

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 TCA 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 reduced expenditures for certain sedative hypnotic and opioid detoxification drugs through imposition of quantity and dosage limitations.

(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 Tennessee Code Annotated §§ 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 the 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 the TennCare Medicaid and TennCare Standard Rules is projected to decrease state annual expenditures by $1,721,500.

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

Darin J. Gordon
Director, Bureau of TennCare

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

Darin J. Gordon
Director, Bureau of TennCare

(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)507-6443
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(l) Any additional information relevant to the rule proposed for continuation that the committee requests.

None

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