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Sequence Number: 09-46-13
 Rule ID(s): 5582
 File Date: 9/27/13
 Effective Date: 12/26/13

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
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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
1200-13-13	TennCare Medicaid
Rule Number	Rule Title
1200-13-13-.04	Covered Services
1200-13-13-.10	Exclusions
1200-13-13-.11	Appeal of Adverse Actions Affecting TennCare Services or Benefits

(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>)

Part 5. Agents which are benzodiazepines or barbiturates. of Subparagraph (c) of Paragraph (1) of Rule 1200-13-13-.04 Covered Services, effective January 1, 2014, is deleted in its entirety and subsequent parts renumbered accordingly.

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

Subparts (vii) Barbiturates and (viii) Benzodiazepines of Part 20. of Subparagraph (a) of Paragraph (3) of Rule 1200-13-13-.10 Exclusions, effective January 1, 2014, are deleted in their entirety and subsequent subparts renumbered accordingly.

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

Subpart (vi) nonprescription drugs; of Part 2. of Subparagraph (b) of Paragraph (5) of Rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits, effective January 1, 2014, is amended by adding the word "or" after the words "nonprescription drugs," so that as amended Subpart (vi) shall read as follows:

- (vi) nonprescription drugs; or

Subpart (vii) of Part 2. of Subparagraph (b) of Paragraph (5) of Rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits, effective January 1, 2014, is amended by replacing the semicolon and word "or" after the words "or its designee" with a period so that as amended Subpart (vii) shall read as follows:

- (vii) 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.

Subpart (viii) barbiturates or benzodiazepines. of Part 2. of Subparagraph (b) of Paragraph (5) of Rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits, effective January 1, 2014, is deleted in its entirety.

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 09/19/2013 (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: 06/17/13

Rulemaking Hearing(s) Conducted on: (add more dates). 09/04/13

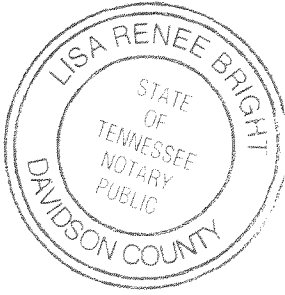
Date: 9/19/13

Signature: [Handwritten 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: September 19, 2013

Notary Public Signature: [Handwritten Signature]

My commission expires on: January 6, 2015

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.

[Handwritten Signature]
Robert E. Cooper, Jr.
Attorney General and Reporter
9-26-13
Date

Department of State Use Only

Filed with the Department of State on: 9/27/13

Effective on: 12/26/13

[Handwritten Signature]
Tre Hargett
Secretary of State

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DEPARTMENT 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 promulgated to repeal current rules which exclude benzodiazepines and barbiturates from the TennCare drug formulary and from TennCare coverage. Effective January 1, 2014, 42 U.S.C. § 1396r-8(d) is amended by § 2502 of the Affordable Care Act which deletes benzodiazepines and barbiturates from the list of drugs subject to restriction by State Medicaid programs and adds them to the list of non-excludable drugs.

- (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, organizations, corporations or governmental entities most directly affected by these Rules are the TennCare recipients, 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 the TennCare Medicaid and TennCare Standard rules is anticipated to increase state annual expenditures by \$4,840,500.

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

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GW10113248

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]:

1. Agents for weight loss or weight gain.
2. Agents to promote fertility or for the treatment of impotence or infertility or for the reversal of sterilization.
3. Agents for cosmetic purposes or hair growth.
4. Agents for symptomatic relief of coughs and colds.
- ~~5. Agents which are benzodiazepines or barbiturates.~~
- ~~6.5.~~ Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- ~~7.6.~~ Nonprescription drugs.
- ~~8.7.~~ 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 his designee.
- ~~9.8.~~ 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.
- ~~10.9.~~ 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.
- (d) The MCC shall be allowed to provide cost effective alternative services as defined in paragraph 1200-13-13-.01(29). Cost effective alternative services are not reimbursable in any circumstances other than those described in that paragraph.

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
 - 1. Air cleaners, purifiers, or HEPA filters
 - 2. Audiological therapy or training
 - 3. Augmentative communication devices
 - 4. Beds and bedding equipment as follows:
 - (i) Powered air flotation beds, air fluidized beds (including Clinitron beds), water pressure mattress, or gel mattress

For persons age 21 and older: Not covered unless a member has both severely impaired mobility (i.e., unable to make independent changes in body position to alleviate pain or pressure) and any stage pressure ulcer on the trunk or pelvis combined with at least one of the following: impaired nutritional status, fecal or urinary incontinence, altered sensory perception, or compromised circulatory status.
 - (ii) Bead beds, or similar devices
 - (iii) Bed boards
 - (iv) Bedding and bed casings
 - (v) Ortho-prone beds
 - (vi) Oscillating beds
 - (vii) Pillows, hypoallergenic
 - (viii) Springbase beds
 - (ix) Vail beds, or similar bed
 - 5. Bed baths and Sitz baths

6. Biofeedback
7. Chiropractor's services
8. Cushions, pads, and mattresses as follows:
 - (i) Aquamatic K Pads
 - (ii) Elbow protectors
 - (iii) Heat and massage foam cushion pads
 - (iv) Heating pads
 - (v) Heel protectors
 - (vi) Lamb's wool pads
 - (vii) Steam packs
9. Diagnostic tests conducted solely for the purpose of evaluating the need for a service which is excluded from coverage under these rules.
- 10.. Ear plugs
11. Floor standers
12. Food supplements and substitutes including formulas

For persons 21 years of age and older: Not covered, except that Parenteral Nutrition formulas, Enteral Nutrition formulas for tube feedings and phenylalanine-free formulas (not foods) used to treat PKU, as required by T.C.A. §56-7-2505, are covered for adults. In addition, oral liquid nutrition may be covered when medically necessary for adults with swallowing or breathing disorders who are severely underweight (BMI<15 kg/m²) and physically incapable of otherwise consuming a sufficient intake of food to meet basic nutritional requirements.
13. Hearing services, including the prescribing, fitting, or changing of hearing aids
14. Humidifiers (central or room) and dehumidifiers
15. Inpatient rehabilitation facility services
16. Medical supplies, over-the-counter, as follows:
 - (i) Alcohol, rubbing
 - (ii) Band-aids
 - (iii) Cotton balls
 - (iv) Eyewash
 - (v) Peroxide

- (vi) Q-tips or cotton swabs
- 17. Methadone clinic services
- 18. Nutritional supplements and vitamins, over-the-counter, except that prenatal vitamins for pregnant women and folic acid for women of childbearing age are covered
- 19. Orthodontic services, except as defined in Rule 1200-13-13-.04(1)(b)5. or 1200-13-14-.04(1)(b)5.
- 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~~
 - (ixvii) 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 (6th) month of therapy.
 - (xviii) 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.
- 21. Purchase, repair, or replacement of materials or equipment when the reason for the purchase, repair, or replacement is the result of enrollee abuse

1200-13-13-.11 APPEAL OF ADVERSE ACTIONS AFFECTING TENNCARE SERVICES OR BENEFITS.

(5) Special Provisions Pertaining to Pharmacy.

- (b) A pharmacist shall dispense a seventy-two (72) hour interim supply of the prescribed drug, as mandated by the preceding paragraph, provided that:
1. The medication is not classified by the FDA as Less Than Effective (LTE) and DESI drugs or any drugs considered to be Identical, Related and Similar (IRS) to DESI or LTE drugs or any medication for which no federal financial participation (FFP) is available. The exclusion of drugs for which no FFP is available extends to all TennCare enrollees regardless of the enrollee's age; or
 2. The medication is not a drug in one of the non-covered TennCare therapeutic categories that include:
 - (i) agents for weight loss or weight gain;
 - (ii) agents to promote fertility or to treat impotence;
 - (iii) agents for cosmetic purposes or hair growth;
 - (iv) agents for the symptomatic relief of coughs and colds;
 - (v) prescription vitamins and mineral products except prenatal vitamins and fluoride preparations;
 - (vi) nonprescription drugs; or
 - (vii) 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; or
 - ~~(viii) barbiturates or benzodiazepines.~~
 3. Use of the medication has not been determined to be medically contraindicated because of the patient's medical condition or possible adverse drug interaction; or
 4. If the prescription is for a total quantity less than a seventy-two (72) hour supply, the pharmacist must provide a supply up to the amount prescribed.
 5. In some circumstances, it is not feasible for the pharmacist to dispense a seventy-two (72) hour supply because the drug is packaged by the manufacturer to be sold as the original unit or because the usual and customary pharmacy practice would be to dispense the drug in the original packaging. Examples would include, but not be limited to, inhalers, eye drops, ear drops, injections, topicals (creams, ointments, sprays), drugs packaged in special dispensers (birth control pills, steroid dose packs), and drugs that require reconstitution before dispensing (antibiotic powder for oral suspension). When coverage of a seventy-two (72) hour supply of a prescription would otherwise be required and when, as described above, it is not feasible for the pharmacist to dispense a seventy-two (72) hour supply, it is the responsibility of the MCC to provide coverage for either

the seventy-two (72) hour supply or the usual dispensing amount, whichever is greater.

6. The Bureau of TennCare shall establish a tolerance level for early refills of prescriptions. Such established tolerance level may be more stringent for narcotic substances. Notwithstanding the requirements of this part, if an enrollee requests a refill of a prescription prior to the tolerance level for early refills established by the Bureau, the pharmacy will deny this request as a service which is non-covered until the applicable tolerance period has lapsed, and will not provide a seventy-two (72) hour supply of the prescribed drug.

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