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**Division of Publications**  
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**For Department of State Use Only**

Sequence Number: 07-01-11  
Rule ID(s): 4961  
File Date (effective date): 07/01/2011  
End Effective Date: 12/08/2011

# Emergency Rule Filing Form

*Emergency rules are effective from date of filing for a period of up to 180 days.*

**Agency/Board/Commission:** Tennessee Department of Finance and Administration  
**Division:** Bureau of TennCare  
**Contact Person:** George Woods  
**Address:** 310 Great Circle Road  
Nashville, Tennessee  
**Zip:** 37243  
**Phone:** (615) 507-6443  
**Email:** [George.woods@tn.gov](mailto:George.woods@tn.gov)

**Rule Type:**

Emergency Rule

**Revision Type (check all that apply):**

Amendments

New

Repeal

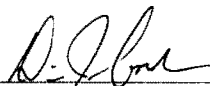
**Statement of Necessity:**

Pursuant to T.C.A. § 4-5-208, the Bureau of TennCare is authorized to adopt emergency rules in the event that the agency is required by enactment of the general assembly to implement rules within a prescribed period of time that precludes utilization of rulemaking procedures for promulgation of permanent rules.

The Appropriations Act, Public Chapter 473, effective July 1, 2011, requires the Bureau of TennCare to provide coverage for smoking cessation products for adult enrollees. Previously, smoking cessation was only covered for children and pregnant women. Further, the Appropriations Act specifically authorizes the promulgation of emergency rules when necessary to fiscally function within the appropriations provided for the TennCare program.

I have made the finding that the attached amendments are required by the above-referenced enactment of the general assembly and the timely implementation of these amendments as mandated precludes promulgation through ordinary rulemaking procedures.

For a copy of these emergency rules contact: George Woods at the Bureau of TennCare by mail at 310 Great Circle Road, Nashville, Tennessee 37243 or by telephone at (615) 507-6446.

  
\_\_\_\_\_  
Darin J. Gordon  
Director, Bureau of TennCare

**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/RuleTitle 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>)

Paragraph (C) the last paragraph of the "BENEFIT FOR PERSONS AGED 21 AND OLDER" column of Part 25. of Subparagraph (b) of Paragraph (1) of Rule 1200-13-13-.04 Covered Services is deleted in its entirety and replaced with a new (C) which shall read as follows:

SERVICE	BENEFIT FOR PERSONS UNDER AGE 21	BENEFIT FOR PERSONS AGED 21 AND OLDER
		(C) Over-the-counter (OTC) drugs for TennCare adults are not covered even if the enrollee has a prescription for such service, unless the drug is listed on the "Covered OTC Drug List" that is available on the TennCare website located at <a href="http://www.tn.gov/tenncare">www.tn.gov/tenncare</a> on the date of service.

Statutory Authority: T.C.A. §§ 4-5-208, 71-5-105 and 71-5-109.

Part 5. "Agents to promote smoking cessation, except such agents shall be covered for pregnant women in accordance with 42 U.S.C. § 1396d." of Subparagraph (c) of Paragraph (1) of Rule 1200-13-13-.04 Covered Services is deleted in its entirety and subsequent Parts renumbered accordingly.

Statutory Authority: T.C.A. §§ 4-5-208, 71-5-105 and 71-5-109.

Subpart (v) "Agents when used to promote smoking cessation, except such agents shall be covered for pregnant women in accordance with 42 U.S.C. §1396d" of Part 20. of Subparagraph (a) of Paragraph (3) of Rule 1200-13-13-.10 Exclusions is deleted in its entirety and subsequent Parts are renumbered accordingly.

Statutory Authority: T.C.A. §§ 4-5-208, 71-5-105 and 71-5-109.

Subpart (v) "agents to promote smoking cessation, except such agents shall be covered for pregnant women in accordance with 42 U.S.C. § 1396d;" of Part 2. of Subparagraph (b) of Paragraph (5) of Rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits is deleted in its entirety and subsequent Subparts are renumbered accordingly.

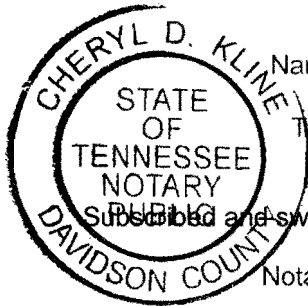
Statutory Authority: T.C.A. §§ 4-5-208, 71-5-105 and 71-5-109.

GW10111168

I certify that this is an accurate and complete copy of an emergency rule(s), lawfully promulgated and adopted.

Date: 6/27/2011

Signature: [Signature]



Name of Officer: Darin J. Gordon

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

Subscribed and sworn to before me on: 6/27/11

Notary Public Signature: [Signature]

My commission expires on: 9/30/2012

All emergency 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.

[Signature]  
Robert E. Cooper, Jr.  
Attorney General and Reporter

6-30-11

Date

Department of State Use Only

Filed with the Department of State on: 07/01/2011

Effective for: 180 \*days

Effective through: 12/28/2011

\* Emergency rule(s) may be effective for up to 180 days from the date of filing.

[Signature]

Tre Hargett  
Secretary of State

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SECRETARY OF STATE  
PUBLICATIONS

## **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)

There is no projected 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;

The Rules are being promulgated because effective July 1, 2011, TennCare is covering smoking cessation products for adult enrollees.

- (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 T.C.A. §§ 4-5-208, 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 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;

These 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 increase state annual expenditures by \$3,500,000.

- (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  
Darin.J.Gordon@tn.gov

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

None

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SERVICE	BENEFIT FOR PERSONS UNDER AGE 21	BENEFIT FOR PERSONS AGED 21 AND OLDER
		<p><del>(C) Over-the-counter drugs for Medicaid adults are not covered even if the enrollee has a prescription for such service, except for prenatal vitamins for pregnant women</del></p> <p><u>(C) Over-the-counter (OTC) drugs for TennCare adults are not covered even if the enrollee has a prescription for such service, unless the drug is listed on the "Covered OTC Drug List" that is available on the TennCare website located at <a href="http://www.tn.gov/tenncare">www.tn.gov/tenncare</a> on the date of service.</u></p>

Statutory Authority: T.C.A. §§ 4-5-208, 71-5-105 and 71-5-109.

Part 5. "Agents to promote smoking cessation, except such agents shall be covered for pregnant women in accordance with 42 U.S.C. § 1396d." of Subparagraph (c) of Paragraph (1) of Rule 1200-13-13-.04 Covered Services is deleted in its entirety and subsequent Parts renumbered accordingly.

(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 to promote smoking cessation, except such agents shall be covered for pregnant women in accordance with 42 U.S.C. § 1396d.
- ~~6.5.~~ Agents which are benzodiazepines or barbiturates.
- ~~7.6.~~ Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- ~~8.7.~~ Nonprescription drugs.
- 9.8. 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.

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.

Statutory Authority: T.C.A. §§ 4-5-208, 71-5-105 and 71-5-109.

Subpart (v) "Agents when used to promote smoking cessation, except such agents shall be covered for pregnant women in accordance with 42 U.S.C. §1396d" of Part 20. of Subparagraph (a) of Paragraph (3) of Rule 1200-13-13-.10 Exclusions is deleted in its entirety and subsequent Parts are renumbered accordingly.

- (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

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)~~ Agents when used to promote smoking cessation, except such agents shall be covered for pregnant women in accordance with 42 U.S.C. § 1396d
- ~~(vi)~~(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
- ~~(vii)~~(vi) Nonprescription drugs
- ~~(viii)~~(vii) Barbiturates
- ~~(ix)~~(viii) Benzodiazepines

Statutory Authority: T.C.A. §§ 4-5-208, 71-5-105 and 71-5-109.

Subpart (v) "agents to promote smoking cessation, except such agents shall be covered for pregnant women in accordance with 42 U.S.C. § 1396d;" of Part 2. of Subparagraph (b) of Paragraph (5) of Rule 1200-13-13-.11 Appeal of Adverse Actions Affecting TennCare Services or Benefits is deleted in its entirety and subsequent Subparts are renumbered accordingly.

- (b) A pharmacist shall dispense a seventy-two (72) hour interim supply of the prescribed drug, as mandated by the preceding paragraph, provided that:
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) agents to promote smoking cessation, except such agents shall be covered for pregnant women in accordance with 42 U.S.C. § 1396d;~~
    - ~~(vi)~~(v) prescription vitamins and mineral products except prenatal vitamins and fluoride preparations;
    - ~~(vii)~~(vi) nonprescription drugs;
    - ~~(viii)~~(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
    - ~~(ix)~~(viii) barbiturates or benzodiazepines.

Statutory Authority: T.C.A. §§ 4-5-208, 71-5-105 and 71-5-109.

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