

**Department of State
Division of Publications**

312 Rosa L. Parks Avenue, 8th Floor Snodgrass/TN Tower
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For Department of State Use Only

Sequence Number: 06-22-11
Rule ID(s): 49560
File Date: 06/17/2011
Effective Date: 11/28/2011

Proposed Rule(s) Filing Form

Proposed rules are submitted pursuant to T.C.A. §4-5-202, 4-5-207 in lieu of a rulemaking hearing. It is the intent of the Agency to promulgate these rules without a rulemaking hearing unless a petition requesting such hearing is filed within sixty (60) days of the first day of the month subsequent to the filing of the proposed rule with the Secretary of State. To be effective, the petition must be filed with the Agency and be signed by twenty-five (25) persons who will be affected by the amendments, or submitted by a municipality which will be affected by the amendments, or an association of twenty-five (25) or more members, or any standing committee of the General Assembly. The agency shall forward such petition to the Secretary of State.

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

Revision Type (check all that apply):

- ☒ 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
1200-13-16	Medical Necessity
Rule Number	Rule Title
1200-13-16-.05	Medical Necessity Criteria
1200-13-16-.06	Determination of Medical Necessity

(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>)

Rules of
Tennessee Department of Finance and Administration
Bureau of TennCare

Chapter 1200-13-16
Medical Necessity

Amendments

Part 2. of Subparagraph (b) of Paragraph (5) of Rule 1200-13-16-.05 Medical Necessity Criteria is amended by deleting the reference to paragraph (22) and replacing it with a reference to paragraph (21) so as amended Part 2. shall read as follows:

2. The weight of medical evidence as ranked in the hierarchy of evidence in rule 1200-13-16-.01(21) and as applied in rule 1200-13-16-.06(6) and (7).

Subparagraph (a) of Paragraph (6) of Rule 1200-13-16-.05 Medical Necessity Criteria is amended by deleting the reference to paragraph (22) in the first sentence and replacing it with a reference to paragraph (21) so as amended Subparagraph (a) shall read as follows:

- (a) A medical item or service is not experimental or investigational if the weight of medical evidence supports the safety and efficacy of the medical item or service in question as ranked in the hierarchy of evidence in rule 1200-13-16-.01(21) and as applied in rule 1200-13-16-.06(6) and (7). This standard is not satisfied by a provider's subjective clinical judgment on the safety and effectiveness of a medical item or service or by a reasonable medical or clinical hypothesis based on an extrapolation from use in diagnosing or treating another condition. However, extrapolation from one population group to another (e.g. from adults to children) may be appropriate. For example, extrapolation may be appropriate when the item or service has been proven effective, but not yet tested in the population group in question.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105 and 71-5-144.

Paragraph (8) of Rule 1200-13-16-.06 Determination of Medical Necessity is amended by deleting the reference to paragraph (22) and replacing it with a reference to paragraph (21) so as amended Paragraph (8) shall read as follows:

- (8) The Bureau of TennCare or the managed care contractor's classification of available medical evidence as defined at rule 1200-13-16-.01(21) and any resulting approval of items or services as described at rule 1200-13-16-.06(6) and (7) shall be binding on TennCare enrollees and providers.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105 and 71-5-144.

I certify that this is an accurate and complete copy of proposed rules, lawfully promulgated and adopted by the (board/commission/other authority) on 04/12/2011 (date as mm/dd/yyyy), and is in compliance with the provisions of TCA 4-5-222. The Secretary of State is hereby instructed that, in the absence of a petition for proposed rules being filed under the conditions set out herein and in the locations described, he is to treat the proposed rules as being placed on file in his office as rules at the expiration of sixty (60) days of the first day of the month subsequent to the filing of the proposed rule with the Secretary of State.



Date: 4/12/2011

Signature: [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: 4-12-2011

Notary Public Signature: Cheryl D Kline

My commission expires on: 9-3-2012

All proposed 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

6-15-11

Date

Department of State Use Only

Filed with the Department of State on: 06/17/2011

Effective on: 11/28/2011

[Signature]

Tre Hargett
Secretary of State

RECEIVED
2011 JUN 17 AM 10:45
SECRETARY OF STATE
PUBLICATIONS

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 have no 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)

(Insert statement here)

The rules are not projected 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;

The rules are being promulgated to update rule references contained in the rules.

- (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 71-5-144.

- (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 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 reviewed and 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 not anticipated to have an effect on state and local government revenues and expenditures.

- (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.

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GW1011089

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Date: _____

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: _____

Notary Public Signature: _____

My commission expires on: _____

All proposed 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

Date

Department of State Use Only

Filed with the Department of State on: _____

Effective on: _____

Tre Hargett
Secretary of State

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