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Sequence Number: 06-20-16  
Rule ID(s): 6202  
File Date (effective date): 6/24/16  
End Effective Date: 12/21/16

# Emergency Rule Filing Form

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

|                                 |  |
|---------------------------------|--|
| <b>Agency/Board/Commission:</b> | Tennessee Department of Finance and Administration           |
| <b>Division:</b>                | Bureau of TennCare   |
| <b>Contact Person:</b>          | George Woods   |
| <b>Address:</b>                 | Bureau of TennCare<br>310 Great Circle Road<br>Nashville, TN |
| <b>Zip:</b>                     | 37243  |
| <b>Phone:</b>                   | (615) 507-6446   |
| <b>Email:</b>                   | <a href="mailto:george.woods@tn.gov">george.woods@tn.gov</a> |

**Rule Type:**

Emergency Rule

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

Amendments

New

Repeal

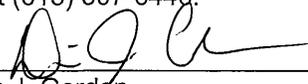
**Statement of Necessity:**

The Appropriations Act, Public Chapter Number 758, Section 38, Item 4.1, effective April 21, 2016, restores the fiscal year 2015-2016 budget reduction of \$1,586,600.00 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. This emergency rule amendment deletes the lifetime coverage limit and permits the Bureau to reinstate medically necessary treatment of opiate addiction for persons age 21 and older utilizing Buprenorphine.

T.C.A. § 4-5-208 permits an agency to adopt an emergency rule when it 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.

Based upon the above information, I have made the finding that the emergency adoption of this rule is required in order to achieve immediate implementation.

For a copy of this emergency rule 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  
Tennessee Department of Finance and Administration

**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)**

| <b>Chapter Number</b> | <b>Chapter Title</b> |
|-----------------------|----------------------|
| 1200-13-13            | TennCare Medicaid    |
| <b>Rule Number</b>    | <b>Rule Title</b>    |
| 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>)

Rule 1200-13-13-.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. §§ 4-5-208, 71-5-105 and 71-5-109.

Rule 1200-13-13-.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. §§ 4-5-208, 71-5-105 and 71-5-109.

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

Date: 5/22/2014

Signature: D.J.G.

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: 5/22/16

Notary Public Signature: Robin A. Page

My commission expires on: 10/18/2016

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.

Herbert H. Slattery III  
Herbert H. Slattery III  
Attorney General and Reporter  
4/23/2016  
Date

**Department of State Use Only**

Filed with the Department of State on: 6/24/16

Effective for: 180 \*days

Effective through: 12/21/16

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

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### **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)

These 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 restore 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. This emergency rule amendment deletes 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 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 the TennCare enrollees, providers, and 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 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;

John G. (Gabe) Roberts  
General Counsel

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

John G. (Gabe) Roberts  
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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Nashville, TN 37243

(615) 507-6936  
gabe.roberts@tn.gov

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

GW10416122

RULES  
OF  
TENNESSEE DEPARTMENT OF FINANCE AND ADMINISTRATION  
BUREAU OF TENNCARE

CHAPTER 1200-13-13  
TENNCARE MEDICAID

**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]:

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.~~

**1200-13-13-10 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.

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<sup>th</sup>) month (183<sup>rd</sup> 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.~~

GW10116131