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Sequence Number: 04-09-18
Rule ID(s): 6740
File Date: 4/9/18
Effective Date: 7/8/18

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

Agency/Board/Commission:	Tennessee Department of Finance and Administration
Division:	Division of TennCare
Contact Person:	George Woods
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Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that ALL new rule and repealed rule numbers are listed in the chart below. Please enter only ONE Rule Number/Rule Title per row)

Chapter Number	Chapter Title
1200-13-14	TennCare Standard
Rule Number	Rule Title
1200-13-14-.04	Covered Services
1200-13-14-.10	Exclusions

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to http://sos-tn-gov-files.s3.amazonaws.com/forms/Rulemaking%20Guidelines_September2016.pdf.

Rule 1200-13-14-.04 Covered Services, Paragraph (1), Subparagraph (c), is amended by adding a new Part 12, which shall read as follows:

12. Opioid products for persons aged twenty-one (21) and older are restricted as follows:
 - (i) "Chronic opioid user" means:
 - (I) A TennCare enrollee whose TennCare paid claims data demonstrates that he has received at least a ninety (90) day quantity of prescribed opioids in the one hundred eighty (180) day period immediately preceding the opioid's prescription date.
 - (II) For a TennCare enrollee who has not been enrolled in TennCare long enough to demonstrate that he is a chronic opioid user as defined in Item (I), the enrollee may demonstrate that he has received at least a ninety (90) day quantity of prescribed opioids in the one hundred eighty (180) day period immediately preceding the opioid's prescription date by supplying paid claims data and medical records from his previous healthcare provider(s) or health insurer(s).
 - (ii) "Non-chronic opioid user" means a TennCare enrollee whose TennCare paid claims data demonstrates he has received less than a ninety (90) day quantity of prescribed opioids in the one hundred eighty (180) day period immediately preceding the opioid's prescription date.
 - (iii) Non-chronic opioid users shall be eligible to receive covered prescription opioid products as follows:
 - (I) A maximum of fifteen (15) dosage days in any six (6) month period; and
 - (II) Daily dosage shall not exceed sixty (60) morphine milligram equivalents (MME) per day.
 - (iv) The restrictions in Subpart (iii) do not apply for enrollees with severe cancer pain undergoing active or palliative cancer treatment and enrollees in hospice and palliative care.
 - (v) The following considerations apply for enrollees who experience more frequent or aggressive pain episodes due to these specific clinical disease states:
 - (I) Enrollees with Sickle Cell may receive up to forty-five (45) days of sixty (60) MME per day in any ninety (90) day period; and
 - (II) Severe burn victims may receive up to forty-five (45) days of sixty (60) MME per day in any ninety (90) day period.
 - (vi) Notwithstanding the restrictions in Subpart (iii), enrollees residing in a Medicaid-certified Nursing Facility may receive up to forty-five (45) days of sixty (60) MME per day in any ninety (90) day period.

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

Rule 1200-13-14-.10 Exclusions, Paragraph (3), Subparagraph (a), Part 18, is amended by inserting a new Subpart (x), which shall read as follows:

- (x) Opioid products are restricted as set out in Rule .04(1)(c)12.

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 Division of TennCare (board/commission/ other authority) on 03/28/2018 (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: 01/16/18

Rulemaking Hearing(s) Conducted on: (add more dates). 03/12/18

Date: 3/28/18

Signature: Wendy Long MD

Name of Officer: Wendy Long, M.D., M.P.H.

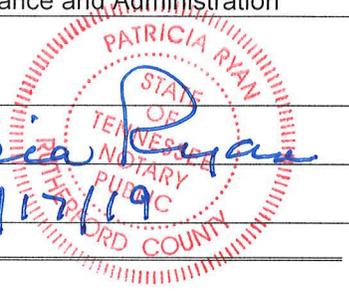
Division of TennCare

Title of Officer: Tennessee Department of Finance and Administration

Subscribed and sworn to before me on: 3/28/18

Notary Public Signature: Patricia Ryan

My commission expires on: 8/17/19



Agency/Board/Commission: Division of TennCare

Rule Chapter Number(s): 1200-13-14

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.

Herbert H. Slatery III
Herbert H. Slatery III

Attorney General and Reporter

4/6/2018

Date

Department of State Use Only

Filed with the Department of State on: 4/9/18

Effective on: 7/8/18

Tre Hargett

Tre Hargett
Secretary of State

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PUBLICATIONS

Public Hearing Comments

One copy of a document that satisfies T.C.A. § 4-5-222 must accompany the filing.

TennCare received one set of comments in response to this rulemaking. The commenter expressed concern that the exceptions to the limits contained in the rule focus too narrowly on individuals with sickle-cell disease and burn victims. The commenter recommended that TennCare identify additional exceptions to the limits or allow exceptions to the limits when supported by a treating physician's attestation of medical necessity. TennCare responded that the limits in the rule are appropriate and necessary at this time, and that TennCare intends to monitor the implementation and impact of the rule on an ongoing basis to ensure that enrollees have access to medically necessary covered services. The final rule contains additional flexibility for TennCare enrollees residing in nursing facilities.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

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://publications.tnsosfiles.com/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;

These rule amendments are being adopted to address the over-use of prescription opioids in response to what has been called the opioid crisis and the opioid epidemic in Tennessee. These rule amendments impose evidence based limitations on the use of opioid prescription medications by adult enrollees in the TennCare Program. These rule amendments continue to permit medically necessary use of prescription opioids for persons age 21 and older, but impose dosage amount limits as well as time limits based on evidence based medical guidelines.

- (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;

These rule amendments are lawfully adopted by the Division of TennCare in accordance with T.C.A. §§ 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 rule amendments are TennCare enrollees, providers, and managed care contractors. The governmental entity most directly affected by this rule amendment is the Division of TennCare, Tennessee Department of Finance & Administration.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

These rule amendments 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 adoption of these rule amendments is anticipated to produce a minimal decrease in state annual expenditures.

- (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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(615) 507-6852

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

GW10118067dkt

**RULES
OF
TENNESSEE DEPARTMENT OF FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE**

**CHAPTER 1200-13-14
TENNCARE STANDARD**

1200-13-14-.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]:

12. Opioid products for persons aged twenty-one (21) and older are restricted as follows:

(i) "Chronic opioid user" means:

(I) A TennCare enrollee whose TennCare paid claims data demonstrates that he has received at least a ninety (90) day quantity of prescribed opioids in the one hundred eighty (180) day period immediately preceding the opioid's prescription date.

(II) For a TennCare enrollee who has not been enrolled in TennCare long enough to demonstrate that he is a chronic opioid user as defined in Item (I), the enrollee may demonstrate that he has received at least a ninety (90) day quantity of prescribed opioids in the one hundred eighty (180) day period immediately preceding the opioid's prescription date by supplying paid claims data and medical records from his previous healthcare provider(s) or health insurer(s).

(ii) "Non-chronic opioid user" means a TennCare enrollee whose TennCare paid claims data demonstrates he has received less than a ninety (90) day quantity of prescribed opioids in the one hundred eighty (180) day period immediately preceding the opioid's prescription date.

(iii) Non-chronic opioid users shall be eligible to receive covered prescription opioid products as follows:

(I) A maximum of fifteen (15) dosage days in any six (6) month period; and

(II) Daily dosage shall not exceed sixty (60) morphine milligram equivalents (MME) per day.

- (iv) The restrictions in Subpart (iii) do not apply for enrollees with severe cancer pain undergoing active or palliative cancer treatment and enrollees in hospice and palliative care.
- (v) The following considerations apply for enrollees who experience more frequent or aggressive pain episodes due to these specific clinical disease states:
 - (I) Enrollees with Sickle Cell may receive up to forty-five (45) days of sixty (60) MME per day in any ninety (90) day period; and
 - (II) Severe burn victims may receive up to forty-five (45) days of sixty (60) MME per day in any ninety (90) day period.
- (vi) Notwithstanding the restrictions in Subpart (iii), enrollees residing in a Medicaid-certified Nursing Facility may receive up to forty-five (45) days of sixty (60) MME per day in any ninety (90) day period.

1200-13-14-.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 or ECF CHOICES programs 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:
 - (x) Opioid products are restricted as set out in Rule .04(1)(c)12.

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