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Sequence Number: 01-08-19
Rule ID(s): 8048
File Date: 1/3/19
Effective Date: 4/3/19

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):
X 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 Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below.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

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 https://sos.tn.gov/products/division-publications/rulemaking-guidelines.

Part 12 of Subparagraph (c) of Paragraph (1) of Rule 1200-13-14-.04 Covered Services is amended by adding Subparts (vii) and (viii) which shall read as follows:

(vii) Opioid prescriptions are subject to prior authorization following the first fill of a new opioid prescription.

(viii) For women of child-bearing age (between the ages of fifteen (15) and forty-four (44)) and ability, when prior authorization is required for an opioid prescription, the prescribing provider must submit information to the enrollee's PBM regarding the enrollee's pregnancy status and use of contraception or family planning methods, and the provision of counseling regarding the risks of becoming pregnant while receiving opioid medication. The information regarding pregnancy status and contraceptive use may, when appropriate, be based on self-reporting by the patient.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-109 and 71-5-197

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 12/05/2018 (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: 9/12/18

Rulemaking Hearing(s) Conducted on: (add more dates). 11/14/18

Date: 12/5/18

Signature: Wendy Long MD

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

Title of Officer: Division of TennCare
Tennessee Department of Finance and Administration

MICHELLE NEISLER
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
MY COMMISSION EXPIRES 3-8-2021

Subscribed and sworn to before me on: December 5. 2018

Notary Public Signature: Michelle Neisler

My commission expires on: March 8, 2021

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
Attorney General and Reporter

12/28/2018
Date

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Filed with the Department of State on: 1/3/19

Effective on: 4/3/19

Tre Hargett
Secretary of State

Public Hearing Comments

There were no comments on this rule.

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 rule is 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 rule is 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;

This rule is being amended to comply with T. C. A. § 71-5-197(f)(1) & (2) (PC 864, Acts 2018) passed by the General Assembly, which requires TennCare to promulgate rules related to prior authorization for opioid prescriptions, as well as certain opioid requirements for women of child-bearing age.

(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 rule is lawfully adopted by the Division of TennCare in accordance with T.C.A. §§ 4-5-202, 71-5-105, 71-5-109 and 71-5-197.

(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 this rule are TennCare enrollees, providers and the managed care contractors. The governmental entity most directly affected by this rule 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;

The rule was 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 this rule is not anticipated to have an impact 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;

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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Nashville, TN 37243
(615) 507-6852
donna.tidwell@tn.gov

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

GW10118288

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

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.

(vii) Opioid prescriptions are subject to prior authorization following the first fill of a new opioid prescription.

(viii) For women of child-bearing age (between the ages of fifteen (15) and forty-four (44)) and ability, when prior authorization is required for an opioid prescription, the prescribing provider must submit information to the enrollee's PBM regarding the enrollee's pregnancy status and use of contraception or family planning methods, and the provision of counseling regarding the risks of becoming pregnant while receiving opioid medication. The information regarding pregnancy status and contraceptive use may, when appropriate, be based on self-reporting by the patient.