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Sequence Number: 01-16-18
Rule ID(s): 6682
File Date: 01/16/18
Last Effective Day: 07/15/18

Emergency Rule Filing Form

Emergency rules are effective from date of filing, unless otherwise stated in the rule, for a period of up to 180 days.

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

X Amendments
___ New
___ Repeal

Statement of Necessity:

On October 26, 2017, President Donald Trump issued a memorandum asking the Secretary of Health and Human Services to consider declaring that the opioid crisis constitutes a Public Health Emergency, which Acting Health and Human Services Secretary Eric D. Hargan did by issuing a determination that a Public Health Emergency exists. The U.S. Department of Health and Human Services has declared that opioid abuse is a serious public health issue, with drug overdose deaths being the leading cause of injury death in the United States. The Tennessee Legislature, Attorney General, and members of the Executive Branch have stated that prescription opioid use in Tennessee is a crisis and an epidemic. This emergency rule amendment places limitations on the coverage of opioid medications by the Division of TennCare. These limitations are evidence based and utilize medical necessity criteria.

T.C.A. § 4-5-208 permits an agency to adopt an emergency rule when the agency finds an immediate danger to the public health, safety or welfare exists, and the nature of this danger is such that the use of any other form of rulemaking authorized by Title 4, Chapter 5 would not adequately protect the public.

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 Division of TennCare by mail at 310 Great Circle Road, Nashville, Tennessee 37243 or by telephone at (615) 507-6446.

Wendy Long M.D.
Wendy Long, M.D.
Director, Division 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 Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below.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 21 and older are restricted as follows:

    (i) For non-chronic opioid users (i.e., enrollees who have used prescription opioids fewer than 90 days in the preceding 180-day period):

        (I) Coverage will be provided for a maximum of 15 days in any 6-month period; and

        (II) Daily dosage shall not exceed 40 morphine milligram equivalents per day (MME per day).

        (III) For enrollees with severe cancer pain undergoing active or palliative treatment and enrollees in hospice and palliative care, the restrictions in items (I) and (II) do not apply.

        (IV) For certain enrollees who experience more frequent or aggressive pain episodes due to certain clinical disease states, the following considerations apply:

            I. Enrollees with Sickle Cell may receive up to 45 days of 40 MME per day in any 90-day period; and

            II. Severe burn victims may receive up to 45 days of 40 MME per day in any 90-day period.

Statutory Authority: T.C.A. §§ 4-5-208, 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 follows:

    (I) For non-chronic opioid users (i.e., enrollees who have used prescription opioids fewer than 90 days in the preceding 180-day period):

        I. Coverage will be provided for a maximum of 15 days in any 6-month period; and,

        II. Daily dosage shall not exceed 40 morphine milligram equivalents per day (MME per day).

        III. For enrollees with severe cancer pain undergoing active or palliative treatment and enrollees in hospice and palliative care, the restrictions in subitems I. and II. do not apply.

IV. For certain enrollees who experience more frequent or aggressive pain episodes due to certain clinical disease states, the following considerations apply:

A. Enrollees with Sickle Cell may receive up to 45 days of 40 MME per day in any 90-day period; and

B. Severe burn victims may receive up to 45 days of 40 MME per day in any 90-day period.

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: 11/15/17

Signature: Wendy Long MD

Name of Officer: Wendy Long, M.D

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

ROBIN A PAGE
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF DAVIDSON

Subscribed and sworn to before me on: 11/15/17

Notary Public Signature: Robin A Page

My commission expires on: 11/3/2020

Agency/Board/Commission: Division of TennCare

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

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. Slatery III
Herbert H. Slatery III
Attorney General and Reporter

12/15/2017
Date

Department of State Use Only

Filed with the Department of State on: 01/16/18

Effective for: 180 *days

Effective through: 07/15/18

** 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://publications.tnsosfiles.com/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 emergency 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 emergency rule amendments continue to permit medically necessary use of prescription opioids for persons age 21 and older, but impose doseage 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 emergency rule amendments 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 emergency rule amendments are TennCare enrollees, providers, and managed care contractors. The governmental entity most directly affected by these emergency rule amendments is the Division 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 or the necessity to promulgate the rule;

These emergency 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

310 Great Circle Road

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

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

GW10217297

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 21 and older are restricted as follows:

(i) For non-chronic opioid users (i.e., enrollees who have used prescription opioids fewer than 90 days in the preceding 180-day period):

(I) Coverage will be provided for a maximum of 15 days in any 6-month period; and

(II) Daily dosage shall not exceed 40 morphine milligram equivalents per day (MME per day).

(III) For enrollees with severe cancer pain undergoing active or palliative treatment and enrollees in hospice and palliative care, the restrictions in items (I) and (II) do not apply.

(IV) For certain enrollees who experience more frequent or aggressive pain episodes due to certain clinical disease states, the following considerations apply:

I. Enrollees with Sickle Cell may receive up to 45 days of 40 MME per day in any 90-day period; and

II. Severe burn victims may receive up to 45 days of 40 MME per day in any 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 follows:

(I) For non-chronic opioid users (i.e., enrollees who have used prescription opioids fewer than 90 days in the preceding 180-day period):

I. Coverage will be provided for a maximum of 15 days in any 6-month period; and,

II. Daily dosage shall not exceed 40 morphine milligram equivalents per day (MME per day).

III. For enrollees with severe cancer pain undergoing active or palliative treatment and enrollees in hospice and palliative care, the restrictions in subitems I. and II. do not apply.

IV. For certain enrollees who experience more frequent or aggressive pain episodes due to certain clinical disease states, the following considerations apply:

A. Enrollees with Sickle Cell may receive up to 45 days of 40 MME per day in any 90-day period; and

B. Severe burn victims may receive up to 45 days of 40 MME per day in any 90-day period.