

Department of State  
Division of Publications  
312 Rosa L. Parks, 8th Floor Snodgrass/TN Tower  
Nashville, TN 37243  
Phone: 615-741-2650  
Fax: 615-741-5133  
Email: [register.information@tn.gov](mailto:register.information@tn.gov)

For Department of State Use Only

Sequence Number: 08-02-01  
Rule ID(s): 4969  
File Date (effective date): 08/02/2011  
End Effective Date: 01/29/2012

## Emergency Rule Filing Form

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

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

**Rule Type:**

Emergency Rule

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

Amendment

New

Repeal

**Statement of Necessity:**

Pursuant to T.C.A. § 4-5-208, the Bureau of TennCare is authorized to adopt emergency rules in the event that the agency 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.

The Appropriations Act, Public Chapter 473, effective July 1, 2011, requires the Bureau of TennCare to reduce expenditures for certain sedative hypnotic and opioid detoxification drugs through imposition of quantity and dosage limitations.

I have made the finding that the attached amendment is required by the above-referenced enactment of the general assembly, and the timely implementation of this amendment as mandated precludes promulgation through ordinary rulemaking procedures.

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

**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)

Chapter Number	Chapter Title
1200-13-13	TennCare Medicaid
Rule Number	Rule Title
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 is amended at Paragraph (1) Benefits covered under the managed care program, Subparagraph (c) Pharmacy, by inserting the number 9 before the existing unnumbered language following Part 8 so that the unnumbered language is numbered as Part 9, and by adding a new Part 10, so that as amended Parts 9 and 10 read as follows:

9. TennCare shall not cover drugs considered by the FDA to be Less Than Effective (LTE) and DESI drugs, or drugs considered to be Identical, Related and Similar (IRS) to DESI and LTE drugs or any other pharmacy services for which federal financial participation (FFP) is not available. The exclusion of drugs for which no FFP is available extends to all TennCare enrollees regardless of the enrollee's age. TennCare shall not cover experimental or investigational drugs which have not received final approval from the FDA.
10. Buprenorphine and burprenorphine/naloxone products and sedative hypnotics for persons aged 21 and older are restricted to the quantity limits specified below:
  - (i) Generic buprenorphine, Subutex (buprenorphine), and Suboxone (buprenorphine/naloxone) products shall not exceed sixteen milligrams (16 mg) per day for a period of up to six (6) months from the initiation of therapy, after which the covered dosage amount shall not exceed eight milligrams (8 mg) per day.
  - (ii) Sedative hypnotic medications shall not exceed fourteen (14) pills per month for sedative hypnotic formulations in pill form such as Ambien and Lunesta, one hundred forty milliliters (140 ml) per month of chloral hydrate, and one (1) bottle every sixty (60) days of Zoipimist.

Statutory Authority: T.C.A. §§ 4-5-208, 71-5-105, 71-5-109 and Public Chapter 473, Acts of 2011.

Part 20. of Subparagraph (a) of Paragraph (3) of Rule 1200-13-13-.10 Exclusions is amended by adding new Subparts (ix) and (x), so as amended, Part 20. shall read as follows:

20. Certain pharmacy items as follows:
  - (i) Agents when used for anorexia or weight loss
  - (ii) Agents when used to promote fertility
  - (iii) Agents when used for cosmetic purposes or hair growth
  - (iv) Agents when used for the symptomatic relief of cough and colds
  - (v) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee

- (vi) Nonprescription drugs
- (vii) Barbiturates
- (viii) Benzodiazepines
- (ix) Generic buprenorphine, Subutex (buprenorphine), and Suboxone (buprenorphine/naloxone) in dosage amounts that exceed the covered dosage amounts listed below:
  - (I) Sixteen milligrams (16 mg) per day for a period of up to six (6) months from the initiation of therapy; or
  - (II) Eight milligrams (8 mg) per day after the sixth (6<sup>th</sup>) month of therapy.
- (x) Sedative hypnotic medications in dosage amounts that exceed the dosage amounts listed below:
  - (I) Fourteen (14) pills per month for sedative hypnotic formulations in pill form such as Ambien and Lunesta;
  - (II) One hundred forty milliliters (140 ml) per month of chloral hydrate; and
  - (III) One (1) bottle every sixty (60) days of Zolpimist.

Statutory Authority: T.C.A. §§ 4-5-208, 71-5-105, 71-5-109 and Public Chapter 473, Acts of 2011.

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



Date: 7/28/2011

Signature: [Handwritten Signature]

Name of Officer: Darin J. Gordon

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

Subscribed and sworn to before me on: 7/28/11

Notary Public Signature: [Handwritten Signature: Cheryl D. Kline]

My commission expires on: 9/31/2012

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.

[Handwritten Signature]

Robert E. Cooper, Jr.  
Attorney General and Reporter

8-2-11

Date

Department of State Use Only

Filed with the Department of State on: 8/2/11

Effective for: 180 \*days

Effective through: 1/29/12

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

[Handwritten Signature]

Tre Hargett  
Secretary of State

RECEIVED  
2011 AUG -2 PM 4: 12  
SECRETARY OF STATE  
PUBLICATIONS

### **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)

There is no projected 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 Rule is necessary to reduce expenditures for certain sedative hypnotic and opioid detoxification drugs through imposition of quantity and dosage limitations.

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

This 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 the TennCare Medicaid and TennCare Standard Rules is projected to decrease state annual expenditures by \$1,721,500.

- (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

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

--

GW10111203

**Department of State  
Division of Publications**

312 Rosa L. Parks, 8th Floor Snodgrass/TN Tower  
Nashville, TN 37243  
Phone: 615-741-2650  
Fax: 615-741-5133  
Email: [register.information@tn.gov](mailto:register.information@tn.gov)

**For Department of State Use Only**

Sequence Number: \_\_\_\_\_  
Rule ID(s): \_\_\_\_\_  
File Date (effective date): \_\_\_\_\_  
End Effective Date: \_\_\_\_\_

# 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>	310 Great Circle Road Nashville, Tennessee
<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):**

Amendment

New

Repeal

**Statement of Necessity:**

Pursuant to T.C.A. § 4-5-208, the Bureau of TennCare is authorized to adopt emergency rules in the event that the agency 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.

The Appropriations Act, Public Chapter 473, effective July 1, 2011, requires the Bureau of TennCare to reduce expenditures for certain sedative hypnotic and opioid detoxification drugs through imposition of quantity and dosage limitations.

I have made the finding that the attached amendment is required by the above-referenced enactment of the general assembly, and the timely implementation of this amendment as mandated precludes promulgation through ordinary rulemaking procedures.

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



**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)

Chapter Number	Chapter Title
1200-13-13	TennCare Medicaid
Rule Number	Rule Title
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 is amended at Paragraph (1) Benefits covered under the managed care program, Subparagraph (c) Pharmacy, by inserting the number 9 before the existing unnumbered language following Part 8 so that the unnumbered language is numbered as Part 9, and by adding a new Part 10, so that as amended Parts 9 and 10 read as follows:

9. TennCare shall not cover drugs considered by the FDA to be Less Than Effective (LTE) and DESI drugs, or drugs considered to be Identical, Related and Similar (IRS) to DESI and LTE drugs or any other pharmacy services for which federal financial participation (FFP) is not available. The exclusion of drugs for which no FFP is available extends to all TennCare enrollees regardless of the enrollee's age. TennCare shall not cover experimental or investigational drugs which have not received final approval from the FDA.
10. Buprenorphine and buprenorphine/naloxone products and sedative hypnotics for persons aged 21 and older are restricted to the quantity limits specified below:
- (i) Generic buprenorphine, Subutex (buprenorphine), and Suboxone (buprenorphine/naloxone) products shall not exceed sixteen milligrams (16 mg) per day for a period of up to six (6) months from the initiation of therapy, after which the covered dosage amount shall not exceed eight milligrams (8 mg) per day.
  - (ii) Sedative hypnotic medications shall not exceed fourteen (14) pills per month for sedative hypnotic formulations in pill form such as Ambien and Lunesta, one hundred forty milliliters (140 ml) per month of chloral hydrate, and one (1) bottle every sixty (60) days of Zolpimist.

Statutory Authority: T.C.A. §§ 4-5-208, 71-5-105, 71-5-109 and Public Chapter 473, Acts of 2011.

Part 20. of Subparagraph (a) of Paragraph (3) of Rule 1200-13-13-.10 Exclusions is amended by adding new Subparts (ix) and (x), so as amended, Part 20. shall read as follows:

20. Certain pharmacy items as follows:
- (i) Agents when used for anorexia or weight loss
  - (ii) Agents when used to promote fertility
  - (iii) Agents when used for cosmetic purposes or hair growth
  - (iv) Agents when used for the symptomatic relief of cough and colds
  - (v) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee

- (vi) Nonprescription drugs
- (vii) Barbiturates
- (viii) Benzodiazepines
- (ix) Generic buprenorphine, Subutex (buprenorphine), and Suboxone (buprenorphine/naloxone) in dosage amounts that exceed the covered dosage amounts listed below:
  - (I) Sixteen milligrams (16 mg) per day for a period of up to six (6) months from the initiation of therapy; or
  - (II) Eight milligrams (8 mg) per day after the sixth (6<sup>th</sup>) month of therapy.
- (x) Sedative hypnotic medications in dosage amounts that exceed the dosage amounts listed below:
  - (I) Fourteen (14) pills per month for sedative hypnotic formulations in pill form such as Ambien and Lunesta;
  - (II) One hundred forty milliliters (140 ml) per month of chloral hydrate; and
  - (III) One (1) bottle every sixty (60) days of Zolpimist.

Statutory Authority: T.C.A. §§ 4-5-208, 71-5-105, 71-5-109 and Public Chapter 473, Acts of 2011.

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

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 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.

\_\_\_\_\_  
Robert E. Cooper, Jr.  
Attorney General and Reporter

\_\_\_\_\_  
Date

**Department of State Use Only**

Filed with the Department of State on: \_\_\_\_\_

Effective for: \_\_\_\_\_ \*days

Effective through: \_\_\_\_\_

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

\_\_\_\_\_  
Tre Hargett  
Secretary of State

### **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)

There is no projected 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 Rule is necessary to reduce expenditures for certain sedative hypnotic and opioid detoxification drugs through imposition of quantity and dosage limitations.

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

This 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 the TennCare Medicaid and TennCare Standard Rules is projected to decrease state annual expenditures by \$1,721,500.

- (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

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

--

GW10111203