Department of State Division of Publications

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For Department of State Use Only

Sequence Number: 08-07-13

Rule ID(s): <u>5513</u>

File Date: 87113 Effective Date: 11513

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

Agency/Board/Commission:	Tennessee Department of Finance and Administration
Division:	Bureau of TennCare
Contact Person:	George Woods
Address:	310 Great Circle Road
Zip:	37243
Phone:	(615) 507-6446
Email:	george.woods@tn.gov

Revision Type (check all that apply):

X Amendment

New

Repeal

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/Rule Title per row)

Chapter Number	Chapter Title
1200-13-13	TennCare Medicaid
Rule Number	Rule Title
1200-13-1304	Covered Services

(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)

Part 25. "Pharmacy Services" of Subparagraph (b) of Paragraph (1) of Rule 1200-13-13-.04 Covered Services is amended by deleting the information contained in the third column headed "Benefit for Persons Aged 21 and Older" in its entirety and replacing it with new information so as amended Part 25. shall read as follows:

SERVICE	BENEFIT FOR PERSONS UNDER AGE 21	BENEFIT FOR PERSONS AGED 21 AND OLDER
25. Pharmacy Services [defined at 42 CFR §440.120(a) and obtained directly from an ambulatory retail pharmacy setting, outpatient hospital pharmacy, mail order pharmacy, or those administered to a long-term care facility (nursing facility) resident].	Covered as medically necessary. Certain drugs (known as DESI, LTE, IRS drugs) are excluded from coverage. Persons dually eligible for Medicaid and Medicare will receive their pharmacy services through Medicare Part D. Pharmacy services are the responsibility of the PBM, except for pharmaceuticals supplied and administered in a doctor's office. For persons who are not dually eligible for Medicare and Medicaid, pharmaceuticals supplied and administered in a doctor's office are the responsibility of the MCO. For persons who are dually eligible for Medicare and Medicaid, pharmaceuticals supplied and administered in a doctor's office are the responsibility of the MCO if not covered by Medicare.	(A) Covered as medically necessary, subject to the limitations set out below. Certain drugs (known as DESI, LTE, IRS drugs) are excluded from coverage. Persons dually eligible for Medicaid and Medicare will receive their pharmacy services through Medicare Part D. (B) Pharmacy services are the responsibility of the PBM, except for pharmaceuticals supplied and administered in a doctor's office. For persons who are not dually eligible for Medicare and Medicaid, pharmaceuticals supplied and administered in a doctor's office are the responsibility of the MCO. For persons who are dually eligible for Medicare and Medicaid, pharmaceuticals supplied and administered in a doctor's office are not covered by TennCare. (C) Pharmacy services with no quantity limits on the number of prescriptions per month for the following non-Medicare enrollees only: individuals enrolled in CHOICES 1 or CHOICES 2; PACE enrollees; and persons receiving TennCare-reimbursed services in an Intermediate Care Facility for Individuals with Intellectual Disabilities or a Home and Community Based Services Waiver for Individuals with Intellectual Disabilities. (D) For hospice patients, drugs used for the relief of pain and symptom control related to their terminal illness are covered as part of the hospice benefit. If the patient is not a Medicare beneficiary, pharmacy services needed for conditions unrelated to the terminal illness are covered by TennCare. There are no quantity limits on the number of prescriptions per month covered by TennCare if the bospice

covered by TennCare if the hospice

- patient is receiving TennCarereimbursed room and board in a Nursing Facility. If the patient is receiving hospice services at home or in a residential hospice, coverage of pharmacy services is as described in sections (C) and (E).
- (E) Subject to (C) and (D) above, pharmacy services for Medicaid adults age 21 and older are limited to five (5) prescriptions and/or refills per enrollee per month, of which no more than two (2) of the five (5) can be brand name drugs. Additional drugs for individuals in (E) shall not be covered.
- (F) Prescriptions shall be counted beginning on the first day of each calendar month. Each prescription and/or refill counts as one (1). A prescription or refill can be for no more than a thirty-one (31) day supply.
- (G) The Bureau of TennCare shall maintain an Automatic Exception List of medications which shall not count against such limit. The Bureau of TennCare may modify the Automatic Exception List at its discretion. The most current version of the Automatic Exception List will be made available to enrollees via the internet from the TennCare website and upon request by mail through the DHS Family Assistance Service Center. Only medications that are specified on the current version of the Automatic Exception List that is available on the TennCare website located on the World Wide Web at www.tn.gov/tenncare on the date of service shall be considered exempt from applicable prescription limits.
- (H) The Bureau of TennCare shall also maintain a Prescriber
 Attestation List of medications available when the prescriber attests to an urgent need. The State may include certain drugs or categories of drugs on the list, and may maintain, and make available to physicians, providers, pharmacists, and the public, a list that shall indicate the drugs or types of drugs the State has determined to so include. The Prescriber

Attestation List drugs may be approved for enrollees who have already met an applicable benefit limit only if the prescribing professional seeks and obtains a Special exemption. In order to obtain a special exemption, the prescribing provider must submit an attestation as directed by TennCare regarding the urgent need for the drug. TennCare will approve the prescribing provider's determination that the criteria for the special exemption are met, without further review, within 24 hours of receipt. Enrollees will not be entitled to a hearing regarding their eligibility for a special exemption if (i) the prescribing provider has not submitted the required attestation. or (ii) the requested drug is not on the Prescriber Attestation List.

- (I) Pharmacy services in excess of five (5) prescriptions and/or refills per enrollee per month, of which no more than two (2) are brand name drugs, are non-covered services, unless (a) each excess drug is specified on the current version of the Prescriber Attestation List and a completed Prescriber Attestation is on file for each listed drug as of the date of the pharmacy service, or (b) the excess drug is specified on the Automatic Exception List of medications which shall not count against such limit.
- (J) Over-the-counter (OTC) drugs for TennCare adults are not covered even if the enrollee has a prescription for such service, unless the drug is listed on the "Covered OTC Drug List" that is available on the TennCare website located at www.tn.gov/tenncare on the date of service.

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

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

There were no public 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 as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

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://state.tn.us/sos/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:

The rule is being promulgated to clarify who gets what pharmacy coverage.

(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 §§ 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, organizations, corporations or governmental entities most directly affected by this Rule are the enrollees, providers, and 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 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 effect 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 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 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

(1)	Any additiona	il information re	levant to the rul	le proposed for co	ontinuation that the	ne committee req	uests.	
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GW10113140

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Rule Number	Rule Title
1200-13-1304	Covered Services

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SERVICE	BENEFIT FOR PERSONS UNDER	BENEFIT FOR PERSONS AGED
	AGE 21	21 AND OLDER
25. Pharmacy Services [defined at 42 CFR §440.120(a) and obtained directly from an ambulatory retail pharmacy setting, outpatient hospital pharmacy, mail order pharmacy, or those administered to a long-term care facility (nursing facility) resident].	Covered as medically necessary. Certain drugs (known as DESI, LTE, IRS drugs) are excluded from coverage. Persons dually eligible for Medicaid and Medicare will receive their pharmacy services through Medicare Part D. Pharmacy services are the responsibility of the PBM, except for pharmaceuticals supplied and administered in a doctor's office. For persons who are not dually eligible for Medicare and Medicaid, pharmaceuticals supplied and administered in a doctor's office are the responsibility of the MCO. For persons who are dually eligible for Medicare and Medicaid, pharmaceuticals supplied and administered in a doctor's office are the responsibility of the MCO if not covered by Medicare.	(A) Covered as medically necessary, subject to the limitations set out below. Certain drugs (known as DESI, LTE, IRS drugs) are excluded from coverage. Persons dually eligible for Medicaid and Medicare will receive their pharmacy services through Medicare Part D. (B) Pharmacy services are the responsibility of the PBM, except for pharmaceuticals supplied and administered in a doctor's office. For persons who are not dually eligible for Medicare and Medicaid, pharmaceuticals supplied and administered in a doctor's office are the responsibility of the MCO. For persons who are dually eligible for Medicare and Medicaid, pharmaceuticals supplied and administered in a doctor's office are not covered by TennCare. (A) Pharmacy services for individuals receiving TennCare-reimbursed services in a Nursing Facility, an Intermediate Care Facility for the Mentally Retarded), the CHOICES program, or a Home and Community Based Services Waiver have no quantity limits on the number of prescriptions per month for the following non-Medicare enrollees only: individuals enrolled in CHOICES 1 or CHOICES 2: PACE enrollees: and persons receiving TennCare-reimbursed services in an Intermediate Care Facility for Individuals with Intellectual Disabilities or a Home and Community Based Services Waiver for Individuals with

Intellectual Disabilities.

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(E)(B) Subject to (C) and (D) (A) above, pharmacy services for Medicaid adults age 21 and older are limited to five (5) prescriptions and/or refills per enrollee per month, of which no more than two (2) of the five (5) can be brand name drugs. Additional drugs for individuals in (E) (B) shall not be covered.

- (<u>F</u>) Prescriptions shall be counted beginning on the first day of each calendar month. Each prescription and/or refill counts as one (1). A prescription or refill can be for no more than a thirty-one (31) day supply.
- (G) The Bureau of TennCare shall maintain an Automatic Exception List of medications which shall not count against such limit. The Bureau of TennCare may modify the Automatic Exception List at its discretion. The most current version of the Automatic Exception List will be made available to enrollees via the internet from the TennCare website and upon request by mail through the DHS Family Assistance Service Center. Only medications that are specified on the current version of the Automatic Exception List that is available on the TennCare website located on the World Wide Web at www.tn.gov/tenncare on the date of service shall be considered exempt from applicable prescription limits.

- (H) The Bureau of TennCare shall also maintain a Prescriber Attestation List of medications available when the prescriber attests to an urgent need. The State may include certain drugs or categories of drugs on the list, and may maintain, and make available to physicians, providers, pharmacists, and the public, a list that shall indicate the drugs or types of drugs the State has determined to so include. The Prescriber Attestation List drugs may be approved for enrollees who have already met an applicable benefit limit only if the prescribing professional seeks and obtains a Special exemption. In order to obtain a special exemption, the prescribing provider must submit an attestation as directed by TennCare regarding the urgent need for the drug. TennCare will approve the prescribing provider's determination that the criteria for the special exemption are met, without further review, within 24 hours of receipt. Enrollees will not be entitled to a hearing regarding their eligibility for a special exemption if (i) the prescribing provider has not submitted the required attestation. or (ii) the requested drug is not on the Prescriber Attestation List.
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	service.

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 by the <u>Tennessee Department of Finance and</u>	Administration (bo	pard/commission/ other authority) on
(mm/dd/yyyy), and is in complianc	e with the provisions	of 1.C.A. § 4-5-222.
I further certify the following:		•
Notice of Rulemaking Hearing filed with the Departme	ent of State on:	04/09/13
Rulemaking Hearing(s) Conducted on: (add more date	es). <u>05/30/13</u>	
Date:		
Signature:	and the state of t	
Name of Officer:	Darin J. Gordon	
Title of Officer:	Director, Bureau of Tennessee Departr	TennCare nent of Finance and Administration
Subscribed and sworn to befo	ore me on:	
Notary Public	Signature:	
My commission e	expires on:	
All rulemaking hearing rules provided for herein have State of Tennessee and are approved as to legality 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 Depar	tment of State on:	
	Effective on:	
•		
		Tre Hargett Secretary of State

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

There were no public 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 as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

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://state.tn.us/sos/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;

The rule is being promulgated to clarify who gets what pharmacy coverage.

(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 §§ 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, organizations, corporations or governmental entities most directly affected by this Rule are the enrollees, providers, and 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 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 effect 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 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 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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(1)	Any additional information relevant to the rule proposed for continuation that the committee requests.
GW	10113140