

Table of Contents

State/Territory Name: Tennessee

State Plan Amendment (SPA) #: 11-010A

This file contains the following documents in the order listed:

- 1) RO Follow-Up Approval Letter
- 2) Pharmacy Approval Letter
- 3) CMS 179 Form
- 4) Approved SPA Pages

Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth St., Suite 4T20
Atlanta, Georgia 30303-8909



March 21, 2012

Darin Gordon, Director
Bureau of TennCare
Department of Finance and Administration
310 Great Circle Road
Nashville, TN 37243

Re: Tennessee Title XIX State Plan Amendment, Transmittal #11-010A

Attention: Mr. Georgia Woods

Dear Mr. Gordon:

This is to affirm approval of the above referenced State Plan Amendment which was submitted to the Regional Office on August 31, 2011. The State's requested effective date of July 1, 2011 has been accepted.

Enclosed for your records are:

1. a copy of the approval letter dated March 19, 2012 that was submitted to the State by Larry Reed, Director, Division of Pharmacy;
2. the original signed 179; and
3. the approved plan pages.

If you have any additional questions regarding this amendment, please contact Kenni Howard, State Coordinator for Tennessee, at 404-562-7413.

Sincerely,

//s//

Jackie Glaze
Associate Regional Administrator
Division of Medicaid & Children's Health Operations

Enclosure(s)

Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850



Center for Medicaid and CHIP Services
Disabled and Elderly Health Programs Group

March 19, 2012

Mr. Darin J. Gordon
Director
Tennessee Department of Finance and Administration
Bureau of TennCare
310 Great Circle Road
Nashville, Tennessee 37243

Attention: Mr. George Woods

Dear Mr. Gordon:

We have reviewed the Tennessee State Plan Amendment (SPA) 11-010A received in the Atlanta Regional Office on August 31, 2011. Under this SPA, the State proposes to limit coverage for certain sedative hypnotic and opioid detoxification drugs for beneficiaries aged twenty-one years and older.

We are pleased to inform you that the Tennessee SPA 11-010A is approved, effective July 1, 2011. The Atlanta Regional Office will forward to you a copy of the CMS-179 form, as well as the pages approved for incorporation into the Tennessee Medicaid State Plan. If you have any questions regarding this amendment, please contact Bernadette Leeds at (410) 786-9463.

Sincerely,

/s/

Larry Reed
Director
Division of Pharmacy

cc: Jackie Glaze, ARA, Atlanta Regional Office
Kenni Howard, Atlanta Regional Office
Susie Baird, Bureau of TennCare

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER: 11-010	2. STATE TENNESSEE
3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
4. PROPOSED EFFECTIVE DATE July 1, 2011	

TO: REGIONAL ADMINISTRATOR
CENTERS FOR MEDICARE & NEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

5. TYPE OF PLAN MATERIAL (Check One):

NEW STATE PLAN AMENDMENT TO BE CONSIDERED AS NEW PLAN AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)

6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR 440 and 441	7. FEDERAL BUDGET IMPACT: a. FFY 2011 \$872,100 b. FFY 2012 \$3,488,400
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1.A.1, pages 25, 26 and unnumbered sixth page of the Attachment that begin with item (12) The member is entitled to an emergency supply...; Attachment 3.1.B.1, pages 25, 26 and unnumbered sixth page of the Attachment that begin with item (12) The member is entitled to an emergency supply...	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Attachment 3.1.A.1, pages 25, 26 and unnumbered sixth page of the Attachment that begin with item (12) The member is entitled to an emergency supply...; Attachment 3.1.B.1, pages 25, 26 and unnumbered sixth page of the Attachment that begin with item (12) The member is entitled to an emergency supply...

10. SUBJECT OF AMENDMENT:
Limitation on Amount Duration and Scope of Medical Care and Services Provided – Prescribed Drugs – Limits on TennCare Coverage for Certain Sedative Hypnotic and Opioid Detoxification Drugs for Adults; Smoking Cessation Products No Longer Excluded for Adults.

11. GOVERNOR'S REVIEW (Check One):
 GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED:
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SIGNATURE OF STATE AGENCY OFFICIAL: //s//	16. RETURN TO: Tennessee Department of Finance and Administration Bureau of TennCare 310 Great Circle Road Nashville, Tennessee 37243 Attention: George Woods
13. TYPED NAME: Darin J. Gordon	
14. TITLE: Director, Bureau of TennCare	
15. DATE SUBMITTED: 08/31/11	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 08/31/11	18. DATE APPROVED: 03/19/12
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: 07/01/11	20. SIGNATURE OF REGIONAL OFFICIAL: //s//
21. TYPED NAME: Jackie Glaze	22. TITLE: Associate Regional Administrator Division of Medicaid & Children Health Opns
23. REMARKS:	

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

LIMITATION ON AMOUNT DURATION AND SCOPE OF MEDICAL
CARE AND SERVICES PROVIDED

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

12.a. Prescribed drugs

(1) Prescription outpatient drugs of any manufacturer which has entered into and complies with an agreement under Section 1927(a) of the Social Security Act will be a covered benefit for all TennCare members when prescribed by an authorized licensed prescriber, unless coverage is excluded or otherwise restricted by TennCare in accordance with the following:

(a) TennCare will not cover any drugs that are permitted to be excluded or restricted under the Social Security Act, Section 1927(d)(2), except agents when used to promote smoking cessation. Effective January 1, 2006, the Medicaid agency will not cover any Medicare Part D drug for full benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

(b) Coverage of prescription drugs will be limited to five (5) prescriptions per month, pursuant to which at least three (3) out of any five (5) prescriptions or refills in the same month must be generic and no more than two (2) prescriptions or refills in the same month may be for brand name (branded) products. Any branded prescriptions are subject to a requirement of prior authorization by the TennCare Bureau as a condition of coverage, and the State shall designate the covered outpatient drugs to which a prior authorization requirement applies. The monthly coverage limitation shall not apply to (1) medications included on a list to be maintained by the State in accordance with the State's

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

LIMITATION ON AMOUNT DURATION AND SCOPE OF MEDICAL
CARE AND SERVICES PROVIDED

Uniform Administrative Procedure Act and (2) medications from the special exception list maintained by the State in accordance with the State Uniform Administrative Procedures Act for enrollees who have already met an applicable benefit limit if, and only if, the prescriber seeks and obtains a special exemption from the otherwise applicable benefit limit. This list of medications subject to exemptions shall also be maintained by the State in accordance with the State's Uniform Administrative Procedures Act. Pharmacies, providers and beneficiaries shall be made aware of these lists through appropriate notice. Individuals under the age of 21 who are receiving benefits under the EPSDT Program, as well as individuals 21 years of age or older who receive services in nursing facilities (NFs) or in intermediate care facilities for the mentally retarded (ICF/MRs), will not be subject to this benefit limit.

- (c) 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. For enrollees who are pregnant while receiving this dosage, the six-month period does not begin until the enrollee is no longer pregnant. At the end of either six-month period, 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, or one (1) bottle every sixty (60) days of Zolpimist.
- (2) No payment will be made for an innovator multiple source drug (brand name drug) if, under applicable State law, a less expensive multiple source drug could have been dispensed, but only to the extent that such amount exceeds the upper payment limit for such multiple source drug. In the event a prescriber indicates on the face of the prescription ("dispense as written") that he is requiring a specific brand name drug be dispensed for a specific TennCare member or if a TennCare member appeals coverage of a generic drug and the appeal process

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

LIMITATION ON AMOUNT DURATION AND SCOPE OF MEDICAL
CARE AND SERVICES PROVIDED

- (12) The member is entitled to an emergency supply of the prescribed drug provided that:
- (a) The manufacturer has a rebate agreement and the medication is not classified by the FDA or regarded by CMS to be less than effective (DESI, LTE or IRS drug); or
 - (b) The medication is not a drug in a non-covered TennCare therapeutic category or class of drugs or products such as: agents used for anorexia, weight loss or weight gain, agents used to promote fertility, agents not listed on the TennCare preferred drug list used for the symptomatic relief of cough and colds, agents used for cosmetic purposes or hair growth, agents not listed on the TennCare preferred drug list which are prescription vitamins and mineral products, agents not listed on the TennCare preferred drug list which are nonprescription (over-the-counter) products and drugs, agents not listed on the TennCare preferred drug list which are barbiturates or benzodiazepines. TennCare will exclude from coverage all of the allowable exclusions described above; or
 - (c) Use of the medication has not been determined to be medically contraindicated because of the member's medical condition or possible adverse drug interaction; or
 - (d) The prescriber did not prescribe a total quantity less than an emergency supply, in which case the pharmacist must provide a supply up to the amount prescribed.
- (13) There are some cases in which it is not feasible for the pharmacist to dispense an emergency supply because the drug is packaged by the manufacturer to be sold as the original unit or because the usual and customary pharmacy practice would be to dispense the drug in the original packaging (inhalers, eye drops, topicals, etc.). When coverage of an emergency supply of a prescription would otherwise be required and when, as described above, it is not feasible for the pharmacist to

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

LIMITATION ON AMOUNT DURATION AND SCOPE OF MEDICAL
CARE AND SERVICES PROVIDED

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

12.a. Prescribed drugs

(1) Prescription outpatient drugs of any manufacturer which has entered into and complies with an agreement under Section 1927(a) of the Social Security Act will be a covered benefit for all TennCare members when prescribed by an authorized licensed prescriber, unless coverage is excluded or otherwise restricted by TennCare in accordance with the following:

(a) TennCare will not cover any drugs that are permitted to be excluded or restricted under the Social Security Act, Section 1927(d)(2), except agents when used to promote smoking cessation. Effective January 1, 2006, the Medicaid agency will not cover any Medicare Part D drug for full benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

(b) Coverage of prescription drugs for Medically Needy beneficiaries will be limited to five (5) prescriptions per month, pursuant to which at least three (3) out of any five (5) prescriptions or refills in the same month must be generic and no more than two (2) prescriptions or refills in the same month may be for brand name (branded) products. Any branded prescriptions are subject to a requirement of prior authorization by the TennCare Bureau as a condition of coverage, and the State shall designate the covered out-patient drugs to which a prior authorization requirement applies. The monthly coverage limitation shall not apply to (1) medications included on a list to be maintained by the State in accordance with the State's Uniform Administrative Procedures Act and

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

LIMITATION ON AMOUNT DURATION AND SCOPE OF MEDICAL
CARE AND SERVICES PROVIDED

- (2) medications from the special exception list maintained by the State in accordance with the State Uniform Administrative Procedures Act for enrollees who have already met an applicable benefit limit if, and only if, the prescriber seeks and obtains a special exemption from the otherwise applicable benefit limit. This list of medications subject to exemptions shall also be maintained by the State in accordance with the State's Uniform Administrative Procedures Act. Pharmacies, providers and beneficiaries shall be made aware of these lists through appropriate notice. Individuals under the age of 21 who are receiving benefits under the EPSDT Program, as well as individuals 21 years of age or older who receive services in nursing facilities (NFs) or in intermediate care facilities for the mentally retarded (ICF/MRs), will not be subject to this benefit limit.
- (c) 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. For enrollees who are pregnant while receiving this dosage, the six-month period does not begin until the enrollee is no longer pregnant. At the end of either six-month period, 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, or one (1) bottle every sixty (60) days of Zolpimist.
- (2) No payment will be made for an innovator multiple source drug (brand name drug) if, under applicable State law, a less expensive multiple source drug could have been dispensed, but only to the extent that such amount exceeds the upper payment limit for such multiple source drug. In the event a prescriber indicates on the face of the prescription ("dispense as written") that he is requiring a specific brand name drug be dispensed for a specific TennCare member or if a TennCare member appeals coverage of a generic drug and the appeal process

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

LIMITATION ON AMOUNT DURATION AND SCOPE OF MEDICAL
CARE AND SERVICES PROVIDED

- (12) The member is entitled to an emergency supply of the prescribed drug provided that:
- (a) The manufacturer has a rebate agreement and the medication is not classified by the FDA or regarded by CMS to be less than effective (DESI, LTE or IRS drug); or
 - (b) The medication is not a drug in a non-covered TennCare therapeutic category or class of drugs or products such as: agents used for anorexia, weight loss or weight gain, agents used to promote fertility, agents not listed on the TennCare preferred drug list used for the symptomatic relief of cough and colds, agents used for cosmetic purposes or hair growth, agents not listed on the TennCare preferred drug list which are prescription vitamins and mineral products, agents not listed on the TennCare preferred drug list which are nonprescription (over-the-counter) products and drugs, agents not listed on the TennCare preferred drug list which are barbiturates or benzodiazepines. TennCare will exclude from coverage all of the allowable exclusions described above; or
 - (c) Use of the medication has not been determined to be medically contraindicated because of the member's medical condition or possible adverse drug interaction; or
 - (d) The prescriber did not prescribe a total quantity less than an emergency supply, in which case the pharmacist must provide a supply up to the amount prescribed.
- (13) There are some cases in which it is not feasible for the pharmacist to dispense an emergency supply because the drug is packaged by the manufacturer to be sold as the original unit or because the usual and customary pharmacy practice would be to dispense the drug in the original packaging (inhalers, eye drops, topicals, etc.). When coverage of an emergency supply of a prescription would otherwise be required and when, as described above, it is not feasible for the pharmacist to