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State/Territory Name: Tennessee

State Plan Amendment (SPA) #: 15-0002

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
Atlanta Regional Office
61 Forsyth Street, Suite 4T20
Atlanta, Georgia 30303



DIVISION OF MEDICAID & CHILDREN'S HEALTH OPERATIONS

March 10, 2016

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 #15-0002

Dear Mr. Gordon:

This is to affirm approval of the above referenced State Plan Amendment which was submitted to the Regional Office on August 28, 2015. The State's requested effective date of October 1, 2015 has been accepted.

Enclosed for your records are:

1. a copy of the approval letter dated March 9, 2016 that was submitted to the State by John M. Coster, 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 North Carolina, at 404-562-7413.

Sincerely,

//s//

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

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

March 9, 2016

Darin J. Gordon
Director, Division of Healthcare Finance & Administration
Bureau of TennCare
310 Great Circle Road
Nashville, TN 37243

Attention: Susie Baird, Director of Policy

Dear Mr. Gordon:

We have reviewed Tennessee State Plan Amendment (SPA) 15-0002, submitted to the Atlanta Regional Office on August 28, 2015. The state proposes to update the State Plan to reflect that the state has a revised Supplemental Rebate Agreement (SRA) that updates the existing SRA that expired on September 30, 2015.

We are pleased to inform you that the amendment is approved, effective July 1, 2015.

A copy of the signed CMS-179 form, as revised per your December 23, 2015 request, as well as the page approved for incorporation into the Tennessee state plan will be forwarded by the Atlanta Regional Office.

If you have any questions regarding this amendment, please contact Ruth Blatt at (410) 786-1767.

Sincerely,

/s/

John M. Coster, Ph.D., R.Ph.
Director
Division of Pharmacy

Cc: Jackie Glaze, Associate Regional Administrator, Atlanta Regional Office
Kenni Howard, Atlanta Regional Office
Mary Holly, Atlanta Regional Office

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Atlanta Regional Office
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DIVISION OF MEDICAID & CHILDREN'S HEALTH OPERATIONS

March 9, 2016

Darin Gordon, Director
Bureau of TennCare
310 Great Circle Road
Nashville, TN 36243

Re: Tennessee Title XIX State Plan Amendment, Transmittal #15-0002 Companion Letter

Dear Mr. Gordon:

This letter is being sent as a companion to our approval of Tennessee's state plan amendment (SPA) 15-002. The SPA proposed to revise and update the State of Tennessee's Supplemental Rebate Agreement, effective October 1, 2015. While we are proceeding with approval of SPA 15-002, in our review of that SPA, we determined that the existing state plan may not be in full compliance with current federal requirements.

Section 1902(a) of the Social Security Act (the Act) requires that states have a state plan for medical assistance that complies with a federal framework for the state program. As part of that federal framework, section 1902(a)(54) of the Act requires that a state that provides medical assistance for covered outpatient drugs complies with the applicable requirements of section 1927 of the Act. Section 1927(k)(2) of the Act sets out the requirements for coverage and rebates for covered outpatient drugs, which are defined to include, among other items, "a drug . . . which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Food, Drug and Cosmetic Act, or which is approved under section 505(j) of such Act." Section 1927(d) sets forth permissible limitations on coverage of such drugs that are supplied by manufacturers that participate in the Medicaid Drug Rebate Program. Of particular relevance, section 1927(d)(4) sets forth requirements for the use of formularies to limit coverage of particular drugs. Section 1927(d)(4)(C) provides that a drug may be excluded from coverage through a formulary only based on a finding by an appropriate committee that the drug does not have "significant, clinically meaningful therapeutic advantages . . . for such population over other drugs included in the formulary, and there is a written explanation (available to the public) of the basis for the exclusion." Certain other additional protections also apply to ensure that, even if a drug is not on the state's formulary, the drug is made available for a patient with demonstrated medical necessity (and is available for a limited period in emergency situations).

During our review of SPA 15-002, CMS submitted a Request for Additional Information (RAI) to the state and we have a concern with a state policy that was referenced in the state's response to the RAI. The state has indicated that it does not cover a new drug that has been approved by

the Food and Drug Administration, until after the TennCare Pharmacy Advisory Committee has reviewed the drug and provided recommendations to TennCare regarding its placement on the formulary, regardless of the drug being a covered outpatient drug of a participating manufacturer in the Medicaid Drug Rebate Program. Thus, Tennessee would exclude coverage of the drug without the required finding prior to review by the formulary committee. Additionally, it does not appear that TennCare provides a method to cover outpatient drugs of participating manufacturers if the drugs are not on the TennCare formulary, either when there is demonstrated medical necessity, or when it is needed for an emergency situation. In response to CMS' concerns, the state referenced a waiver authority in its 1115 demonstration that enables the state to establish a drug formulary that does not comply with the requirements of Section 1927(d)(4) of the Social Security Act (the Act), stating that the waiver authority allows the state to exclude such drugs.

Our preliminary conclusion is that the waiver granted under section 1115 of the Act does not provide authority to restrict coverage of a drug without any finding as to its therapeutic benefits compared to other drugs. Such a restriction on coverage would be outside the definition of a formulary. While the section 1115 waiver allows the state to deviate from formulary requirements (such as the composition of the formulary committee), it does not permit the state to restrict coverage without any finding that would constitute the operation of a finding.

Please provide Tennessee's explanation regarding how the current language in the 1115 demonstration Terms and Conditions allows the state to exclude coverage of a covered outpatient drug of a participating manufacturer prior to a determination of the formulary status of the drug. Please indicate whether such a policy was referenced in Tennessee's application for approval of the demonstration project (either the original application, or applications for renewal). Additionally, please explain how the state's practices would comply with the requirement for access to prescription drugs in an emergency situation.

Please respond within 90 days of receipt of this letter. During the 90-day period, we are happy to provide any technical assistance that you need.

If you have any questions regarding this letter, please contact Kenni Howard of my staff at 404-562-7413. We look forward to working with you on this issue.

Sincerely,

//s//

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

Cc: Ruth Blatt, Central Office

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES		1. TRANSMITTAL NUMBER: TN-15-0002	2. STATE TENNESSEE
		3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE & NEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES		4. PROPOSED EFFECTIVE DATE October 1, 2015	
5. TYPE OF PLAN MATERIAL (<i>Check One</i>):			
<input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT			
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (<i>Separate Transmittal for each amendment</i>)			
6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR 440 and 441		7. FEDERAL BUDGET IMPACT: a. FFY 2016 (\$4,215,240) b. FFY 2017 (\$4,215,240)	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1.A.1, Item 12: 12.a.(8), page 28; Attachment 3.1.B.1, Item 12., 12.a.(8), page 28. .		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>) Attachment 3.1.A.1, Item 12: 12.a.(8), page 28; Attachment 3.1.B.1, Item 12., 12.a.(8), page 28.	
10. SUBJECT OF AMENDMENT: Limitation on Amount, Duration and Scope of Medical Care and Services Provided – Prescribed Drugs.			
11. GOVERNOR'S REVIEW (<i>Check One</i>):			
<input checked="" type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="checkbox"/> OTHER, AS SPECIFIED:			
<input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
12. SIGNATURE OF STATE AGENCY OFFICIAL: //s//		16. RETURN TO: Tennessee Department of Finance and Administration Division of Health Care 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:			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED:08-28-15		18. DATE APPROVED: 03-09-16	
PLAN APPROVED – ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: 10-01-15		20. SIGNATURE OF REGIONAL OFFICIAL: //s/	
21. TYPED NAME: Jackie Glaze		22. TITLE: Associate Regional Administrator Division of Medicaid & Children's Health Opns	
23. REMARKS:			

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE TENNESSEEMETHODS AND STANDARDS FOR ESTABLISHING PAYMENT
RATES – OTHER TYPES OF CARE

Except as otherwise specifically provided in this State Plan, the state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and applicable restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.

The state will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.

CMS has authorized the state of Tennessee to enter into supplemental rebate agreements with drug manufacturers for drugs provided to Medicaid beneficiaries. The Supplemental Rebate Agreement (SRA) submitted to CMS on August 28, 2015, has been authorized for pharmaceutical manufacturers' new agreements and renewals.

Supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

All drugs covered by the program, irrespective of a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.

(9) Reserved.

(10) In accordance with the provisions of the Act, TennCare began the development and implementation of a preferred drug list (PDL) on July 1, 2003. TennCare will move to a single, statewide preferred drug list (PDL) for the entire pharmacy program. Furthermore, TennCare will employ a single pharmacy benefits manager (PBM) to process all TennCare pharmacy claims and respond to all prior approval requests.

TN No. TN-15-0002

Supersedes

TN No. 08-007

Approval Date 03-09-16

Effective Date 10/01/15

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE TENNESSEE

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT
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