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State/Territory Name: Tennessee

State Plan Amendment (SPA)#: 21-0004

This file contains the following documents in the order listed

- 1) Approval Letter
- 2) CMS 179 Form
- 3) Approved SPA Pages

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



<u>Center for Medicaid and CHIP Services</u> Disabled and Elderly Health Programs Group

August 18, 2021

Mr. Stephen M. Smith Director, Division of TennCare 310 Great Circle Road Nashville, Tennessee 37243

Dear Mr. Smith,

The CMS Division of Pharmacy team has reviewed Tennessee's State Plan Amendment (SPA) 21-0004 received in the CMS Medicaid & CHIP Operations Group on June 14, 2021. This SPA proposes to allow for limitation on amount, duration and scope of medical care and services provided for prescribed drugs through value-based and supplemental rebate agreements with drug manufacturers for drugs provided to Medicaid beneficiaries.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that TN-21-0004 is approved with an effective date of July 1, 2021. We are attaching a copy of the signed CMS-179 form, as well as the pages approved for incorporation into Tennessee's state plan.

If you have any questions regarding this request, please contact Michael Forman at 410-786-2666 or michael.forman@cms.hhs.gov.

Sincerely,



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

Cc: Aaron Butler, Division of TennCare Jonathan Reeve, Division of TennCare George Woods, Division of TennCare Renee Williams-Clark, Division of TennCare Tandra Hodges, CMS Division of Program Operations

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER: TN-21-0004	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 5. TYPE OF PLAN MATERIAL <i>(Check One)</i> :	4. PROPOSED EFFECTIVE DATE July 1, 2021	
Image: New State Plan Image: Amendment to be considered as New Plan Image: Amendment		
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)		
6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR 440, 441 and 447	7. FEDERAL BUDGET IMPACT:a. FFY 2021 \$0b. FFY 2022 \$0	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:	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.	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 (Check One): ☐ GOVERNOR'S OFFICE REPORTED NO COMMENT ☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED ☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 	OTHER, AS SPECIFIED:	
12. SIGNATURE OF STATE AGENCY OFFICIAL:	16. RETURN TO: Tennessee Department of Finance and Administration	
13. TYPED NAME: Stephen Smith	Division of TennCare 310 Great Circle Road	
14. TITLE: Director, Division of TennCare	Nashville, Tennessee 37243	
15. DATE SUBMITTED: June 14, 2021	Attention: George Woods	
FOR REGIONAL OFFICE USE ONLY		
17. DATE RECEIVED: June 14, 2021	18. DATE APPROVED: August 18	3, 2021
PLAN APPROVED – ON		
19. EFFECTIVE DATE OF APPROVED MATERIAL: July 1, 2021	20. SIGNATURE OF REGIONAL OF	FICIAL:
21. TYPED NAME: John M. Coster, Ph.D., R.Ph.	22. TITLE: Director, Division of Pharmacy	
23. REMARKS:		

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE TENNESSEE

METHODS 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 outcomes-based drug pricing discounts and 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 value-based payment agreements and supplemental rebate agreements with drug manufacturers for drugs provided to Medicaid beneficiaries. The Supplemental Rebate Agreement (SRA) and the Value-based Agreement (VBA-Rx) submitted to CMS on June 14, 2021, have been authorized for pharmaceutical manufacturers' new agreements and renewals.

Savings recognized from value-based agreements and 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.

Approval Date ______08/18/21____

Effective Date 07/01/21

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

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Effective Date <u>07/01/21</u>