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State/Territory Name: Tennessee

State Plan Amendment (SPA) #: 17-0003

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

November 17, 2017

Wendy Long, M.D.
Director, Health Care Finance and Administration
Bureau of TennCare
310 Great Circle Road
Nashville, TN 37243

Re: TN State Plan Amendment 17-0003

Dear Dr. Long:

This is to affirm approval of the above referenced State Plan Amendment which was submitted to the Regional Office on May 23, 2017. The state's requested effective date of April 1, 2017 has been accepted.

Enclosed for your records are:

1. A copy of the approval letter dated November 15, 2017 that was submitted to the State by John M. Coster, Director, Director 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//

Shantrina Roberts
Acting 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

November 15, 2017

Wendy Long, MD
Director, Division of Healthcare Finance and Administration
State of Tennessee
Bureau of TennCare
310 Great Circle Road
Nashville, TN 37243

Dear Dr. Long,

We have reviewed Tennessee State Plan Amendment (SPA) 17-0003, Prescribed Drugs, received in the Atlanta Regional Office on May 23, 2017. This SPA proposes to bring Tennessee into compliance with the pharmacy reimbursement requirements in the Covered Outpatient Drug final rule with comment period (COD final rule) (CMS-2345-FC) (81 FR 5170) published on February 1, 2016.

SPA 17-0003 establishes reimbursement for covered outpatient drugs using an actual acquisition cost methodology and implements a professional dispensing fee (PDF) reimbursement of \$9.16 for pharmacies with a prescription volume of 65,000 or more claims per year. For pharmacies with a prescription volume of less than 65,000 claims per year, the PDF will be \$10.09. This SPA also includes reimbursement methods for 340B drugs, physician-administered drugs, clotting factor, federal supply schedule, and drugs purchased at nominal price.

In considering the proposed PDF, the state was required to provide data and studies to demonstrate that the acquisition cost methodology and professional dispensing fees being paid are sufficient to ensure that TennCare beneficiaries will have access to pharmacy services. In keeping with the requirements of section 1902 (a)(30)(A) of the Social Security Act, we believe the state has demonstrated that their reimbursement is consistent with efficiency, economy, and quality of care, and are sufficient to ensure that care and services are available at least to the extent they are available to the general population in the geographic area.

We believe that there is evidence regarding the sufficiency of Tennessee's professional dispensing fee to, at this time, approve SPA 17-0003 with an effective date of April 1, 2017. Specifically, Tennessee has reported to CMS that the 1,648 of the state's 1,704 pharmacies participate in TennCare's pharmacy network.

With a 96.7 percent participation rate, we can infer that TennCare beneficiaries will have access to pharmacy services at least to the extent available to the general population since Medicaid requires that beneficiaries be provided access to all covered outpatient drugs of participating drug manufacturers with a rebate agreement through a broad pharmacy network. In contrast, commercial insurers often have more limited drug formularies and a more limited pharmacy network.

Nevertheless, after reviewing your methodology used to arrive at the PDF, CMS would like to encourage Tennessee to continue timely access monitoring procedures and to consider the inclusion of additional overhead costs, which were excluded in this recent survey, in your next cost of dispensing survey. This amendment to implement a PDF reimbursement of \$9.16 for pharmacies with a prescription volume of 65,000 or more claims per year is lower than the national average PDF and that of neighboring states. For example, Mississippi has a PDF of \$11.29; Georgia has a PDF of \$10.63; West Virginia has a PDF of \$10.49; Virginia's PDF is \$10.65; Indiana has a PDF of \$10.48; and Kentucky and Alabama each have a PDF of \$10.64.

We believe that the difference between Tennessee's PDF and those of the neighboring states listed above may be the result of Tennessee omitting certain pharmacy overhead costs from the PDF survey. We recognize that not all categories of costs were specifically identified in the regulatory definition of PDF. The state may have interpreted some of these overhead costs as optional, however, the definition of PDF at 447.502 includes, "...overhead associated with maintaining the facility and equipment necessary to operate the pharmacy." In evaluating your PDF, we found that your percentage of overhead costs included in the PDF was lower than other states. For that reason, we encourage you to continue to monitor access to pharmacy services.

As noted above, we believe that there is evidence regarding the sufficiency of Tennessee's dispensing fee from provided data and other credible sources to approve SPA 17-0003 with an effective date of April 1, 2017. If based on continued access monitoring and/or any updated cost of dispensing surveys Tennessee finds that an additional SPA amendment is appropriate, we encourage the state to make such a request promptly. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Tennessee's state plan will be forwarded by the Atlanta Regional Office.

If you have any questions regarding this amendment, please contact Mickey Morgan at (410) 786-4048 or Mickey.morgan@cms.hhs.gov.

Sincerely,

/s/

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

cc: Aaron Butler, Tennessee Director of Policy
Jonathan Reeve, Tennessee Senior Policy Analyst
Shantrina Robert, Acting ARA, CMS, Atlanta Regional Office
Kenni Howard, CMS, Atlanta Regional Office

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: HEALTH CARE FINANCING ADMINISTRATION		1. TRANSMITTAL NUMBER: TN-17-0003	2. STATE TENNESSEE
		3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES		4. PROPOSED EFFECTIVE DATE April 1, 2017	
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 x <input 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, Part 447, Subpart 1		7. FEDERAL BUDGET IMPACT: a. FFY 2017 (\$2,351,181) b. FFY 2018 (\$4,915,270)	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 4.19-B, item 12.a., pages 1 of 6, 2 of 6, 3 of 6, 4 of 6, 5 of 6 and 6 of 6		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>): Attachment 4.19-B, item 12.a., pages 1 of 3, 2 of 3, 3 of 3	
10. SUBJECT OF AMENDMENT: Methods and standards for establishing payment rates-other types of care-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: Wendy Long			
14. TITLE: Director, Bureau of TennCare			
15. DATE SUBMITTED: 05/23/17			
FOR REGIONAL OFFICE USE ONLY			
17. DATE Received: 05/23/17		18. DATE APPROVED: 11/14/17	
PLAN APPROVED – ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: 04/01/17		20. SIGNATURE OF REGIONAL OFFICIAL: /s/	
21. TYPED NAME: Shantrina Roberts		22. TITLE: Acting Associate Regional Administrator Division of Medicaid & Children Health Opns	
23. REMARKS: Approved with following changes to Block #8: Block #8 changed to read: Attachment 4.19-B item 12a, 1 of 5, 2 of 5, 3 of 5, 4 of 5, 5 of 5.			

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE TENNESSEE

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT
RATES – OTHER TYPES OF CARE

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) Payments for covered outpatient drugs shall generally be defined according to the type of pharmacy being reimbursed. Payments made in accordance with 42 CFR § 447.512 (i.e., basing ingredient cost of a drug on Actual Acquisition Cost) and 42 CFR § 447.502 (describing the professional dispensing fee) are as follows:

(a) Ambulatory Pharmacies

- i. Ambulatory pharmacies are licensed by the Tennessee Board of Pharmacy and include retail pharmacies and any other entities that dispense outpatient drugs directly to enrollees.
- ii. Payments to ambulatory pharmacies for covered outpatient legend and over-the-counter drugs will be made at—
 - a. The Federal Upper Limit (FUL), plus a professional dispensing fee; or
 - b. The Average Actual Acquisition Cost (AAAC), if there is no FUL or if the AAAC is lower than the FUL, plus a professional dispensing fee; or
 - c. The National Average Drug Acquisition Cost (NADAC), if there is no AAAC or if the NADAC is lower than the AAAC, plus a professional dispensing fee; or
 - d. The Wholesale Acquisition Cost (WAC) minus three percent for brand-name drugs or WAC minus six percent for generic drugs, if there is no AAAC or NADAC, plus a professional dispensing fee; or
 - e. The Usual and Customary charge to the public, if it is lower than the four preceding options.

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- iii. The professional dispensing fees for ambulatory pharmacies will be tiered based on annual prescription volume. The tiers are—
 - \$10.09 for pharmacies with a prescription volume of less than 65,000 claims per year; and
 - \$8.33 for pharmacies with a prescription volume of 65,000 or more claims per year.

(b) 340B Covered Entities

- i. 340B covered entities are providers that participate in the 340B Drug Pricing Program and that fill enrollees' prescriptions with drugs purchased at prices authorized under Section 340B of the Public Health Service Act.
- ii. Payments to 340B covered entities will be made at—
 - a. The 340B ceiling price, plus a professional dispensing fee; or
 - b. The 340B covered entities' Acquisition Cost, if lower than the 340B ceiling price, plus a professional dispensing fee.
- iii. Payments to 340B covered entities for drugs obtained outside the 340B Drug Pricing Program will be made according to the same methodology applicable to ambulatory pharmacies.
- iv. Drugs acquired through the 340B Drug Pricing Program and dispensed by 340B contract pharmacies are not covered.
- v. The professional dispensing fee for 340B covered entities when dispensing drugs obtained through the 340B Drug Pricing Program is set at \$15.40. The professional dispensing fee for 340B covered entities when dispensing drugs obtained outside the 340B Drug Pricing Program will be tiered based on annual prescription volume. The tiers are the same as those for ambulatory pharmacies.

TN No. 17-0003

Supersedes

Approval Date: 11/14/17

Effective Date: 04/01/17

TN No. 14-002, 15-0001, 11-005

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

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METHODS AND STANDARDS FOR ESTABLISHING PAYMENT
RATES – OTHER TYPES OF CARE

- (c) Pharmacies that purchase drugs through the Federal Supply Schedule will be reimbursed no more than the Actual Acquisition Cost of the drug, plus a professional dispensing fee that is tiered in the same manner as the dispensing fee for ambulatory pharmacies.
 - (d) Pharmacies that purchase drugs at Nominal Price (outside of the 340B Drug Pricing Program or the Federal Supply Schedule) will be reimbursed no more than the Actual Acquisition Cost of the drug, plus a professional dispensing fee that is tiered in the same manner as the dispensing fee for ambulatory pharmacies.
 - (e) Reimbursement for compounded prescriptions will consist of an ingredient cost based on the same methodology applied to ambulatory pharmacies, and a professional dispensing fee that is tiered according to the pharmacist's reported level of effort. The tiers are—
 - Level 1 (0-15 minutes) – \$10.09
 - Level 2 (16-30 minutes) – \$15.00
 - Level 3 (31 or more minutes) – \$25.00
- (2) Drug payments to which the requirements of 42 CFR § 447.512 do not apply shall adhere to the following methodology:
- (a) Long-Term Care Pharmacies
 - i. Long-term care pharmacies are licensed by the Tennessee Board of Pharmacy and are closed-door pharmacies (i.e., are not open to the general public). Long-term care pharmacies dispense drugs only to long-term care facilities and/or to other group facilities.
 - ii. Payments to long-term care pharmacies for covered outpatient legend and over-the-counter drugs will be made at—
 - a. The Federal Upper Limit (FUL), plus a professional dispensing fee; or

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- b. The Average Actual Acquisition Cost (AAAC), if there is no FUL or if the AAAC is lower than the FUL, plus a professional dispensing fee; or
 - c. The National Average Drug Acquisition Cost (NADAC), if there is no AAAC or if the NADAC is lower than the AAAC, plus a professional dispensing fee; or
 - d. The Wholesale Acquisition Cost (WAC) minus three percent for brand-name drugs or WAC minus six percent for generic drugs, if there is no AAAC or NADAC, plus a professional dispensing fee.
- iii. The professional dispensing fee for long-term care pharmacies is set at \$12.15.
 - iv. Long-term care pharmacies must dispense medications in a manner that enables the return to stock of unused portions, with a credit to TennCare for those portions.
- (b) Specialty Pharmacies
- i. Specialty pharmacies are licensed by the Tennessee Board of Pharmacy. Specialty pharmacies dispense only specialty drugs that are not dispensed by ambulatory pharmacies and distribute these drugs primarily through the mail.
 - ii. Payments to specialty pharmacies will be made at—
 - a. The Average Actual Acquisition Cost (AAAC), plus a professional dispensing fee; or
 - b. The Wholesale Acquisition Cost (WAC) minus three percent for brand-name drugs or WAC minus six percent for generic drugs, if there is no AAAC, plus a professional dispensing fee.
 - iii. The professional dispensing fee for specialty pharmacies is set at \$10.09.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE TENNESSEE

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT
RATES – OTHER TYPES OF CARE

- (c) Blood Clotting Factors and Other Blood Products
 - i. For entities other than specialty pharmacies, hemophilia treatment centers (HTCs), and hemophilia-related centers of excellence that are 340B covered entities, payment for blood clotting factors and other blood products will be made at the Average Actual Acquisition Cost, plus a professional dispensing fee of \$153.54.
 - ii. For specialty pharmacies, HTCs, and hemophilia-related centers of excellence that are 340B covered entities, payment for blood clotting factors and other blood products will combine the ingredient cost methodology applicable to 340B covered entities, defined previously in 12.a.(1)(b), with a professional dispensing fee of \$153.54.
- (d) Investigational drugs are not a covered service.