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State/Territory Name: Tennessee

State Plan Amendment (SPA) #: 20-0004

This file contains the following documents in the order listed:

1) Approval Letter
2) CMS 179 Form/Summary Form (with 179-like data)
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

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

September 4, 2020

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) 20-0004 received in the CMS Division of Program Operations on June 10, 2020. This SPA proposes to amend Tennessee's professional dispensing fees (PDF) to $11.98 for pharmacies with a prescription volume of less than 65,000 claims per year, $8.37 for pharmacies with a prescription volume of 65,000 or more claims per year, and $11.98 for pharmacies that opened within one year of the state's cost-of-dispensing survey. This SPA also proposes changes to the PDF for 340B covered entities, compounded prescriptions, long-term care pharmacies, blood clotting factors and other blood products, out-of-state pharmacies, and pharmacies that fail to respond to the state's mandatory pharmacy survey.

Additionally, the SPA proposes to increase the PDF for non-specialty drugs dispensed by in-state specialty pharmacies to $11.98 and the PDF for specialty drugs (regardless of which type of pharmacy dispenses them) to $45.94. The SPA states that, "Specialty pharmacies are licensed by the Tennessee Board of Pharmacy. Specialty pharmacies primarily dispense specialty drugs that are not dispensed by ambulatory pharmacies and distribute these drugs through the mail. Specialty drugs do not appear on the National Average Drug Acquisition Cost (NADAC) list maintained by CMS. Reimbursement in this category is based on the classification of the drug being dispensed rather than the type of pharmacy dispensing the drug."

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 to Medicaid beneficiaries 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 pharmacy provider network at this time to approve SPA 20-0004. Specifically, Tennessee has reported to CMS that 1,488 of the state's 1,608 licensed in-state retail pharmacies are enrolled in Tennessee's TennCare program. With a 92.5 percent participation rate, we can infer that Tennessee's 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.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 20-0004 is approved with an effective date of May 1, 2020. 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 CMS Division of Program Operations. If you have any questions regarding this request, please contact Michael Forman at (410) 786-2666 or michael.forman@cms.hhs.gov.

Sincerely,

[redacted]

Cynthia R. Denemark, R.Ph.
Deputy Director
Division of Pharmacy
DEHPG/CMCS/CMS

cc: Jonathan Reeve, Division of TennCare
Aaron Butler, Division of TennCare
George Woods, Division of TennCare
James G. Scott, Division Director, CMS Division of Program Operations
Tandra Hodges, CMS Division of Program Operations
Cheryl Wigfall, CMS Division of Reimbursement Review

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

1. TRANSMITTAL NUMBER: 20-0004

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

4. PROPOSED EFFECTIVE DATE
May 1, 2020

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, Part 447, Subpart I.

7. FEDERAL BUDGET IMPACT:
a. FFY 2020 $1,421,252
b. FFY 2021 $3,457,493

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 4.19B, 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 (*If Applicable*)

Attachment 4.19B, Item 12.a., pages 1 of 5, 2 of 5, 3 of 5, 4 of 5, and 5 of 5.

10. SUBJECT OF AMENDMENT:
Methods and Standards for Establishing Payment Rates – Other Types of Care – 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 [redacted]

13. TYPED NAME: Stephen Smith

14. TITLE: Director, Division of TennCare

15. DATE SUBMITTED: June 10, 2020

16. RETURN TO:
Tennessee Department of Finance and Administration
Division of TennCare
310 Great Circle Road
Nashville, Tennessee 37243

Attention: Jonathan Reeve

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 6/10/20

18. DATE APPROVED: 9/4/20

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 5/1/20

20. SIGNATURE OF REGIONAL OFFICIAL: [redacted]

21. TYPED NAME: Todd McMillion

22. [redacted] ment Review

23. REMARKS:

FORM CMS-179 (07/92)

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.

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

iii. The professional dispensing fees for ambulatory pharmacies will be tiered based on annual prescription volume. The tiers are—

- $11.98 for pharmacies with a prescription volume of less than 65,000 claims per year;
- $8.37 for pharmacies with a prescription volume of 65,000 or more claims per year; and
- $11.98 for pharmacies that opened within one year of the State's cost-of-dispensing survey.

(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 will be based on the type of claim being submitted. For claims submitted as 340B claims, the professional dispensing fee is set at $15.40. For claims submitted as non-340B claims, the professional dispensing fee is set at $11.98.

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(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) – $11.98 for pharmacies with a prescription volume of less than 65,000 claims per year, and $10.00 for pharmacies with a prescription volume of 65,000 or more claims per year
- 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

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

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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 $11.98.

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 / Specialty Drugs

i. Specialty pharmacies are licensed by the Tennessee Board of Pharmacy. Specialty pharmacies primarily dispense specialty drugs that are not dispensed by ambulatory pharmacies and distribute these drugs through the mail. Specialty drugs do not appear on the National Average Drug Acquisition Cost (NADAC) list maintained by CMS. Reimbursement in this category is based on the classification of the drug being dispensed rather than the type of pharmacy dispensing the drug.

ii. Payments to specialty pharmacies for specialty drugs will be made at—

a. The Average Actual Acquisition Cost (AAAC), plus a professional dispensing fee; or

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STATE TENNESSEE

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

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 non-specialty drugs dispensed by in-state specialty pharmacies is set at $11.98. The professional dispensing fee for specialty drugs (regardless of which type of pharmacy dispenses them) is set at $45.94.

(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 $172.69.

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 $172.69.

(d) Out-of-State Pharmacies

i. For out-of-state pharmacies that have a prescription volume of less than 65,000 claims per year and that are located in border areas closer to TennCare members than Tennessee pharmacies are, the professional dispensing fee for drugs other than specialty drugs and blood clotting factors is set at $11.98.

ii. For all other out-of-state pharmacies serving TennCare members (including out-of-state specialty pharmacies), the professional dispensing fee for drugs other than specialty drugs and blood clotting factors is set at $8.37.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

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iii. The professional dispensing fee for specialty drugs dispensed by out-of-state pharmacies is set at $45.94.

iv. The professional dispensing fee for blood clotting factors and other blood products dispensed by out-of-state pharmacies is set at $172.69.

(e) Pharmacies that Fail to Respond to a Mandatory Pharmacy Reimbursement Survey

i. The State conducts periodic surveys of pharmacy providers participating in the TennCare program. These surveys address such subjects as Average Actual Acquisition Cost, the costs associated with professional dispensing of prescription drugs, and other topics related to pharmacy reimbursement, and are necessary to establish reimbursement rates in accordance with federal requirements (see 42 CFR § 447.518). Since the results of these surveys are used to calculate pharmacy reimbursement rates, participation by all TennCare pharmacy providers is mandatory.

ii. For pharmacies that fail to provide a useable response to two mandatory surveys, the professional dispensing fee is set at the State's lowest calculated rate of $8.37.

iii. For pharmacies that fail to provide a useable response to three mandatory surveys, the professional dispensing fee is set at $5.00.

iv. A pharmacy that receives a lower dispensing fee because of failure to provide a useable response to a mandatory survey may resume receiving its usual dispensing fee by submitting a useable response to the next mandatory survey.

(f) Investigational drugs are not a covered service.