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State/Territory Name: Texas

State Plan Amendment (SPA)#: 24-0018

This file contains the following documents in the order listed below:

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Medicaid Benefits and Health Programs Group

August 29, 2024

Emily Zalkovsky
State Medicaid Director
Post Office Box 13247, MC: H-100
Austin, Texas 78711

Dear Director Zalkovsky,

We have reviewed Texas State Plan Amendment (SPA) 24-0018 received in the Centers for Medicare and Medicaid Services (CMS) OneMAC application on July 19, 2024. This SPA proposes to amend the State Plan to create a new, temporary non-preferred status, and establish criteria for new-to-market drugs that have not yet been reviewed by the Drug Utilization Review Board.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that TX-24-0018 is approved with an effective date of September 1, 2025.

We are attaching a copy of the signed CMS-179 form, as well as the pages approved for incorporation into the Texas state plan. If you have any questions regarding this amendment, please contact Whitney Swears at Whitney.Swears@cms.hhs.gov.

Sincerely,

[redacted]

Cynthia R. Denemark, R.Ph.
Director
Division of Pharmacy

cc: Priscilla Parrilla, Texas Pharmacy Director
Ford Blunt, CMS, Medicaid and CHIP Operations Group

DEPARTMENT OF HEALTH ANDHUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB No. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES

1. TRANSMITTAL NUMBER: 24-0018

2. STATE: TX

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
September 1, 2025

5. FEDERAL STATUTE/REGULATION CITATION
42 CFR Part 456 Utilization Control and 42 CFR Section 456.703 Drug Use Review Program

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 2025 $ 22,499
b. FFY 2026 $ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Appendix 1 to Attachment 3.1-A, Page 24a
Appendix 1 to Attachment 3.1-B, Page 24a

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*
Appendix 1 to Attachment 3.1-A, Page 24a (TN 18-0001)
Appendix 1 to Attachment 3.1-B, Page 24a (TN 18-0001)

9. SUBJECT OF AMENDMENT
The purpose of this amendment is to create a new, temporary non-preferred status, and establish criteria for authorizing drugs with temporary non-preferred status, to new-to-market drugs added to the Vendor Drug Program formulary that have not yet been reviewed by the Drug Utilization Review Board.

10. 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: Sent to Governor's Office this date. Comments, if any, will be forwarded upon receipt.

11. SIGNATURE OF STATE AGENCY OFFICIAL
[redacted]

12. TYPED NAME
Emily Zalkovsky

13. TITLE
State Medicaid Director

14. DATE SUBMITTED
July 19, 2024

15. RETURN TO

Emily Zalkovsky
State Medicaid Director
Post Office Box 13247, MC: H-100
Austin, Texas 78711

FOR CMS USE ONLY

16. DATE RECEIVED
07/19/2024

17. DATE APPROVED
08/29/2024

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
09/01/2025

19. [redacted]

20. TYPED NAME OF APPROVING OFFICIAL
Cynthia R. Denemark, R.Ph.

21. TITLE OF APPROVING OFFICIAL
Director, Division of Pharmacy

22. REMARKS

12a. Prescribed Drugs

(1) A program benefit offered by the manufacturer or labeler of the drug partially or wholly in lieu of a supplemental rebate and accepted by the state; and

(2) Written evidence offered by a manufacturer or labeler supporting the inclusion of a product on the PDL.

The state will examine information from any or all of these sources when considering the drugs to be included in the PDL.

The state will only include on the PDL drugs provided by a manufacturer or labeler that: (1) has reached an agreement with the state for supplemental rebates for drugs provided to Medicaid recipients; or (2) has not reached an agreement for supplemental rebates, if the state determines that inclusion of the drug on the PDL will have no negative cost impact. Manufacturers or labelers that offer a program benefit must first have a supplemental rebate agreement.

The state will grant temporary non-preferred status, and establish criteria for authorizing drugs with temporary non-preferred status, to new-to-market drugs added to the Vendor Drug Program formulary that have not yet been reviewed by the DUR Board.

(b) Supplemental Medicaid Drug Rebate Agreement: Pursuant to Section 1927 of the Act, the state has the following policies for Medicaid supplemental rebates and program benefits:

(1) A model agreement between the state and a drug manufacturer for drugs provided to the Medicaid population, effective February 15, 2018, and entitled "Texas Health and Human Services Commission, Title XIX Vendor Drug Program, Supplemental Rebate Agreement," has been authorized by CMS.

(2) 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.

(3) A model program benefit agreement between the state and the drug manufacturer for program benefits provided to the Medicaid program, submitted to CMS on September 14, 2004 and entitled "Texas Health and Human Services Commission Title XIX Vendor Drug Program Benefit Agreement" has been authorized by CMS.

(4) Program benefits will consist of benefits, services, or expenditures that the state would otherwise bear under its state plan as medical or administrative expense.

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