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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:

- 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



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,

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

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

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES		
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 Secti 456.703 Drug Use Review Program 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	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a. FFY 2025 \$ 22,499 b. FFY 2026 \$ 0 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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Appendix 1 to Attachment 3.1-A, Page 24a (TN 18-0001) Appendix 1 to Attachment 3.1-B, Page 24a (TN 18-0001)	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, te for authorizing drugs with temporary non-preferred s Drug Program formulary that have not yet been revie	tatus, to new-to-market drugs added to the Vendor	
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.	
12. TYPED NAME Emily Zalkovsky 13. TITLE State Medicaid Director 14. DATE SUBMITTED	Emily Zalkovsky State Medicaid Director Post Office Box 13247, MC: H-100 Austin, Texas 78711	
July 19, 2024 FOR CMS	LIGE ONLY	
16. DATE RECEIVED 07/19/2024	17. DATE APPROVED 08/29/2024	
	NE COPY ATTACHED	
18. EFFECTIVE DATE OF APPROVED MATERIAL 09/01/2025		
20. TYPED NAME OF APPROVING OFFICIAL Cynthia R. Denemark, R.Ph.	21. TITLE OF APPROVING OFFICIAL Director, Division of Pharmacy	
22. REMARKS		

FORM CMS-179 (09/24)

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) <u>Supplemental Medicaid Drug Rebate Agreement:</u> 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.

TN: _	24-0018	Approval Date: _	08/29/2024
Supersedes TN: 1		Effective Date:	

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