Table of Contents

State/Territory Name: Texas

State Plan Amendment (SPA) #: 15-0022

This file contains the following documents in the order listed:

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

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

Disabled & Elderly Health Programs Group

October 7, 2015

Ms. Kay Ghahremani
State Medicaid/CHIP Director
Health and Human Services Commission
Post Office Box 13247
Mail Code H100
Austin, Texas 78711

Dear Ms. Ghahremani:

We have reviewed Texas State Plan Amendment (SPA) 15-0022, Prescribed Drugs, received in the Dallas Regional Office on August 21, 2015. The amendment proposes to change all references to the Pharmaceutical and Therapeutic Committee and transfers all of its function to the Drug Utilization Review (DUR) board. In addition, the scope of the DUR board is updated to accurately reflect the membership and current duties of the board.

Based on the information provided, we are pleased to inform you that consistent with the regulations at 42 CFR 430.20, SPA 15-0022 is approved with an effective date of January 1, 2016. A copy of the signed CMS-179 form as well as the pages approved for incorporation into the Texas state plan will be forwarded by the Dallas Regional Office.

If you have any questions regarding this SPA, please contact Renee Hilliard at (410) 786-2991.

Sincerely,

[redacted]

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

cc: Bill Brooks, ARA, Dallas Regional Office
Cheryl Rupley, Dallas Regional Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE AND MEDICAID SERVICES	1. TRANSMITTAL NUMBER: **15-022**	2. STATE: **TEXAS**
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE AND MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE: **January 1, 2016**	

5. TYPE OF PLAN MATERIAL *(Circle 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:	7. FEDERAL BUDGET IMPACT:	
The DUR Board is established in accordance with provisions of §531.0736 of the Texas Government Code, Social Security Act of §1927 (g)(3), and 42 C.F.R. § 456.716.	a. **FFY 2016**	**SEE ATTACHMENT**
	b. **FFY 2017**	**$0**
	c. **FFY 2018**	**$0**
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: **SEE ATTACHMENT TO BLOCKS 8 & 9**	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: **SEE ATTACHMENT TO BLOCKS 8 & 9**	

10. SUBJECT OF AMENDMENT:

The proposed amendment revises all references to the Pharmaceutical and Therapeutics Committee by inserting the Drug Utilization Review Board (DUR) Board in its stead. The scope of the DUR board is also updated to accurately reflect the membership makeup and current duties of that committee.

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

12. SI[redacted]:	16. RETURN TO:
13. TYPED NAME: **Kay Ghahremani**	**Kay Ghahremani** **State Medicaid Director** **Post Office Box 13247, MC: H-100** **Austin, Texas 78711**
14. TITLE: **State Medicaid Director**	
15. DATE SUBMITTED: **August 21, 2015**	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 21 August, 2015	18. DATE APPROVED: 7 October, 2015
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: 1 January, 2016	20. SIGNATURE OF REGIONAL OFFICIAL: [redacted]
21. TYPED NAME: Bill Brooks	22. TITLE: Associated Regional Administrator Division of Medicaid & Children's Health

23. REMARKS:

FORM CMS – 179 (07-92)

Attachment to Blocks 8 & 9 of CMS Form 179

Transmittal Number 15-022

Number of the Plan Section or Attachment	**Number of the Superseded Plan Section or Attachment**
Appendix 1 to Attachment 3.1-A	Appendix 1 to Attachment 3.1-A
Page 24	Page 24 (TN 09-39)
Page 24a	Page 24a (TN 12-03)
Page 24b	Page 24b (TN 04-16)
Page 24c	Page 24c (TN 04-16)
Appendix 1 to Attachment 3.1-B	Appendix 1 to Attachment 3.1-B
Page 24	Page 24 (TN 09-39)
Page 24a	Page 24a (TN 12-03)
Page 24b	Page 24b (TN 04-16)
Page 24c	Page 24c (TN 04-16)

State: Texas
Date Received: 8/21/15
Date Approved: 10/7/15
Date Effective: 1/1/16
Transmittal Number: TX 15-0022

12a. Prescribed Drugs

Prescribed drugs are limited as follows:

(a) Number of Prescriptions: Each eligible recipient is entitled to a basic number of prescriptions each month.

(b) Number of Refills: As many as 11 refills may be authorized by the prescriber, but the total number authorized must be dispensed within 12 months of the date of the original prescription subject to state and federal laws for controlled substance drugs.

(c) Coverage of Drugs in the Texas Drug Code Index (TDCI): The state will reimburse only for the drugs of pharmaceutical manufacturers who have entered into and have in effect a rebate agreement in compliance with Section 1927 of the Social Security Act, unless the exceptions in Section 1902(a)(54), 1927(a)(3) or 1927(d) apply. The state permits coverage of participating manufacturers' drugs, even though it may be using other restrictions. The prior authorization program provides for a 24-hour turnaround from receipt of the request for prior authorization. The prior authorization program also provides for a 72-hour supply of drugs in emergency situations.

(d) Prior Authorization Procedures: A health care practitioner who prescribes a drug that is not included on the Preferred Drug List (PDL) for a Medicaid recipient must request prior authorization of the drug to the state agency or its designee. Specific procedures for the submission of requests for prior authorization will be available both on the Health and Human Services Commission's (HHSC) Internet website and in printed form. A health care practitioner may request a printed copy of the procedures and forms from HHSC. This prior authorization requirement does not apply to a newly enrolled Medicaid recipient until the 31st calendar day after the date of the determination of the recipient's Medicaid eligibility.

(e) Preferred Drug List: The state agency will consider a drug listed on the TCDI for inclusion in the PDL based on the following factors:

(1) The recommendations of the Drug Utilization Review Board (DUR) Board;

(2) The clinical efficacy of the drug consistent with the determination of the Food and Drug Administration and the recommendations of the DUR Board;

(3) Comparison of the price of the drug and the price of competing drugs to the Texas Medicaid outpatient drug program;

12a. Prescribed Drugs, continued

(4) 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

(5) 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.

(f) 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, submitted to CMS on January 29, 2004, 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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12a. Prescribed Drugs, continued

(5) For program benefits, only the direct costs associated with the Program Benefit investment, including non-monetary benefits such as in-kind goods and services, in the program by the manufacturer or labeler will count as reducing the amount of the supplemental rebate owed. The savings or reduced claim experience that may result from the investment does not reduce the amount of the supplemental rebate owed.

(6) Program benefits received by the State will be treated as supplemental rebates and will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement. For those manufacturers who have a Program Benefit Agreement, the State will determine the amount of supplemental rebate owed by the manufacturer at the end of a year. This amount represents 1) the potential total amount of Program Benefit investment by the manufacturer for the year, and 2) the basis for determining the amount of supplemental rebate that will be shared with the Federal government. For the CMS-64, the State will reduce its other Federal claims by the amount of the Federal share of the entire supplemental rebate owed at the end of the "Texas Health and Human Services Commission Title XIX Vendor Drug Program Supplemental Rebate Agreement" term.

(7) Where the program benefit amount is less than the supplemental rebate amount, the program benefit amount plus the difference between the full supplemental rebate amount and the program benefit amount will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

(g) Drug Utilization Review Board (DUR Board): The DUR Board is established in accordance with Section 531.0736 of the Texas Government Code, and Section 1927 (g)(3) of the Social Security Act. The DUR Board is appointed by the executive commissioner of HHSC.

(1) The DUR Board consists of at least 17 physicians and pharmacists of whom two are nonvoting managed care organization members. In addition to these 17 members, the DUR Board will include one consumer advocate who represents Medicaid recipients.

(2) The DUR Board shall develop recommendation for preferred PDLs to be adopted by the State Agency, suggest to the State Agency restrictions or prior authorization requirements on prescription drugs, recommend to the State Agency educational interventions for Medicaid providers, review drug utilization across Medicaid, and perform other duties that may be specified by law and otherwise make recommendations to the State Agency.

12a. Prescribed Drugs, continued

(3) The DUR Board shall meet at least quarterly to consider products in PDL categories, and other clinical topics the State Agency recommends for consideration. In developing its recommendations for a PDL, the DUR Board shall consider, for each product included in a category of products, the clinical efficacy, safety, cost-effectiveness and any program benefit associated with the product. The DUR Board shall inform the State Agency of its reasons of recommending drugs for the PDL. The DUR Board shall maintain confidentiality of information used in considering their recommendations including any information deemed confidential by law.

(h) Public Notice: The State Agency will publish notice of the meetings of the DUR Board. The notices will include the topics to be considered at the upcoming meeting and instructions concerning filing of written comments and application to provide public testimony before the committee. The PDL will be published on the HHSC website. Within 10 days following the State Agency's decision on the recommendations of the DUR Board, the Agency will publish revisions to the PDL on the HHSC website.

(i) No payment will be made for drugs in hospitals, nursing facilities and other institutions where those drugs are included in the reimbursement formula and vendor payments to the institution.

(j) Expanded pharmacy benefits under EPSDT will end on the last day of the month in which the individuals has his or her 21st birthday.

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