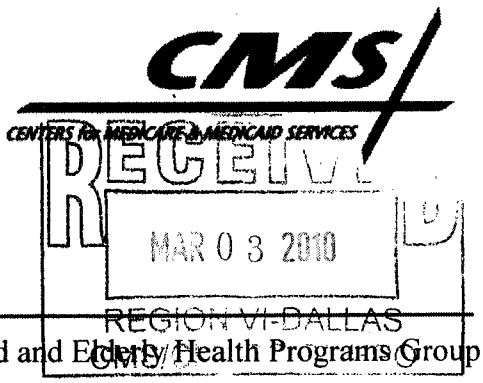
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, MD 21244-1850



Center for Medicaid & State Operations

Disabled and Elderly Health Programs Group

February 26, 2010 FEB 2 6 2010

Billy Millwee
Interim State Medicaid Director
Post Office Box 13247: MC: H-100
Austin, Texas 78711-5200

Dear Mr. Millwee:

We have reviewed Texas' State Plan Amendment (SPA) 09-039 received in the Dallas Regional Office on December 7, 2009, and we are pleased to inform you that it is approved, effective June 1, 2010. Under this SPA, the State of Texas proposes to extend the allowable number of Medicaid drug refills to 11 refills when dispensed within 12 months of the date of the original prescription.

This SPA otherwise modifies the criteria for a drug's inclusion on the preferred drug list (PDL) to include a drug provided by a manufacturer or labeler that has not reached a supplemental rebate agreement (SRA) with the State if its inclusion will have no negative cost impact. Drugs included on the PDL without an SRA must also be considered as clinically effective as other pharmaceutical options on the PDL.

The Dallas Regional Office will forward to you a copy of the CMS-179 form, as well as the pages approved for incorporation into the Texas Medicaid State Plan. If you have any questions regarding this amendment, please contact Gail Sexton at (410) 786-4583.

Sincerely,

[redacted]

Director
Division of Pharmacy

cc: Bill Brooks, ARA, Dallas Regional Office
Ford Blunt, 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: **09-039**

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: **June 1, 2010**

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:
42 CFR §440.120(a)
Section 1905(a)(12) of the Act – Prescribed Drugs;
Section 1927(d)(4) – formulary requirements;
Section 1927(d)(6) – prescription drug refills

7. FEDERAL BUDGET IMPACT: SEE ATTACHMENT
a. FFY **2010** **$00**
b. FFY **2011** **$00**
c. FFY **2012** **$00**

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
SEE ATTACHMENT

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
SEE ATTACHMENT

10. SUBJECT OF AMENDMENT:
The proposed amendment modifies the prescribed drugs benefit to extend the allowable number of refills to eleven refills when dispensed within twelve months of the date of the original prescription. The amendment also modifies the criteria for a drug's inclusion on the preferred drug list (PDL) to include drugs provided by a manufacturer or labeler that has not reached a supplemental rebate agreement with the state if its inclusion will have no negative cost impact.

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. SIGNATURE OF STATE AGENCY OFFICIAL:
[redacted]

13. TYPED NAME:
Billy Millwee

14. TITLE:
Interim State Medicaid Director

15. DATE SUBMITTED:
December 7, 2009

16. RETURN TO:
Billy Millwee
Interim State Medicaid Director
Post Office Box 13247: MC: H-100
Austin, Texas 78711-5200

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 8 December, 2009

18. DATE APPROVED: 2-26-2010

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 1 June, 2010

20. SIGNATURE OF REGIONAL OFFICIAL:
[redacted]

21. TYPED NAME: Bill Brooks

22. TITLE: Associate Regional Administrator
Div of Medicaid & Children's Health

23. REMARKS:

FORM CMS – 179 (07-92)

Attachment to Blocks 8 and 9 to CMS Form 179

TX Transmittal No. 09-039, Amendment No. 885

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 03-025)
Page 24a	Page 24a (TN 03-025)
Appendix 1 to Attachment 3.1-B	Appendix 1 to Attachment 3.1-B
Page 24	Page 24 (TN 03-025)
Page 24a	Page 24a (TN 03-025)

STATE Texas
DATE REC'D 12-8-09
DATE APP'VD 2-26-10
DATE EFF 6-1-10
HCFA 179 09-39
A

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 eleven refills may be authorized by the prescriber, but the total number authorized must be dispensed within twelve 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:

a) The recommendations of the Pharmaceutical and Therapeutics Committee (P&T Committee);

b) The clinical efficacy of the drug consistent with the determination of the Food and Drug Administration and the recommendations of the P&T Committee;

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

12a. Prescribed Drugs, continued.

d) 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

e) 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:

a) 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.

b) 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.

c) 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.

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

SUPERSEDES: TN- 03-25

12a. Prescribed Drugs

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

12a. Prescribed Drugs, continued.

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