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State/Territory Name: Texas

State Plan Amendment (SPA) #: 17-0011

This file contains the following documents in the order listed:

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- 4) Approved Pages



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

September 22, 2017

Ms Jami Snyder State Medicaid Director Post Office Box 13247, MC: H-100 Austin, TX 78711

Dear Ms Snyder:

We have reviewed Texas's State Plan Amendment (SPA) 17-0011, Prescribed Drugs, received in the Dallas Regional Office on June 27, 2017.

This amendment is to bring the state plan into compliance with the applicable requirements of 42 Code of Federal Regulations (CFR) §447.518, relating to payment for covered outpatient drugs, specifically as it relates to addressing reimbursement methodology for 340B drugs, physician administered drugs, clotting factor, federal supply schedule and drugs purchased at nominal price. The proposed amendment does not affect previously approved pharmacy reimbursement components in SPA 15-005.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 17-0011 is approved with an effective date of April 1, 2017. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Texas's state plan will be forwarded by the Dallas Regional Office.

If you have any questions regarding this amendment, please contact Pamela Schweitzer at (410) 786-2832 or <u>pamela.schweitzer@cms.hhs.gov</u>.

Sincerely,

s/s

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

CC: Bill Brooks, ARA, CMS, Dallas Regional Office Billy Bob Farrell, CMS, Dallas Regional Office Ford Blunt, CMS, Dallas Regional Office Beren Dutra, Texas Health & Human Services

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: 17-0011	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: April 1, 2017		
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: SE a. FFY 2017 \$0	E ATTACHMENT	
42 Code of Federal Regulations (CFR) §447.518	b. FFY 2018 \$0 c. FFY 2019 \$0		
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:	9. PAGE NUMBER OF THE SUPERSE OR ATTACHMENT (If Applicable):	DED PLAN SECTION	
SEE ATTACHMENT TO BLOCKS 8 & 9	SEE ATTACHMENT TO BLOCKS 8	& 9	
10. SUBJECT OF AMENDMENT:			
The purpose of this amendment is to bring the state plan into compliance with the applicable requirements of 42 Code of Federal Regulations (CFR) §447.518, relating to payment for covered outpatient drugs.			
11. GOVERNOR'S REVIEW (Check One):			
GOVERNOR'S OFFICE REPORTED NO COMMENT	OTHER, AS SPECIFIED: Sent to Governor's Office this date. Comments, if any, will be forwarded upon receipt.		
COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
12. SIGNATURE OF STATE AGENCY OFFICIAL:	16. RETURN TO: Jami Snyder		
13. TYPED NĂME: Jami Snyder	State Medicaid Director Post Office Box 13247, MC: H-100 Austin, Texas 78711		
14. TITLE: State Medicaid Director			
15. DATE SUBMITTED: June 27, 2017			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED: June 27, 2017	18. DATE APPROVED: September 22	2, 2017	
PLAN APPROVED – ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: April 1, 2017	20. SIGNATURE OF REGIONAL OFFICE		
21. TYPED NAME: Bill Brooks	22. TITLE: Associate Regional Adm Division of Medicaid an		
23. REMARKS:			

Attachment to Blocks 8 & 9 of CMS Form 179

Transmittal Number 17-0011

Number of the Plan Section or Attachment

Attachment 4.19-B Page 2b Page 2c Page 2c.1 Page 2c.2 Page 2c.3 Page 2d

Number of the Superseded Plan Section or Attachment

Attachment 4.19-B Page 2b (TN 15-0005) Page 2c (TN 15-0005) Page 2c.1 N/A - New Page 15-0005 Approved Page 2c.2 N/A - New Page 2-16-17 Page 2c.3 N/A - New Page Page 2d (TN 15-0005)

Pharmacy Reimbursement Methodology

1. General

The upper limit for payment for prescribed drugs, whether legend or nonlegend items, will be based on the lower of the actual acquisition cost (AAC) plus a professional dispensing fee or the usual and customary charge, as defined and determined by the Texas Health and Human Services Commission (HHSC) or its designee. These provisions do not apply to payment for drugs included in a provider's reimbursement formula, such as inpatient or bundled payments.

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2. Reimbursement Methodology:

HHSC or its designee reimburses contracted Medicaid pharmacy providers according to the professional dispensing fee formula defined in this section.

The professional dispensing fee is determined by the following formula: Professional Dispensing Fee = (((Actual Acquisition Cost + fixed component) divided by (1 - the percentage used to calculate the variable component)) - AAC) + delivery incentive + preferred generic incentive.

(a) Drug Ingredient Cost

AAC is defined in Section IIC (Legend and Nonlegend Medications).

(b) Professional Dispensing Fee Determination

- (1) The fixed component is \$7.93.
- (2) The variable component is 1.96%.
- (3) The total professional dispensing fee shall not exceed \$200 per prescription.
- (4) A delivery incentive shall be paid to approve providers who certify a form prescribed by HHSC or its designee that the delivery services meet minimum conditions for payment of the incentive. These conditions include: making deliveries to individuals rather than just to institutions, such as nursing homes; offering no-charge prescription delivery to all Medicaid recipients requesting delivery in the same manner as to the general public; and publicly displaying the availability of prescription delivery services at no charge. The delivery incentive is \$0.15 per prescription and is to be paid on all Medicaid prescriptions filled. This delivery incentive is not to be paid for over-the-counter drugs, which are prescribed as a benefit of this program.
- (5) A preferred generic incentive of \$0.50 per prescription shall be paid on all Medicaid prescriptions filled for preferred generic drugs for which a manufacturer has agreed to pay a supplemental rebate. Preferred generic drugs are subject to the requirements for placement on the Preferred Drug List (PDL).

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(c) Legend and Nonlegend Medications

For all medications, legend and nonlegend, covered by the Vendor Drug Program (VDP) and appearing in the Texas Drug Code Index (TDCI) and updates, the following requirements must be met:

- (1) A participating pharmacy is reimbursed based on the lesser of AAC plus a Professional Dispensing Fee per prescription, or the usual and customary price charged the general public.
- (2) AAC is defined as the Texas Retail Pharmacy Acquisition cost (RetailPAC); long- term care pharmacy acquisition cost (LTCPAC); specialty pharmacy acquisition cost (SPAC); or the 340B price (see subsection (F) of this section). Pharmacies subject to LTCPAC are "Long-term care (LTC) pharmacies." LTC Pharmacies serve LTC Patients, as determined by the Single State Agency, and must be "closed door pharmacies." Closed door pharmacies do not have public- facing operations and do not accept outpatient walk-in patients.
 - (A) AAC is verifiable by invoice audit conducted by HHSC to include necessary supporting documentation that will verify the final cost to the provider.
 - (B) The RetailPAC, LTCPAC, and SPAC will be based on the National Average Drug Acquisition Cost (NADAC) as defined here:

RetailPAC: Ingredient cost = NADAC LTCPAC: Ingredient cost = (NADAC - 2.4%) SPAC: Ingredient cost = (NADAC - 1.7%)

(C) If NADAC is not available for a specific drug, the RetailPAC, LTCPAC, and SPAC will be defined as follows:

RetailPAC: Ingredient cost = (WAC - 2%) LTCPAC: Ingredient cost = (WAC - 3.4%) SPAC: Ingredient cost = (WAC - 8%)

- (D) If NADAC OR WAC is not available for a specific drug, the ingredient cost will be based on pharmacy invoice.
- (E) In compliance with 42 Code of Federal Regulations (C.F.R.) §§447.512 and 447.514, reimbursement for drugs subject to Federal Upper Limits (FULs) may not exceed FULs in the aggregate.

TN: ___17-0011_____ Approval Date: September 22, 2017

Supersedes TN: ___N/A - NEW_ Effective Date: April 1, 2017___ Superseded TN 15-0005 (Approved 2-16-17)

(c) Legend and Nonlegend Medications (continued)

(F) The reimbursement for 340B covered entities that fill prescriptions for Medicaid recipients with drugs purchased under Section 340B of the Public Health Services Act ("Section 340B") is AAC, up to the 340B ceiling price, plus a professional dispensing fee per prescription. The state defines AAC as follows:

NEW DRUG PRICING

BRAND/GENERIC: WAC minus 23.1 percent

ESTABLISHED DRUG PRICING

BRAND/GENERIC DRUGS (excluding HIV PRODUCTS and HEMOPHILIA PRODUCTS): WAC minus 57 percent

HIV PRODUCTS: WAC minus 40 percent HEMOPHILIA PRODUCTS: WAC minus 32 percent

- (G) 340B covered entities that fill prescriptions for Medicaid recipients with covered outpatient drugs not purchased under Section 340B are reimbursed at AAC, plus HHSC's professional dispensing fee. AAC for covered outpatient drugs not purchased under Section 340B, as defined at Section 2(c)(2), is based on NADAC or WAC. If WAC is not available, the ingredients cost will be determined using pharmacy invoice.
- (H) A contracted pharmacy under contract with a 340B covered entity described in section 1927(a)(5)(B) of the Social Security Act that fill prescriptions for Medicaid recipients with drugs purchased under Section 340B will be reimbursed at AAC, up to the 340B ceiling price, as defined as section 2(c)(2)(F), plus the professional dispensing fee.

(c) Legend and Nonlegend Medications (continued)

- (I) Indian Health Service (IHS), Tribal, and Urban Indian Organizations (I/T/U) that fill prescriptions for Medicaid recipients are reimbursed AAC, plus HHSC's professional dispensing fee per prescription. AAC for covered outpatient drugs not purchased under Section 340B, as defined at Section 2(c)(2), is based on NADAC or WAC. If WAC is not available, the ingredients cost will be determined using pharmacy invoice.
- (J) Drugs acquired at the Federal Supply Schedule (FSS) are reimbursed AAC plus HHSC's professional dispensing fee per prescription.
- (K) Drugs acquired at the Nominal Price are reimbursed AAC plus HHSC's professional dispensing fee per prescription.
- (L) Reimbursement for physician-administered drugs and biologicals. In determining the reimbursement methodology for physician-administered drugs and biologicals, Reimbursement for physician- administered drugs and biologicals are based on the lesser of the billed amount, a percentage of the Medicare rate, or one of the following methodologies:
 - (1) If the drug or biological is considered a new drug or biological (that is, approved for marketing by the Food and Drug Administration within 12 months of implementation as a benefit of Texas Medicaid), it may be reimbursed at an amount equal to 89.5 percent of average wholesale price (AWP).
 - (2) If the drug or biological does not meet the definition of a new drug or biological, it may be reimbursed at an amount equal to 85 percent of AWP.
 - (3) Physician-administered drugs purchased under the 340B Drug Program are reimbursed as described under this section of the state plan.Drugs and infusion drugs, may be reimbursed at an amount equal to 106 percent of the average sales price (ASP). Additional information related to physician reimbursement may be found in Attachment 4.19-B, pages 1a to 1a.3 of the Texas Medicaid State Plan.
- (M) Investigational drugs are not a current Texas Medicaid pharmacy benefit.

- (c) Legend and Nonlegend Medications (continued)
 - (1) Notice of a public hearing to receive comments on proposed changes to general pricing determinations derived under these policies shall be published in the Texas Register.
 - (2) Definitions. As used in Section IIC, these terms shall be defined as follows:
 - (N) Reported Manufacturer Price–Information on pricing submitted to VDP by the manufacturer, including Average Wholesale Prices, Average Manufacturer Price, wholesaler costs, direct prices and institutional or contract prices.
 - (O) Wholesale Costs-The net cost of a product to a drug wholesaler or distributor.

TN: _17-0011____ Approval Date: <u>September 22,</u> 2017 Supersedes TN: _15-0005____ Effective Date: _April 1, 2017