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State/Territory Name: Vermont

State Plan Amendment (SPA) #: 18-0001

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form (with 179-like data)
- 3) Approved SPA Page



Disabled and Elderly Health Programs Group

June 8, 2018

Mr. Al Gobeille Secretary, Agency of Human Services P.O. Box 182709 Waterbury, VT 05671-1000

Dear Mr. Gobeille:

We have reviewed Vermont's State Plan Amendment (SPA) 18-0001, Prescribed Drugs, submitted to the Boston Regional Office on May 17, 2018. This SPA proposes to bring Vermont into compliance with the 340B drug pricing program requirements in the Covered Outpatient Drug Final Rule with comment period (CMS-2345-FC).

The Centers for Medicare & Medicaid Services (CMS) issued a companion letter with the approval package for SPA 17-0005, which required the state to remove reference to reimbursement for drugs purchased through the 340B program from SPA 17-0005 and submit a subsequent SPA to become fully compliant with the requirements of the Covered Outpatient Drug Rule. The state has included language in Attachment 4-19-B, Item 12-a, page 4c to meet Medicaid's 340B Drug Pricing Program requirements:

- 1. Payment for drugs, including specialty drugs, purchased through the federal 340B program by 340B covered entities will be at the 340B actual acquisition cost, not to exceed the 340B ceiling price, plus the 340B professional dispensing fee (PDF).
- 2. Payment for physician administered drugs, including specialty physician administered drugs, purchased through the federal 340B program by 340B covered entities will be at the 340B actual acquisition cost, not to exceed the 340B ceiling price.
- 3. Drugs acquired through the federal 340B drug price program and dispensed by 340B contract pharmacies are not covered.
- 4. Payment for drugs purchased outside of the 340B program by 340B covered entities and contract pharmacies will be reimbursed using the logic in Section 12.a.(1) plus the PDF listed in Section 12.a.(2).
- 5. A 340B entity may carve out of the 340B drug pricing program (i.e. the 340B entity opts not to bill Medicaid for drugs purchased through the 340B program.) Payment for non-340B drugs purchased by a 340B entity that has drugs carved out of the 340B program will be reimbursed using the logic in 12.a.(1) plus the PDF listed in Section 12.a.(2).
- 6. The 340B PDF is \$11.13 for non-specialty drugs. The 340B PDF is \$17.03 for specialty drugs.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 18-0001 is approved with an effective date of April 1, 2018. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Vermont's state plan will be forwarded by the Boston Regional Office. If you have any questions regarding this amendment, please contact Yolonda Williams at (410) 786-6618 or yolonda.williams@cms.hhs.gov.

Sincerely,

/s/

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

CC: Richard R. McGreal, ARA, CMS, Boston Regional Office Dylan Frazer, Vermont Agency of Human Services

TRANSMITTAL AND NOTICE OF APPROVAL OF	1. TRANSMITTAL NUMBER:	2. STATE:
STATE PLAN MATERIAL	18-0001	VERMONT
FOR: CENTERS FOR MEDICARE AND MEDICAID SERVICES	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES 5. TYPE OF PLAN MATERIAL <i>(CHECK ONE):</i>	4. PROPOSED EFFECTIVE DATE(S)4/1/18	
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:		
42 CFR Part 447	a. FFY 2018 \$ (170,629) b. FFY 2019 \$ (294,804)	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Att. 4.19-B page 4c	 9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) N/A 	
10. SUBJECT OF AMENDMENT: 340B Drug Pricing Program		
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 12. SIGNATURE OF STATE AGENCY OFFICIAL: AI Gobeille Date: 2018.05.08 16:41:33 Digitally signed by AI Gobeille Digitally signed by AI Gobeille Digitally signed by AI Gobeille Digitally signed by AI Gobeil	Young	OF ADMINISTRATION signed by Susanne R. 118.05.16 17:39:08 -04'00'
13. TYPED NAME:	DYLAN FRAZER	
AL GOBEILLE 14. TITLE: SECRETARY, AGENCY OF HUMAN SERVICES	AGENCY OF HUMAN SERVICES 280 STATE DRIVE, CENTER BUIL WATERBURY, VT 05671-1000	DING
15. DATE SUBMITTED: 5/17/18 FOR REGIONAL OFFICE USE ONLY		
17. DATE RECEIVED: 05/17/18	18. DATE APPROVED: 06/08/18	
PLAN APPROVED - ONE COPY ATTACHED		
19. EFFECTIVE DATE OF APPROVED MATERIAL: 04/01/18	20. SIGNATURE OF REGIONAL OFFICIAL:	
21. TYPED NAME: Richard R. McGreal	22. TITLE Associate Regional Administrator	
23. REMARKS		

OFFICIAL

Attachment 4.19-B Page 4c

METHODS AND STANDARDS OF ESTABLISHING PAYMENT RATES - OTHER MEDICAL CARE (Continued)

- 12. a. Prescribed Drugs (continued)
 - (10) 340B Drug Rebate Program:
 - i. Payment for drugs, including specialty drugs, purchased through the federal 340B program by 340B covered entities will be at the 340B actual acquisition cost, not to exceed the 340B ceiling price, plus the 340B professional dispensing fee (PDF).
 - ii. Payment for physician administered drugs, including specialty physician administered drugs, purchased through the federal 340B program by 340B covered entities will be at the 340B actual acquisition cost, not to exceed the 340B ceiling price.
 - iii. Drugs acquired through the federal 340B drug price program and dispensed by 340B contract pharmacies are not covered.
 - iv. Payment for drugs purchased outside of the 340B program by 340B covered entities will be reimbursed using the logic in Section 12.a.(1) plus the PDF listed in Section 12.a.(2).
 - v. A 340B entity may carve out of the 340B drug pricing program (i.e. the 340B entity opts not to bill Medicaid for drugs purchased through the 340B program.) Payment for non-340B drugs purchased by a 340B entity that has drugs carved out of the 340B program will be reimbursed using the logic in 12.a.(1) plus the PDF listed in Section 12.a.(2).
 - vi. The 340B PDF is \$11.13 for non-specialty drugs. The 340B PDF is \$17.03 for specialty drugs.

Effective Date: <u>04/01/18</u>

Approval Date: <u>06/08/18</u>