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State/Territory Name: Vermont

State Plan Amendment (SPA) #: 17-0005

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

Disabled and Elderly Health Programs Group

April 20, 2018

Al Gobeille, Secretary
Vermont Agency of Human Services
280 State Drive, Center Building
Waterbury, VT 05671-1000

Dear Mr. Gobeille:

We have reviewed the Vermont State Plan (SPA) Amendment TN# 17-0005 received in the Boston Regional Office on June 29, 2017. This SPA proposes to bring Vermont into compliance with the reimbursement requirements in the Covered Outpatient Drug final rule with comment period (CMS-2345-FC).

Vermont SPA 17-0005 includes reimbursement methods that use, among others, the National Average Drug Acquisition cost, plus the professional dispensing fee of $11.13 for non-specialty drugs, and a $17.03 specialty drug professional dispensing fee. This SPA also includes reimbursement rates for federal supply schedule drugs, drugs purchased at a nominal price, physician administered drugs, and payment for clotting factor.

In keeping with the requirements of section 1902 (a)(30)(A) of the Social Security Act, we believe the state has demonstrated that their reimbursement is consistent with efficiency, economy, and quality of care, and are sufficient to ensure that care and services are available to Medicaid beneficiaries at least to the extent they are available to the general population in the geographic area.

That is, available data from July 2016 through June 2017 indicates that a patient traveled on average eleven miles to access a retail pharmacy. Additionally, half of Medicaid beneficiaries only need to travel within 4-5 miles of their home to access a retail pharmacy. From this data we can infer that Vermont Medicaid beneficiaries will have access to pharmacy services at least to the extent available to the general population.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 17-0005 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 Vermont's state plan will be forwarded by the Boston Regional Office. If you have any questions

regarding this amendment please contact Yolonda Williams, of my staff, at (410) 786-6618 or via email at yolonda.williams@cms.hhs.gov if you have any questions.

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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

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
Room 2275
Boston, Massachusetts 02203

Division of Medicaid and Children's Health Operations / Boston Regional Office

April 20, 2018

VIA E-MAIL
Cory Gustafson, Commissioner
Department of Vermont Health Access
280 State Drive
Waterbury, VT 05671

Dear Mr. Gustafson:

This letter is being sent as a companion to our approval of the Vermont State Plan Transmittal Notice (TN) 17-0005, which amends the state plan to implement required changes from the Covered Outpatient Drug Rule. The changes in this state plan amendment are effective on April 1, 2017.

During the review process for SPA 17-0005, it was determined that Vermont required additional time to adequately address its reimbursement for drugs purchased through the 340B program. Therefore, in consultation with CMS it was agreed that the state would 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.

When submitting the subsequent SPA to address reimbursement requirements for drugs purchased through the 340B program, please ensure that the state addresses the following items in Attachment 4.19-B, Item 12-a, page 4B, Section (4):

1. Please provide the reimbursement methodology for 340B purchased drugs. The state may consider the following language: "Payment for drugs purchased through the 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."

2. Describe reimbursement for 340B covered entities purchasing drugs outside of the 340B program (i.e. payment for drugs purchased outside of the 340B program by 340B covered entities will be reimbursed using the lowest of logic in Section 12.a.(1)., plus the PDF listed in Section 12.a.(s)).

3. Does the state allow for 340B entities or providers to carve out of the 340B drug pricing program? Please include the reimbursement methodology on the state plan page.

4. How are Physician-Administered drugs and specialty drugs purchased through the 340B drug pricing program? Please include this language on the state plan page.

5. How were providers, advocates and beneficiaries engaged in the discussion of the use of 340B purchased medications? What were their concerns and how did the state address these concerns?

6. How did the state determine that Medicaid provider access is sufficient to enlist enough providers to assure access to care and services in Medicaid at least to the extent that care and services are available to the general population in the geographic area and are included in the access monitoring for pharmacy?

The state has 90 days from the date of this letter to respond. Within that period, the state may submit SPAs to address the inconsistencies or submit a corrective action plan describing in detail how the state will resolve the issues identified above in a timely manner. Failure to respond may result in the initiation of a formal compliance process. During the 90 days, CMS will provide any required technical assistance.

If you have questions concerning this letter, please contact Gilson DaSilva, Division of Medicaid and Children's Health Operations at (617) 565-1227.

Sincerely,

/s/

Richard R. McGreal
Associate Regional Administrator

cc: Dylan Frazer, VT Medicaid Policy Unit

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: CENTERS FOR MEDICARE AND MEDICAID SERVICES

1. TRANSMITTAL NUMBER: 17-0005

2. STATE: VERMONT

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

4. PROPOSED EFFECTIVE DATE(S)
4/1/17

5. TYPE OF PLAN MATERIAL *(CHECK 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 §447.512; Section 1927 of the Social Security Act

7. FEDERAL BUDGET IMPACT:
a. FFY 2017 $ (271,987)
b. FFY 2018 $ (524,975)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Att. 4.19-B pages 4a and 4b

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*
Att. 4.19-B pages 4a and 4b; repeal page 4a(1)

10. SUBJECT OF AMENDMENT: Pharmacy Reimbursement

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
SIGNATURE OF SECRETARY OF ADMINISTRATION
Susanne R. Young
Digitally signed by Susanne R. Young
Date: 2017.06.23 17:11:00 -04'00'

12. SIGNATURE OF STATE AGENCY OFFICIAL:
Al Gobeille
Digitally signed by Al Gobeille
Date: 2017.06.17 12:43:58 -04'00'

13. TYPED NAME:
AL GOBEILLE

14. TITLE:
SECRETARY, AGENCY OF HUMAN SERVICES

15. DATE SUBMITTED: 6/29/17

16. RETURN TO:
DYLAN FRAZER
AGENCY OF HUMAN SERVICES
280 STATE DRIVE, CENTER BUILDING
WATERBURY, VT 05671-1000

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: June 29, 2017

18. DATE APPROVED: April 20, 2018

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: April 1, 2017

20. SIGNATURE OF REGIONAL OFFICIAL:
/s/

21. TYPED NAME: Richard R. McGreal

22. TITLE Associate Regional Administrator

23. REMARKS
State approves pen & ink change to Box 6

FORM CMS-179 (07-92)

Instructions on Back

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

12 a. Prescribed Drugs

(1) Payment of brand and generic covered outpatient drugs, including over-the-counter drugs and compounded drug products, dispensed by an enrolled pharmacy will include the reimbursement for the Actual Acquisition Cost (AAC) of the drug plus a professional dispensing fee (PDF). All covered outpatient drugs will be reimbursed the lowest of:

a. The National Drug Average Acquisition Cost (NADAC) + PDF;
b. The Wholesale Acquisition Cost (WAC) + 0% + PDF;
c. The State Maximum Allowable Cost (SMAC) + PDF;
d. The Federal Upper Limit (FUL) + PDF
e. AWP-19% + PDF;
f. Submitted Ingredient Cost + Submitted dispensing fee;
g. The provider's Usual and Customary (U&C) charges; or
h. The Gross Amount Due (GAD).

(2) A Professional Dispensing Fee (PDF) will be paid for (a) through (e) above:

a. The Professional Dispensing Fee for a retail community, institutional or long-term care pharmacy is $11.13.
b. The Professional Dispensing Fee for specialty drugs including but not limited to biologics and limited distribution drugs is $17.03.

(3) Payment for Clotting Factors from specialty pharmacies will include the Actual Acquisition Cost (AAC) plus a professional dispensing fee as described in (2) above. Reimbursement shall be the lowest of:

a. The National Drug Average Acquisition Cost (NADAC) + PDF;
b. The Wholesale Acquisition Cost (WAC) + 0% + PDF;
c. The State Maximum Allowable Cost (SMAC) + PDF;
d. AWP-19% + PDF;
e. Submitted Ingredient Cost + Submitted dispensing fee;
f. The provider's Usual and Customary (U&C) charges; or
g. The Gross Amount Due (GAD).

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

12. a. Prescribed Drugs (continued)

(4) Payment for Clotting Factors through Hemophilia Treatment Center specialty pharmacies will be reimbursed at the lowest of:

a. The Wholesale Acquisition Cost (WAC) + 0% + PDF;
b. The State Maximum Allowable Cost (SMAC) + PDF;
c. AWP-19% + PDF;
d. Submitted Ingredient Cost + Submitted dispensing fee;
e. The provider's Usual and Customary (U&C) charges; or
f. The Gross Amount Due (GAD).

(5) Facilities purchasing drugs through the Federal Supply Schedule (FSS) or the drug pricing program under 38 U.S.C. 1826, 42 U.S.C. 256b, or 42 U.S.C. 1396-8, other than the 340B drug pricing program will be reimbursed no more than the actual acquisition cost for the drug plus a $11.13 professional dispensing fee.

(6) Facilities purchasing drugs at Nominal Price (outside of 340B or FSS), will be reimbursed no more than the Actual Acquisition Cost for the drug plus a $11.13 Professional Dispensing Fee. Nominal Price as defined in 447.502 of the Code of Federal Regulations, Part 42 means a price that is less than 10% of the average manufacturer price (AMP) in the same quarter for which the AMP is computed.

(7) Investigational drugs are not a covered service under the DVHA pharmacy program.

(8) Rates for all Physician Administered Drug prices are 93% of Medicare's Average Sales Price (ASP) +6%. Rates for Physician Administered Drugs will be updated every six months using the latest version of Medicare's ASP pricing file. Medicaid reimbursement for Physician Administered Drugs may not exceed the amount that Medicare recognizes for such services. All rates are published on DVHA's website.