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State/Territory Name: Maryland

State Plan Amendment (SPA) #: 17-0004

This file contains the following documents in the order listed:

- 1) Approval Letters
- 2) CMS 179 Form
- 3) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
150 S. Independence Mall West
Suite 216, The Public Ledger Building
Philadelphia, Pennsylvania 19106-3499



Region III/Division of Medicaid and Children's Health
SWIFT: 061320174015

September 1, 2017

Dennis R. Schrader, Secretary
Maryland Department of Health
201 West Preston Street
Baltimore, Maryland 21201

Dear Mr. Schrader:

We have reviewed Maryland's State Plan Amendment (SPA) 17-0004 received in the Philadelphia Regional Office on June 9, 2017. This SPA proposes to bring Maryland into compliance with the reimbursement requirements in the Covered Outpatient Drug final rule with comment period (CMS-2345-FC). Please find attached the approval letter, Form 179 and related SPA pages for incorporation into your state plan from the CMS Division of Pharmacy for this amendment.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 17-0004 is approved with an effective date of April 1, 2017.

If you have any questions regarding this amendment, please contact Terry Simananda at (410) 786-8144 or terry.simananda@cms.hhs.gov or my staff, Talbatha Myatt at (215) 861- or talbatha.myatt@cms.hhs.gov.

Sincerely,

/s/

Francis T. McCullough
Associate Regional Administrator

cc:

Susan J. Tucker, Executive Director, OHS-Maryland DHMH



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

August 30, 2017

Dennis R. Schrader, Secretary
Maryland Department of Health
201 W. Preston Street
Baltimore, MD 21201

Dear Mr. Schrader:

We have reviewed Maryland's State Plan Amendment (SPA) 17-0004 received in the Philadelphia Regional Office on June 9, 2017. This SPA proposes to bring Maryland into compliance with the reimbursement requirements in the Covered Outpatient Drug final rule with comment period (CMS-2345-FC).

SPA 17-0004 establishes reimbursement for covered outpatient drugs using an actual acquisition cost methodology and implements a professional dispensing fee of \$10.49. This SPA also includes reimbursement for 340B drugs, physician-administered drugs, clotting factor, federal supply schedule, and drugs purchased at nominal price. The state provided data and studies to demonstrate that the acquisition cost methodology and pharmacy dispensing fees being paid are sufficient to assure that Maryland's beneficiaries will have access to pharmacy services at least to the extent as 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 17-0004 is approved with an effective date of April 1, 2017. A copy of the revised signed CMS-179 form, as well as the pages approved for incorporation into Maryland's state plan will be forwarded by the Philadelphia Regional Office.

If you have any questions regarding this amendment, please contact Terry Simananda at (410) 786-8144 or terry.simananda@cms.hhs.gov.

Sincerely,

/s/

Meagan T. Khau
Deputy Director
Division of Pharmacy

cc: Francis T. McCullough, ARA, CMS, Philadelphia Regional Office
Talbatha Myatt, CMS, Philadelphia Regional Office
Susan J. Tucker, Executive Director, Maryland Department of Health

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER: 17-0004	2. STATE Maryland
	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 April 1, 2017	

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: NA 42 CFR Part 447	7. FEDERAL BUDGET IMPACT: a. FFY 2017: \$ 279,000.00 b. FFY 2018: \$ 279,000.00
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8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Att. 4.19B pages 35 & 35A (Amend) Att. 4.19B pages 35B (Delete)	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Att. 4.19B pages 35 & 35A Att. 4.19B pages 35B
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10. SUBJECT OF AMENDMENT: To revise Maryland's reimbursement methodology for covered outpatient drugs for Medicaid fee-for-service program from an estimated acquisition cost (EAC) to an actual acquisition cost (AAC) based reimbursement methodology as required by CMS-2345-FC.

11. GOVERNOR'S REVIEW (Check One):

GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED:
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED Susan J. Tucker, Executive Director
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL Office of Health Services

12. SIGNATURE OF S/s/	NCY OFFICIAL:	16. RETURN TO: Susan J. Tucker, Executive Director ●HS - DHMH 201 W. Preston St., 1 st floor Baltimore, MD 21201
13. TYPED NAME: JH	cMahon	
14. TITLE: Deputy Secretary, ●Office of Health Care Financing		
15. DATE SUBMITTED: 6/8/2017		

FOR REGIONAL OFFICE USE ONLY	
17. DATE RECEIVED: June 9, 2017	18. DATE APPROVED: August 30, 2017
PLAN APPROVED - ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: April 1, 2017	20. SIGNATURE OF REGIONAL OFFICIAL: /s/
21. TYPED NAME: Francis M. McCullough	22. TITLE: Associate Regional Administrator

23. REMARKS:
7/31/17 - state authorized Pen + Inis change to Box 6

A. Payment for Drugs shall be as follows:

1. Payment for covered outpatient legend and non-legend drugs dispensed by a retail community pharmacy shall be lower of:
 - a. The provider's usual and customary (U & C) charge to the public, as identified by the claim charge, or
 - b. The National Average Drug Acquisition Cost (NADAC) of the drug plus a Professional Dispensing Fee (PDF) of \$ 10.49 and when NADAC is unavailable:
 - i. The Wholesale Acquisition Cost (WAC) + 0% plus a PDF of \$ 10.49; or
 - ii. The Federal Upper Limit (FUL) plus a PDF of \$ 10.49; or
 - iii. The State Actual Acquisition Cost (SAAC) plus a PDF of \$ 10.49. SAAC is defined as the ingredient cost of any drug based upon a survey of providers' actual prices paid to acquire drug marketed or sold by specific manufacturers, when NADAC is unavailable.
2. Payment for specialty drugs not dispensed by a retail community pharmacy but dispensed primarily through the mail shall be lower of:
 - a. The provider's usual and customary (U & C) charge to the public, as identified by the claim charge, or
 - b. The National Average Drug Acquisition Cost (NADAC) of the drug plus a Professional Dispensing Fee (PDF) of \$ 10.49 and when NADAC is unavailable:
 - i. The Wholesale Acquisition Cost (WAC) + 0% plus a PDF of \$ 10.49; or
 - ii. The Federal Upper Limit (FUL) plus a PDF of \$ 10.49; or
 - iii. The State Actual Acquisition Cost (SAAC) plus a PDF of \$ 10.49.
3. Payment for drugs not dispensed by a retail community pharmacy (i.e., institutional or long-term care facility pharmacies) shall be the lower of:
 - a. The provider's usual and customary (U & C) charge to the public, as identified by the claim charge, or
 - b. The National Average Drug Acquisition Cost (NADAC) of the drug plus a Professional Dispensing Fee (PDF) of \$ 11.49 and when NADAC is unavailable:
 - i. The Wholesale Acquisition Cost (WAC) + 0% plus a PDF of \$ 11.49; or
 - ii. The Federal Upper Limit (FUL) plus a PDF of \$ 11.49; or
 - iii. The State Actual Acquisition Cost (SAAC) plus a PDF of \$ 11.49.
4. Payment for clotting factor from specialty pharmacies, hemophilia treatment centers (HTC) and Centers of Excellence shall be the lower of:
 - a. The provider's usual and the customary (U & C) charge to the public, as identified by the claim charge, or

- b. Wholesale Acquisition Cost (WAC) + 0% plus a Professional Dispensing Fee (PDF) of \$10.49, or
 - c. The Actual Acquisition cost (AAC) + 8% plus a PDF of \$10.49. AAC is defined as the invoice submitted by the provider to the Program for a clotting factor.
2. 340B covered entities and Federally Qualified Health Centers (FQHCs) that fill Medicaid member prescriptions with drugs purchased at the prices authorized under Section 340B of the Public Health Services Act will be reimbursed no more than the actual acquisition cost for the drug plus a \$12.12 Professional Dispensing Fee. 340B covered entities that fill Medicaid member prescriptions with drugs not purchased under the Section 340B of the Public Health Services Act will be reimbursed in accordance to section (A) (1) – (4).
 3. Drugs purchased through the Federal Supply Schedule (FSS) will be reimbursed no more than the actual acquisition cost for the drug plus a \$10.49 Professional Dispensing Fee.
 4. Drugs purchased at Nominal Price (outside of 340B or FSS) will be reimbursed no more than the actual acquisition cost for the drug plus a \$10.49 Professional Dispensing Fee.
 5. Physician administered drugs (PADs) submitted under the medical benefit will be reimbursed at the provider's acquisition cost. PADs purchased at the prices authorized under Section 340B of the Public Health Services Act and submitted by FQHCs under the medical benefit will be part of all-inclusive payment rate.
 6. Investigational drugs are not a covered service under the Maryland Medicaid.

Delete Page

TN: 17-0004
Supersedes TN #: 11-16

Approved Date:
August 30, 2017

Effective Date:
April 1, 2017