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**State Name:** Delaware

**State Plan Amendment (SPA) #:** 16-001

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

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 Operations**

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SWIFT #030120164099

October 13, 2016

Mr. Stephen M. Groff, Director  
Division of Medicaid and Medical Assistance  
P.O. Box 906  
New Castle, DE 19720-0906

Dear Mr. Groff:

We are pleased to inform you of the approval of Delaware State Plan Amendment (SPA) 16-001. This amendment revises the State Plan regarding the Pharmaceutical Services, specifically to require entities that purchase 340B drug products to request to use these drugs for all Department of Medical Assistance Programs (DMAP) patients, including Medicaid fee-for-service patients and for patients whose care is covered by Medicaid Managed Care Organizations.

Enclosed is a copy of the approved SPA page and the signed CMS-179 form. The effective date of this amendment is January 1, 2016.

If you have any questions, you may contact Michael Cleary at (215) 861-4282.

Sincerely,

/S/

Francis McCullough  
Associate Regional Administrator

Enclosures

<b>TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL</b>		1. TRANSMITTAL NUMBER: SPA #16-001	2. STATE DELAWARE
<b>FOR: HEALTH CARE FINANCING ADMINISTRATION</b>		3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES		4. PROPOSED EFFECTIVE DATE January 1, 2016	
5. TYPE OF PLAN MATERIAL (Check One): <input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)			
6. FEDERAL STATUTE/REGULATION CITATION: 1927(a)(1) and 1927 (a)(4) of the Social Security Act 42 CFR §440.120 42 CFR Part 10		7. FEDERAL BUDGET IMPACT: a. FFY 2016      \$ -0- b. FFY 2017      \$ -0-	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:  ATTACHMENT 4.19-B Page 14		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable):  ATTACHMENT 4.19-B Page 14	
10. SUBJECT OF AMENDMENT: PHARMACEUTICAL SERVICES – 340B <del>EXCLUSION</del> ENTITY PARTICIPATION			
11. GOVERNOR'S REVIEW (Check One): <input type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input checked="" type="checkbox"/> OTHER, AS SPECIFIED: <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED      Governor's comments under separate <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL      correspondence			
12. SIGNATURE OF STATE AGENCY OFFICIAL: //Stephen M. Groff – signature//		16. RETURN TO:  Stephen M. Groff Director Division of Medicaid and Medical Assistance P.O. Box 906 New Castle, Delaware 19720-0906	
13. TYPED NAME: Stephen M. Groff, Director, Division of Medicaid and Medical Assistance			
14. TITLE: Designee for Rita M. Landgraf, Secretary, Delaware Health and Social Services			
15. DATE SUBMITTED: February 11, 2016			
<b>FOR REGIONAL OFFICE USE ONLY</b>			
17. DATE RECEIVED: February 11, 2016		18. DATE APPROVED: October 13, 2016	
PLAN APPROVED – ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: January 1, 2016		20. SIGNATURE OF REGIONAL OFFICIAL: /S/	
21. TYPED NAME: Francis McCullough		22. TITLE: Associate Regional Administrator	
23. REMARKS:  Pen and Ink change to Box #10 changing Subject of Amendment to "Pharmaceutical Services - 340B Entity Participation"			

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES – OTHER TYPES OF CARE

REIMBURSEMENT FOR PHARMACEUTICALS

Overview

The Delaware Medical Assistance Program (DMAP) will reimburse pharmaceuticals using the lower of:

- The usual and customary (U & C) charge to the general public for the product,
- National Average Drug Acquisition Cost (NADAC) or if a NADAC is not available the Average Wholesale Price (AWP) minus 19%,
- A State-specific maximum allowable cost (DMAC) when the purchase price is not appropriately represented by either the NADAC or the Average Wholesale Price (AWP) minus 19%,
- The Federal Upper Limit (FUL) will not be used since the NADAC reflects the actual acquisition cost.

Entities that qualify for special purchasing under Section 602 of the Veterans Health Care Act of 1992, and entities exempt from the Robinson-Patman Price Discrimination Act of 1936 must charge the DMAP no more than their actual acquisition cost (AAC) plus a professional dispensing fee. The AAC must be supported by invoice and payment documentation.

Entities that purchase Section 340B of the Public Health Service Act products must request to use these drugs for all DMAP patients, including Medicaid fee-for-service patients and for patients whose care is covered by Medicaid Managed Care Organizations.

Professional Dispensing Fee

The professional dispensing fee rate is ten dollars (\$10.00). There is one-time professional fee per thirty (30)-day period unless the class of drugs is routinely prescribed for a limited number of days.

Definitions

Delaware Maximum Allowable Cost (DMAC) - a maximum price set for reimbursement:

- when a single source product has Average Selling Prices provided by the manufacturer that indicates the AWP is exaggerated, or
- when the NADAC does not reflect the most current cost of a multiple source drug, or
- if a single provider agrees to a special price.

Any willing provider can dispense the product.

TN No. SPA #16-001	Approval Date <u>October 13, 2016</u>
Supersedes	
TN No. SPA #14-0008	Effective Date <u>January 1, 2016</u>