Table of Contents

State/Territory Name: Pennsylvania

State Plan Amendment (SPA) #: PA-16-0038

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS Pharmacy Team Approval Letter
- 3) CMS Form 179/Summary Form (with 179-like data)
- 4) 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

SWIFT #100520164031

November 16, 2016

Theodore Dallas
Secretary of Human Services
Department of Human Services
Room 333, Health & Welfare Building
P.O. Box 2675
Harrisburg, Pennsylvania 17105-2675

Dear Mr. Dallas:

We are pleased to inform you of the approval of Pennsylvania State Plan Amendment (SPA) 16-0038. This amendment proposes a new supplemental rebate agreement (SRA) with manufacturers on a single-state basis that applies to the Fee-for-Service population only. The state will no longer participate in The Optimal PDL Solution (TOP\$).

Enclosed is a copy of the approved SPA pages and the signed CMS-179 form. Per your approval, we made the requested changes to block seven on the CMS-179 form. The effective date of this amendment is July 1, 2016.

If you have any questions, you may contact Mary McKeon at (215) 861-4181.

/s/

Francis McCullough Associate Regional Administrator DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-14-26 Baltimore, Maryland 21244-1850



Disabled & Elderly Health Programs Group

MOV 0 3 2016

Mr. Theodore Dallas
Secretary of Human Services
Commonwealth of Pennsylvania
Department of Human Services
Office of Medical Assistance Programs
Bureau of Policy, Analysis and Planning
P.O. Box 8046
Harrisburg, PA 17105

Dear Mr. Dallas:

cc:

We have reviewed Pennsylvania State Plan Amendment (SPA) 16-0038 received in the Regional Office on September 15, 2016. The state is proposing a new supplemental rebate agreement (SRA) with manufacturers on a single-state basis that applies to the Fee-for-Service population only. The state will no longer participate in The Optimal PDL Solution (TOP\$).

Based on the information provided, we are pleased to inform you that SPA 16-0038 is approved with an effective date of July 1, 2016. The approval extends only to the authority of the state to enter into a supplemental rebate agreement under section 1927 of the Social Security Act. Per your approval, we made the requested changes to block seven on the CMS-179 form. A copy of the CMS-179 form, as well as the pages approved for incorporation into the Pennsylvania 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.

Sincerely,

/s/

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

Francis McCullough, ARA, Philadelphia Regional Office Mary McKeon, Philadelphia Regional Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES HEALTH CARE FINANCING ADMINISTRATION		FORM APPROVED OMB NO. 0938-0193		
TRANSMITTAL AND NOTICE OF APPROVAL OF	I. TRANSMITTAL NUMBER:	2. STATE		
STATE PLAN MATERIAL	16-0038	Pennsylvania		
for: Health care financing administration	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)			
TO: REGIONAL ADMINISTRATOR	4. PROPOSED EFFECTIVE DATE	The second secon		
HEALTH CARE FINANCING ADMINISTRATION	July 1, 2016			
DEPARTMENT OF HEALTH AND HUMAN SERVICES 5. TYPE OF PLAN MATERIAL (Check One):	1			
5. TYPE OF PLAN MATERIAL (Check Une):				
☐ NEW STATE PLAN ☐ AMENDMENT TO BE	CONSIDERED AS NEW PLAN	M AMENDMENT		
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AME		ch amendment)		
6. PEDERAL STATUTE/REGULATION CITATION:	7. FEDERAL BUDGET IMPACT:			
Section 1927 of the Social Security Act		2016 \$0		
		2017 \$0		
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:	9. PAGE NUMBER OF THE SUPER OR ATTACHMENT (If Applicable			
Page 5b of Attachment 3.1A/3.1B		1653		
	Page 5b of Attachment 3.1A/3.1B			
10. SUBJECT OF AMENDMENT:				
Changes in supplemental rebates for pharmacy services				
	A STATE OF THE PARTY OF THE PAR			
11. GOVERNOR'S REVIEW (Check One):				
☐ GOVERNOR'S OFFICE REPORTED NO COMMENT		CIFIED: Review and		
☐ GOVERNOR'S OFFICE REPORTED NO COMMENT ☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED	approval authorit	y has been delegated		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL	approval authorit			
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURALE SPATE ARENAN OFFICIAL:	approval authorit to the Department 16. RETURN TO:	y has been delegated		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania	y has been delegated		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURALE SPATE ARENA OFFICIAL: /S/ 13. TYPED NAME:	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services	y has been delegated at of Public Welface		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURALE SPATE ALENDA OFFICIAL: /S/ 13. TYPED NAME: Theodore Dallas	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Pro-	y has been delegated at of Public Welface		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURALE SPATE ALENDA OFFICIAL: /S/ 13. TYPED NAME: Theodore Dallas 14. TITLE:	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services	y has been delegated at of Public Welface		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURE SPATE AMENOM OFFICIAL: /S/ 13. TYPED NAME: Theodore Dallas 14. TITLE; Secretary of Human Services	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Propured in the Policy, Analysis and Platent Commonwealth of Policy, Analysis and Platent Commonwealth Commonweal	y has been delegated at of Public Welface		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURALE SPATE ALENDA OFFICIAL: /S/ 13. TYPED NAME: Theodore Dallas 14. TITLE:	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Propured of Policy, Analysis and Plate P.O. Box 8046	y has been delegated at of Public Welface		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURES SPATE AMENON OFFICIAL: S	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Properties of Policy, Analysis and Plate P.O. Box 8046 Harrisburg, Pa.17105	y has been delegated at of Public Welface		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURES SPATE AMENON OFFICIAL: S 13. TYPED THAME: Theodore Dallas 14. TITLE: Secretary of Human Services 15. DATE SUBMITTED: SEP 1 5 2016 FOR REGIONAL OF	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Properties of Policy, Analysis and Plate P.O. Box 8046 Harrisburg, Pa.17105 PICE USE ONLY 18. DATE APPROVED:	y has been delegated at of Public Welface		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURE SPATE ARENA OFFICIAL: S 13. TYPED NAME: Theodore Dallas 14. TITLE: Secretary of Human Services 15. DATE SUBMITTED: SEP 1 5 2016 FOR REGIONAL OF SEP 15, 2016	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Properties and Players of Policy, Analysis and Players, Pa. 17105 FICE USE ONLY 18. DATE APPROVED: November 3, 2016	y has been delegated at of Public Welface		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURES SPATE AMENON OFFICIAL: S 13. TYPED THAME: Theodore Dallas 14. TITLE: Secretary of Human Services 15. DATE SUBMITTED: SEP 1 5 2016 FOR REGIONAL OF PLAN APPROVED - ON	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Properties and Players of Policy, Analysis and Players, Pa. 17105 FICE USE ONLY 18. DATE APPROVED: November 3, 2016	y has been delegated at of Public Welfare gravus anning		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURE SPATE ARENA OFFICIAL: S 13. TYPED NAME: Theodore Dallas 14. TITLE: Secretary of Human Services 15. DATE SUBMITTED: SEP 1 5 2016 FOR REGIONAL OF SEP 15, 2016	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Propuration of Policy, Analysis and Plate P.O. Box 8046 Harrisburg, Pa.17105 FICE USE ONLY 18. DATE APPROVED: November 3, 2016 E COPY ATTACHED	y has been delegated at of Public Welfare gravus anning		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURE SPATE AMENON OFFICIAL: S 13. TYPED THAME: Theodore Dallas 14. TITLE: Secretary of Human Services 15. DATE SUBMITTED: SEP 1 5 2016 FOR REGIONAL OF PLAN APPROVED ON 19. EFFECTIVE DATE OF APPROVED MATERIAL:	approval authorit to the Department to the Department to the Department of the Department of Pennsylvania Department of Human Services Office of Medical Assistance Program of Policy, Analysis and Play P.O. Box 8046 Harrisburg, Pa.17105 PICE USE ONLY 18. DATE APPROVED: November 3, 2016 E COPY ATTACHED 30 SIFTM DITTER OF RECEIVALT 2016	y has been delegated at of Public Welfare		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURE SPATE AMENOM OFFICIAL: S	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Properties of Policy, Analysis and Play. Bureau of Policy, Analysis and Play. P.O. Box 8046 Harrisburg, Pa.17105 PICE USE ONLY 18. DATE APPROVED: November 3, 2016 E COPY ASTACHED 20. SHEW AFTER THE RECECTION AT APPROVED.	y has been delegated at of Public Welfare		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURE SPATE AMENOMOFFICIAL: S	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Properties of Policy, Analysis and Plate P.O. Box 8046 Harrisburg, Pa.17105 PICE USE ONLY 18. DATE APPROVED: November 3, 2016 E COPY ATTACHED 30 SHIM ATTACHED ASSOCIATE REGIONAL Admin/S	y has been delegated at of Public Welfare		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURE SPATE ALENCE OFFICIAL: S	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Properties of Policy, Analysis and Plate P.O. Box 8046 Harrisburg, Pa.17105 PICE USE ONLY 18. DATE APPROVED: November 3, 2016 E COPY ATTACHED 30 SHIM ATTACHED ASSOCIATE REGIONAL Admin/S	y has been delegated at of Public Welfare		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURE SPATE AMENOMOFFICIAL: S	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Properties of Policy, Analysis and Plate P.O. Box 8046 Harrisburg, Pa.17105 PICE USE ONLY 18. DATE APPROVED: November 3, 2016 E COPY ATTACHED 30 SHIM ATTACHED ASSOCIATE REGIONAL Admin/S	y has been delegated at of Public Welfare		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURE SPATE AMENOMOFFICIAL: S	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Properties of Policy, Analysis and Plate P.O. Box 8046 Harrisburg, Pa.17105 PICE USE ONLY 18. DATE APPROVED: November 3, 2016 E COPY ATTACHED 30 SHIM ATTACHED ASSOCIATE REGIONAL Admin/S	y has been delegated at of Public Welfare		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURE SPATE AMENOMOFFICIAL: S	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Properties of Policy, Analysis and Plate P.O. Box 8046 Harrisburg, Pa.17105 PICE USE ONLY 18. DATE APPROVED: November 3, 2016 E COPY ATTACHED 30 SHIM ATTACHED ASSOCIATE REGIONAL Admin/S	y has been delegated at of Public Welfare		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURE SPATE AMENOMOFFICIAL: S	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Properties of Policy, Analysis and Plate P.O. Box 8046 Harrisburg, Pa.17105 PICE USE ONLY 18. DATE APPROVED: November 3, 2016 E COPY ATTACHED 30 SHIM ATTACHED ASSOCIATE REGIONAL Admin/S	y has been delegated at of Public Welfare		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL 12. SIGNATURALE SPATE ALENAL OFFICIAL: 13. TYPED NAME: Theodore Dallas 14. TITLE: Secretary of Human Services 15. DATE SUBMITTED: SEP 1 5 2016 FOR REGEONAL OF 17. DATE RECEIVED: September 15, 2016 PLAN APPROVED ON 19. EFFECTIVE DATE OF APPROVED MATERIAL: July 1, 2016 21. TYPED NAME: Fran McCullough 23. REMARKS.	approval authorit to the Department 16. RETURN TO: Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Properties of Policy, Analysis and Plate P.O. Box 8046 Harrisburg, Pa.17105 PICE USE ONLY 18. DATE APPROVED: November 3, 2016 E COPY ATTACHED 30 SHIM ATTACHED ASSOCIATE REGIONAL Admin/S	y has been delegated at of Public Welfare		

STATE P	LAN UNDER T	ITLE XIX OF	THE SOCIAL	SECURITY ACT
STATE:	COMMONWEA	LTH OF PE	NNSYLVANIA	

ATTACHMENT 3.1A/3.1B Page 5b

	R١		

12. Prescribed Drugs, Dentures, Prosthetic Devices and Eyegiasses

12a. Prescribed Drugs (42 CFR 440.120(a)) (continued)

1. Drug Rebate Agreements

- a. The Commonwealth is in compliance with section 1927 of the Social Security Act. The state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.
- b. The Commonwealth will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the Commonwealth and a pharmaceutical manufacturer will be separate from the federal rebates.
- c. CMS authorized a rebate agreement between the Commonwealth and a drug manufacturer for drugs provided to Medicaid beneficiaries, the Pennsylvania Medicaid Supplemental Rebate Agreement.
- d. The Commonwealth will continue single state-specific supplemental rebates in addition to federal rebates provided for in Title XIX. The single state rebate agreements will be separate from the federal rebates. Supplemental rebates received by the Commonwealth in excess of those required under the federal drug rebate agreement will be shared with the federal government on the same percentage basis as applied under the federal rebate agreement.
- e. CMS has authorized the Commonwealth of Pennsylvania to enter into the Pennsylvania Medicaid Supplemental Rebate Agreement effective July 1, 2016 for the Commonwealth of Pennsylvania.
- f. Supplemental rebates received by the Commonwealth in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.
- g. All drugs covered by the program, inespective of a prior authorization requirement, will comply with provisions of the national drug rebate agreement.

TN No. <u>16-0038</u> Supersedes TN No. <u>15-0011</u>