

Table of Contents

State/Territory Name: Pennsylvania

State Plan Amendment (SPA) #: PA-14-0051

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 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 Operations

SWIFT # 021720154009

FEB 19 2015

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

Dear Mr. Dallas:

The Centers for Medicare & Medicaid Services (CMS) has completed its review of Pennsylvania's State Plan Amendment (SPA) PA-14-0051. We are pleased to inform you that SPA PA-14-0051 has been approved.

SPA PA-14-0051 proposed to add compounded prescriptions, Mozobil, Ranexa, Rilutek, Soliris, and Xenazine to the list of drugs that require prior authorization.

The effective date of this amendment is December 9, 2014. This SPA was approved by the CMS Pharmacy Team on February 3, 2015. You should have received a letter from John M. Coster, Director of the Division of Pharmacy.

Enclosed, please find the signed CMS 179 form, and the approved SPA pages.

If you have any questions concerning this letter, please contact Mary McKeon at (215) 861-4181.

Sincerely,



/s/

Francis McCullough
Associate Regional Administrator

Enclosures

cc: Daniel DeLellis, DHS, Bureau of Policy, Analysis and Planning
Terry Simananda, Division of Pharmacy, CMCS

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

February 3, 2015

Ms. Beverly Mackereth
Secretary of Public Welfare
Commonwealth of Pennsylvania
Office of Medical Assistance Programs
Bureau of Policy, Analysis and Planning
P.O. Box 8046
Harrisburg, PA 17105-2675

Dear Ms. Mackereth:

We have reviewed Pennsylvania State Plan Amendment (SPA) 14-0051, Prescribed Drugs – Limitations on Payment, received in the Regional Office on December 23, 2014. This amendment proposed to add compounded prescriptions, Mozobil, Ranexa, Rilutek, Soliris, and Xenazine to the list of drugs that require prior authorization.

We are pleased to inform you that the amendment is approved, effective December 9, 2014. 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

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

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	1. TRANSMITTAL NUMBER: 14-051	2. STATE Pennsylvania
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
FOR: HEALTH CARE FINANCING ADMINISTRATION	4. PROPOSED EFFECTIVE DATE December 9, 2014	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES		

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: Section 1927 of the Social Security Act	7. FEDERAL BUDGET IMPACT: a. FFY 2015 \$0.00 b. FFY 2016 \$0.00
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Page 5eb of Attachment 3.1.A	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Page 5eb of Attachment 3.1.A

10. SUBJECT OF AMENDMENT:
Prescribed Drugs - Limitations on Payment

11. GOVERNOR'S REVIEW (Check One):

GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED: Review and approval authority has been delegated to the Department of Public Welfare

COMMENTS OF GOVERNOR'S OFFICE ENCLOSED

NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SIGNATURE OF STATE AGENCY OFFICIAL: /s/	16. RETURN TO: 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
13. TYPED NAME: Beverly D. Mackereth	
14. TITLE: Secretary of Human Services	
15. DATE SUBMITTED: DEC 22 2014	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:	18. DATE APPROVED: FEB 03 2015
PLAN APPROVED - ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: DEC 09 2014	20. SIGNATURE OF REGIONAL OFFICIAL: /s/
21. TYPED NAME:	22. TITLE: Associate Regional Administrator
23. REMARKS:	

DESCRIPTION OF LIMITATIONS

SERVICE	LIMITATIONS
12. <u>Prescribed Drugs, Dentures, and Prosthetic Devices, and Eyeglasses</u>	
12.a. Prescribed Drugs (continued)	<u>Limitations on Payment</u>
	3. Drugs not included on the Preferred Drug List, and designated as non-preferred. 4. Reserved 5. Reserved 6. Synagis 7. Xolair 8. Tysabri 9. Early Refills – a request for a refill when more than 15 percent of an earlier-dispensed medication would remain when taken in compliance with the directions and quantity prescribed. 10. Reserved 11. Legend and non-legend cough and cold medications when prescribed for children under 6 (six) years of age. 12. Reserved 13. Reserved 14. Benzodiazepines when prescribed for children under age 21 or that represents duplicate therapy. 15. Reserved 16. Nuedexta 17. Makena 18. Xyrem 19. Kalydeco 20. Korlym 21. H.P. Acthar Gel 22. Vecamyi 23. Immune Globulins 24. Compounded Prescriptions 25. Mozobil 26. Ranexa 27. Rilutek 28. Soliris 29. Xenazine
	(f) Drug Rebate Agreements
	1. 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. 2. 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. 3. CMS authorized a rebate agreement between the Commonwealth and a drug manufacturer for drugs provided to Medicaid recipients, "TOP\$ sm The Optimal PDL Solution State Supplemental Rebate Agreement Among Participating Medicaid Programs Provider Synergies, L.L.C. and (Manufacturer)". 4. The Commonwealth will continue state-specific supplemental rebates and will also participate in a multi-state pooling program that will negotiate supplemental rebates in addition to federal rebates provided for in Title XIX. This multi-state pooling program is known as The Optimal PDL Solution (TOP\$ sm). TOP\$ sm rebate agreements will be separate from the federal rebates. TOP\$ sm 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. 5. CMS has authorized the Commonwealth of Pennsylvania to enter into "The Optimal PDL Solution (TOP\$ sm).". The TOP\$ sm supplemental rebate agreement is effective October 1, 2013 for the Commonwealth of Pennsylvania.

TN# 14-051
 Supersedes
 TN# 14-024

Approval Date **FEB 03 2015** Effective Date: December 9, 2014