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**State/Territory Name: Pennsylvania**

**State Plan Amendment (SPA) #: PA-14-024**

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**

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SWIFT # 060620144060

**JUL 17 2014**

Beverly Mackereth  
Secretary of Public Welfare  
Department of Public Welfare  
Room 333, Health & Welfare Building  
P.O. Box 2675  
Harrisburg, Pennsylvania 17105-2675

Dear Ms. Mackereth:

The Centers for Medicare & Medicaid Services (CMS) has completed its review of Pennsylvania's State Plan Amendment (SPA) PA-14-024. We are pleased to inform you that SPA PA-14-024 has been approved.

SPA PA-14-024 proposed to add Immune Globulins to the list of drugs that require prior authorization. This amendment reflects changes in the prior authorization policy for pharmacy services.

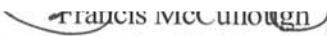
The effective date of this amendment is June 2, 2014. This SPA was approved by the CMS Pharmacy Team on July 8, 2014. You should have received a letter from Larry Reed, Director of the Division of Pharmacy.

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 Sorge, DPW, 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**

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July 8, 2014

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

Dear Ms. Mackereth:

We have reviewed Pennsylvania State Plan Amendment (SPA) 14-024, Prescribed Drugs – Limitations on Payment, received in the Regional Office on June 5, 2014. This amendment proposed to add Immune Globulins to the list of drugs that require prior authorization.

We are pleased to inform you that the amendment is approved, effective June 2, 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/

Joseph L. Fine  
Acting Director  
Division of Pharmacy

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

<b>TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL</b>		1. TRANSMITTAL NUMBER: 14-024	2. STATE Pennsylvania
<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 June 2, 2014	
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: Section 1927 of the Social Security Act		7. FEDERAL BUDGET IMPACT: a. FFY 2014 \$0.00 b. FFY 2015 \$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): <input type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL		<input checked="" type="checkbox"/> OTHER, AS SPECIFIED: Review and approval authority has been delegated to the Department of Public Welfare	
12. SIGNATURE OF STATE AGENCY OFFICIAL:  /s/		16. RETURN TO: Commonwealth of Pennsylvania Department of Public Welfare 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 Public Welfare			
15. DATE SUBMITTED: JUN - 4 2014			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED: JUN 04 2014		18. DATE APPROVED: JUL 08 2014	
PLAN APPROVED - ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: JUN 02 2014		20. SIGNATURE OF REGIONAL OFFICIAL: /s/	
21. TYPED NAME: FRANCIS McCULLOUGH		ASSOCIATE REGIONAL ADMINISTRATOR	
23. REMARKS:			



SERVICE	LIMITATIONS
12. <u>Prescribed Drugs, Dentures, and Prosthetic Devices, and Eyeglasses</u>	
12.a. Prescribed Drugs (continued)	<p data-bbox="500 394 727 415"><u>Limitations on Payment</u></p> <ol style="list-style-type: none"> <li>3. Drugs not included on the Preferred Drug List, and designated as non-preferred.</li> <li>4. Reserved</li> <li>5. Reserved</li> <li>6. Synagis</li> <li>7. Xolair</li> <li>8. Tysabri</li> <li>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.</li> <li>10. Reserved</li> <li>11. Legend and non-legend cough and cold medications when prescribed for children under 6 (six) years of age.</li> <li>12. Reserved</li> <li>13. Reserved</li> <li>14. Benzodiazepines when prescribed for children under age 21 or that represents duplicate therapy.</li> <li>15. Reserved</li> <li>16. Nuedexta</li> <li>17. Makena</li> <li>18. Xyrem</li> <li>19. Kalydeco</li> <li>20. Korlym</li> <li>21. H.P. Acthar Gel</li> <li>22. Vecamyl</li> <li>23. Immune Globulins</li> </ol> <p data-bbox="500 1079 834 1100">(f) Drug Rebate Agreements</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>3. CMS authorized a rebate agreement between the Commonwealth and a drug manufacturer for drugs provided to Medicaid recipients, "TOP\$<sup>sm</sup> The Optimal PDL Solution State Supplemental Rebate Agreement Among Participating Medicaid Programs Provider Synergies, L.L.C. and (Manufacturer)".</li> <li>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\$<sup>sm</sup>). TOP\$<sup>sm</sup> rebate agreements will be separate from the federal rebates. TOP\$<sup>sm</sup> 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.</li> <li>5. CMS has authorized the Commonwealth of Pennsylvania to enter into "The Optimal PDL Solution (TOP\$<sup>sm</sup>). The TOP\$<sup>sm</sup> supplemental rebate agreement is effective October 1, 2013 for the Commonwealth of Pennsylvania.</li> </ol>

TN# 14-024  
 Supersedes  
 TN# 13-048

Approval Date

JUL 08 2014

Effective Date: June 2, 2014