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State/Territory Name: Pennsylvania

State Plan Amendment (SPA) #: PA-11-010

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 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 # 090120114020

SEP 1 2011

Mr. Gary D. Alexander
Secretary
Department of Public Welfare
P.O. Box 2675
Harrisburg, Pennsylvania 17105-2675

Dear Secretary Alexander:

We are pleased to inform you of the approval of Pennsylvania State Plan Amendment (SPA) 11-010, which allows Pennsylvania to require prior authorization for Neudexta and Makna. In addition, the State will continue to provide coverage of compounded hydroxyprogesterone caproate (17-P) as part of the home health benefit. Enclosed is a copy of the approved SPA pages and the signed CMS-179 form. The effective date of this amendment is July 11, 2011.

If you have any questions, you may contact Harry Mirach at (215) 861-4284 or Kia Banton at (215) 861-4252.

Sincerely, — /s/ ↗

Francis McCullough ✓
Acting Associate Regional Administrator

Enclosures

Cc: John Hummel, DPW, Bureau of Policy, Analysis and Planning
Daniel Sorge, DPW, Bureau of Policy, Analysis and Planning

Do you know someone who has been denied medical insurance because of a pre-existing condition? If so, they may be eligible for the new Pre-Existing Condition Insurance Plan. Call toll free 1-866-717-5826 (TTY 1-866-561-1604) or visit www.pcip.gov and click on "Find Your State" to learn more

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	1. TRANSMITTAL NUMBER: 11-010	2. STATE Pennsylvania
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FOR: HEALTH CARE FINANCING ADMINISTRATION	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
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TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE July 11, 2011
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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 2011 -(\$47,954.00) b. FFY 2012 -(\$569,556.00)
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8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Page 5cb of Attachment 3.1A	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Page 5cb of Attachment 3.1A
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10. SUBJECT OF AMENDMENT: Changes in the payment policy for pharmacy services	
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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: <i>/s/</i>	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
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13. TYPED NAME: Gary D. Alexander	
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14. TITLE: Acting Secretary of Public Welfare	
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15. DATE SUBMITTED: JUN 15 2011	
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FOR REGIONAL OFFICE USE ONLY	
17. DATE RECEIVED	18. DATE APPROVED: AUG 8 2011
PLAN APPROVED - ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL	20. SIGNATURE OF REGIONAL OFFICIAL: <i>/s/</i>
21. TYPED NAME: Francis McLaughlin	22. REGIONAL ADMINISTRATOR

23. REMARKS:

[REDACTED]

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
 STATE: COMMONWEALTH OF PENNSYLVANIA
 DESCRIPTION OF LIMITATIONS

ATTACHMENT 3.1A
 Page 58b

SERVICE	LIMITATIONS
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12. Prescribed Drugs, Dentures, and Prosthetic Devices, and Eyeglasses

12.a. Prescribed Drugs
 (continued)

Limitations on Payment

3. Drugs not included on the Preferred Drug List, and designated as non-preferred.
4. Botulinum Toxins
5. *Reserved*
6. Synagis
7. Xolair
8. Tysabri
9. Early Refills – a request for a refill when more than 25 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. Buprenorphine agents, except the initial prescription.
14. Benzodiazepines when prescribed for children under age 21.
15. Conventional antipsychotic agents when prescribed for children under 6 (six) years of age.
16. Nuedexta
17. Makena

(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 state and a pharmaceutical manufacturer will be separate from the federal rebates.

3. A rebate agreement between the state and a drug manufacturer for drugs provided to Medicaid recipients, submitted to CMS on October 1, 2005, and entitled "State of Pennsylvania Department of Public Welfare Supplemental Rebate Agreement" has been authorized by CMS.

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 (TOPSSM). TOPSSM rebate agreements will be separate from the federal rebates. TOPSSM 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 state of Pennsylvania to enter into "The Optimal PDL Solution (TOPSSM). The TOPSSM supplemental rebate agreement was authorized by CMS on 3/13/2007 and is effective January 1, 2007 for the state of Pennsylvania.

Note: See the revised Drug Rebate approval letter from CMS (dated 3/2/10) and the full agreement text at the end of this section by clicking here.

TN# 11-010
 Supersedes
 TN# 10-002

AUG 8 2011

Approval Date _____

Effective Date July 11, 2011