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State/Territory Name: New York

State Plan Amendment (SPA) #: 14-0038

This file contains the following documents in the order listed:

- 1) NY Regional Office Approval Letter
- 2) CO Division of Pharmacy Approval Letter
- 3) CMS-179 form
- 4) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
New York Regional Office
26 Federal Plaza, Room 37-100
New York, NY 10278



DIVISION OF MEDICAID AND CHILDREN'S HEALTH OPERATION

April 24, 2015

Jason A. Helgersen
State Medicaid Director
New York State Department of Health
Bureau of Federal Relations & Provider Assessments
99 Washington Ave -One Commerce Plaza- Suite 1460
Albany, NY 12210

Dear Mr. Helgersen:


We have received a copy of Larry Reed's letter to you, in which he notified you of the approval of New York's State Plan Amendment (SPA) 14-0038. This amendment proposes to revise the NY single-state Medicaid Supplemental Rebate Agreement (SRA) to include definitions and structural changes that would provide the option of including Medicaid managed care utilization for accrual of supplemental rebates.

Approval of NY SPA 14-038 extends only to the NY single-state Medicaid SRA and attachment templates submitted to the Centers for Medicare & Medicaid Services (CMS) on December 31, 2014. These revised SRA documents will replace the current SRA packet submitted to CMS on March 31, 2010. If changes are subsequently made to the SRA or its' attachments, a new SPA and any required documents should be submitted to CMS for review and authorization.

Mr. Reed advised you that the New York Regional Office would forward you the signed CMS-179 form as well as copies of the approved pages. These documents are enclosed. Please note the approval date of the SPA is April 24, 2015 and the effective date is October 1, 2014.

If you have any questions, please contact Ivelisse Salce at (212) 616-2411.

Sincerely,


Michael Melendez
Associate Regional Administrator
Division of Medicaid and Children's Health

Cc: Gail Sexton, Division of Pharmacy Analyst

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

April 24, 2015

Jason A. Helgerson
State Medicaid Director
New York State Department of Health
Bureau of Federal Relations & Provider Assessments
99 Washington Ave –One Commerce Plaza- Suite 1460
Albany, NY 12210

Dear Mr. Helgerson:

We have reviewed New York (NY) State Plan Amendment (SPA) 14-038 received in the NY Regional Office on December 31, 2014. This amendment proposes to revise the NY single-state Medicaid Supplemental Rebate Agreement (SRA) to include definitions and structural changes that would provide the option of including Medicaid managed care utilization for accrual of supplemental rebates. We are pleased to inform you that the amendment is approved, effective October 1, 2014.

Approval of NY SPA 14-038 extends only to the NY single-state Medicaid SRA and attachment templates submitted to the Centers for Medicare & Medicaid Services (CMS) on December 31, 2014. These revised SRA documents will replace the current SRA packet submitted to CMS on March 31, 2010. If changes are subsequently made to the SRA or its' attachments, a new SPA and any required documents should be submitted to CMS for review and authorization.

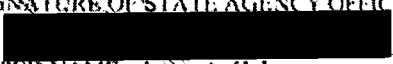

A copy of the signed CMS-179 form, as revised, as well as the pages approved for incorporation into the NY state plan, will be forwarded by the NY Regional Office. If you have any questions regarding this amendment, please contact Gail Sexton at (410)-786-4583.

Sincerely,

/s/

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

cc: Michael Melendez, ARA, DMCHO, New York Regional Office
Ivelisse Salce, New York Regional Office

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL		1. TRANSMITTAL NUMBER: 14-038	2. STATE New York
FOR: HEALTH CARE FINANCING ADMINISTRATION		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 October 1, 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: §1402 of the Social Security Act, and 42 CFR 417 1927 NYL		7. FEDERAL BUDGET IMPACT: a. FFY 10/01/14-09/30/15 \$ (468,893) b. FFY 10/01/15-09/30/16 \$ (30,967,293)	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A Supplement: Page 2(b) Attachment 3.1-B Supplement: Page 2(b)		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Attachment 3.1-A Supplement: Page 2(b) Attachment 3.1-B Supplement: Page 2(b)	
10. SUBJECT OF AMENDMENT: State Specific Supplemental Rebate Agreement (FMAP = 50%)			
11. GOVERNOR'S REVIEW (Check One):			
<input checked="" type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="checkbox"/> OTHER, AS SPECIFIED: <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
12. SIGNATURE OF STATE AGENCY OFFICIAL: 		16. RETURN TO: New York State Department of Health Bureau of Federal Relations & Provider Assessments 99 Washington Ave - One Commerce Plaza Suite 1460 Albany, NY 12210	
13. TYPED NAME: Jason A. Helgeson			
14. TITLE: Medicaid Director Department of Health			
15. DATE SUBMITTED: DEC 31 2014			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED:		18. DATE APPROVED: 04/25/2015	
PLAN APPROVED - ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: 10/01/2014		20. SIGNATURE OF REGIONAL ADMINISTRATOR: 	
21. TYPED NAME: MICHAEL MELENDEZ		22. TITLE: ASSOCIATE REGIONAL ADMINISTRATOR DIVISION OF MEDICAID & CHILDREN'S HEALTH	
23. REMARKS:			

**New York
2(b)**

10. Prior approval is required for all dental care except preventive prophylactic and other routine dental care services and supplies.
- 12a. Prior authorization or dispensing validation is required for some prescription drugs. The State has established a preferred drug program with prior authorization for drugs not included on the preferred drug list. The prior authorization complies with the requirements of Section 1927(d)(5) of the Social Security Act and provides for a 24-hour turnaround by either telephone or other telecommunications device from receipt of request and provides for a 72-hour supply of drugs in emergency circumstances. In addition, brand-name drugs that have a FDA approved, A-rated generic equivalent must be prior authorized unless exempted by the Commissioner of Health. Prior authorization is required for a generic equivalent of a brand name drug, including a generic equivalent that is on the preferred drug list or the clinical drug review program, when the net cost of the brand name drug, after consideration of all rebates, is less than the cost of the generic equivalent.

Drugs for which Medical Assistance reimbursement is available are limited to the following:

1. Outpatient drugs of any manufacturer which has entered into and complies with a rebate agreement under Sections 1902(a)(54) and 1927(a) of the Act with the Centers for Medicare and Medicaid Services (CMS) which are prescribed for a medically accepted indication. All drugs covered by the National Drug Rebate Agreements remain available to Medicaid beneficiaries, although some may require prior authorization. Drugs for the treatment of erectile dysfunction, as set forth in 42 U.S.C. §1396r-8(d)(2)(K), are not a covered service, on and after April 1, 2006, unless such drugs are used to treat conditions other than sexual or erectile dysfunction and these uses have been approved by the Food and Drug Administration.
2. Supplemental Rebate Programs

The State is in compliance with Section 1927 of the Social Security Act. The State has the following policies for the Supplemental Rebate Programs for the Medicaid population.

- a) CMS has authorized the State of New York to enter into the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. The NMPI Supplemental Rebate Agreement (SRA) and the Amendment to the SRA submitted to CMS on March 30, 2006 have been authorized for pharmaceutical manufacturers' existing agreements through their current expiration dates. The updated NMPI SRA submitted to CMS on June 30, 2013 has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.
- b) CMS has authorized the State of New York to enter into Medicaid State-specific Supplemental Rebate Agreement directly with manufacturers to receive supplemental rebates of covered outpatient drugs for Medicaid beneficiaries. The State-specific Supplemental Rebate Agreement was submitted to CMS on December 31, 2014 and has been authorized by CMS.

TN#: 14-0038

Approval Date: **04/24/2015**

Supersedes TN#: 13-0029

Effective Date: **10/01/2014**

**New York
2(b)**

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Drugs for which Medical Assistance reimbursement is available are limited to the following:

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