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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. 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 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 Melender

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:

cc:

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES HEALTH CARE FINANCING ADMINISTRATION		FORM APPROAT
TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	L TRANSMITTAL NUMBER: 14-038	2. STATE
FOR: HEALTH CARE FINANCING ADMINISTRATION	3. PROGRAM IDENTIFICATION	New York
TO: REGIONAL ADMINISTRATOR	SOCIAL SECURITY ACT (ME	DICAID)
HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES 5. TYPE OF PLAN MATERIAL (Check One):	4. PROPOSED EFFECTIVE DATE October 1, 2014	
TO THE OF FLAN MATERIAL ICHECK Oney:		And the state of t
□ NEW STATE PLAN □ AMENDMENT TO BE CON	SIDERED AS NEW PLAN F	7
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMEN	DMENT (Separate Transmitted for and	☑ AMENDMFN1
	7. FEDERAL BUDGET IMPACT:	
\$1402 of the Social Security Act, and 42 CFR 127	a. FFY 10/01/14-09/30/15 S (468.893)	
8. PAGE NUMBER OF THE PLAN SECTION OR A FTACHMENT:	b. FFY 10/01/15-09/30/16 \$ (30	967 70 ti
	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)	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): ☐ GOVERNOR'S OFFICE REPORTED NO COMMENT ☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED	□ OTHER, AS SPE	CIFIED;
NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL. 12. SIGNATURE OF STATE AGENCY OFFICIAL:	16. REIT'RN TO:	and the second s
	New York State Department of Hea	ioi.
13. TYPED NAME: Juston A. Helgerson	Burcau of Federal Relations & Provider Assessments 99 Washington Ave - One Commerce Plaza	
14. TITLE: Mèdicaid Director	Suite 1460	
Department of Health	Albany, NY 12210	
15. DATE SUBMITTED: DEC 3 1 2014	t the state of the	
FOR REGIONAL OFF	ICE LISE ONLY	
17. DATE RECEIVED:	18. DATE APPROVED: 04/25/2015	
PLAN APPROVED - ONE		
19. EFFECTIVE DATE OF APPROVED MATERIAL: 10/01/2014	20 SIGNATURE OF THE WOULD	
21. TYPED NAME: MICHAEL MELENDEZ	22. TITLE: ASSOCIATE REGIO DIVISION OF MEDICAID & CH	NAL ABMINISTRATO IILDREN'S HEALTH
23. REMARKS:	·	
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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#: <u>13-0029</u> Effective Date: 10/01/2014

New York 2(b)

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