Department of Health & Human Services
Centers for Medicare & Medicaid Services
26 Federal Plaza, Room 37-100 North
New York, NY 10278

September 30, 2010

Donna Frescatore
Medicaid Director
Office of Health Insurance Programs
New York State Department of Health
Corning Tower
Empire State Plaza
Albany, New York 12237

Dear Ms. Frescatore:

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) 10-10. This SPA expands the supplemental rebate program to include contracting with manufactures who either do not participate in National Medicaid Pooling Initiative (NMPI) or offer rebates on certain drugs through the NMPI.

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. The revised pages of Attachment 3.1-A and 3.1-B included in your letter of July 3, 2010 have replaced the corresponding pages that were originally submitted on March 31, 2010.

Please note the approval date of the SPA is September 29, 2010 and the effective date is January 1, 2010.

If you have any questions, please contact Ana J. Balbuena (212) 616-2415.

Sincerely,

/s/

Sue Kelly
Associate Regional Administrator
Division of Medicaid and Children's Health

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid, CHIP and Survey & Certification

September 29, 2010

Donna Frescatore
Medicaid Director & Deputy Commissioner
State of New York Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Dear Ms. Frescatore:

We have reviewed New York State Plan Amendment (SPA) 10-10, Prescribed Drugs, received in the Regional Office on March 31, 2010. This amendment establishes a state specific supplemental agreement and allows the State to negotiate supplemental rebates with pharmaceutical manufacturers for Medicaid covered outpatient drugs. We are pleased to inform you that the amendment is approved, effective January 1, 2010.

A copy of the pages approved for incorporation into the New York's State Plan will be forwarded by the New York Regional Office. If you have any questions regarding this request, please contact Angel Davis at (410) 786-4693.

Sincerely,

/s/

Larry Reed
Director
Division of Pharmacy

cc: Sue Kelly, ARA New York Regional Office
Ana Balbuena, New York Regional Office

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 FOR: HEALTH CARE FINANCING ADMINISTRATION	1. TRANSMITTAL NUMBER: **10-10**	2. STATE **New York**
	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 **January 1, 2010**	

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 **2010 $0** b. FFY **2011 ($6.5 million)**
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: **Attachment 3.1A Supplement page 2b, Attachment 3.1B Supplement page 2b** **** SEE REMARKS**	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: **Attachment 3.1A Supplement page 2b, Attachment 3.1B Supplement page 2b**

10. SUBJECT OF AMENDMENT:
State Specific Supplemental Drug Rebate Program

11. GOVERNOR'S REVIEW *(Check One)*:
☒ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:	16. RETURN TO: **New York State Department of Health** **Corning Tower** **Empire State Plaza** **Albany, New York 12237**
13. TYPED NAME: **Donna Frescatore**	
14. TITLE: **Deputy Commissioner Department of Health**	
15. DATE SUBMITTED: 3/31/10	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:	18. DATE APPROVED: SEP 29 2010
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: JAN 01 2010	20. SIGNATURE OF REGIONAL OFFICIAL:
21. TYPED NAME: **Sue Kelly**	22. TITLE: **Associate Regional Administrator Division of Medicaid and State Operations**

23. REMARKS:

Originally submitted pages on March 31, 2010 were revised with pages via State's email of July 3, 2010. (Attachment 3.1-A and Attachment 3.1-B)

Approval date is September 29, 2010 and the effective date is January 1, 2010.

FORM HCFA-179 (07-92)

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 March 20, 2008 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 March 31, 2010 and has been authorized by CMS.

[b)] c) The prior authorization process complies with the requirements of Section 1927 of the Social Security Act and provides for a 24-hour turn-around response by either telephone or telecommunications device from the receipt of a prior authorization request. In emergency situations, providers may dispense a 72-hour supply of medications.

[c)] d The terms of the supplemental rebate programs apply only to covered outpatient drugs for which the State is eligible for federal financial participation. Supplemental rebates received by the State in excess of those required under the National Drug Rebate Program will be shared with the Federal Government on the same percentage basis as applied under the National Drug Rebate Agreement.

[d)] e) Any [contracts]Supplemental Rebate Agreement not [approved] authorized by CMS will be submitted to CMS for [approval] authorization.

[e)] f) All drugs covered by the programs will comply with the provisions of the national drug rebate agreement.

3. Any changes to the NMPI Supplemental Rebate Agreement must be submitted to CMS for [approval] authorization. Any changes to the State-specific Supplemental Rebate Agreement NY State holds directly with the manufacturer must be submitted to CMS for authorization.

4. As provided by the Act, a new drug manufactured by a company which has entered into a rebate agreement may be covered subject to prior approval, unless the drug is subject to the allowable exclusion categories provided by the Act.

5. As specified in Section 1927(b)(3)(D) of the Act, not withstanding any other provisions of law, rebate information disclosed by a manufacturer shall not be disclosed by the state for purposes other than rebate invoicing and verification.

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