CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Department of Health and Human Services
Centers for Medicare & Medicaid Services
Region II
26 Federal Plaza Rm. 3800
New York, N.Y. 10278

MAR 1 2 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) 09-52. This SPA provides for dispensing of brand name drugs that are less expensive than the generic equivalent of the same drug. The SPA also adjusts the co-payments in this situation so that the beneficiary is not penalized for having a brand name drug dispensed. 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 4.18 A and Attachment 4.18C included in your letter of January 21, 2010 have replaced the corresponding pages that were originally submitted on October 8, 2009.

Please note that the approval date of the SPA is March 12, 2010 and the effective date is October1, 2009.

If you have any questions, please contact Julie Alberino at (212) 616-2415.

[redacted]

Acting Associate Regional Administrator
Division of Medicaid and Children's Health

Enclosure

cc: Sue Irwin
David Mosovic

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: **09-52**

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
October 1, 2009

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:
NYS Social Services Law Section 365-a(4)(a-1)(ii) & 367-a(9)(d(ii)

7. FEDERAL BUDGET IMPACT:
a. FFY ~~2010~~ **($2,343,700)**
b. FFY **2011 ($5,998,700)**

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Attachment 4.18-A, page 1c, Attachment 4.18-C page 1c, Attachment 3.1-A Supplement page 2b, Attachment 3.1-B Supplement page 2b, Attachment 4.19-B, pages 4(d) & 4(e) ** SEE REMARKS

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Attachment 4.18-A, page 1c, Attachment 4.18-C page 1c, Attachment 3.1-A Supplement page 2b, Attachment 3.1-B Supplement page 2b, Attachment 4.19-B, pages 4(d) & 4(e)

10. SUBJECT OF AMENDMENT:
Dispense Brand Drugs When Less Expensive

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:
[redacted]

13. TYPED NAME: **Deborah Bachrach**

14. TITLE: **Deputy Commissioner**
Department of Health

15. DATE SUBMITTED:
10/8/09

16. RETURN TO:
New York State Department of Health
Corning Tower
Empire State Plaza
Albany, New York 12237

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:

18. DATE APPROVED: MAR 12 2010

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: OCT 01 2009

20. SIGNATURE OF REGIONAL OFFICIAL:
[redacted]

21. TYPED NAME: **Michael Melendez**

22. TITLE: **Acting Associate Regional Administrator**
Division of Medicaid and State Operations

23. REMARKS:

Pen & Ink change in Block 7 to reflect FFY 2010 & 2011 authorized by State in e-mail of 12/10/09.

Originally submitted pages Attachment 4.18A, page 1c and Attachment 4.18C, page 1c were replaced with revised pages via State e-mail of 01/21/2010.

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 Program
   The State is in compliance with Section 1927 of the Social Security Act. The State has the following policies for the Supplemental Rebate Program 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) 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) The terms of the supplemental rebate program 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) Any contracts not approved by CMS will be submitted to CMS for approval.
   e) All drugs covered by the program 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.

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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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.

Type of Service	Method of Reimbursement
Prescribed Drugs	Reimbursement is the lower of: 1) the upper limit if established by the Federal Government for specific multiple source drugs, plus a dispensing fee, or 2) the billing pharmacy's usual and customary price charged to the general public, or 3) the state maximum acquisition cost (SMAC) plus dispensing fee, or 4) the Estimated Acquisition Cost (EAC) established by State Department of Health, plus dispensing fee. (a) For sole or multi-source brand name drugs, the EAC is defined as average wholesale price (AWP) less sixteen and twenty-five one hundredths percent. (b) For multi-source generic drugs, the EAC is defined as the lower of AWP less twenty-five percent. (c) For specialized HIV pharmacies, the EAC is defined as AWP of the drug less twelve percent. The dispensing fee for generic prescription drugs will be $4.50 per prescription and for brand name prescription drugs will be $3.50. However, for brand name prescription drugs, when the net cost of the brand name drug, after consideration of all rebates is less than the cost of the generic equivalent, the dispensing fee shall be $4.50 per prescription. The State Department of Health's prescription drug pricing service will determine whether a prescription drug is generic or brand name. A SMAC may be established for any drug, including brand name multi-source drugs, for which two or more A-rated therapeutically equivalent, multi-source drugs where a significant cost difference exits. The drugs used for the SMAC price calculation formula will be active (non-obsolete) drugs eligible for rebates under the Federal Medicaid Drug Rebate Program authorized by Section 1927 of the Social Security Act and which are available in sufficient quantities in the marketplace. The source of comparable drug prices will be nationally recognized comprehensive data files maintained by a vendor under contract with the State. While the final SMAC pricing methodology is proprietary, multiple drug pricing resources are utilized to determine the preliminary acquisition cost for generic drugs. These resources include pharmacy providers, wholesalers, drug file vendors such as First Data Bank, and pharmaceutical manufacturers. The preliminary acquisition cost for each product is maintained in a SMAC pricing file database. Products are then sorted into drug groups by GSN (Generic Code Number Sequence Number) which denotes the same generic name, strength, and dosage form. The vendor will apply the proprietary formula to the estimated acquisition costs in each GSN giving due consideration to the lower cost products. Multipliers are used to increase the applicable lowest price by a percentage. The resulting price becomes the SMAC price which is then applied to all drug products in that specific GSN. The SMAC file is updated monthly. New York's SMAC list is available from a vendor under contract with the Department.

Compound Drugs: Reimbursement is determined by the State Department of Health at the cost of ingredients plus a dispensing fee of $3.50 with an additional amount of $0.75 as the compounding fee.

Exception: Physician Override: Reimbursement for those brand name drugs for which there are generic equivalent drugs for which reimbursement is not to exceed the aggregate of the specified upper limit for the particular drug established by the Centers for Medicare and Medicaid Services, plus a dispensing fee, will be paid at the lower of the estimated acquisition cost, plus a dispensing fee, or at the provider's usual and customary price charged to the general public when the prescriber has obtained a prior authorization when required for the brand-name drug, indicated that the brand name drug is required by placing "daw" (dispense as written) in the box located on prescription form and by writing "brand necessary" or "brand medically necessary" in his/her own handwriting on the face of the prescription.

Where it has been determined that reimbursement plus a dispensing fee does not exceed the aggregate for all drugs under the Federal Upper Limit (FUL) program , the writing by the prescriber of "brand necessary" or "brand medically necessary" will not be required. Prior authorization will not be required for these select drugs.

Indian Health Clinics and tribal clinics which have licensed pharmacies, may submit fee-for-service claims for pharmacy services provided to Native Americans and will be reimbursed at the net acquisition cost for those drugs purchased through the Federal Supply Schedule or at an amount determined by the reimbursement methodology indicated above for all other purchased drugs.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE New York

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The following charges are imposed on the categorically needy for services:

SERVICE	TYPE OF CHARGE			AMOUNT AND BASIS FOR DETERMINATION
	DEDUCTIBLE	COINSURANCE	CO-PAY	
Pharmacy				
1. Brand- name drugs			X	$3.00
2. Generic drugs			X	$1.00
3. Non-prescription drugs			X	$0.50
4. Preferred brand name drugs and brand name drugs, when cost after consideration of all rebates, is less than the generic equivalent			X	$1.00

TN#: 09-52
Supercedes TN#: 08-42

Approval Date: MAR 12 2010
Effective Date: OCT 01 2009

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE New York

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The following charges are imposed on the medically needy for services other than those provided under Section 1916 of the Act:

SERVICE	TYPE OF CHARGE			AMOUNT AND BASIS FOR DETERMINATION
	DEDUCTIBLE	COINSURANCE	CO-PAY	
Pharmacy				
1. Brand- name drugs			X	$3.00
2. Generic drugs			X	$1.00
3. Non-prescription drugs			X	$0.50
4. Preferred brand name drugs and brand name drugs, when cost after consideration of all rebates, is less than the generic equivalent			X	$1.00

TN#: 09-52 **Approval Date:** MAR 1 2 2010

Supercedes TN#: 08-42 **Effective Date:** OCT 0 1 2009