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State/Territory Name: New York

State Plan Amendment (SPA) #: 17-0005

This file contains the following documents in the order listed:

1) NY Regional Office Approval Letter
2) CO 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

December 7, 2017

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 completed our review of the submission of New York State Plan Amendment (SPA) 17-0005 which was received in our office on June 15, 2017 and find it acceptable for incorporation into New York's Medicaid State Plan. This amendment proposes to allow the New York State Department of Health to move to actual acquisition cost (AAC) using the National Average Drug Acquisition Cost (NADAC) as the primary basis for its lower of reimbursement methodology for prescription drugs submitted for payment to the medical assistance program, along with a professional dispensing fee (PDF) of $10.00.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 17-0005 is approved with an effective date of April 1, 2017.

The $10 PDF fee that the state submitted in its SPA is set by state statute, and was calculated including a small efficiency fee. In considering the proposed PDF, the state was required to provide adequate data, such as national or state surveys or studies, or other reliable data to demonstrate that the acquisition cost methodology and PDF being paid are sufficient to ensure that New York Medicaid beneficiaries will have access to pharmacy services. In keeping with the requirements of section 1902 (a)(30)(A) of the Social Security Act, we believe the state has demonstrated that their reimbursement is consistent with efficiency, economy, and quality of care, and is sufficient to ensure that care and services are available at least to the extent they are available to the general population in the geographic area.

Specifically, New York has reported to CMS that as of April 6, 2017 there are 5,042 pharmacies enrolled in the Medicaid Fee-For-Service (FFS) program with 4,865 residing in-state. With a 90% participation rate of New York State licensed pharmacies residing in-state, we can infer that New York Medicaid beneficiaries will have access to pharmacy services at least to the extent available to the general population since Medicaid requires that beneficiaries be provided access to all covered outpatient drugs of participating drug manufacturers with a rebate agreement

through a broad pharmacy network. In contrast, commercial insurers often have more limited drug formularies and a more limited pharmacy network.

During our review of the state's methodology to determine the $10 PDF, we noted that New York plans to annually update the PDF through the state's annual budget process to reflect current costs of dispensing. We encourage the state to undertake this process to assure that the PDF keeps pace with the actual costs of dispensing.

As noted above, we believe that there is evidence regarding the sufficiency of New York's PDF from provided data and other credible sources to approve SPA 17-0005 with an effective date of April 1, 2017. If based on continued access monitoring and/or any updated data, such as cost of dispensing surveys, New York finds that an additional SPA amendment is appropriate, we encourage the state to make such a request promptly.

Mr. Coster advised you that the New York Regional Office would forward you the signed CMS-179 form, as well as the pages approved for incorporation into New York's state plan. These documents are enclosed.

CMS appreciates the significant amount of work your staff dedicated to this state plan amendment. If you have any questions concerning this SPA, please contact Ivelisse M. Salce at (212) 616-2411 or Ivelisse.Salce@cms.hhs.gov.

Sincerely,

[redacted]

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

Cc: Pamela Schweitzer, Pharmacy Division

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: **17-0005**	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 **April 1, 2017**	
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: **§1902(r)(5) of the Social Security Act, and 42 CFR 447**	7. FEDERAL BUDGET IMPACT: **(in thousands)** **a. FFY 04/01/17-09/30/17 $2,750.00** **b. FFY 10/10/17-09/10/18 $5,500.00**	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: **Attachment 4.19-B: Page 4(d); Page 4(d)(1); Page 4(d)(2); Page 4(e)**	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: **Attachment 4.19-B: Page 4(d); Page 4(e)**	
10. SUBJECT OF AMENDMENT: **Pharmacy Drug Reimbursement (FMAP = 50%)**		
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]	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. Helgerson**		
14. TITLE: **Medicaid Director** **Department of Health**		
15. DATE SUBMITTED: JUN 15 2017		
FOR REGIONAL OFFICE USE ONLY		
17. DATE RECEIVED:	18. DATE APPROVED: **DECEMBER 07, 2017**	
PLAN APPROVED – ONE COPY ATTACHED		
19. EFFECTIVE DATE OF APPROVED MATERIAL: **APRIL 04, 2017**	20. SIGNATURE OF REGIONAL OFFICIAL: [redacted]	
21. TYPED NAME: **MICHAEL MELENDEZ**	22. TITLE: **Associate Regional Administrator** **Division of Medicaid and Children's Health Operations**	
23. REMARKS:		

FORM HCFA-179 (07-92)

New York
4(d)

[For dates of service on and after April 1, 2011 and ending on March 31, 2013, and April 1, 2013 and ending on March 31, 2015, payments for pharmacy services, which includes payments made to pharmacy providers for all pharmacy services and products, including supply and drug costs, dispensing fees, e-prescription reimbursement, medication therapy management, and immunization services, will be reduced by 0.33%.

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 source drugs and multi-source brand name drugs, the EAC is defined as average wholesale price (AWP) less seventeen percent or the wholesale acquisition cost of a prescription drug based on package size dispensed from, as reported by the prescription drug pricing service used by the department, minus zero and forty-one hundredths percent.
(b) For multi-source generic drugs, the EAC is defined as the lower of AWP less twenty-five percent, or the maximum acquisition cost.

The dispensing fee for generic and brand name prescription drugs will be $3.50.]

Outpatient Drug Reimbursement

1. Reimbursement for Prescribed Drugs (including specialty drugs) dispensed by a retail pharmacy; an institutional or long term care pharmacy; an Indian Health Service, tribal or urban Indian pharmacy; or any other pharmacy enrolled in the NYS Medicaid FFS Program is as follows:

    a. Reimbursement for Brand Name Drugs is the lower of:

        i. National Average Drug Acquisition Cost (NADAC) or, in the event of no NADAC pricing available, Wholesale Acquisition Cost (WAC) less 3.3%; plus, the professional dispensing fee in Section 2; or
        ii. the billing pharmacy's usual and customary price charged to the general public.

    b. Reimbursement for Generic Drugs is the lower of:

        i. NADAC or, in the event of no NADAC pricing available, WAC less 17.5%; plus, a professional dispensing fee; or
        ii. the Federal Upper Limit (FUL) plus the professional dispensing fee in Section 2; or
        iii. the State Maximum Acquisition Cost (SMAC) plus the professional dispensing fee in Section 2; or
        iv. the billing pharmacy's usual and customary price charged to the general public.

New York
4(d)(1)

c. Reimbursement for Nonprescription Drugs is the lower of:
   i. NADAC or, in the event of no NADAC pricing available, WAC; plus, if a covered outpatient drug, the professional dispensing fee in Section 2;
   ii. the FUL plus, if a covered outpatient drug, the professional dispensing fee in Section 2; or
   iii. the SMAC plus, if a covered outpatient drug, the professional dispensing fee in Section 2; or
   iv. the billing pharmacy's usual and customary price charged to the general public.

2. The professional dispensing fee for covered outpatient drugs, including 340B-purchased drugs, when dispensed by a retail pharmacy; an institutional or long term care pharmacy; an Indian Health Service, tribal or urban Indian pharmacy; or any other pharmacy enrolled in the NYS Medicaid FFS Program, is $10.00.

3. Payment for drugs dispensed by pharmacies that are acquired at a nominal price as referenced in 42 CFR § 447.502 is at actual acquisition cost plus the professional dispensing fee in Section 2.

4. Payment for drugs dispensed by pharmacies that are acquired via the Federal Supply Schedule is at actual acquisition cost plus the professional dispensing fee in Section 2.

5. Payment for drugs dispensed by the pharmacy of a 340B covered entity as described in section 1927(a)(5)(B) of the Act, or a contract pharmacy under contract with a 340B covered entity as described in section 1927(a)(5)(B) of the Act, shall be as follows:
   a. 340B purchased drugs – actual acquisition cost not to exceed the 340B ceiling price, plus the professional dispensing fee in Section 2;
   b. Non-340B purchased drugs – in accordance with lower of logic in section 1 plus the professional dispensing fee in Section 2.

6. Payment for clotting factor dispensed by a pharmacy enrolled in the NYS Medicaid FFS Program is at the lower of: SMAC, as described below, not to exceed WAC, plus the professional dispensing fee in Section 2; or the billing pharmacy's usual and customary price charged to the general public.

   SMAC is established for clotting factor products using multiple clotting factor pricing resources including but not limited to wholesalers, drug file vendors such as First Data Bank, pharmaceutical manufacturers, and the Hemophilia Services Consortium, Inc. pricing. The Hemophilia Services Consortium, Inc. subcontracts with the New York Blood Center (both not-for-profit corporations) to negotiate with manufacturers and distributors to obtain the best volume discount for the Consortium's safety net hospital.

   The SMAC file is stored in a database where valid statistical calculations are used to evaluate and compare the various pricing benchmarks to develop the SMAC price. The SMAC file is updated monthly and applied to all clotting factor products.

   Payment for 340B-purchased clotting factor dispensed by a Hemophilia Treatment Center, whether the pharmacy is owned by the covered entity or has a contract pharmacy arrangement, shall be in accordance with Section 5.a.

New York
4(d)(2)

7. Practitioner-administered drugs billed under the medical benefit are reimbursed as follows:
   a. When administered during an office visit, payment is made at actual acquisition cost by invoice, not to exceed Medicare Part B price. No professional dispensing fee is paid.

   b. When administered by a practitioner in an ordered ambulatory setting, payment is at actual acquisition cost, not to exceed Medicare Part B price. Drugs purchased by covered entities at the prices authorized under Section 340B of the Public Health Services Act must be billed at their actual acquisition cost. No professional dispensing fee is paid.

   c. When administered in an outpatient setting to a patient of a disproportionate share hospital, clinic, or emergency department, payment may be made through either the Ambulatory Patient Group (APG) classification and reimbursement system, as referenced in page 1(b)(ii) of this Attachment, or, if carved out of the APG system, in accordance with Section 7.b.

      Reimbursement for drugs in the APG reimbursement are paid as follows:
      1. Practitioner-administered drugs assigned to an APG and paid through the APG drug band are reimbursed based on the weighted average, using Medicaid paid claims data. Payment for drugs purchased by covered entities at the prices authorized under Section 340B of the Public Health Services Act and paid through the APG drug band are paid at 75% of the drug's APG band payment amount.
      2. Practitioner-administered drugs assigned to an APG and paid through the APG Fee Schedule are paid in accordance with Section 7.b.

      No professional dispensing fee is paid.

   d. Federally Qualified Health Centers (FQHC) and Indian Health Services/Tribal/Urban Indian Clinic Facilities have the option of receiving their payment through the Federal Prospective (PPS) rate, or through the APG reimbursement methodology as an "alternative rate setting methodology". In the event the facility chooses to be reimbursed through the Federal PPS Rate, the rate is considered inclusive of any practitioner administered drugs. In the event the facility has opted for the APG reimbursement methodology, payment for drugs administered by a practitioner during a visit to the facility will be in accordance with Section 7.c. If a facility's Medicaid reimbursement under APGs is lower than what their payment would have been under the Federal PPS rate, the facility is entitled to receive a supplemental payment reflecting the difference between what they were paid under APGs and what they would have been paid using the PPS rate. No professional dispensing fee is paid.

8. Reimbursement for Investigational Drugs is not a covered service. The Department may consider Medicaid coverage on a case by case basis for life-threatening medical illnesses when no other treatment options are available. If/when approved by a Medical Director, reimbursement is at actual acquisition cost. When dispensed by a pharmacy enrolled in the NYS Medicaid FFS Program, reimbursement includes the professional dispensing fee in Section 2.

New York
4(e)

Compound Drugs: Reimbursement is determined by the State Department of Health at the cost of ingredients plus the current dispensing 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.